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Initiating HPV Co-testing for Women Aged 30-65 in an Ob/Gyn Practice Setting

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by

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Abstract

The purpose of this project was to improve the rate of successful human papilloma virus (HPV) screening in a small Texas based Women's Health clinic through co-testing. The intended goal was to increase the rate of HPV screening from a 73% baseline to 95% over a 10-week period for women aged 30–65 years old. Approximately 79 million American women are currently infected with HPV, and 14 million people contract it every year. Seventy percent of cervical cancers today are caused by HPV, with an estimated 12,820 new case of invasive cervical cancer expected to be diagnosed by the conclusion of 2017. Moreover, in this same year, and estimated 4,210 American women are expected to die from HPV-related complications. Women between the ages of 30 and 65 years are eight times more likely to contract invasive cervical cancers through HPV than those under 30 years. Therefore, this project incorporated multiple interventions, including increased patient screening appointments, the initiation of quality improvement meetings, and the implementation of the HPV co-testing protocol. Upon completion, 107 patients between the ages of 30 and 65 had been successfully co-tested for HPV, with 104 patients having negative screening results, and three patients with positive results. There was a statistically significant improvement in the rate of HPV screening, from 73% to 93%. Therefore, the implementation of co-testing had a positive impact on HPV screening rates.

Keywords: human papilloma virus, HPV, cervical cancer, co-testing, women.

The human papillomavirus (HPV) is a viral infection that is spread through physical contact. HPV infections are the most prevalent sexually transmitted diseases (STD) in the world, and are associate with significant economic and physical burden (Miranda et al., 2013). Patients who have HPV and persistently become infected are at an elevated risk for many types of cancers, including cervical, anal, vulvar, vaginal, and oropharyngeal (Miranda et al., 2013). Primary care clinics need to treat these infections effectively, but with many infections having no major symptoms, screening for HPV is critical effective for treatment and prevention. This project aims to introduce the most current national HPV screening guidelines into a small women's health clinic in hopes of improving HPV screening rate.

Statement of the Problem

The prevalence of STDs is one of the most underestimated factors in the public health battle (Centers for Disease Control and Prevention [CDC], 2016a). Approximately 110 million people living in the US are currently living with an STD (CDC, 2016). The prevalence of HPV has been steadily increasing, which is especially problematic for women over the age of 35, who suffer more severe health complications than younger patients (CDC, 2016).

Background and Significance

The ramifications of untreated STDs are immense. Short-term effects of untreated STDs include pelvic inflammatory disease, epididymitis, and pregnancy complications (Royer et al., 2013). Long-term, STDs can result in ectopic pregnancies, infertility, urethritis, and an increase in the risk of contracting HIV (Royer et al., 2013). Untreated HPV can cause oral and upper respiratory lesions, genital warts, and cancer of the cervix, throat, female genitals, and the anus (CDC, 2016). One of the most concerning aspects of HPV is that while it is less common in women over the age of 30, when found, it is more likely to cause significant health problems,

such as cancer (CDC, 2012). Statistics show that fewer than 2 out of 100,000 women under the age of 30 contract cervical cancer, while women above the age of 30 are 8 times more likely to be diagnosed with cancer (CDC, 2012).

With all of these potential complications, adequate screening is imperative for the health of these patients. With millions of new sexually transmitted infections occurring every year in America, the medical costs to the U.S. economy are tremendous. Research has found that the 19.7 million recorded cases of STIs in 2008 cost the nation somewhere between $11 and $20 billion, with HPV trailing only HIV at nearly $3 billion (Owusu-Edusei et al., 2013). Owusu-Edusei et al. (2013) go on to acknowledge the importance of screening in keeping costs down, noting that if it were not for current screening efforts, billions more dollars would need to be spent on these patients. Other research has shown that screening is effective in reducing the physical and financial burden of HPV to the nation, especially in at-risk populations, such as minorities, the impoverished, and those living in high crime areas (Owusu-Edusei & Doshi, 2012; Satterwhite et al., 2013). Missing or incorrectly performing screening procedures can incur a heavy burden on both the nation and on individual patients; therefore, primary care clinics need to prioritize these interventions (Owusu-Edusei & Doshi, 2012; Satterwhite et al., 2013). A new method, a co-testing procedure involving a traditional Pap smear and HPV screening, has become increasingly popular in primary care as a potential solution to the aforementioned screening difficulties (Stoler et al., 2011).

Assessment

The setting for this project and where these assessments were performed was in a clinic located in San Antonio, Texas. Surrounding institutions and locations include San Antonio College, a major hospital, and a public park. The clinic was located in one of the outermost wings of the hospital, and was independently run by one physician. In addition to the one physician, the clinic was staffed by four medical assistants. Each medical assistant had the ability to perform the necessary procedures articulated within their scope of practice, such as administering injections, drawing blood, ordering supplies and equipment, preparing exam rooms, scheduling appointments, recording vital signs, and recording patient medical histories.

The patient population was predominantly Caucasian (42%), followed by Hispanic (31%), Asian (Hindu-Indian) (12%), African American (13%), and Asian (Oriental) (2%). The average patient age was 38 years old, with a median age of 36 years, and a range from 12 to 71 years of age. The clinic's patient population was almost entirely female (94%), and the majority of patients have insurance, as Medicare, Medicaid, nor Tricare insurances are not accepted by the clinic. The most common insurance provider was Blue Cross Blue Shield (37%), followed by United Health (29%), Aetna (15%), Humana (8%), Signa (7%), and Oscar (4%). The most common individual diagnoses included submucous/intramural leiomvoma of uterus, menopausal and female climacteric states, supervision of high risk pregnancy, and irregular menstruation.

The clinic physician completed hospital rounds prior to arrival at the clinic on Monday, Tuesday, Thursday, and Friday. The physician reserved Wednesday mornings for performing surgeries and procedures at the hospital before arriving at the clinic later in the day

The duration of each appointment/examination varies by patient encounter. For general gynecological encounters, the physician spent on average 3 minutes, while and ultrasound or appointment for a pellet procedure took as long as 15 minutes. The clinic utilized a flexible and easy to use Microsoft Word template for recording patient appointments. The paper charting system used by the clinic is less efficient than using an electronic medical record. Consequently, there was often a backlog of documentation, with the physician spending approximately 1 hour each day completing their documentation before leaving the clinic. Virtually every element of the clinic was affected by a lack of technology, from paper charting to the use of obsolete equipment. The ultrasound machine was fairly new, as was the mobile card reader that allowed patients to pay for services with a credit card. This card reader was a relatively new device to the clinic, with patients previously required to pay using either cash or check. The clinic held no staff meetings, and the only time that the staff formally met was when a representative from a pharmaceutical presented a new product. There were no quality improvement checks or initiatives undertaken by the clinic, due in part to the nature of the clinic's workload. When interviewed, none of the staff could identify areas of the clinic's practice requiring quality improvement or a need for evidence-based practice.

Clinic appointments were scheduled to commence at 10:00 a.m. With only the one provider for the clinic, any delays, irrespective of their source, had a snowball effect on the entire day, often resulting in long patient wait times. The physician usually arrived after 10:30 a.m., and was called out of the office on average two days out of the week to deliver babies or to perform other procedures. From the encounters and procedures observed, only 77% occurred without interruption. The physician had to leave the room to request or to personally retrieve necessary supplies during 45% of procedures. In summary, the days rarely went as scheduled

owing to various interruptions; consequently, patients were usually not seen until at least 1 hour after their scheduled appointment time. The unpredictable nature of the clinic's schedule means that there were periods in which the staff was extremely busy, which was then be followed by periods of relative inactivity when the physician departed for the hospital for a procedure.

In the fall of 2016, a microsystem assessment was performed of the clinic's processes and it was determined that STD screening, particularly HPV screening, was not being completed in accordance with clinical practice guidelines. Of the 46 eligible patients identified through chart reviews, only 33 (72%) had an annual HPV screening completed.

Organization's Readiness for Change

The staff's level of readiness for the project was determined through the use of the Practice Improvement Capacity Rating Scale (Robert Wood Johnson Foundation, 2014). This assessment is well-known in health care for its ability to identify the readiness of personnel for performing quality improvement tasks (Robert Wood Johnson Foundation, 2014). The assessment was completed through an interview with the physician and each of the clinic's staff. After averaging the scores from all interviews (Table 1), the final score of 260 indicates the clinic's readiness for quality improvement initiatives.

Table 1

Results of Practice Improvement Capacity Rating Scale

Question	Weight	Criteria	Scripted Questions	Red 0	Yellow 5	Green 10	Score
1	3	**Commitment: Senior Leadership QI Champion sponsor**	Can you tell me about the commitment that senior leadership (the administration/the practice) has made to the project? • Designated leader? • Regular team meetings? • Time, finances, resources?			10	30
2	3	**Commitment: Financial Resources**	How do the leader and the QI team fit in QI work with their other responsibilities in the practice?			10	30
3	3	**Level of Physician Leader Support**	Do you have a physician leader who supports this effort? What is the relationship between this person and the QI team?			10	30
4	3	**Level of Practice Administrator Support**	Does your practice administrator or office manager support this effort?			10	30
5	3	**Competing Priorities**	Are there any changes that have occurred/are going to occur that may have an effect on this project? Are there any other projects the practice will be working on while this QI project is going on?			10	30
6	2	**Communication**	Does the rest of the staff know about this effort? How are you communicating the work being done by the QI team to the rest of the practice?			10	20
7	2	**Access/ Use of QI Infrastructure/ Resources Available in the Community**	Does your practice participate in any community improvement efforts? Any EMR sponsored or trade industry sponsored improvement efforts?	0			0
8	2	**Prior Experience Executing QI Projects**	Tell me about the improvement work your practice has done in the past. What kind of experience do the members of the QI team bring to the effort? Do you keep a record of what you have tried and how it went?	0			0
9	2	**QI team designated with appropriate representation**	Who is/ will be on your QI team? Why?			10	20

Question	Weight	Criteria	Scripted Questions	Red 0	Yellow 5	Green 10	Score
10	2	**Reliability of data**	How reliable do you think your reports are? Does the information seem accurate to you? Do you compare your data to other national benchmarks? Is there someone who looks one the reports for accuracy?			10	20
11	2	**Reliability of data collection**	How reliable do you think your data are? Do you think the data you need are reliably entered into the EMR with each encounter? Is there a way to tell if they are?			10	20
12	2	**External Payment Incentives from Commercial/ Governmental Payers Linked to the QI Project**	Is the practice being paid to participate in an improvement effort other than MU? Are you being paid to report on or met quality measures?			10	20
13	1	**Meaningful Use**	Where is your practice in terms of applying for meaningful use?		5		5
14	1	**Source of IT support**	What do you do when you need to add fields to collect data or run reports? • Do you do this in office? • Do you need to contact someone outside the office? • Does this arrangement meet your needs/ the needs for the QI project and QI team?	0			0
15	1	**Use of EMR/Registry/ Analytic Reporting Tool for Measurement/Data Reporting**	What data will you be collecting for this project? How do you plan to collect the data you will need for this project? • Is the information currently collected in your EMR? • Can you get reports based on the data from your EMR?		5		5
Final Score				Red 0–99	Yellow 100–249	Green ≥250	260

Stakeholders involved in the information gathering process included the physician, all clinic staff members, and the patient population. A strengths, weaknesses, opportunities, and

threats (SWOT) analysis can be used to assess both the internal and external factors affecting the clinic and is used as part of the readiness assessment (Nelson, Batalden, Godfrey, & Lazar, 2011). One of the strengths of the clinic was the staff's eagerness to try new initiatives to improve patient care and overall clinic efficiency. A weakness identified through the SWOT analysis was that the staff had been working at the clinic for many years, which may make any changes difficult for them to accept. An opportunity identified via the analysis was that because it is a private clinic, the staff was free to create their own schedule for meetings or quality improvement activities as they see fit, and were not bound by the schedule of another organization. However, one major threat to the clinic's readiness was the lack of time due to double booking and low staffing, which made it difficult for the clinic to identify the time to enact change. Evidence-based assessments are important tasks needed to be complete by the clinicians in order to ensure that the highest quality of care is provided (Jensen-Doss & Hawley, 2010). However, the lack of quality meetings in the clinic, the need to optimize patient care protocols and procedures is apparent, and the staff is onboard with the proposed project.

Project Identification

Purpose

The purpose of this project was to improve the rate of successful HPV screening in a small San Antonio based clinic. Specifically, the goal was to incorporate HPV co-testing with a Pap smear during visits to the Well-Woman exam. This co-testing approach was added to the clinical guidelines of the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP) in 2012.

Objectives

The primary objective of this project was to increase the rate of HPV screening from 73% currently, to 95% through HPV co-testing. Secondary objectives include increasing the average appointment time length from 3–5 minutes to 15 minutes for Well-Woman's exams and to implement biweekly quality improvement meetings for all staff.

Anticipated Outcomes

Co-testing was not among the clinic's standard practices. Standard practice was to conduct a Pap smear independent of any other screening procedures. While the intervention in this project applies to all women seen within the clinic, the primary focus of this project was women over the age of 30, per the recommendations in the screening guidelines. The specific objectives of the project included: (a) increasing the allotted appointment times for Well-Woman's exams; (b) improving the completion rate of all aspects of the Well-Woman's exams, including HPV co-testing; and (c) initiating regular quality improvement meetings for the entire clinic staff. The expected primary outcome for this project will be an increased rate of HPV screening, which should increase from 73% to 95% over 10 weeks. Other anticipated outcomes include: (a) staff will attend regular quality improvement meetings, which they will conduct on their own after the project has been completed; and (b) appointment times for consultation and annual checkups will be extended.

Summary and Strength of the Evidence

Cancer is one of the leading causes of mortality in the United States and around the world. According to the CDC (2017), cancer was the second leading cause of mortality in the United States, causing 591,699 deaths in 2015, just behind heart disease at 614,348 deaths. To this into perspective, the number of cancer deaths in the US is more than the next five leading

causes of death combined (CDC, 2017). In 2016, 1,685,210 people were diagnosed with cancer, leading to 595,690 deaths (National Cancer Institute [NCI], 2017).

Unfortunately, the global burden of cancer appears to be worsening, with there being little indication of improvement in the prevalence or mortality of cancer. The NCI (2017) has projected that worldwide cancer cases will increase by 50%, from 14 million to 21 million, between 2012 and 2030. Over this same period, cancer deaths across the globe are expected to increase by 60%, from 8 million to 13 million (NCI, 2017). The economic impact of cancer is substantial, with approximately $125 billion having been spent on cancer care and related services in 2010 (NCI, 2017). This figure is also expected to rise as the economic cost of cancer to the US is expected to reach $156 billion in 2020 (NCI, 2017).

According to the ACS (2017), an estimated 12,820 new diagnoses of cervical cancer are expected to be made in 2017, resulting in the deaths of 4,210 women. The cost of cervical cancer was approximately $1.3 billion in 2010, with this figure expected to increase to $1.7 billion in 2020 (NCI, 2017). Cervical cancer most commonly occurs in midlife, with the majority of cases found in women aged 20–50 years (NCI, 2017). HPV is significantly related to cervical cancer, with HPV being responsible for 70% of all cases (NCI, 2017). Although cervical cancer was once among the deadliest forms of cancer, the introduction of Pap smear testing 60 years ago has seen the cervical cancer death rate decrease by over 50% since the 1940s. Part of the reason for this dramatic reduction in cervical cancer mortality rests with the regularity of screening, the rate of which depends on the patient profile (usually every 1–3 years or 1–5 years) (ACS, 2017). Regular screening also increases early detection, which is important in light of the difficulty of treating advanced forms of cervical cancer.

Nonetheless, the screening protocols for cervical cancer have recently changed. In early 2012, new guidelines were jointly created by the ACS, ASCCP, and ASCP in regard to the prevention of and screening procedures for cervical cancer. The new guidelines recommend that co-testing with the HPV test, or the HPV reflex screening, is the preferred screening method rather than a standalone Pap smear test in patients aged 30–65 (ACS, 2017; Agency for Healthcare Research and Quality [AHRQ], 2012; ASCCP, 2016). This recommendation is based on clinical research showing that incorporating the HPV test into the cytology of the specimen improves the detection rate of cervical cancer and decreases the frequency in growth of invasive cervical cancers compared to using only a Pap smear (ACS, 2017; AHRQ, 2012; ASCCP, 2016).

A large clinical trial conducted by the Addressing the need for advanced HPV diagnostics group (ATHENA) investigated the effectiveness of HPV co-testing in over 47,000 women, examining both women with atypical squamous cells of undetermined significance (ASC-US) and normal cervical cytology (Stoler et al., 2011). Upon their initial visit, study participants had co-testing performed, with their next follow-up appoint scheduled 3-years later (Stoler et al., 2011). Women who tested positive at either initial or follow-up appointment were promptly referred to either further investigation (i.e., colposcopy) and/or treatment (Stoler et al., 2011). The results of this study showed that concurrent HPV testing alongside a Pap smear yielded more accurate results than Pap smear testing alone, improving both the detection of cervical pre-cancer cells and invasive cancer (Stoler et al., 2011). The study was one of the largest in this field, and the findings were instrumental in the development of new cervical cancer screening guidelines developed by the ACS, ASCCP, and the ASCP.

Cox et al. (2013) compared different cervical cancer screening methods against one another in relation to participants over the age of 30. Some of the strategies measured included

cytology with reflex HPV, co-testing with reflex for ASC-US, co-testing with genotyping and cytology triage, and cytology alone (Cox et al., 2013). The results of the study showed that while elaborate screening protocols offered greater sensitivity, they also required additional workups, including colposcopies that can be costly to the patient and the health care system. The study found that incorporating HPV testing into cervical cancer screening represented the most efficacious balance between achieving a high level of sensitivity and potential over-servicing through unnecessary screening and additional colposcopies (Cox et al., 2013).

The ACS performed two cohort studies to determine the value of HPV co-testing with Pap smears. These studies involved approximately 1,065,723 women seen through the Kaiser Permanente Northern California facility (Silver et al., 2016). The first cohort, or "open cohort," involved women who were screened for cervical cancer at KPNC between the years of 2003 and 2012 (Silver et al., 2016). The second cohort, or the "closed cohort," comprised women who had begun co-testing in 2003, and who were followed through to 2012 to determine the effect of repeated screenings over time (Silver et al., 2016). The average age of women participating in the study was 44 for the open cohort and 46 for the closed cohort. The participants were assessed at three time intervals: 2004–2006, 2007–2009, and 2010–2012 (Silver et al., 2016). The results for the open cohort showed that the detection of cervical cancer increased throughout the length of the study, increasing from 82 out of 100,000 women screened in the 2004–2006, to 126 out of 100,000 women screened 2010–2012 (Silver et al., 2016). The results for the closed cohort also showed improvement across the duration of the study, with the largest increase occurring between the years of 2004 to 2006, and 2007 to 2009, during which the number of women screened rose from 80 out of 100,000 to 118 out of 100,000 women (Silver et al., 2016). The study concluded that co-testing decreased the pre-cancer and cancer rates in both samples, and

that co-testing is effective in reducing the burden of cervical cancer places on society (Silver et al., 2016).

Another study attempted to incorporate the new co-testing guidelines into practice at a large health care facility (Katki et al., 2013). Through a process of benchmarking, the investigators changed the facility's protocols to co-testing based on risk thresholds and educational efforts (Katki et al., 2013). The investigators analyzed the most critical aspects of the co-testing procedure and developed a study protocol with view toward increasing the effectiveness of screening. Health care facility staff received education regarding the significance of screening and the importance of the protocol for ensuring compliance. Over 965,359 patients were sampled over 7-year study period, from 2003 to 2010, with 100% of participants having been assessed for compliance using the new screening protocols (Katki et al., 2013). The types of cancer cells assessed included low-grade squamous intraepithelial lesions (LSIL), ASC-US, and HPV positive/ASC-US (Katki et al., 2013). The results of the study suggest that benchmarking was an effective strategy for incorporating co-testing into the targeted health care setting, and that co-testing reduced the risk of inaccurate screenings by as much as 80% (Katki et al., 2013).

Arriaga et al. (2013) investigated the effects of a protocol for increasing the performance of operating rooms. Seventeen operating room teams from three different institutions participated in 106 simulated crisis situations. These teams were selected at random, with half of the participating teams performing the simulations without a crisis protocol, and the other half with crisis protocols (Arriaga et al., 2013). The results of the study showed that the teams who used the crisis protocols omitted only 6% of processes, while teams who were not using the crisis protocols omitted 23% of processes (Arriaga et al., 2013). These results were verified through a multivariate model that accounted for the composition of the teams, institutional habits or bias,

specific scenarios, and study fatigue (Arriaga et al., 2013). In addition, 97% of participating teams indicated that they would want to use the crisis-specific protocols in future scenarios (Arriaga et al., 2013).

Protocols have also proven useful in large scale situations. A stepped wedge cluster randomized controlled trial published in the *Annals of Surgery* sought to identify the effect of a safety protocol for a variety of hospital procedures (Haugen et al., 2015). The trial took place in Norway, in both a 1,100 bed tertiary teaching hospital and a smaller 300 bed community hospital. Over the course of the month long trial, 2,212 control procedures and 2,263 protocol procedures were documented. The specialties involved in the study included cardiology, neurology, orthopedic, urology, and general medicine (Haugen et al., 2015). The protocol consisted of 20 items derived from the World Health Organization's guidelines for safety, and the study sought to measure the effect of this protocol on the frequency of complications, mean length of stay, and in-hospital mortality (Haugen et al., 2015). The results showed significant positive outcomes across all variables under observation. Complication rates dropped from 19.9% to 11.5%, mean length of stay decreased by 0.8 days, and in-hospital mortality decreased from 1.9% to 0.2% following procedures that utilized the protocols (Haugen et al., 2015). The study concluded that targeted protocols can have a positive effect on patient outcomes in large health care systems.

Methods

The primary aim of the project was to implement HPV co-testing for women aged 30–65 years. The objectives included increasing the rate of HPV screening from the current level of 73% to 95% through HPV co-testing, increasing the average appointment duration from 5 to 15 minutes for Well-Woman's exams, and implementing biweekly quality improvement meetings

for all staff. Outcomes that were subject to measurement during this project included protocol utilization per eligible patient, percentage of protocol completed by staff per co-testing procedure, percentage of correctly altered time slots, and overall HPV screening rate.

Project Intervention

The HPV co-testing initiative included three major interventions. The first of these major interventions was to standardize the appointment time slots for Well-Woman exams to 15 minutes. Prior to project initiation, patients were allocated 5-minute appointments, regardless of the encounter type. The inability to differentiate between the time requirements in the appointment template for various encounters impacted the overall organization of the clinic's work practices and increased the likelihood for errors. By increasing the appointment times for Well-Woman exams, global improvements to the patient's encounter experience are expected, from completion of the entire exam to proper specimen collection.

The second intervention involved the initiation of quality improvement meetings in the clinic. These meetings are scheduled to be held on the first and third Tuesday of the month, as agreed upon by the staff. These meetings should help the clinic staff to focus on the resolution of clinical issues that might otherwise be impossible for a single person to resolve. Quality improvement programs are valuable components of primary care clinics (U.S. Department of Health and Human Services, 2011). Positive outcomes from a quality improvement program include improved patient health outcomes, increased efficiency in managerial processes, cost reductions due to a drop in preventable errors, enhanced communication between staff, and the ability to solve problems before they cause serious damage to the clinic (U.S. Department of Health and Human Services, 2011). Effective quality improvement should be considered integral to the management of any clinic, with such program benefiting the organization as a whole.

The final intervention involved the development of a protocol to guide the clinic's staff in the enactment of HPV co-testing. In addition to these new co-testing guidelines, a protocol was introduced to be following during every eligible visit to ensure that all steps involved in the HPV co-testing process were performed correctly. The co-testing procedure uses the same sample collected for the regular Pap smear. Consequently, patients undergoing co-testing are tested for both cervical cancer cells and/or cervical cell changes, plus HPV via a single sample. The clinic is associated with and utilized the co-located hospital laboratory for pathology purposes; therefore, requesting HPV testing was simply a matter of adding an additional laboratory work order for the original Pap smear sample. Similar protocol processes have proven effective in larger health care system, including perioperative environments and hospital settings (Arriaga et al., 2013; Haugen et al., 2015; Katki et al., 2013). These studies demonstrated that the protocols resulted in less errors being made, enhanced the efficiency of specified processes, and increased effectiveness, thus leading to improved outcomes, all of which would benefit the clinic.

The instituted protocol was composed of seven steps for completion by clinic staff during eligible patient encounters. These seven steps are described thusly.

1) Verify that the appointment time slot has been changed from 5 minutes to 15 minutes.
2) Confirm that the charts have been prepared in advance and checked the day before the appointment.
3) Ensure all exam rooms have been supplied with sufficient stock of appropriate materials and that specimen labels have been created before the procedure begins.
4) Staff to verify patient eligibility for HPV co-testing/screening before the encounter.
5) Staff to ensure that all charting of the Well-Woman's exam has been completed before the end of the day.

6) Verify that specimens have been correctly labeled and prepared for transport and submission to the laboratory.
7) Staff to ensure that the next patient in the queue eligible for HPV co-testing is identified in advance and that their appointment time has been recorded.

The investigator guided the staff in how to properly complete the protocol at the beginning of the project, with the goal that the staff would be able to complete the protocol independently as the project progressed.

Copies of the protocol were posted in every examination room. The medical assistant responsible for assisting the physician would use the protocol during the examination and mark the boxes after each task was completed. Staff were instructed that should the protocol not be completed during a single visit, that the tick boxes for the yet to be completed tasks should be left blank, and the protocol placed in the front of the patient's chart once the encounter had ended. At the close of the project, projected protocol utilization should be somewhere in the order of >90%. Another projected outcome is for >90% of protocols to be successfully completed by the end of the project. A third projected outcome is that over 75% of eligible patient appointment times will be altered from 5 minutes to 15 minutes at the close of the project. Finally, overall HPV screening rates are projected to rise above 90% by the end of the project.

Results

A total of 104 eligible patients entered the practice during the 10 weeks of the project. Of these, 104 (100%) were screened utilizing the HPV co-testing method. There was little fluctuation over the course of the project in the number of patients screened.

Participants in this project tended to be middle-aged (Table 2), as was typical for this clinic as a whole. Other than Hispanic, the clinic saw a large number of women from the Hindu-Indian population, much higher than other clinics in the San Antonio area. This may be due in

part to the provider's ability to speak fluent Hindi, the provider's native language. The clinic's entire patient population was insured, with the majority of patients covered under Blue Cross Blue Shield (Table 2).

Table 2

Demographics for Well-Woman Appointments

Age	*M*	*SD*
	47.1	8.7
Ethnicity	*n*	*%*
White Non-Hispanic	47	45
Black Non-Hispanic	6	5.8
Asian (Hindu-Indian)	19	18.3
Asian (Oriental)	2	1.9
Hispanic	30	28.8
Insurance	*n*	%
United Health Care	40	38.5
Blue Cross Blue Shield	43	41.3
Aetna	11	10.6
Humana	10	9.6

Data evaluations took place at pre-intervention, mid-intervention, and post-intervention intervals. This research protocol allowed for changes in outcomes as a direct result of the intervention to be captured. Moreover, the staff's familiarity with the intervention and new processes developed over time and the protocol for data analysis needed to capture these changes. The staff indicated having become more accustomed to the co-testing approach over the

course of the project, with the data reflecting an improvement in protocol completion rates over the course of the project (Table 3).

Table 3

Protocol Completion Rate for Well-Woman Appointments

Measure	Weeks 1-3	Weeks 4-7	Weeks 8-10
Number of patients seen for Well-Woman appointments	35	35	34
Number of correctly completed protocols	16(46%)	25(71%)	32(94%)

Increasing the standard patient appointment allocation to 15 minutes was the first element of the project. Over the course of the project, the number of time slots allocated in the schedule template for Well-Woman exams went from 45% to 84%. This indicates a 39% increase over the course of the project (Table 4).

Table 4

Changes in Appointment Allocation Time for Well-Woman Appointments

Measure	Weeks 1-3	Weeks 4-7	Weeks 8-10
Number of patients seen for Well-Woman appointments	35	35	34
Number of 15 minute appointment slots aligned for Well-Woman exams	13(45%)	23(66%)	29(84%)

Before the project began, the clinic correctly screened 73% patients aged between 30 and 65 years for HPV. The goal of the project was to increase that screening figure to 95%. At the end of the project, 93% of eligible patients had been correctly screened for HPV (Table 5).

Table 5

Overall HPV Screening Rate for Well-Woman Appointments

Measure	Weeks 1-3	Weeks 4-7	Weeks 8-10
Number of patients seen for Well-Woman appointments	35	35	34
Number of patients successfully screened for HPV	26(73%)	30(87%)	32(93%)

Discussion

This 10-week intervention project was completed on schedule with over 100 eligible patients. The project's successes include an increase in protocol compliance, correctly allocated appointment slots for Well-Woman exams, and an overall increase in the rate of HPV screening. However, the project fell 7% short of the national guideline recommendations for HPV screening, with these guidelines recommending that 100% of patients be screened (AHRQ, 2012; ASCCP, 2016; CDC, 2012). Implementation of the protocol provided data regarding all aspects of the HPV screening process, with the most inaccurate aspect of the clinic's HPV screening process being laboratory preparation. The staff reported that the protocol gave them greater confidence with the procedure. One of the main difficulties with the project was a lack of support from the provider, who *allowed* for the project rather than assisting in its implementation. This sentiment impacted the rest staff, with the project being met with some initial resistance.

However, as the project continued, the staff not only began to adhere to the protocol, but began to seeing benefits in the changed process. This turnaround in the attitudes of staff might be due in part to the meetings conducted for quality improvement and teamwork, which provided the staff with an opportunity to voice their complaints about internal processes and to come together on solutions.

One of the main changes observed by end of the project was a change in the level of organization in the clinic. As previously mentioned, the lack of organization was identified as an impediment to the performance of everyday tasks. The HPV co-testing procedure introduced a more structured regimen into the clinic, especially as the project moved forward. This sense of structure was apparent not only in the project's protocol, but in other clinic events, such as properly scheduling patient appointments, the efficient processing of referrals, and the ordering and stocking of supplies. The staff reported being comforted by the presence of the protocol because if they were to forget part of the procedure, they could refer back to the protocol for instruction. Another important change resulting from the project was a greater sense of teamwork and understanding of each staff member's role. Prior to the commencement of the project, roles in the clinic were fractured and interpersonal conflicts were frequent. Ove the course of the 10-week project, the staff grew to understand each other's strengths, weaknesses, and goals more thoroughly. Again, this improvement was reported to be due to the quality improvement meetings, where staff felt free to express themselves and to share their ideas in a safe place.

A major strength of the project was that it resulted in a better sense of direction for the staff. During pre-implementation interviews, the most common response to the question of "Do you have a purpose here beyond your daily tasks?" was either indifference or "No." In post-intervention interviews, staff reported a greater sense of purpose in the workplace, crediting this

change to the education that they received before the project regarding the importance of HPV screening, backed by statistics on its effects on the population. Most of the staff were women in a similar age range to participants eligible for this study; consequently, learning about HPV was personally relevant for them. Prior to project implementation, staff reported limited knowledge with regard to the significance of the tests and tasks that they performed. This greater understanding of the significance of their roles had a positive impact on overall clinic morale, which the staff reported had improved over the course of the project.

Limitations

There were a several cases of staff having initiated the HPV co-testing protocol with ineligible patients, such as those who were not in the age range or who had already completed recent HPV screening. In many of these cases, the protocols were completed either in their entirety or only partially, although co-testing was not performed. In addition, cases in which the patient was not successfully co-tested, regardless of protocol use, were excluded from the final data analysis. All of the patients involved in the study were insured, and many were willing to pay out of pocket for services that their insurance did not cover, such as hormone therapy. The relative wealth of the patient population may make it difficult to generalize project results to clinics that accept Medicare, Medicaid, or the uninsured. The clinic is small in terms of staff numbers, which made the education and implementation of the project simpler than it might have been with a larger clinic or health service.

Recommendations

The project was successful in improving the clinic's rate of HPV screening, and for improving staff morale and job satisfaction. It was recommended that the clinic continue to use the protocol, or something similar, for maintaining the processes put in place for the Well-

Woman exams and HPV co-testing procedures. The overall increase in the clinic's level of efficiency had system-wide effects, and a similar approach could be used to improve other processes. Personalization of the protocol and the development of future protocols was a recommendation for the staff. Over the course of the project, the staff showed improved compliance with procedural policies and had a higher success rate in terms of being able to see processes through to completion. This effect might have been even more profound had the staff played a larger role in the development of the protocols. Ensuring appropriate appointment times for patient encounters was also something that made a very important to the overall efficiency of the clinic. It is recommended that the staff continue to schedule appointment times based on the nature of the case rather than a set duration for all visits. Many of the patients attending the clinic were up-to-date on their screenings, which may be a result of the high quality health insurance available to them. HPV co-testing would be just as valuable, if not more so, among populations lacking regular access to primary care; consequently, a national set of guidelines should be developed for implementation in all clinics. Additional educational activities are recommended for the staff and the clinic's patients as many had a poor understanding of HPV and its effects. Improving the knowledge of clinic staff regarding the subject of HPV had a positive impact on the staff, and could be effective in motivating patients to keep up-to-date with their screenings.

Prior to this project, the clinic was completely lacking in standardized protocols. Based on the state of disorganization within the clinic at pre-intervention assessment, the implementation of the protocol was intended to improve productivity and efficiency in terms of HPV co-testing and overall systems of work. The protocol was successful in improving the performance of the clinic with respect to HPV screening, and its implementation had a positive effect on staff morale, and the performance of other routine clinic/office tasks. Following the

completion of this project, the staff have begun to develop similar protocols for other clinic activities, such as hormone therapy procedures and ultrasound exams. The staff have also indicated a desire to maintain the quality improvement meeting schedule following project completion; whereupon they hope to develop further protocols, and to address other issues in the operation of clinic. Notwithstanding, the provider for the clinic is not completely supportive of these new measures, but has tentatively agreed to allow the meetings and development of clinical protocols to continue.

Implications for Practice

PhD-prepared nurse practitioners have the ability to identify problems at both a systems-based and procedural level. The educational preparation of these nurse practitioners ensures that they know how to find accurate evidence on topics pertinent to their workplaces and where to go looking for that evidence. Moreover, the nurse practitioners' understanding of advance research theory means that they are expertly prepared to make meaning of national guideline documents and research articles, ranging from randomized controlled trials to single descriptive studies, which might occasionally overwhelm others. Having identified best practice based on evidence, the PhD-prepared nurse practitioner is ideally poised to spearhead the implementation of these best practices to improve patient and organizational outcomes. Moreover, the PhD-prepared nurse practitioner should be aware of the imperative to review and critique their own practices and results of their projects in order to determine the efficacy of such projects in terms of individual patient and population outcomes. Their nursing background allows the nurse practitioner to effectively communicate with other staff members, which is a necessary condition for increasing the likelihood of adherence and project morale.

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