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Quality Improvement Measures for Cervical Screening Guidelines in a Clinic for Uninsured Adults

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QUALITY IMPROVEMENT MEASURES FOR CERVICAL SCREENING GUIDELINES IN A CLINIC FOR UNINSURED ADULTS

by

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Dedication & Acknowledgements

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Abstract

Cervical cancer, a completely curable disease with early detection and management, is an international concern. Early identification allows for treatment of the disease, which prevents or slows progression, ultimately reducing morbidity and mortality. Due to the regressive nature of most cervical lesions, the duration between cervical cytology has been lengthened to prevent over diagnosis and treatment. This was reflected in the 2012 United States Preventative Services Task Force (USPSTF) clinical practice guideline for cervical cancer screening.

The purpose of this project was to determine the effectiveness of a quality improvement initiative to increase adherence to the 2012 USPSTF guideline at a volunteer medical clinic for the working uninsured. In this retrospective, time series observational evaluation, data were collected via chart review regarding adherence to the guideline. The intervention consisted of the placement of a visual algorithm educational tool for clinical decision-making for cervical cytology screening in each exam room. Data were collected during three time periods: (1) the 3 months prior to initial education of clinic staff regarding the guideline; (2) the 3months between initial education and introduction of the algorithm; and (3) the 3 months post introduction of the algorithm.

A total of 335 charts were reviewed. There was a significant difference in the proportion of appropriate screening among the three groups ($X^{2=}$ 6.83 p=.03). There was also a significant difference in appropriate screening rates between the new and established patients' group, controlling for group (p<.0001). The use of the interventional algorithm is recommended to improve adherence to evidence-based practice guideline related to cervical screening as it decreases harm(s) to the patient by reduction of fear, cost to the patient, and overtreatment of benign regressive lesions.

Keywords: Pap smear, cervical cytology, clinical practice guidelines

Chapter One: Introduction

Cervical cancer, a completely curable disease with early detection and management, is an international concern. There are approximately 530,000 new cases worldwide each year (World Health Organization [WHO], 2013) with more than 8.1 instances per 100,000 women in the United State alone (U.S. Department of Health and Human Services [USDHHS], 2010). Providers have been using Pap smears to screen for cervical pathology since Dr. Papanicoulaou created the technique in the 1950's. New technology and a greater understanding of the course of the disease has elicited change in both screening techniques and recommended time intervals between screenings.

Screening programs, the foundation of the wellness model of health, detect disease in its earliest possible state. Early identification allows treatment for the disease, which prevents or slows progression, ultimately reducing morbidity and mortality. Cervical cytology testing has been one of the most successful cancer screening programs to date. In the United States, the incidence of cervical cancer decreased more than 60% between 1955 and 1992 due to the success of cervical cytology screening (USDHHS, 2010). Additional evidence suggested implementation of cervical cytology screening to a previously non-screened population decreases cervical cancer rates by 60-90% within three years due to the very slow nature of growth of cervical cancer (Sasieni, Cuzick, & Lynch-Farmery, 1996; "Screening for squamous," 1996).

The tremendous success of cervical cytology screening has been attributed to three factors:

1. The growth from detectable change in cervical cytology (low-grade dysplasia) until the development to carcinoma in situ followed by invasive carcinoma is very slow, which allows time for treatment;
2. Cellular changes are easily identified with microscopy;
3. Early treatment is available for premalignant lesions. (Hartman, Hall, Nanda, Boggess, & Zolnoun, 2002)

Updating the Clinical Practice Guideline

Clinical practice guidelines are based on evidence reviews. Since the inception of evidence-based practice in the 1990's, clinical practice guidelines have been critically evaluated in an effort to guide clinical decisions. The rapidly growing evidence-based practice movement has created the need to critically evaluate established protocols and guidelines. Shojania et al. (2007) conducted a survival analysis of published clinical guides and concluded that data from 25% of Cochrane reviews may be out-of-date within two years of publication, and 1 in every 15 may be outdated by the time of publication. Guidelines must be reviewed and updated as new evidence warrants modifications of previous recommendations (Graham, Mancher, Wolman, Greenfield, & Steinberg, 2011).

Cervical cancer screening recommendations were revised in 2002 by the Agency for Healthcare Research and Quality (AHRQ) due to new testing procedures using a liquid-based cytology screening (Hartman et al., 2002). Further advances in HPV screening and a greater understanding of the slow evolution of HPV to carcinoma in situ have propelled the revision of the AHRQ screening guidelines (Vesco et al., 2011b). New screening guidelines are stratified based on age. HPV co-testing is recommended for women over the age of 30 years.

Problem

The updated 2012 clinical practice guideline for cervical cancer screening has implications for clinical practice. In a volunteer clinic in the southeastern United States that provides medical care to the working uninsured, the majority of clinicians performing

gynecologic exams are volunteer nurse practitioner students, nurse practitioners, and physicians. Currently, providers of gynecologic care are practicing under the 2002 clinical practice guideline for cervical cancer screening. This created an opportunity to implement the updated clinical practice guideline for cervical cancer screening. The PICOT statement for this project was (P) Will primary care and gynecology providers volunteering women's health services at a clinic for the working uninsured (O) adhere to (C) 2012 clinical practice guideline for cervical cancer screening after the (I) implementation of a quality improvement initiative (T) three months post-implementation?

Purpose

The purpose of this project was to determine the effectiveness of a quality improvement initiative to increase the use of the 2012 United States Preventative Services Task Force (USPSTF) clinical practice guideline for cervical cancer screening at a volunteer medical clinic for the working uninsured.

Project Description

Rodger's theory of innovation served as a framework for this quality improvement project. Cervical screening algorithms were placed in exam rooms and at charting areas to reinforce the new guideline. Three months post-intervention a practice evaluation will be conducted by chart review. The outcome measure will be the compliance of the revised 2012 cervical cytology clinical practice guideline.

Definition of Terms

Conventional Cytology

Cervical cells are taken from the cervix and smeared directly onto a microscope slide after collection. The slide is then sprayed with a fixative to preserve the cells during transport to the laboratory for evaluation.

Liquid-Based Cytology

Cervical cells are taken from the cervix and immersed into a solution. Then, the laboratory evaluates cells.

Carcinoma in Situ

Carcinoma in Situ comprises severely dysplastic cells called cervical intraepithelial neoplasia III or pre-invasive cervical carcinoma.

Human Papillomavirus (HPV)

HPV is a virus transmitted during intercourse. Cervical cancer is caused by the human papillomavirus in 97% of all cases (American Society for Colposcopy and Cervical Pathology [ASCP], 2011).

Chapter Two: Review of the Literature

This chapter describes search methods utilized to gather evidence regarding screening for cervical cancer followed by a brief discussion of cervical cancer, its pathology, diagnosis, and prognosis. Identification of the parameters for evidence-based clinical practice guidelines is presented. Finally, the history of cervical cancer screening is outlined, and the three current guidelines for screening are compared.

Search Methods

A search of literature was conducted to obtain the highest level, most current evidence with respect to cervical cancer screening. Search terms used were "cervical cytology" and "clinical practice guidelines and cervical cytology." The preceding terms were searched in the following databases: Cochrane Database of Systematic Reviews (4 identified and included), PubMed (69,213 identified and 7 included), CINAHL (1,859 identified and 8 included), and MEDLINE (13,811 identified and 5 included). Articles published in languages other than English were excluded. Academic, scholarly peer-reviewed articles were included. Saturation of level of evidence was reached at 24 articles.

Cervical Cancer

In 2007, approximately 530,000 new cases of cervical cancer worldwide were identified, resulting in 270,000 deaths (WHO, 2013). In 2009, the incidence rate for cervical cancer was 8.1 cases per 100,000 women per year in the United States, resulting in mortality rates at 2.4 deaths per 100,000 women per year (USDHS, 2010). The incidence in Florida is higher than the

national incidence rate, with 8.1 to 11.2 per 100,000 populations (Centers for Disease Control and Prevention [CDC], 2012a). In Duval County, where the project was conducted, the incidence of cervical cancer is 10.5 (CI 9.2, 12.0) per 100,000 (NCI, 2011). The county ranks 11th in cervical cancer incidence in Florida.

Classification of Cervical Cytology

The 2001 Bethesda System is a uniform reporting system of terminology designed to report cervical cytology findings using standardized nomenclature. The system provides a clear explanation of cervical physiology or pathology, which decreases provider misunderstanding of abnormal cervical cytology (Davey, 2003). Standardization of terminology allows providers to make more accurate decisions for treatment and management of abnormal cervical cytology. The 2001 Bethesda System has three main categories: (a) specimen type, conventional smear or liquid-based preparation, (b) specimen adequacy, either satisfactory or unsatisfactory with reason specified and (c) interpretation, including organisms, and cellular changes (see Table 2.1).

Etiology

The human papillomavirus (HPV) plays a significant role in cervical carcinoma as it is detected in greater than 90% of cases; even more significant, 99.7% of cervical neoplasias worldwide can be contributed to HPV (Walboomers et al., 1999). Approximately 80% of sexually active women will be infected with HPV, and a majority of these women will clear the infection without clinical disease (Stanley, 2009; Einstein et al., 2009). Currently, 100 different types of HPV subtypes have been identified to infect humans (Galani & Christodoulou, 2009). Infection with one of the oncogenic high-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 69, and 82 is the cause of virtually all cervical cancers (Trottier & Franco, 2006; Walboomers et al., 1999). These subtypes are divided into low-risk and high-risk types that may

cause anogenital lesions. Women who are exposed to low- risk HPV types and develop benign epithelial lesions typically begin an effective cell-mediated immune response and the lesions regress (Einstein et al., 2009).

The most common HPV subtypes that cause lesions include 6, 11, 40, 42, 43, 44, 54, 61, 72, and 81. HPV types 16 and 18 are the most common, causing 70% of oncogenic lesions (Clifford, Smith, Aguado, & Franceschi, 2003**;** Smith et al., 2007). New technology such as situ hybridization polymerase chain reaction (PCR) and Hybrid Capture technology utilizing ribonucleic acid has given clinicians the ability to co-screen for types 16 and 18 while performing the Pap smear. Notably, young women ages 16-23 have a high rate of HPV clearance from type 16 and 18 within 36 months ranging from 85.3 percent (95% CI, 75.0 to 91.5) for HPV 16 and 91.1 percent (95% CI, 84.6 to 94.9) for HPV 18 (Insignga, Dasbach, Elbasha, Law, & Barr, 2007).

Evolution of Cervical Cytology Screening

From the 1950's until the late 1990's conventional cytology was used for screening, as this was the best way to collect cervical cells for identification of abnormalities. The procedure, introduced by Dr. Papanicolaou, included scraping the cervix with a spatula and brush to obtain cervical and endocervical cells for evaluation. The specimen was then placed onto a glass slide. A fixative of 95% ethanol was then sprayed onto the collection of cells. Specimen preservation was extremely tedious, as the specimen had to be sprayed at approximately 10 inches. If the specimen air-dried prior to the application of the fixative, the cells could become damaged. This conventional cytology technique reported sensitivity of 80% and specificity of 99% (Soost, Lange, Lehmacher, & Ruffing-Kullmann, 1991).

Table 2.1

The 2001 Bethesda System for Classification of Cervical Cytology

Result	Interpretation
Positive for Organism	• Trichomonas vaginalis • Fungal organisms morphologically consistent with Candida • Shift in flora suggestive of bacterial vaginosis • Bacteria morphology consistent with Actinomyces • Cellular changes consistent with Herpes simplex virus
Non-Neoplastic Findings	• Reactive cellular changes associated with: o Inflammation o Radiation o Intrauterine device (IUD) • Glandular cells status post hysterectomy • Atrophy • Endometrial cells
Epithelial Cell Abnormalities	• Squamous Cell o Atypical squamous cells: • Of undetermined significance (ASC-US) • Cannot exclude High Grade Squamous Intrathelial Lesion (ASC-H) o Low grade squamous intraepithelial lesion (LSIL) Encompasing: HPV/ mild dysplasia/CIN 1 o High grade squamous intraepithelial lesion (HSIL) Ecompassing moderate and severe dysplasia, CIS; CIN 2 and CIN 3 o Squamous cell carcinoma • Glandular Cell o Atypical • Endocervical cells NOS • Endometrial cells NOS • Glandular cells NOS o Atypical • Endometrial cells, favor neoplastic • Glandular cells, favor neoplastic o Endocervical adenocarcinoma *in situ* o Adenocarcinoma • Endocervical • Endometrial • Extrauterine • Not otherwise specified (NOS)

From "Cervical Cytology Classification and the Bethesda System." by D. Davey, 2003, *Cancer Journal, 9,* p. 328-329.

False negative rates in conventional cytology have been documented at 50% of specimens (Sprenger, Schwarzman, Kirkpatrick, Fox, & Heinzerling, 1996). False-negative specimens have been attributed to sampling and fixative errors, body fluids such as blood or mucus which can

obscure the cervical cells, screening techniques, and laboratory interpretation errors (Abulafia & Sherer, 1999).

Approval by the Food and Drug Administration (FDA) of liquid-based cytology in 1996 advanced cervical cytology screening significantly ("The Thin Prep Pap Test," 2010). Collection of the cervical specimen evolved with the introduction of new spatulas and brushes for specimen collection. Suspension of the cervical cells in a liquid-based solution decreased the false positive rate by allowing cells to become suspended in the solution, instead of becoming obscured by blood and mucus (Abulafia & Sherer, 1999). While the use of liquid cytology has been advantageous regarding obscurity of specimens, evidence has suggested no meaningful differences between conventional cytology and liquid-based cytology (USPSTF, 2012).

In 1999, the FDA approved the QIAGEN Hybrid Capture® 2 (hc2) DNA test to detect the presence of high-risk types of HPV ("The Digene HPV Test," 2012). The liquid-based cytology test quickly led to reflex testing of high-risk HPV. The inclusion of HPV testing with cervical screening identified patients with non-resolving high-risk HPV lesions that required monitoring.

HPV Vaccines and Cervical Cancer Prevention

According to the CDC (2012b), each year 15,000 HPV-associated cancers (cervical, anal, vaginal, vulvar and oropharyngeal) could be prevented in the United States with the use of HPV vaccines in women. The two HPV vaccines, which are licensed by the FDA and recommended by CDC, are Cervarix (by GlaxoSmithKline) and Gardasil (Merck). The vaccines provide protection against cervical disease and cancer which are caused by HPV types 16 and 18. Current HPV vaccines prevent the approximately 70% of cervical cancers (American Cancer Society [ACS], 2012). The vaccines are administered in three doses—an initial dose, followed

by the second dose in one month, and concluding with the third dose at six months. The age of vaccination is recommended prior to sexual activity. The preteen check should include Tanner staging and HPV vaccinations. The CDC recommends that "all 11 or 12 year old girls get the 3 doses (shots) of either brand of HPV vaccine to protect against cervical cancer" (CDC, 2012b, p. 5).

HPV vaccines efficacy rates have touted >98% protection in randomized clinical trials against the obligate precursor lesions cervical intraepithelial neoplastic grade 2/3 (CIN2/3) and adenocarcinoma in situ (Stanley, 2008). As vaccination rates for HPV prior to sexual activity continue to increase, conversely, HPV-related cancers will continue to decrease. The ACS (2012) recommended continued screening based on age and risk factors without regard to HPV vaccinations due to cervical cancers caused by HPV not covered by the vaccinations.

Clinical Practice Guidelines

In 1990, the Institute of Medicine [IOM] defined clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field & Lohr, 1990, p. 8). This definition sparked the movement toward evidenced-based clinical practice guidelines. This movement continued without precise structure until 2008 when the IOM was charged by the United States Congress to conduct a study of the best methods used in developing clinical practice guidelines. This study was to produce evidenced-based criterion for organizations developing such clinical guidelines to ensure that each body was objective, scientifically valid, and consistent or trustworthy in its guideline development (Graham et al., 2011). To become "trustworthy" the clinical practice guideline should

1. Be based on a systematic review of the existing evidence;

2. Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
3. Consider important patient subgroups and patient preferences, as appropriate;
4. Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
5. Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and
6. Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations. (Graham et al., 2011 p. 2)

Since the inception of evidenced-based clinical practice guidelines, approximately 2,700 guidelines have been documented in the National Guidelines Clearinghouse (NGC), a part of the Agency for Health Care Research and Quality (AHRQ). These guidelines may be found at the NGC Website at http://guideline.gov/. Clinical practice guidelines offer clinicians and patients clear, concise, evidence-based options for a particular disease state or condition. The IOM recommends that all guidelines comply with the standards for trustworthiness and reflect best practices for guideline development, including

1. Establishing transparency;
2. Management of conflict of interest;
3. Guideline development group composition;
4. Clinical practice guideline–systematic review intersection;
5. Establishing evidence foundations for and rating strength of recommendations;
6. Articulation of recommendations;
7. External review; and
8. Updating. (Graham et al., 2011, p. 2-3)

Rating Strength of Evidence and Recommendations

Recommendations for screening for cervical cancer guidelines are based on the strength of evidence. The most common rating scale is that of the USPSTF (see Table 2.2).

New Clinical Practice Guidelines for Cervical Cytology

In 2012, three separate scientific bodies published new guidelines for cervical cancer screening. These bodies were (a) the USPSTF; (b) a combined group, including the ACS,

American Society for Colposcopy and Cervical Pathology (ASCCP); and the American Society for Clinical Pathology (ASCP); and the American College of Obstetricians and Gynecologists (ACOG).

Table 2.2

USPSTF Grade Definitions for Strength of Recommendations

Grade	Recommendation
A	The USPSTF strongly recommends that clinicians provide the service to eligible patients. *The USPSTF found good evidence that the service improves important health outcomes and concludes that benefits substantially outweigh harms*.
B	The USPSTF recommends that clinicians provide this service to eligible patients. *The USPSTF found at least fair evidence that[the service improves important health outcomes and concludes that benefits outweigh harms*.
C	The USPSTF makes no recommendation for or against routine provision of the service. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation*.
D	The USPSTF recommends against routinely providing the service to asymptomatic patients. *The USPSTF found at least fair evidence that the service is ineffective or that harms outweigh benefits*.
I	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. *Evidence that the service is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined*.

From "Current Methods of the US Preventive Services Task Force: A Review of the Process," by R.P. Harris et al., 2001, *American Journal of Preventive Health, 30,* p. 33.

USPSTF Cervical Cytology Screening Guideline Development

After a decade of new evidence on liquid cytology and the benefits of HPV testing, a new systematic review was commissioned by the USPSTF. Vesco et al. (2011b) reviewed the available evidence; 35 studies reported in 66 articles were screened for quality (see Figure.2.1). The foundation for the clinical practice guideline update was based on a meta-analysis of the data. There were a total of 141,566 participants in the four studies of liquid-based cytology versus conventional cytology (Pap smear) when evaluating sensitivity and specificity (Vesco et

al., 2011b). Five studies were related to the start of cervical cancer screening; twelve studies evaluated HPV for primary cervical cancer screening; four studies evaluated the use of HPV

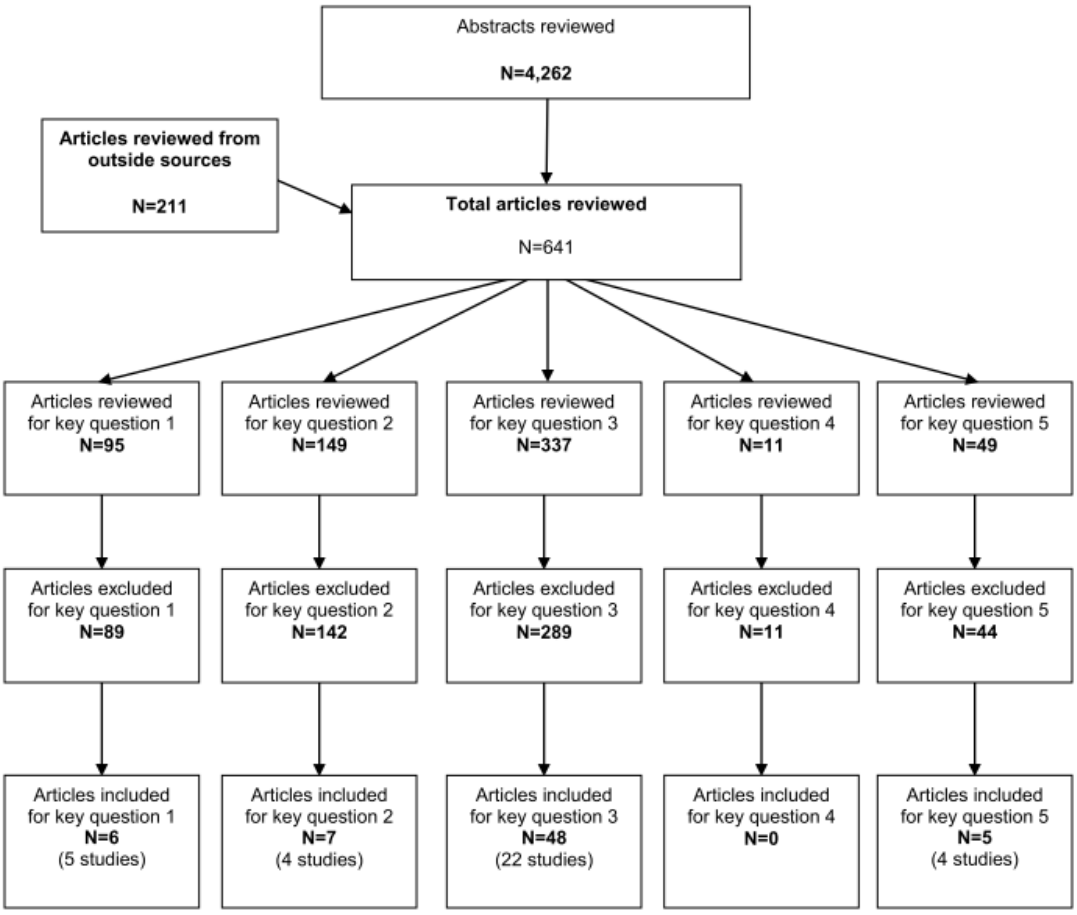

Figure 2.1. Evidence summary for revised cervical cancer screening recommendations. From "Screening for Cervical Cancer: A Systematic Evidence Review for the U.S. Preventive Services Task Force, Evidence Report no. 86," by K.K. Vesco et al., 2011b, Rockville, MD: Agency for Healthcare Research and Quality, p. 138.

testing plus cytology screening; one study evaluated cytology triage of primary HPV testing; six studies evaluated HPV for triage of abnormal cytology to colposcopy; and four studies evaluated the harms of HPV testing. Vesco at al. (2011b) considered studies as fair to good with two systematic reviews. Descriptions of each study with the number of participants and outcome measures were provided. There were no systematic reviews for HPV testing over the last five

years. The majority of the data were conducted after the 2003 initial USPSTF Clinical Practice Guideline for Cervical Cancer Screening. The systematic review was utilized to answer five key questions.

Key question 1: Initiation of cervical cancer screening. Evidence suggested cervical cytology in women should begin at 21 years of age. Screening before age 21 correlated to high rates of HPV with regressive cervical change, but very few cases of cervical cancer (Vesco et al., 2011b).

Key questions 2 and 4: Liquid-based cytology compared to conventional cytology. The review determined liquid-based cytology does not differ from conventional cytology in sensitivity, specificity, or relative cervical intraepithelial neoplasia detection. Unfortunately, conventional cytology yields a lower proportion of satisfactory specimens due to slide preparation error, blood and mucus obstruction, and fixative errors (Vesco et al., 2011b).

Key question 3: HPV primary screening alone or followed by cytology triage and/or combination HPV and cytology screening (co-testing). In women age 30 or older, a single HPV Hybrid Capture 2 (HC2) test was significantly more sensitive (40% greater) than cytology alone for detecting cervical intraepithelial neoplasia 3+. The tradeoff for improved sensitivity was decreased specificity. A single HC2 test is 3-5% less specific than cytology. The disease detection of HPV testing proved to be better screening for follow-up diagnostic testing. The false positive rate and cost of diagnostic testing were found to be harms created by HPV testing with improved sensitivity. In women 35 years and older, the triage principle of HPV testing, combined with reflex cytology (co-testing in the same LBC specimen), provided a more accurate screen to substantiate cost for a diagnostic colposcopy. Abnormal cytology may have resolved after one or more screening rounds, thus decreasing over diagnosis and over treatment of HPV

associate cervical change due to resolving HPV lesions. In a naïve population, to which triage principles of cytology are not applied, cytology with reflex HPV co-testing was much more sensitive than cytology alone. There was very little data on women younger than 30 using a primary HPV screen (including cytology or without). The few studies that suggested using HPV testing in ages less than 30 showed decreased sensitivity by 11% compared to cytology. Unfortunately, due to decreased sensitivity, greater false positives rate translated to unnecessary colposcopies, increased costs, and psychological fear (Vesco et al., 2011b).

Key question 5: Harms of HPV testing. Approximately 80% of sexually active women will be infected with the HPV virus and a majority of these women will clear the infection without clinical disease (Stanley, 2009, Einstein et al., 2009). Primary screening for HPV for the general population raised red flags concerning over diagnosis (during the regressive HPV state), costs associated with repeated cytology triage, referral for diagnosis (colposcopy referral), and psychological ramifications (Vesco et al., 2011b).

Specific recommendations. The USPSTF recommendations reflect the synthesis of evidence presented in the prior meta-analysis. The recommendations apply to

> Women who have a cervix, regardless of sexual history. This recommendation statement does not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive). (USPSTF, 2012, p. 1)

ACS/ASCCP/ASCP Cervical Cytology Screening Guidelines

The last cervical cancer screening guideline by the ACS was in 2002, prior to the availability of DNA testing for HPV. New evidence and access to DNA HPV testing prompted a joint guideline review and update by the ACS, ASCCP, and ASCP. Since 2002, significant evidence has been introduced regarding stratified screening for age in combination with

screening for high-risk HPV types 16 &18 with conventional cytology (co-testing). The two-year (2009-2011) systematic evidence review coupled with contributions from six working groups led to the updated guideline for cervical cancer screening. The working groups addressed six topics: best cytology screening intervals, stratification of screening for women, combinations of cytology and HPV results with differing results, exiting strategy from screening, use of HPV vaccination for screening (Saslow et al., 2012).

The cervical cytology screening guidelines published by ACS/ASCCP and ASCP in 2012 were markedly similar to the USPSTF's guideline (Saslow et al., 2012). The ACS/ASCC/ASCP and the USPSTF stratified age and risk for screening created a cut off age for exiting screening and created co-test strategies with DNA HPV testing. The difference between the USPSTF and the ACS/ASCCP/ASCP guidelines was time interval for co-testing. The USPSTF recommended women age 30–65 years be screened by either cytology every three years or co-tested every five years; whereas, the ACS/ASCCP/ASCP stated that co-testing every five years was preferred to cytology alone. The ACS/ASCCP/ASCP also identified cytology alone every three years as an acceptable strategy.

ACOG Cervical Cytology Screening Guideline

The American College of Obstetricians and Gynecology (ACOG) partnered with the USPSTF to develop the updated clinical guideline for cervical cancer screening. ACOG sent official representatives to the working groups who aided in development of the new guidelines established by the ACS/ASCCP/ASCP. ACOG recognized the similarity of the new guidelines produced by both organizations. ACOG reviewed both screening guidelines and provided its

own recommendations based on the new guidelines of both groups. Its recommendations represented a hybrid of the two organizations (ACOG, 2012). Table 2.3 contains a comparison of the three major guidelines for cervical cancer screening.

Table 2.3

Comparison of Cervical Cancer Guidelines

Population	USPSTF	ACS/ASCCP/ASCP	ACOG
< 21 years	No screening Grade: D recommendation.	Women should not be screened regardless of the age of sexual initiation or other risk factors. Strong recommendation	No screening regardless of age of onset of sexual activity or other behavior-related risk factors Level A evidence
21–29 years	Screening with cytology every 3 years Grade: A recommendation Recommend against HPV co-testing women <30 years. Grade: D recommendation	Screening with cytology alone every 3 years Strong recommendation HPV co-testing should not be used for women <30 years. Strong recommendation	Screening with cytology every 3 years Level A evidence HPV co-testing women should not be performed<30 years Level A evidence
30–65 years	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) Strong recommendation **OR** Cytology alone every 3 years (acceptable) Weak recommendation	Recommends screening with cytology every 3 years with HPV co-testing every 5 years Level A evidence
Older than 65	No screening of 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 Grade of recommendation not given	Do not screen with adequate screening history Level A evidence
After hysterectomy	No 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 (ie, 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. Strong recommendation	Women who have had a hysterectomy with removal of the cervix should stop screening and not restart for any reason Level A evidence
HPV vaccinated against type 16/18	Women who have been vaccinated should continue to be screened. Grade of recommendation not given	Women who have been vaccinated should continue to be screened. Grade of recommendation not given	Women who have been vaccinated should continue to be screened. Level C evidence

NOTE. USPSTF, U.S. Preventive Services Task Force; ACS/ASCCP/ASCP, American Cancer Society/American Society for Colposcopy and Cervical Pathology; ASCP, American Society for Clinical Pathology; HPV, human papillomavirus; CIN, cervical intraepithelial.

ACOG practice bulletin no. 131. (2012). Screening for Cervical Cancer. *Obstetrics and Gynecology, 120*, 1222-1238. http://dx.doi.org/10.1097/AOG.0b013e318277c92a

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Summary

In summary, the systematic review conducted by Vesco et al. (2011b) was ordered by the USPSTF to update the 2003 clinical practice guideline for cervical cancer screening. Due to the advancements in HPV testing and co-testing, at present the identification of high-risk HPV is more easily identified. The regressive nature of most HVP lesions allows for testing time to be lengthened, which prevents over diagnosis and treatment. This evidence was used to create an algorithm to educate and reinforce the updated cervical cytology screening guideline for clinicians who perform women's health exams at a volunteer clinic for the working uninsured.

Chapter Three: Methodology

This chapter includes a description of the design, setting and sample for the project and the methods and procedures for the project. This chapter concludes with a discussion of the protection of human subjects, analysis of project feasibility, and evaluation measures.

Design

The project was an evaluation of a quality improvement initiative to increase the use of the 2012 USPSTF clinical practice guideline for cervical cancer screening. A chart review was employed to determine compliance with the guideline.

Setting

The setting for this project was a volunteer clinic in a large metropolitan area in the southeastern United States. The clinic medical staff was comprised of advanced practice nurses and physicians providing free primary healthcare to low-income working, uninsured adults. The clinic also served as an educational site for supervised nurse practitioner students to provide women's health examinations. There were approximately 650 female patients in this practice, approximately 80 of whom have undergone cervical screening in an average year. Sixteen advanced practice nurses and five physicians provide these services.

Evolution of Current Practice

In November 2012, ACOG published practice bulletin no. 131, which endorsed the new USPSTF guideline for cervical cancer screening. Use of the guidelines at the clinic was relatively inconsistent until University of North Florida (UNF) faculty conducted a review of

guidelines with the full-time clinicians in October 2013. Beginning in November 2013, nursing faculty continued to reinforce the new guideline each time students were supervised at the clinic. Full-time clinicians adapted easily to the change; however, incidental findings during chart reviews indicated varied adherence to the guideline among the volunteer clinicians. This is likely due to variance in specialization among the volunteer clinicians, many of whom were not women's health specialists and may not been aware of the new guideline.

The quality improvement initiative project was a visual presentation of the 2012 USPSTF clinical practice guideline for clinical decision-making on the appropriateness of cervical cytology screening presented in an algorithm form (see Appendix A). Several providers expressed confusion over the decision to screen due to the complexity of the decision-making process. The simple algorithm provided in this project served as an educational decision tool to improve clinical practice.

The algorithm created for this project was based on the elaboration likelihood model [ELM] (Petty & Cacioppo, 1986). The ELM model was founded on the premise that attitudes that guide decisions and other behaviors may be changed with persuasion. Petty and Cacioppo described the use of active information processors in the brain as decision makers by comparing new information to the past experiences of the decision maker. The ELM model emphasizes the use of persuasive communication to motivate the consumer to make a cognitive structural change that will result in a positive central processing change (Petty & Cacioppo, 1986). Printed algorithms have provided visualization for the systematic and sequential steps in decision-making. Use of algorithms and care pathways in healthcare have promoted the highest standard of care when using evidence-based clinical practice guidelines and decision-making (Miller, Ryan, & York 2005).

The Committee on Standardization of Clinical Algorithms of the Society for Medical Decision Making has proposed criteria for construction of clinical practice guidelines (1992). Based on the 2012 USPSTF clinical practice guideline, the algorithm for this project was a simple classification algorithm that served only as a decision model and did not advocate for intervention. The model used only yes and no decision nodes with pathway arrows. The algorithm for this project was based on three-decision yes or no nodes. The design of the algorithm allowed for (a) understanding if the patient has prior screening; (b) understanding if the patient has had a prior abnormal cytology screening; (c) use of a risk assessment to identify high risk patients who need more frequent cervical cytology than the recommended low-risk screening; (d) use of screening pathways based on age; and (e) use of screening pathways based on exclusion criteria (over age 65 or hysterectomy without previous history or high-grade precancerous lesion).

The color choice for the algorithm was a cool color palette due to the association of calm, peace, pleasantness, love, happiness, and restfulness (Bellizzi & Hite, 1992). Two shades of blue were selected for the background and the body of the decision nodes. Black and white lettering was used for emphasis in the blue decision nodes. The algorithms were printed on 9 in x 13 in sheets of paper and laminated on both sides. The lamination process allowed for cleaning of the algorithm.

The algorithms were placed in all exam rooms designated for women's health examinations. The algorithms were affixed to the wall above the Mayo stands which held the medical equipment for cervical cytology screening. The placement of the algorithm was deliberate, allowing the clinician to follow the decision tree to confirm suitable patients for cervical cytology at the time of exam. Additional algorithms were placed at the clinicians'

charting desk with a copy of the clinical practice guideline and the follow-up protocols for abnormal screenings from ASCCP. A large poster-size algorithm was placed in the lunchroom as a reminder of the current guideline.

Sample

A convenience sample consisting of the medical records of all women who had women's health exams at the clinic between November 1, 2013 and April 31, 2014 were used for this project.

Procedures

Data were collected from the records of women receiving women's health services during each of three time periods: (a) August 1 to October 31, 2013, the three months representing baseline adherence to the new guideline; (b) November 1 to January 31, 2013, the three months immediately following initiation of nursing faculty education to full-time clinic staff and nurse practitioner students; and (c) February 1 to April 31, 2014, the three months immediately following introduction of the algorithms into the clinic.

Medical records were selected from those coded in the medical record system as ICD-9 code V72.3. These codes represented a routine gynecologic exam with or without a cervical cytology. The medical records in each time period were selected and reviewed by the primary investigator who also maintained a women's healthcare practice at the clinic. A flow sheet was used to perform the chart audit for adherence to the USPSTF guideline (see Appendix B). No personal identifying or health protected patient data was collected.

Protection of Human Subjects and Data Security

Permission to conduct this project was obtained from the executive board of the clinic and the Institutional Review Board for the University of North Florida. Data collected from

patient charts included no identifiable information. The Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations were strictly followed by the primary investigator.

Each chart reviewed was assigned a number and designation of data point one, two, or three (point one-1, point two-1, point three-1) to protect patient information. Data were entered into an electronic spreadsheet on the principal investigator's password protected laptop computer at the clinic. Data from the spreadsheet were analyzed using IBM SPSS Statistics 2.2.

Chapter Four: Results

This chapter describes the adherence to the 2012 USPSTF Clinical Practice Guideline for cervical cytology and presents a comparison in adherence rates among three time periods: August 2013-October 2013 (baseline, no intervention), November 2013-January 2014 (no intervention, but after a review of the clinical practice guidelines by the UNF faculty instruction of nurse practitioner students), and February 2013-April 2013 (after introduction of the visual cue/algorithm).

Participants

Four hundred-ten records were initially identified through review of ICD-9 codes meeting the inclusion criteria for this project. Unavailability of charts due to yearly purging of non-qualified patients decreased the convenience sample size to 335. Records included were those of women over the age of 18 who underwent a women's health exam from the period of August 2013-April 2014. Patients who had abnormal cervical cytology in the prior year were excluded from the sample, as this population was not eligible for screening.

Characteristics of the Participants

New patients were classified as patients who were new to the clinic and required a baseline women's health exam at the Volunteers in Medicine clinic (VIM). Established patients were patients who had a women's health exam previously at VIM. Three time periods were measured for evaluation of adherence: August 2013- October 2013, November 2013-January 2014 and February 2014-April 2014. Data were collected regarding four variables that impact

decision-making for cervical cancer screening: the age group of the women and the presence or absence of autoimmune disease, hysterectomy with cervical cancer, and hysterectomy without cervical cancer (see Table 4.1). The three groups were similar with respect to autoimmune rates (p=.19), hysterectomy with cervical cancer rates (p=1.00), hysterectomy without cervical cancer rates (p=.39), and age group rates (p=.10). See Table 4.1 for the detailed description of each groups.

Table 4.1

Sample Characteristics

Variable	Group							
	Baseline N=131		Post-education N=95		Post-algorithm N=109		Total N=335	
	N	%	N	%	N	%	N	%
New Patient								
No	68	51.9	60	63.2	70	64.2	198	59.1
Yes	63	48.1	35	36.8	39	35.8	137	40.9
Age Group								
<21 years and >65 years	1	0.8	1	1.1	1	1.9	3	0.001
21-29	46	33.6	48	50.5	38	34.9	132	38.89
30-65	84	65.6	46	48.4	70	64.2	200	60.29
Autoimmune Disease								
No	131	100	93	97.9	107	98.2	331	98.8
Yes	0	0	2	2.1	2	2.1	4	1.2
Hysterectomy with Cervical Cancer								
No	130	99.2	95	100	109	100	334	99.7
Yes	1	0.8	0	0	0	0	1	0.3
Hysterectomy without Cervical Cancer								
No	128	97.7	93	97.9	103	94.5	324	96.7
Yes	3	2.3	2	2.1	6	1.8	11	3.3

Appropriateness of Screening

The majority of patients were screened appropriately at all three time periods (see Table 4.2). Overall, there was a significant difference in the proportion of appropriate screening

among the three groups (X^2= 6.83 p=.03). After Bonferroni adjustment for pair-wise comparisons, the rate of appropriate screening was significantly higher for patients in group 3

Table 4.2

Appropriate Screening by Group

Appropriate Screening	Group*							
	Baseline N=131		Post-education N=95		Post-algorithm N=109		Total N=335	
	N	%	N	%	N	%	N	%
No	22	16.8	16	16.8	7	6.4	45	13.4
Yes	109	83.2	79	83.2	102	93.6	290	86.6

*Significant differences after Bonferroni adjustment between group 1 and 3 (adjusted p=.04)

(Post-algorithm) compared to the first group (Baseline) (93.6% vs 83.2% respectively). There was no significant difference in rate of appropriate screening by age group (X^2=0.47; p=.79).

Established versus New Patients

To evaluate for differences in appropriate screening between new and established patients, a Cochran-Mantel-Haenszel test was performed. This test obtains an overall comparison of appropriate screening rates adjusted for the stratification by group. There were 198 (59.1%) established patients and 137 (40.9%) new patients. There was a significant difference in appropriate screening rates between the new and established patients group, controlling for group (p<.0001). The significant difference was within the baseline group only with OR of 61.45 (95% CI 3.63, 1039.14) (see Table 4.3).

There was a significant difference in the proportion of appropriate screening among the three groups for both established patients (X^2=13.86 p=.001) and for new patients respectively (X^2=7.09; p=.03). The rate of appropriate screening for new patients was significantly higher for patients in the baseline group compared to the post-education (100.0% vs 88.6% p=.02) (see Table 4.4).

Table 4.3

Appropriate Screening: Established versus New Patients Stratifying by Group

Patients	Group							
	Baseline N=131		Post-education N=95		Post-algorithm N=109		Total N=335	
	N	%	N	%	N	%	N	%
New (N=137)								
No	0	0	4	11.4	2	5.1	6	1.0
Yes	63	100	31	88.6	37	94.9	131	39.1
Total	63	48.1	35	100	39	100	137	40.9
Established (N=198)								
No	22	32.3	12	20	5	7.1	39	11.6
Yes	46	67.7	48	80	65	92.3	159	47.5
Total	68	51.9	60	100	70	100	198	59.1

Table 4.4

Appropriate Screening of New Patients by Group

Appropriate Screening	Group*							
	Baseline N=63		Post-education N=35		Post-algorithm N=39		Total N=137	
	N	%	N	%	N	%	N	%
No	0	0	4	11.4	2	5.1	6	4.4
Yes	63	100	31	88.6	37	94.9	131	95.6

*Significant differences after Bonferroni adjustment between group 1 and 2 (adjusted p=.02)

After Bonferroni adjustment for pair-wise comparisons, the rate of appropriate screening for established patients was significantly higher for patients post-algorithm introduction compared to the baseline group (92.9% vs 67.7%, p=.0006) (see Table 4.4). The odds of appropriately screening of established patients were 6.21 times higher post-algorithm introduction compared to baseline (95% CI 2.19, 17.62).

Underscreening and Overscreening

Forty-five (13%) patients received inappropriate screening for cervical cancer. Only one was a case of underscreening (too infrequent cervical cytology), while 44 were cases of overscreening (too frequent cervical cytology).

Table 4.5

Appropriate Screening of Established patients by Group

Appropriate Screening	Group*							
	Baseline N=68		Post-education N=60		Post-algorithm N=70		Total N=198	
	N	%	N	%	N	%	N	%
No	22	32.4	12	20.0	5	7.1	39	19.7
Yes	46	67.7	48	80	65	92.9	159	80.3

*Significant differences after Bonferroni adjustment between group 1 and 3 (adjusted p=.0006)

Chapter Five: Discussion

This chapter provides a discussion of the project findings relevant to the use of a cervical cytology screening algorithm for adherence to clinical practice guideline. In addition, limitations of the project are articulated and implications of clinical practice and future research are delineated. New updates on cervical cancer screening and future research are presented.

Adherence to the Guideline

Use of the algorithm contributed to improved adherence in using the 2012 USPSTF clinical practice guideline for cervical cancer screening. This was especially true among established patients at the clinic. Exposure to the teaching of the 2012 USPSTF clinical practice guideline prior to the introduction of the algorithm likely influenced the improved outcome post-algorithm due to greater understanding of the guideline. Thus, a cumulative effect is likely to have been at work.

New Patients

Patients new to the clinic were more appropriately screened for cervical cytology during all three timeframes. This is likely due to the relative simplicity of the guideline for screening new patients. All patients new to the clinic should have a Pap smear, excluding patients who (a) are <21 years or >65 years; (b) present a medical record with a normal Pap within guideline parameters; (c) have undergone a hysterectomy without a history of cervical CIN2+; or (d) are currently under a plan of care for an abnormal cytology screen with another provider.

The percentage of new patients appropriately screened dropped from 100% at baseline to 88.6% post-education and rose to 94.9% post-algorithm introduction. Several factors may have influenced the change from baseline group to the post-education group. The baseline timeframe was in late summer to fall 2013 (August, September, and October). The baseline group did not have a wide variance of providers administering the screenings for cervical cancer because several volunteer providers took vacations during this time. The decreased amount of providers performing examinations could be contributed to the success rate of the baseline new patient group. Another factor that may have contributed to the decrease in the post-education group may have been the complexity of the new guideline without the visual algorithm. The six decision points (previous abnormal, new versus established patient, autoimmune disease, hysterectomy with or without cervical cancer, and age) may have been difficult to remember without educational reinforcement. The positive change in appropriateness from the post-education to the algorithm group may be related to the algorithm placement at the provider's point of care (above the Mayo stand where the speculum and cytology media is placed) for appropriate decision reinforcement. Posting of the algorithm around the clinic may have improved the post-algorithm outcome due to heightened awareness of the guideline derived from visual prompts.

Additionally, not all providers of women's health care received the verbal educational update of the clinical practice guideline. Several providers who needed to fulfill commitments to the clinic for service by the end of the year were not present for education of the new guideline.

Overscreening in New Patients

The lack of overscreening in new patients within the baseline group may have been attributed to the fact that one provider did the majority of the women's health exams. The post-education group had a greater variance of providers. The addition of a more varied provider

group (who may or may not have had the education of the new clinical practice guideline), during the post-education time period, may have contributed to the overscreening of the group. The principle investigator theorized that the varied group of providers continued the old practice of entry Pap smears on all new female patients without regard to the new clinical practice guideline. There was a pattern for overscreening in the post-education group. Of the four patients in the age range of 21-29 who were screened unnecessarily in this group, three presented with documentation of a normal Pap smear within the previous two years, and one had a history of hysterectomy without CIN2+. It is difficult to evaluate the reason for overscreening in the patients who presented with documented Pap smears. The availability of the past medical record at the time of the exam is not known.

Overscreening of Established Patient

Established patients were more likely to experience overscreening as compared to the new patient group. The principle investigator theorized that the use of varied providers without current knowledge of the new clinical practice guideline contributed to the use of overscreening in the established patient. In contrast to new patients without documented Pap smears, all established patient had a documented Pap smear that provided a baseline for provider decision-making regarding the need for cervical cytology. Twenty of the twenty-two (91%) of patients inappropriately screened had documentation of a normal Pap smear within the previous two years, and the remaining two (9%) had a history of hysterectomy without CIN 2+. It is possible that the pattern of overscreening was related to lack of knowledge of the extended screening period for cervical cancer screening.

Pap Smear Overuse

Predictably, this project found the most inappropriate screening procedure was the overuse of Pap smears in established patients. The results from this project are consistent with national findings regarding the overuse of Pap smears for screening. In 2012, a national survey of the members of the American Congress of Obstetricians and Gynecologists found physicians continued to recommend annual Pap smears (74% aged 21-29 years, 53% aged ≥30 years) because they felt patients were not comfortable with lengthened screening intervals and also felt t patients would not return for annual exams without yearly Pap smears (Perkins, Anderson, Gorin, & Schulkin, 2013).

Potential Confounders

There was much variation within the clinic with respect to those who provide women's health services. These variations included provider education, provider beliefs, and provider practice patterns.

Clinicians who perform women's health exams at the clinic included one full-time family nurse practitioner and volunteer clinicians. Volunteer providers included women's health nurse practitioners, family nurse practitioners, OB-GYN physicians, family practice physicians, and physician's assistants. Those whose specialties were in the field of women's health received updates on clinical practice guidelines during mandatory continuing education. This may not have been the case for those whose specialty was not women's health. This inconsistency may have created gaps in implementation of the current clinical practice guideline. This was apparent because despite the evidence of the harms of overusing cervical cytology, several providers admitted to the principle investigator that they continued to do Pap smears annually, stating it is "better to be safe than sorry."

Practice patterns varied greatly within the clinic. Volunteer providers may have worked as little as one day a month or as much one or two days a week. In addition to volunteers, local University of North Florida faculty members worked with nurse practitioner students providing women's health examinations one day a month. The varied use of providers for women's health exams may make it difficult to maintain a strict standard of care in the future.

Limitations

Although the full-time nurse practitioner was fully aware of the CPG and the project because of her position as the clinical director of the clinic, other clinicians did not participate in a one-on-one discussion of the project or the CPG. An educational module, CEU, or lecture on the 2012 USPSTF guideline for cervical cancer screening should have targeted all providers of women's health exams to improve the each clinician's knowledge of the guideline and use of the algorithm.

In this clinic, patients must requalify for care each year, based on income and family size. The annual date of requalification varies on the entry date of the previous year. If the patient no longer meets criteria for care, the chart is purged from the system. Charts which were reviewed for the project were, therefore, only those charts which were not purged for non-requalification. This limited access to data from the first two data collection points may have influenced the results.

Implication for Clinical Practice

Recommendations for the Clinic

A multidisciplinary evaluation, educational intervention, and implementation strategy is recommended to continue to improve adherence. Identification of cervical cancer screening

procedures that comply with the clinical practice guideline must be well understood by all personnel who participate in the care of the woman undergoing the women's health exam.

Patient history targeted to cervical cancer screening. A self-reported patient history including pointed questions regarding auto-immune disease, past screening, and past cervical health would facilitate identification of major factors influencing screening decisions. A simple yes/no question format would provide a quick visual assessment of the need for cervical cytology. Recommendations for history triage questions include

1. Is this your first Pap smear? Yes or No, if not, what was the date of the Pap smear and the results?
2. Have you been diagnosed with any of the following: high-grade precancerous cervical lesion or cervical cancer, human immunodeficiency virus or acquired immunodeficiency syndrome, lupus, rheumatoid arthritis, or other autoimmune disease or have you been exposed to diethylstilbestrol? Yes or No if other disease, please indicate type
3. Did you have a hysterectomy for a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer?
4. Are you in the age group between 21 and 65 years of age? If so, which is your age group? a) 21-29 years old or b) 30-65 years of age.

If "yes" is answered to any of the questions, the patient may need cytology. The visual triage site line should maintain "yes" or "no" in a vertical fashion to visually cue "yes" criteria. Education of this targeted cervical screening history information should be tailored to medical assistants, nurses, and all providers who administer women's health exams.

Identification of knowledge deficit. A survey measuring the current knowledge of medical assistants, nurses, and providers would be helpful in identifying gaps in knowledge. This information would facilitate targeted education efforts. Items on the survey should evaluate understanding of cervical cytology, awareness of change in clinical practice regarding obtaining cervical cytology specimens, knowledge of high-risk HPV types, the association with cervical pathology, and the understanding of triage principles regarding the need for cervical cytology.

Group education. A group education session could be conducted targeting two specific groups, medical assistants and nurses and providers of women's health exams. This tailored education should include review of the clinical practice guideline, reasons for the update (greater understanding of pathophysiology HPV and regression of low risk HPV lesions), and the harms associated with too frequent cervical cytology (patient fear and anxiety, elevated costs, unnecessary cervical procedures which could damage/alter future fertility). Information revealed in the survey will be broadly addressed in the group setting(s) to improve understanding of the clinical practice guideline without revealing the identity of the individuals with knowledge deficits. A group lecture should include a 15-minute review of the updated clinical practice guideline with emphasis placed on high-risk HPV pathophysiology and low-risk lesion regression, which prompted the extended screening schedule. Women's health staff members who are unable to attend the educational meeting should have a one-on-one teaching session to ensure understanding of the new clinical practice guideline. Educational materials should be provided to all staff that participates in the administration of women's health exams. Materials should include a copy of the compilation of the survey (in aggregate) with explanations and rationales, a copy of the clinical practice guideline, and a copy of the algorithm.

Ongoing evaluation. A regular pattern of chart reviews would be helpful to continue to monitor overall adherence to the guideline. Systematic chart review would also allow identification of providers who are not in adherence with the clinical practice guidelines. Personal feedback should be tailored to these provider's education needs.

Availability to access past medical records. Patients should be scheduled for new entry women's health exams after applicable medical records are obtained and available for

evaluation. Access to patient history will allow for a more accurate assessment of need for cervical cytology.

Recommendations for All Providers of Women's Health Exams

Careful examination of screening criteria is essential to providing the highest level of care in the women's health exam. Adherence to the clinical practice guideline provides the greatest benefit and least cost to the patient with the least amount of harm. A multidisciplinary approach to implement appropriately triage and screening of patients should be employed from the history throughout the examination by the medical assistant, the nurse, and the patient provider. Continued education on the rapidly advancing changes in the understanding of the HPV virus and approach to screening should be followed.

Further Research

Identification of providers who consistently make inappropriate decisions regarding cervical cancer screening should be the focus of future research. Evidence-based clinical practice guidelines are best practice standards. Most providers are accepting of the guidelines, as they are based on the highest level of evidence. A small group of providers take opposition to evidence-based guidelines, as they are viewed as "cook book medicine" and a threat to individualized provider decision-making regarding patient evaluation and treatment. The highest level of care is patient-centered, evidence-based practice. Clinical practice guidelines provide clinicians with updated, concise, evidence-based protocols for clinical practice.

A strategy to uncover misunderstandings and under-education of clinical practice guidelines is the administration of an initial survey to identify barriers to adherence. Survey development should revolve around the reasons providers do not adhere to the screening guidelines. Proposed targeted survey items should include understanding of the development of

clinical practice guidelines, updating clinical practice guidelines, assessment of provider knowledge (awareness or lack of awareness), evaluation of attitudes concerning use of guidelines (positive or negative), evaluation of provider perception of the guideline (confusion of the triage of cytology or frustration with the complexity of the triage of cytology), observation of behavior regarding use of guidelines (compliance or refusal to adhere to guidelines), and identifying reasons for adherence to the old techniques (fear of missing an advanced case of cervical dysplasia, lack of motivation to adhere new techniques, or patient expectation of yearly Pap smears).

Future Research on Women as Consumers of Medicine

National survey results have indicated that some providers of women's health exams feel women may want yearly Pap smears (Perkins et al., 2013). A randomized survey of women age 18-70 should be conducted to ascertain women's opinions, attitudes, and knowledge regarding Pap smears. Survey items should be evaluated to understand the demographic which may misunderstand the utility of Pap smears for screening. Use of public service announcements to target the demographic audience should be considered to educate the public on the harms of annual Pap smears in patients who do not meet criteria for cervical cytology.

New Advances

In April 2014, the FDA approved the cobas® HPV DNA test for primary cervical cancer screening for women age 25 and older (U.S. Food and Drug Administration, 2014). The broaden use of the test is intended to be implemented alone to test for 14 high-risk HPV types. The test results will allow the provider to make decisions regarding the need for additional diagnostic cervical cytology. The FDA advised that women who test positive for HPV 16 or HPV18 should be evaluated by colposcopy because the two types are responsible for 70% of

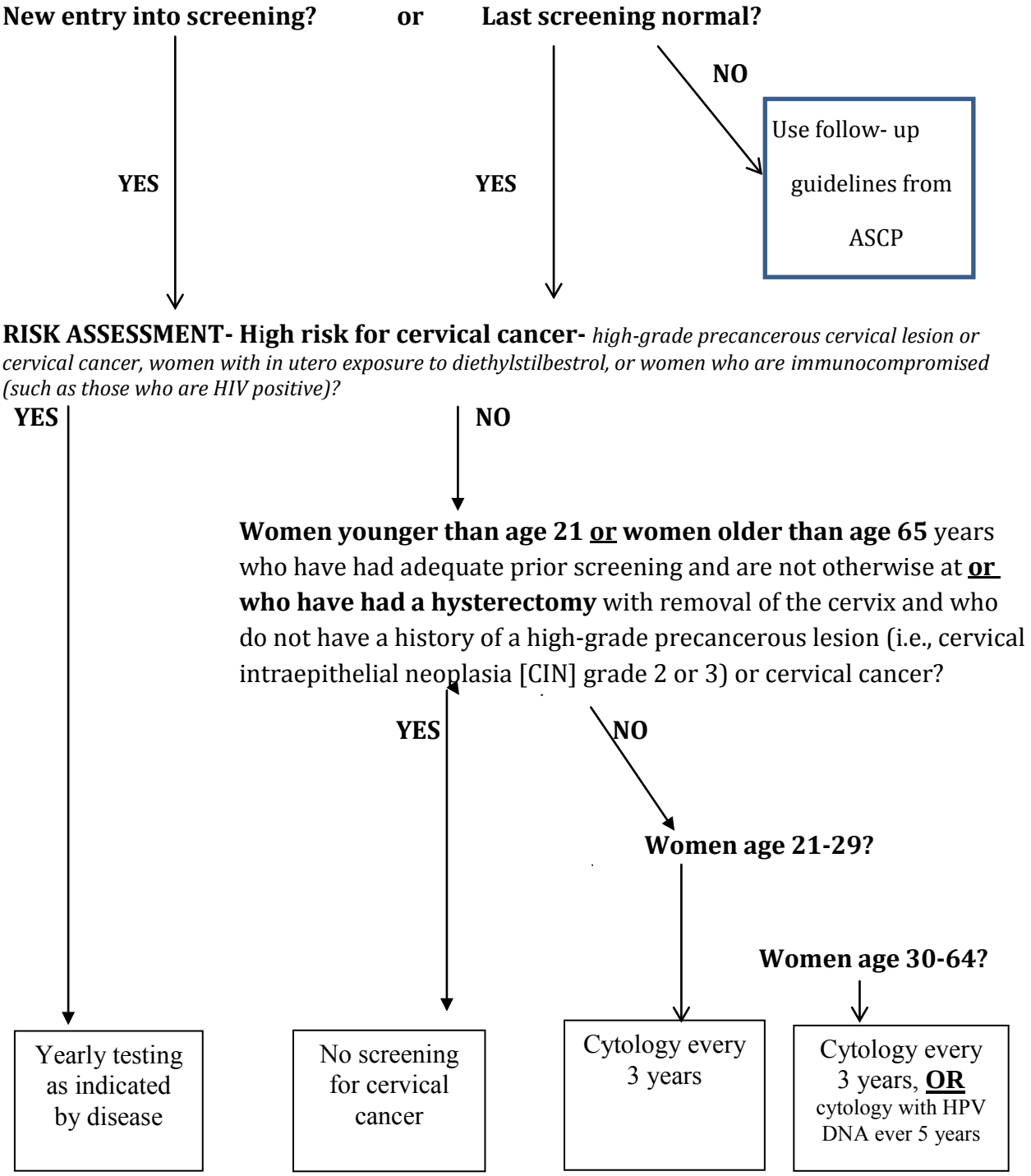
cervical cancer cases. The detection of the remaining 12 high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) serves as a referral for Pap testing to determine if there is a need for colposcopy.

The complexity of screening for cervical cancer has continued to increase. With the addition of HPV DNA testing for women over the age of 25, confusion will arise concerning co-testing (currently recommended for ages 30 and over) versus Pap screening in women aged 25-30 years of age. Current guidelines call for Pap testing on women ages 21-30. While the FDA has approved the use of the cobas® HPV DNA test for primary screening, recommendations from the ACOG, USPSTF, and the ACS/ASCCP/ASCP are needed.

Conclusion

The goal of this project was to determine whether the use of a simple algorithm could improve adherence to current cervical cytology screening guideline at a clinic for the working uninsured in the southeastern United States. Use of the algorithm yielded significant improvement in provider adherence rates to the 2012 USPSTF clinical practice guideline for cervical cancer screening. The majority of inappropriate use of screening techniques was due to overuse of cervical cytology. Targeted education to improve adherence to evidence-base practice guidelines regarding cervical screening will decrease harms to the patient by reduction of fear, cost to the patient, and overtreatment of benign regressive lesions.

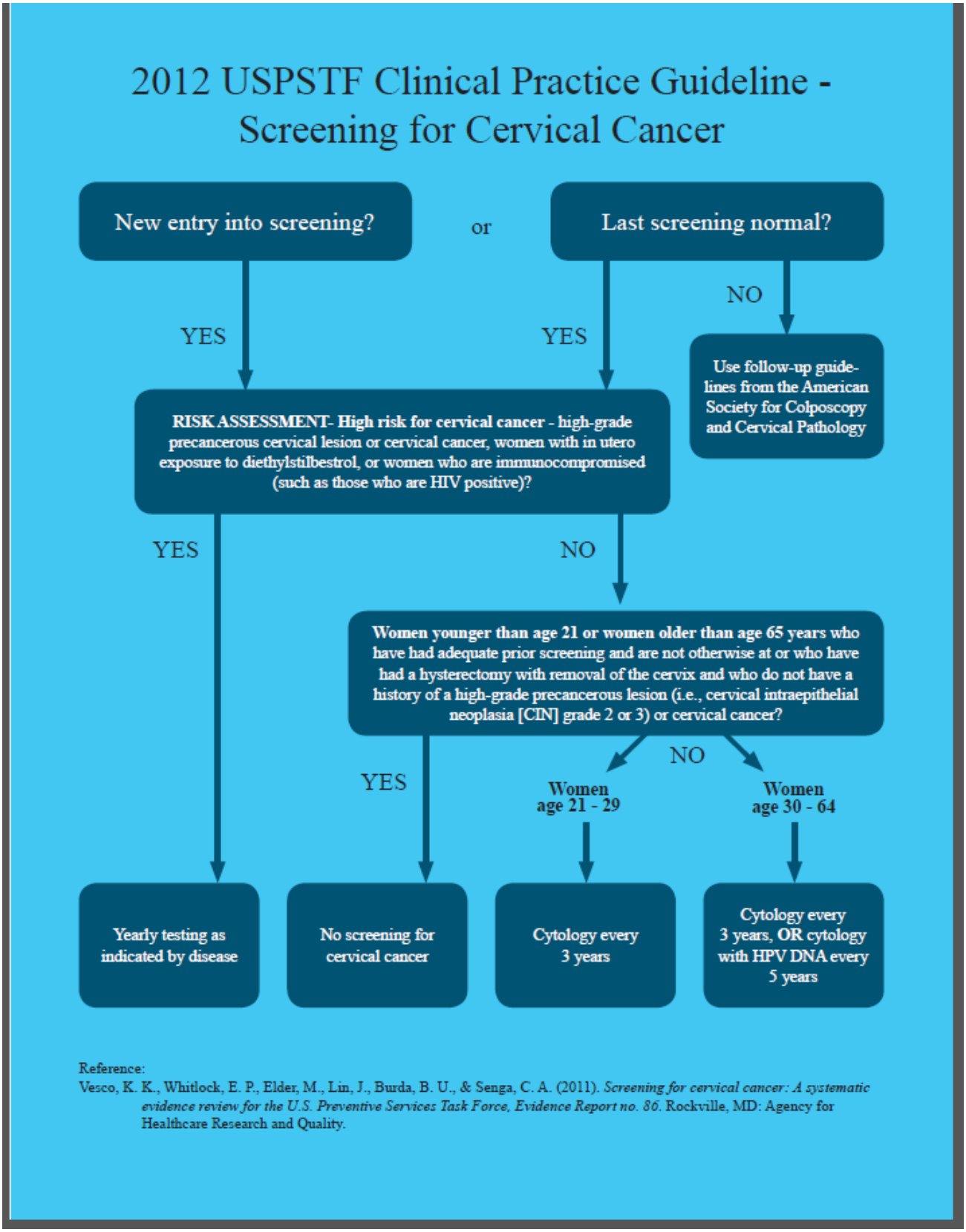
Appendix A: Screening algorithm



Reference:

Vesco, K. K., Whitlock, E. P., Elder, M., Lin, J., Burda, B. U., & Senga, C. A. (2011b). *Screening for cervical cancer: A systematic evidence review for the U.S. Preventive Services Task Force, Evidence Report no. 86*. Rockville, MD: Agency for Healthcare Research and Quality.

Algorithm as Posted in the Clinic



Reference:
Vesco, K. K., Whitlock, E. P., Elder, M., Lin, J., Burda, B. U., & Senga, C. A. (2011). *Screening for cervical cancer: A systematic evidence review for the U.S. Preventive Services Task Force, Evidence Report no. 86.* Rockville, MD: Agency for Healthcare Research and Quality.

Appendix B

Data Collection Sheet

Chart	<21	21-29		30-65		>65		Hysterectomy		HPV Vaccine
	No Screen	Q3Yrs	No HPV	Q3Yrs w/HPV	Q5Yrs w/o HPV	No screen		No screen		Screen as app to age
						Adeq prior scr	No risk factors	No cervix	No hx cx CA	
Point 1 #1										
Point 1 #1										
Point 1 #1										
Point 2 #1										
Point 2 #2										
Point 2 #3										
Point 3 #1										
Point 3 #2										
Point 3 #3										
etc.										

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