HPV SELF-SAMPLING TO IMPROVE ACCESS TO CERVICAL CANCER SCREENING AT A WOMEN'S HEALTH CLINIC IN ANCHORAGE, ALASKA

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Olivia Anne Mills, titled HPV Self-sampling to Improve Access to Cervical Cancer Screening in a Women's Health Clinic in Anchorage, Alaska and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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ABSTRACT

Purpose: The purpose of this quality improvement (QI) project was to evaluate the acceptability of HPV self-sampling for cervical cancer screening for rural Alaskan women at a community-based clinic.

Background: Over 91% of cervical cancer diagnoses are caused by persistent high-risk human papillomavirus infection. Regular and timely screening has been shown to reduce the prevalence for cervical cancer, however, there are barriers that may limit access to screening resources. Traditionally, cervical cancer screening requires in-person clinic visits where a provider will perform a Pap test. There is emerging scholarly research on the use of HPV self-sampling for cervical cancer screening which would reduce or eliminate the need for women to attend in-person screening.

Method: The PDSA model was used as a framework to guide the plan for implementation and data analysis. The design of this one-month project was a pre- and post-survey which was sent through the participant's email and a self-sampling intervention that was mailed directly to the participants for them to complete and return in the mail. Participants were recruited through the electronic medical record at Women's Care of Alaska which is an outpatient obstetrics and gynecology clinic in Anchorage, Alaska.

Results: Fourteen participants were sent HPV self-sampling kits. Twelve participants responded to the pre-survey and nine participants responded to the post-survey. Of the nine post-survey responses, eight of the participants completed and returned the kit in the mail. Seven out of eight of the participants who completed and returned their kit would choose self-sampling over in-

person Pap testing if given the choice (87.5%). The consensus from the post-survey is that self-sampling for HPV is highly accepted by participants as an option for cervical cancer screening. **Conclusion:** The implementation was successful, as evidenced by the positive feedback from the participants. HPV self-sampling is a promising evidence-based resource to improve access to cervical cancer screening, however, it requires further research and guideline recommendations.

INTRODUCTION

Cervical cancer screening is traditionally done in the outpatient clinical setting where a provider utilizes a tool to gently scrape cells from the cervix and vagina to detect abnormal cells under a microscope—better known as a papanicolaou (pap) test (National Cancer Institute [NCI], 2020). In addition to pap testing, human papillomavirus (HPV) screening can be performed either alone, or with pap co-testing (NCI, 2020). Routine screening allows for early detection and treatment of cervical cancer which significantly reduces morbidity and mortality (Dunyo et al., 2018).

Cancers can be caused by gene mutations that turn on oncogenes or turn off tumor suppressor genes (American Cancer Society [ACS], 2020). HPV has two proteins known as E6 and E7 which are known to turn off some tumor suppressor genes, such as p53 and Rb which allows the cells in the lining of the cervix to excessively multiply (ACS, 2020). This rapid growth allows for changes to develop in additional genes, which in some cases, can lead to cancer. Most HPV infections will clear spontaneously, however, screening for HPV has greater sensitivity to detect cervical cancerous and precancerous lesions compared to routine Pap testing alone (World Health Organization [WHO], 2020). Therefore, HPV screening is a highly effective method to detect cervical cancer or precancerous lesions at earlier, and more treatable stages. However, despite advances in screening, there are disproportionate rates of cervical cancer incidence and mortality among vulnerable populations primarily due to lack of access to screening opportunities (Kobetz et al., 2018). An important risk factor for the incidence of cervical cancer, is low population coverage (Aarnio et al., 2020). In addition to the difficulties and barriers women face to attend in-person cervical cancer screening, this past year has

highlighted the critical need for remote testing. The COVID-19 pandemic substantially reduced accessibility to preventative services, including routine pap testing (Miller et al., 2021).

The intervention that will be described in this paper is an at-home HPV self-sampling method for cervical cancer screening in a women's health clinic in Anchorage, Alaska. To perform HPV self-sampling, the individual uses a specified swab to take a vaginal specimen and then sends the sample through the mail to a laboratory for testing (Ogale et al., 2019) Self-sampling reduces the need for women to attend in-person visits and has been shown to be more effective for reaching underscreened women compared to sending invitations for in-person screening (Arbyn et al., 2018). Self-sampling for HPV screening has the potential to improve access to women's health services which leads to higher screening rates and ultimately improves the rates for cervical cancer detection (Gupta et al., 2018).

Background Knowledge and Significance

Although regular and timely screening can reduce the prevalence of cervical cancer, there are various barriers that often affect the ability for women to access screening, causing disparities in pap testing and HPV screening (Akinlotan et al., 2017). Additionally, cervical cancer used to be the most common cause of cancer-related deaths among women in the United States (US) (Centers for Disease Control & Prevention [CDC], 2020). Today, cervical cancer is the fourth most common type of cancer among women worldwide, but because of the slow progression from infection to malignancy, it is also one of the most preventable types of cancer. Pap smear screening has been in clinical practice since the 1950s, and it is estimated that there has been a significant decrease in early and late state cervical cancer incidence (Yang et al., 2018). Between 1976 to 2009, there was a combined incidence decrease of early and late-stage

cervical cancers from 15.1 to 8.6 cases per 100,000 women (Yang et al., 2018). This decrease in early and late stage cervical cancer incidence has been estimated as a reduction of approximately 105,000 cases of cervical cancer (Yang et al., 2018).

It is estimated that HPV is the most common sexually transmitted infection in the US (National Cervical Cancer Coalition [NCCC}, n.d.). By age 50, about 80% of women will have been infected with a type of HPV, however, the majority of these cases do not progress to cervical cancer (NCCC, n.d.). There are over 100 different strains of HPV, and many are considered low-risk and do not cause cervical cancer (CDC, 2020). There are high-risk HPV (hrHPV) types that cause cervical cell abnormalities which may lead to cancer. Furthermore, over 90% of cervical cancer diagnoses are caused by persistent infection by two types of hrHPV: HPV-16 and HPV-18 (Ashtarian et al., 2017; NCCC, n.d.; World Health Organization, 2020). According to the CDC (2020), data from 2013-2017 show that about 45,300 HPV-associated cancers occurred in the US annually. About 25,400 of these cancers were among women, and 19,900 among men, with cervical cancer being the most common form of HPV-associated cancer among women, and oropharyngeal cancers being the most common among men (CDC, 2020). The CDC and the American Cancer Society report that in general, HPV is thought to be the cause of more than 90% of cervical cancers (CDC, 2020; ACS, 2020). Therefore, in addition to the Pap test, cervical cancer screening can also include testing for HPV based on age and national guidelines (Nardi, Sandhu, & Selix, 2016).

The U.S. Preventative Services Task Forces (USPSTF) guidelines and the American Cancer Society (ACS) guidelines for cervical cancer screening (Appendix F) have been updated within the past 10 years to reflect the evidence-based recommendation for HPV only testing as

an option alongside traditional pap testing (NCI Staff, 2020; USPSTF, 2018). In 2012, the USPSTF recommended pap testing every three years for women aged 21 to 65 years, or pap testing with HPV co-testing every five years for women aged 30-65 years. In 2018 the USPSTF updated these guidelines which recommends pap testing every three years for women aged 21 to 29 years, and for women aged 30-65 years pap testing every three years, hrHPV testing alone every five years, or pap testing with hrHPV co-testing every five years (USPSTF, 2018). In 2012, the ACS recommended pap testing every three years for women aged 21-29 years, and for women aged 30-65 years to pap test with HPV co-testing every three years or to pap test alone every three years (NCI Staff, 2020). The ACS updated their recommendations in 2020 which is no screening for women aged 21-24 years, for women aged 25 to 29 years HPV testing alone every five years, pap testing with HPV co-testing every five years, or pap testing every three years. For women aged 30-65 years, HPV testing every five years, pap testing with HPV co-testing every five years, or pap testing every three years (NCI Staff, 2020).

Regular screening allows for early detection of abnormal cells at pre-malignant phases and leads to timely treatment when necessary (Ashtarian et al., 2017). A study by Yang et al. (2019) concluded that many early and late-stage cervical cancers can be prevented with the use of widespread pap smear screening; this study highlights the need for an intervention that is able to increase screening participation. Cervical cancer is often preceded by persistent hrHPV infection, therefore, screening has been developed to detect the presence of hrHPV types in the cervical cells (Fokom Defo & Fokom Domgue, 2020). Compared to traditional cervical cancer screening through the pap smear which utilizes cytology testing, HPV testing is more sensitive for detecting cervical cancer (Fokom Defo & Fokom Domgue, 2020). Guidelines in the U.S.

(Appendix F) and international guidelines for cervical cancer screening have transitioned toward including the option for HPV only testing because of the high sensitivity and accuracy for detecting cervical cancer (NCI Staff, 2020; (Chrysostomou et al., 2018). Primary HPV testing also allows for longer screening intervals compared to pap testing because progression to cancer occurs years after initial infection with hrHPV (Chrysostomou et al., 2018). HPV testing can be performed either through self-sampling or clinician-collected sampling. HPV self-sampling has been shown to provide similar accuracy to clinician-collected samples (Chao & McCormack, 2019). Additionally, evidence supports the use of HPV self-sampling to reach underscreened women and to increase screening participation compared to traditional pap testing (Winer et al., 2019). In developed countries, cytology screening methods have been shown to be successful in decreasing the incidence and mortality rates of cervical cancer. However, in developing countries, the incidence and mortality from cervical cancer remain high due to low screening coverage using cytology (Allende et al., 2020). To improve the screening rates among developing countries, HPV self-sampling has been shown to be effective at detecting HPV which is the essential precursor for the development of precancerous cervical lesions and cervical cancer (Allende et al., 2020).

Cost-effectiveness is also a benefit of HPV self-sampling. Primary HPV testing allows for longer screening intervals and requires less training for sample collection (Malone, Barnabas, et al., 2020). In a UK trial among women who have never been screened for cervical cancer, a directly mailed HPV self-sampling kit strategy was considered the most cost-effective because of higher uptake and a subsequent increase in detection of moderately abnormal cells, including CIN2+ (Malone, Barnabas, et al., 2020). In the systematic review by (Malone, Tiro, et al., 2020),

14 out of 16 studies reported the HPV self-sampling is cost-effective, either in addition to an existing screening program or as a primary screening program. In this systematic review, it was found that the most common theme for HPV self-sampling cost-effectiveness was the level of increasing screening attendance (Malone, Barnabas, et al., 2020). Additionally, the cost-effectiveness among the studies was impacted by the reduced costs of self-sampling materials and testing compared to in-person testing, higher sensitivity to detect CIN2+, and increased participation among women who have never been screen or who are underscreened (Malone, Tiro, et al., 2020).

With the emerging role of primary HPV screening, self-sampling has become a promising method for women to access crucial cervical cancer screening and has been shown to have comparable sensitivity with clinician-collected samples (Winer et al., 2019). Furthermore, studies have exhibited that mailing HPV self-sampling kits to underscreened women increase participation compared to inviting women into the clinic for in-person screening (Winer et al., 2019). Follow-up compliance for self-sampling has also been shown to be high (Winer et al., 2019). Countries such as Australia and the Netherlands have implemented the option for primary HPV screening and have included the option for HPV self-sampling among women who are underscreened (Winer et al., 2019).

Local Problem

Cervical cancer screening varies by sociodemographic influences, educational attainment, income, insurance, and immigration status—leading to disparities in cervical cancer incidence and mortality (Akinlotan et al., 2017). Additionally, some of these barriers include reluctancy due to lack of awareness, cultural beliefs, and access to healthcare services (Akinlotan et al.,

2017; Ashtarian et al., 2017). There are also significant motivating factors that impact women to participate in screening such as recommendations by providers, friends and family, awareness of cervical cancer, and easy and affordable access to pap testing (Ashtarian et al., 2017).

The state of Alaska lacks many healthcare resources, furthermore, rural Alaska lacks these resources at a greater extent. Alaska is geographically the largest state, with an estimated population of 731,545 people, and 238,379 of these people living in rural Alaska (Rural Health Information Hub, 2020). There are 35 Federally Qualified Health Center (FQHC) sites located outside of urbanized areas which presents a challenge to the populations in the rural areas with limited access or no access to preventative services, including routine cervical cancer screening (Rural Health Information Hub, 2020). In 2019, the cervical cancer screening rate in Alaska was 81.7% which ranked the state of Alaska sixteenth in the nation (America's Health Rankings, 2020). This is compared to the U.S. average cervical cancer screening rate of 80.0%. However, in 2020, the screening rate in Alaska decreased to 80.8%, decreasing the ranking of Alaska to 25th in the nation regarding cervical cancer screening rates. The U.S. average screening rate for cervical cancer also decreased to 79.9% in 2020 (America's Health Rankings, 2020). In addition to Alaska's lack of resources, the COVID-19 pandemic further reduced access to preventative services and routine screening. Access to affordable and reliable testing is the quality improvement that will be addressed throughout this paper.

Intended Improvement

Project Purpose

The pap smear is widely accepted as one of the most effective methods to detect cervical cancer. However, reluctance and barriers exist that makes the reality of regular in-person

screening for many women unattainable. The purpose of this project is to evaluate the acceptability of HPV self-sampling for cervical cancer screening for rural Alaskan women utilizing a community-based clinic. The goal of using a primary HPV self-sampling method is to reduce some of the barriers women face that limit their access to screening. Self-sampling for cervical cancer screening empowers women to collect their own sample in private, with ease, in their home, and reduces the need for in-person clinic visits (Vahabi & Lofters, 2018).

HPV self-sampling does not require women to collect a sample directly from the cervix, instead, a vaginal sample is collected and sent to a laboratory for analysis (Yeh et al., 2019). HPV self-sampling does not diagnose cervical cancer, however it identifies women who are at a high risk for developing cervical cancer (Yeh et al., 2019). Testing for HPV through self-sampling, compared to cytology testing, requires less resources and has been shown to have high acceptance among women and comparable accuracy to clinician-collected samples (Aarnio et al., 2020; Bergengren et al., 2018). Therefore, HPV self-sampling is a promising intervention to increase access to routine cervical cancer screening and to increase detection rates of cervical cancer. The aim of this project is to improve access to cervical cancer screening using mail-in HPV self-sampling.

Project Question

Will the use of an at-home HPV self-sampling kit be an acceptable option for women in rural Alaska to participate in cervical cancer screening?

Specific Aims

The purpose of this project is to evaluate the acceptability of a self-sampling option for women in rural Alaska to screen for cervical cancer. Self-sampling has been shown to have high

acceptance among women as a feasible screening option, is cost-effective, and has been shown through multiple studies to have similar accuracy to clinician-collected samples (Arbyn et al., 2018; Madzima et al., 2017). Therefore, it is predicted that this project will achieve positive acceptance and uptake among the participants.

Project Objectives

The proposed project includes the following objectives:

1. Identify clinic patients in need of cervical cancer screening and send out the HPV self-sampling kits directly to their homes.
2. Have participants conduct a pre- and post-survey questionnaire to assess their experiences with the intervention and to assess the likelihood of the women utilizing self-sampling in the future, if given the option.
3. Evaluate the number of women who complete and return the self-sampling kit in the mail.

Theoretical Framework

The theoretical framework used to guide this project was E.M. Roger's Diffusion of Innovation (DOI) Theory. This theory originated with the intent to explain how an idea or intervention spreads throughout a specific population (LaMorte, 2019). This framework is a guide to determine how likely a social system will adopt a new idea, behavior, or intervention. Diffusion refers to an innovation that is communicated and implemented over time throughout members of a system. Applying the DOI framework to the HPV self-sampling screening intervention provides a guide for diffusing this intervention across the healthcare system, including diffusion across the target patient population and the providers.

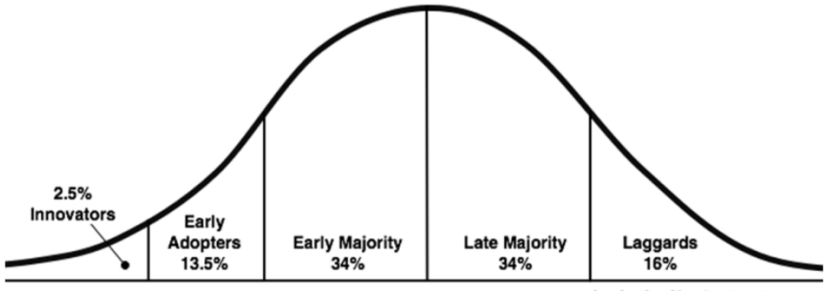
For successful implementation of a new concept, it is crucial for both the patient population and the providers to have a positive perception of the idea, behavior, or intervention. For this QI project, success of the intervention relies on acceptance and adoption by the providers at the clinic and acceptance and adoption by the target population. Implementing change can cause resistance and uncertainty. However, using Roger's DOI theory can help address some of these challenges in both the clinic providers and among the target population to facilitate an effective approach for implementing change.

Five Established Adopter Categories

When diffusing an innovation across a social system, some people within the system may be more inclined to adopt the new idea compared to others. There are traits and characteristics that people have depending on if they are more likely to adopt an innovation early or adopt an innovation later; these traits and characteristics are split up into five distinct categories (LaMorte, 2019). Understanding the characteristics of the target patient population and of the providers helps predict whether an idea, belief, or intervention will be accepted. According to Roger's DOI, there are five categories that adopters may fall into and based on the category, there are different strategies to encourage implementation. The five categories are: innovators, early adopters, early majority, late majority, and laggards (LaMorte, 2019).

Figure 1

E.M. Roger's DOI Theoretical Framework: Five Adopter Categories.



Innovators are interested in the innovation, want to be the first to try it, and are generally accepting of new ideas (LaMorte, 2019). Early adopters are often the opinion leaders and embrace change. They do not generally need more information to adopt a new idea (LaMorte, 2019). The early majority are rarely leaders, but they adopt a new idea faster than the average person. To appeal to the early majority type, they generally need to see evidence of the effectiveness of the change (LaMorte, 2019). The late majority are skeptical of change and will not try a new idea, belief, or intervention until it is first tried by the majority. Information on how the change has been successfully adopted in other settings will appeal to this target population (LaMorte, 2019). Laggards are more conservative and bound by tradition. They are highly skeptical of change, and it is generally a challenge to change their perspective. To appeal to this target population, statistics, fear appeals, and pressure from other adopter groups may help (LaMorte, 2019).

According to evidence on acceptance of HPV self-sampling, there have been high levels of acceptance among women across various settings, including immigrant, rural, vulnerable, and women in low resource settings (Murchland et al., 2019). In a study among various diverse rural

communities in Guatemala, over 80% of women said that they preferred using a self-sampling method for cervical cancer screening rather than being screened in the clinic (Murchland et al., 2019). Furthermore, a French questionnaire-based study on the acceptability of HPV self-sampling concluded that women were highly accepting of self-sampling, including underscreened women. This study also discussed the need to include education on cervical cancer and cervical cancer screening as part of the self-sampling programs, which will further improve implementation (Bertucci et al., 2020). Based on this evidence, it is predicted that the population of women in rural Alaska will be more likely to be early adopters and early majority and will have a high acceptance of HPV self-sampling.

The providers also play a key role in successful adoption of the change. In a study on clinician and patient acceptability of HPV self-sampling concluded that most providers (78%) reported that they would recommend HPV self-sampling if the test had high sensitivity and was cost effective (Mao et al., 2017). Among these providers, approximately one-third reported performing pap screening daily. The most common reason for providers not to recommend self-sampling was for concern of a missed clinic visit which may lead to a missed opportunity to address other health issues (Mao et al., 2017). This study suggests that providers are highly accepting of self-sampling, which may place providers in the innovator and early adopter categories. The providers are the drivers of this change and can help the target patient population have the resources and education to adopt the change as well.

Five Key Factors

The DOI Theory includes four stages to adopt a change including: awareness, decision to adopt (or reject), initial testing of the innovation, and continued use of the innovation (LaMorte,

2019). There are five key factors that impact the adoption of the innovation, which are all influenced by the specific adopter category (LaMorte, 2019). The five key factors are: relative advantage, compatibility, complexity, trialability, and observability (LaMorte, 2019). According to the DOI theory, addressing each of these key factors encourages successful implementation of an intervention within a specific target population.

Relative Advantage

Relative advantage is the extent to which the new intervention is perceived as better than what it is replacing. Current participation in HPV screening requires the patient to present to the clinic where a provider collects a cervical sample. In rural Alaska, in-person screening presents a challenge because of the travel, cost, and understanding of the need for screening. However, studies show that hrHPV screening through self-sampling with appropriate follow-up may be more effective than routine pap smears for detecting cervical cancer which would eliminate the need to travel to a clinic for initial screening (Aarnio et al., 2020; Gupta et al., 2018). HPV self-sampling has also been shown to detect more cases of CIN2+ at a lower cost compared to Pap smear testing (Aarnio et al., 2020). Studies have also shown that self-sampling is more effective in reaching underscreened women compared to sending reminders for in-person visits (Arbyn et al., 2018). The relative advantage for implementing a self-sampling option for HPV screening in rural Alaska is supported by the literature to be feasible and effective.

Compatibility

Compatibility is the congruity of the needs, priorities, and values of the potential adopters (LaMorte, 2019). The intervention should be suitable for the specific target population. Among women in rural and indigenous communities, self-sampling has been shown to be highly

accepted and the positive attitude toward self-sampling has been shown to be similar across various cultures and countries (Madzima et al., 2017; Murchland et al., 2019). Additionally, clinicians have been shown to be accepting and supportive of HPV self-sampling (Mao et al., 2017). Self-sampling has high acceptance and positive perception among rural and indigenous communities in addition to provider acceptance, which supports the compatibility of this intervention in rural Alaska.

Complexity

Complexity is the difficulty of use of the intervention (LaMorte, 2019). Evidence shows that HPV self-sampling is convenient, private, easy to use, and cost-effective (Madzima et al., 2017; Vahabi & Lofters, 2018). Women were successful in carrying out the self-sampling testing with simple written instruction among various countries and age groups (Madzima et al., 2017). In the literature review by Madzima et al. (2017), studies show that self-collected samples were comparable to physician collected samples for sensitivity for identifying hrHPV. In a German study among women ages 20-30 years old, the consensus of the participants was that the self-sampling method was “easy” (Gupta et al., 2018). In another study by (Chatzistamatiou et al., 2020), 74.4% of women felt adequately confident that they were able to follow the self-sampling instructions correctly. Based on the literature, women have reported that self-sampling is not difficult to use with adequate instructions included.

Trialability

Trialability is the ability to test the intervention at a smaller scale before it is implemented throughout the entire target population (LaMorte, 2019). In a small-scale Canadian study, it was found that women who had not attended in-person screening but subsequently

received self-sampling kits, were 3.7 times more likely to participate in screening compared to the control group (Madzima et al., 2017). Another study in Finland where they sent a reminder letter and then the self-sampling kit saw an increase in total participation in screening from 63% to 78% (Madzima et al., 2017). In various studies, directly mailing the self-sampling kit was shown to have the highest participation rates, and having kits that were small enough to fit into mailboxes were preferred compared to kits that had to be collected at a post office (Madzima et al., 2017). (Goldstein et al., 2020) performed a study in rural China that showed the capability for HPV self-sampling to be implemented on a larger scale which was evidenced by the ability to screen 3,600 women in less than one week. This study concluded that HPV self-sampling is cost-effective, efficient and practical for treating an ethnically diverse group of women (Goldstein et al., 2020). There have been numerous trials among various diverse populations that have shown positive evidence supporting the use of self-sampling which supports the trialability of this intervention.

Observability

Observability is the extent that the intervention is able to produce concrete results (LaMorte, 2019). The intended observable results for this intervention would be to improve participation rates of cervical cancer screening. The Alaska state average for cervical cancer screening was 80.8%, therefore, the goal of this project is to achieve an 80% participation rate (America's Health Rankings, 2020). In the studies that offered HPV self-sampling in the literature review by Madzima et al. (2017), there was an increase in screening participation rates. In a study done in Finland, there was an increase in cervical cancer screening participation from 63% to 78% through utilizing a self-sampling intervention (Madzima et al., 2017). A Canadian

study concluded that women who received an HPV self-sampling kit were 3.7 times more likely to undergo screening compared to traditional in-person screening (Madzima et al., 2017). Additionally, in a study done in Hong Kong, most women preferred self-sampling and it was estimated that self-sampling could increase participation rates of screening by 6.5% (Gupta et al., 2018). Many of the women in this study noted that having the ability to use a self-sampling method removed key logistical barriers related to required clinic visits (Gupta et al., 2018). Studies show that self-sampling has higher participation rates compared to in-person visits (Gupta et al., 2018). According to a meta-analysis by the WHO, women were twice as likely to accept HPV screening through self-sampling especially when the self-sampling kits were sent directly to the women's homes (Ogale et al., 2019). Additionally, follow-up for abnormal results is a key concern for self-sampling. In two studies that specifically assessed follow-up for self-sampling, showed that a little more than half of the participants who used self-sampling followed up on positive HPV results (Madzima et al., 2017). In a randomized controlled trial in the Netherlands, 89.1% of the women with positive test results for hrHPV through self-sampling adhered to further follow-up (Madzima et al., 2017). HPV self-sampling improves access to screening which positively impacts cervical cancer detection rates and leads to earlier follow-up and treatment.

There is significant evidence that addresses each of the five key DOI factors which suggests self-sampling for cervical cancer could be a positive and acceptable intervention within the rural Alaskan setting. Cervical cancer screening is one of the many resources that is lacking throughout rural Alaska. HPV self-sampling is an evidence-based solution that can overcome many of the rural challenges. Using this theoretical framework suggests that self-sampling for

HPV may be an effective and useful intervention to reduce healthcare disparities affecting woman in rural Alaska.

Literature Synthesis

Evidence Search

A literature review was conducted of scholarly research related to HPV self-sampling for cervical cancer screening. PubMed and CINAHL were searched with key terms "HPV self-sampling," "self-sampling cervical cancer," and "HPV self-sampling screening." The date was adjusted to 2016 to the present.

Using the CINAHL search tool, the term "HPV self-sampling" showed 128 results. The publication date was changed to 2016 to the present which reduced the results to 92 total results. The second term, "self-sampling cervical cancer" yielded 41 search results from 2016 to the present. The third search term, "HPV self-sampling screening" yielded 25 results between 2016 to the present.

Using the PubMed search tool, the first key term "HPV self-sampling" initially yielded 1,048 results. The date was adjusted for 2016 to present, which showed 578 results. The second key term, "self-sampling cervical cancer" yielded 1,221 results, and then 595 after the date was adjusted to 2016 to the present. The third key term, "HPV self-sampling screening" showed 755 results. Once the date was adjusted to 2016 to the present, 439 studies were yielded.

Studies were reviewed for critical concepts, including a focus on studies that discussed the accuracy of self-sampling compared to clinician-collected sampling for detecting HPV, the cost effectiveness of HPV self-sampling, and the acceptance of HPV self-sampling among

women. Exclusion criteria included the removal of reviews that did not discuss one of these key concepts. Therefore, 18 studies were selected for the literature synthesis (Appendix H).

The 18 included studies showed that using a self-sampling tool for HPV screening is an effective method to detect HPV compared to clinician-collected samples (Allende et al., 2020; Arbyn et al., 2018; Bergengren et al., 2018; Chao & McCormack, 2019; El-Zein et al., 2018; Gupta et al., 2018), is cost-effective (Aarnio et al., 2020; Goldstein et al., 2020; Wong et al., 2020), and HPV self-sampling is a well-accepted method among women of various backgrounds and socioeconomic status (Bakiewicz et al., 2020; Bertucci et al., 2020; Chatzistamatiou et al., 2020; El-Zein et al., 2018; Fokom Defo & Fokom Domgue, 2020; Harder et al., 2018; Maza et al., 2018; Peeters et al., 2020; Shin et al., 2019; Tranberg et al., 2018a, 2018b; Wong et al., 2020).

Three of the 18 studies were qualitative studies (Bakiewicz et al., 2020; Bertucci et al., 2020; Harder et al., 2018). Five of the studies were cross-sectional studies (Allende et al., 2020; Bergengren et al., 2018; Chatzistamatiou et al., 2020; Maza et al., 2018; Wong et al., 2020). Five out of the 18 studies were randomized controlled trials (Aarnio et al., 2020; El-Zein et al., 2018; Peeters et al., 2020; Tranberg et al., 2018a, 2018b). Two of the studies were longitudinal studies (Goldstein et al., 2020; Shin et al., 2019). Two articles were literature reviews (Chao & McCormack, 2019; Gupta et al., 2018). Lastly, one article was a meta-analysis (Arbyn et al., 2018).

Current Practice Recommendations

The Unites States Preventative Services Task Force (USPSTF) recommends cervical cancer screening every three years with cytology pap testing alone for women aged 21 to 29

years. For women ages 30 to 65 years old, the USPSTF recommends cytology screening alone every three years, hrHPV testing alone every five years, or cytology testing with hrHPV co-testing every five years (USPSTF, 2018). The current standard of practice in the US requires women to attend in-person screening where a healthcare provider collects their sample. Clinicians collect cytology sample through pap smear and can perform co-testing by testing for hrHPV through the same sample (American Cancer Society, 2020). Primary HPV testing has been shown to be better at preventing cervical cancers compared to pap testing alone (American Cancer Society, 2020). Co-testing is convenient because it does not require more unnecessary testing and is added onto the pap smear sample, however, self-sampling for hrHPV screening would allow further convenience for cervical cancer screening by eliminating the need for a clinic visit for initial screening.

HPV Self-Sampling Screening Benefits

Cervical cancer is the fourth most common cancer in women (Allende et al., 2020). More than half of all new cervical cancer diagnoses are among women who have never been screened or who have not been screened routinely (Crawford et al., 2016). One of the largest barriers that prevents women from participating in routine cervical cancer screening is a lack of access to healthcare and screening resources (Crawford et al., 2016). According to the World Health Organization (2020), 90% of the deaths from cervical cancer worldwide in 2018 occurred in low-income countries which emphasizes the need for improved access to and resources for cervical cancer screening. The current guidelines and methods for cervical cancer screening can be improved with the option for convenient HPV self-sampling (Arbyn et al., 2018). Most developed countries have adapted cervical cancer screening methods that include primary HPV

screening alone or in addition to clinician collected cytology screening via Pap smear. However, HPV self-sampling in combination with a follow-up pap smear for abnormal results has been shown to be more effective at detecting precancerous lesions rather than a pap smear alone (Gupta et al., 2018). The evidence shows that there are significant benefits of self-sampling for HPV, specifically on the effectiveness for detecting HPV, the economic benefit, and the acceptance among women for utilizing this method for screening (Aarnio et al., 2020; Arbyn et al., 2018; Bertucci et al., 2020).

Comparable Accuracy to Clinician Collected Samples

According to (Allende et al., 2020), hrHPV screening used as a method to detect cervical high-grade intraepithelial neoplasia (CIN 2+) is shown to be effective and could be used as an alternative method for initial cervical cancer screening. A cross-sectional study was done in order to investigate the reliability of HPV self-sampling compared to clinician-collected sampling among postmenopausal women showed that 83.2% of the study participants had the same clinically relevant finding from both sampling methods (Bergengren et al., 2018). This study concluded that there was no significant difference between clinician-collected sampling and self-sampling for detecting HPV (Bergengren et al., 2018). HPV testing is categorized into two categories: polymerase chain reaction (PCR) testing and signal amplification tests. Self-sampled HPV testing based on PCR for the detection of CIN 2+ showed no statistically significant difference in sensitivity and specificity compared to clinician-collected samples (Chao & McCormack, 2019). However, self-sampled HPV testing that utilizes signal amplification were shown to be not as accurate for detecting CIN2+ (Chao & McCormack, 2019). In support of these results, there is significant evidence that shows PCR testing for self-

sampled HPV testing was similarly accurate to clinician-collected samples (Arbyn et al., 2018; El-Zein et al., 2018; Goldstein et al., 2020; Gupta et al., 2018).

Cost-effectiveness and Feasibility

HPV only testing allows for longer testing intervals between testing which may contribute to reduced cost. Additionally, in a study performed to evaluate the cost-effectiveness of cervical cancer prevention, the most cost-effective strategy was to combine preadolescent HPV vaccination with primary HPV testing every five years (Chrysostomou et al., 2018). A study by (Aarnio et al., 2020), showed that self-sampling for HPV resulted in 1633 more screened women and 107 more histologically CIN2+ diagnoses at a lower cost compared to clinician-collected pap smears (€229,446 vs. €782,772, respectively). HPV testing is more sensitive for detecting hrHPV than cytology pap testing alone and is less resource intensive (Fokom Defo & Fokom Domgue, 2020). Self-sampling has been shown to be easy to use with no specific training required and is more cost-effective than cytology (Fokom Defo & Fokom Domgue, 2020; Goldstein et al., 2020). HPV self-sampling significantly reduces the burden of resources and cost-implications which will allow women in low- and middle- income countries (LMICs) to more readily access screening (Fokom Defo & Fokom Domgue, 2020; Wong et al., 2020).

Acceptance Across Various Settings

Acceptance from participants for self-sampling is crucial for participation and evidence shows that among women who have never been screened or who are underscreened were more likely to prefer HPV self-sampling than those who had regular screening (Wong et al., 2020). The majority of women (>80%) who participated in a study by (Wong et al., 2020) reported that

self-sampling for HPV screening was convenient, easy to use, and that they had confidence in performing the test. A study by (Tranberg et al., 2018b), concluded that offering women the opportunity to participate in self-sampling for HPV screening instead of traditional cytology screening improved participation rates and showed that there was a high compliance with follow-up for abnormal results. In this study, there were three groups, one intervention group was directly mailed a self-sampling kit, the other intervention group was mailed an invitation letter to opt-in to receive a self-sampling kit, and the control group received standard in-person care (Tranberg et al., 2018b). Among the participants in the directly mailed group, 38% of the women either completed and returned the kit or attended regular in-person pap testing. The opt-in strategy resulted in 30.9% participation; however, the majority of this percentage (22.6%) were women who attended regular in-person pap testing. The participation rate was 25.2% in the control group, which is 12.8% lower than the directly mailed kit group (Tranberg et al., 2018b). Thus, the highest percentage of participation in screening was among the directly mailed group. The results of these studies are also in line with other studies supporting the acceptance of self-sampling for cervical cancer screening among women from various backgrounds (Bakiewicz et al., 2020; Bertucci et al., 2020; Chatzistamatiou et al., 2020; Harder et al., 2018; Maza et al., 2018; Peeters et al., 2020; Shin et al., 2019). According to the literature, using HPV self-sampling is highly acceptable across varying cultures and backgrounds, however acceptance can be further improved through proper communication and education on the similar accuracy compared to conventional clinician-collected screening methods (Chao et al., 2018). Using a self-collected method is a feasible intervention that may help improve screening rates, especially in low- and middle-income countries (Fokom Defo & Fokom Domgue, 2020). A study

concluded that all socioeconomic groups resulted in higher screening participation with self-sampling, but Western immigrants and lower socioeconomic groups benefitted the most (Tranberg et al., 2018a).

Strengths, Weaknesses, and Gaps of Evidence

The evidence for HPV self-sampling is relatively new and developments are constantly being made which is a significant strength of this intervention. A crucial limitation among the studies on HPV self-sampling is the lack of congruence on the potentially influencing factors that relate to the unique target populations. In a meta-analysis by (Arbyn et al., 2018), the response rates for self-sampling were shown to be highly variable among different settings. In one meta-regression which included eight studies, age was not a significant factor that influenced participation with self-sampling, however, in another meta-analysis by (Yeh et al., 2019) found that there may be a slightly stronger impact on self-sampling uptake among women over 50 years of age. Additionally, in the meta-analysis by (Arbyn et al., 2018), some of the studies reported lower response for self-sampling among women who have never been screened compared to women who have been screened before, whereas, some of the studies in this meta-analysis reported the opposite trend.

Another concern with implementing HPV self-sampling in lieu of attending in-person clinic visits for cervical cancer screening is follow-up protocol. Various studies have shown that many women who have historically been underscreened but have tested HPV-positive with a self-sampled method, will visit a clinic for follow-up care, diagnosis, and management (Gupta et al., 2018). In a study done in Chile on HPV self-sampling showed that 106 out of 124 (85%) women who were identified as HPV-positive through self-sampling attended follow-up

colposcopy (Gupta et al., 2018). In another study in Norway, 32 out of 34 (94.1%) women who tested HPV-positive through self-sampling attended follow-up (Gupta et al., 2018) Furthermore, in an Australian study, 106 out of 140 (75.7%) women who tested positive for hrHPV attended follow-up colposcopy or cytology within 6 months (Gupta et al., 2018). These studies show promising evidence that women will be likely to follow-up with abnormal results, however, there is not a current standard of care protocol put in place regarding follow-up for self-sampling testing. Additionally, a key gap with follow-up for self-sampling is the linkage between the self-sampling test and the healthcare system. There is a need for more regulations on the self-sampling kits and a need for understanding on how to integrate self-sampling results into the healthcare system (Ogale et al., 2019). Despite the limitations of HPV self-sampling, the benefits of the intervention are strong. With careful planning and implementation, the unique factors of each target population may be addressed.

METHODS

Project Design

The purpose of this quality improvement (QI) project was to determine the acceptability of HPV self-sampling for cervical cancer screening for women at a women's health clinic in Anchorage, Alaska. Self-sampling for HPV has been used in areas where there is a lack of in-person screening resources, and there is growing research that supports the use of self-sampling to in lieu of the traditional Pap smear (Yeh et al., 2019). This project intended to evaluate the experience and acceptance that women have using HPV self-sampling. Currently, there are not any FDA approved HPV self-sampling kits, therefore, this quality improvement project did not intend to replace clinician-collected HPV testing or traditional pap smear screening with HPV

co-testing for the participants included in this project and all women were encouraged to schedule an appointment in the clinic as well regardless of participation in the project. To evaluate the effectiveness of this project for quality improvement, data was collected on:

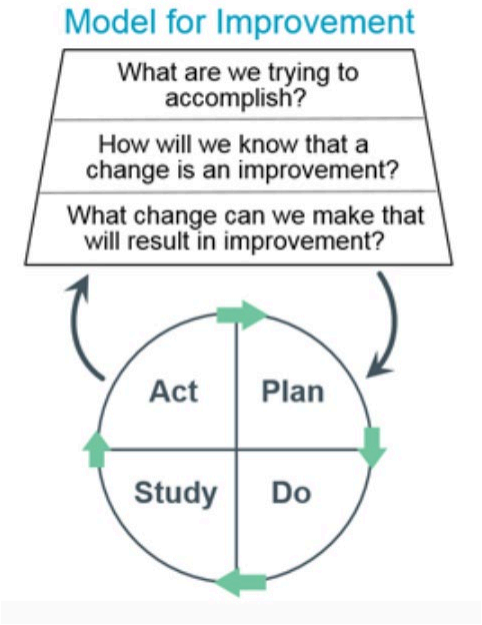
1. The number of women who returned their completed HPV self-sampling kit in the mail.
2. A pre-survey on demographics and potential barriers to screening.
3. A post-survey on participation in the project, how likely the participant was to use self-sampling in the future, and the convenience of self-sampling.

Model for Improvement

The Model for Improvement was developed by the Associates in Process Improvement and is an organizational tool used to accelerate improvement (Institute for Healthcare Improvement, n.d.). The Model for Improvement has two parts; the first includes three fundamental questions shown in Figure 2 (Institute for Healthcare Improvement, n.d.; Yang et al., 2018). The three questions to be addressed by the Model for Improvement are: What are we trying to accomplish? How will we know that a change is an improvement? What change can we make that will result in improvement?

Figure 2

Model for Improvement, Institute for Healthcare Improvement



What Are We Trying to Accomplish?

To address the first question of the model, a project aim was established (Institute for Healthcare Improvement, n.d.). The aim should be time-specific, measurable, and with clear intention. The aim should also define the specific target population that will be affected by the project. The Institute of Medicine outlines six overarching "Aims for Improvement" for health care which include: safe, effective, patient-centered, timely, efficient, and equitable (Institute for Healthcare Improvement, n.d.). These aims are a helpful guideline for many organizations to help develop specific aims for projects. The aim of this QI project was to achieve 80% participation rate with self-sampling within one month of sending out kits to participants.

How Will We Know That a Change is an Improvement?

The next question as a part of the model is to determine if a change leads to improvement. To determine if a change is effective, quantitative measures were established (Institute for Healthcare Improvement, n.d.). The quantitative measure that was used for this quality improvement project was the number of women who complete and return the self-sampling kit and a 0-10 Likert scale used in the post-survey questionnaire to assess likelihood of using self-sampling again in the future.

What Change Can We Make That Will Result in Improvement?

The last question that was addressed according to the Model for Improvement was to determine the change concept. All changes do not lead to improvement; however, all improvements require change (IHI, n.d.). Many different changes can lead to an improvement, but according to the IHI, there are a limited number of change concepts that have been developed to lead to specific changes. A change concept is the general approach to change that has been found to be useful for developing specific ideas for changes (IHI, n.d.). The change concept for this QI project was based on the IHI concept to improve the customer/patient interface (IHI, n.d.). For this intervention to be effective, the patient must recognize and appreciate the improvement. Currently, this intervention will not replace in-person screening, however, the acceptability of the intervention was determined by the likelihood of women using this intervention in the future if they were given the option. This project was to increase access to and to improve convenience for HPV screening, therefore, the change concept was to improve the patient interface.

Plan-Do-Study-Act (PDSA) Cycle

The second part of the Model for Improvement is the Plan-Do-Study-Act (PDSA) cycle which is a guideline for testing a change in a real work setting (Institute for Healthcare Improvement, n.d.). The PDSA cycle is a framework for testing change, by planning it, trying it on a small scale, observing the results, and adjusting the plan based on the lessons that were learned (IHI, n.d.). Testing this change helped determine if the project resulted in improvement, to minimize resistance upon implementation, and to evaluate if changes needed to be made to the plan (IHI, n.d.).

Plan

The first step in the PDSA cycle is to plan the intervention, which also includes the plan for collecting data (IHI, n.d.). The objective of this intervention was to determine the acceptance of using HPV self-sampling for cervical cancer screening. Mailing HPV self-sampling kits has been shown to increase screening uptake compared to traditional screening methods, which supports the feasibility of mailing self-sampling kits (Winer et al., 2019). A randomized controlled trial by Winer et al. (2019) supports the feasibility of HPV self-sampling, therefore, it is predicted that this intervention will be an effective quality improvement project and the participants will have a positive experience with the self-sampling kits.

During this phase, the provider at WCAK was consulted by the principal investigator (PI) to identify the need for HPV self-sampling and how this intervention could fill a gap within the practice. The EHR at this clinic was searched over a three-day period among nine providers for women ages 30-65. Data was collected on the age, demographics, and when they had their last

pap smear with or without HPV co-testing. There was a total of 88 patients that were identified between age 30-65 years over the three-day period.

It was found that many women had reported that they had a pap smear in the last three to five years, however, there was not always results recorded on file. According to this information, most women at this clinic are up to date with their pap smear, however, many of their lab results were not documented in their chart. Over the three-day period that the EHR was searched, 58 out of 88 (65.9%) women had documentation of current pap test results in their chart (Appendix F). For this project, documentation of pap test results within the chart included either pap results with or without HPV co-testing recorded in the EHR under "lab results" or the results were scanned in from another clinic and found under "imaging." This screening rate is 14.9% lower than the Alaska state average cervical cancer screening rate from 2020 which is 80.8% (America's Health rankings, 2020). Patients with pap test results that were self-reported were not counted as having a documented pap test. Patients who had self-reported documentation of a pap test or who had their last documented pap test more than five years ago were grouped together and considered not up to date on screening. 30 out of 88 (34.1%) of the patients had either a self-reported pap test result or had not had a pap test within five years, therefore, were not considered up to date on screening (Appendix F). Demographic data was collected in the EHR, including race and ethnicity based on self-report and age range. Regardless of when the last pap was documented in their chart, the majority of the women (66 out of 88, 75%) identified as white. The most common age for women to have up to date pap test results documented in their chart were women who were age 30-39 years old (36 out of 58, 62%). According to this chart review at WCAK, the screening rate is lower than the Alaska state average, therefore, the goal of this

project was to have an 80% participation rate to reflect the Alaska state average. To achieve this goal, 80% of the project participants will report that they completed and returned their HPV self-sampling kit in the mail.

During the planning phase of this QI project, the Everlywell HPV self-sampling kit was chosen to be used as the intervention because it tests for 14 high-risk HPV strains, including 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. This kit tests for all these strains with reflex to HPV 16 and HPV 18/45 (Everlywell, n.d.). According to the WHO (2020), the strains HPV 16 and 18 cause 70% of cervical cancers and pre-cancerous lesions, which is the reason that reflex to hrHPV was an important factor regarding selection of the self-sampling kit. The Everlywell kit included a vaginal swab packet, biohazard bag to enclose the sample, and a prepaid shipping label so participants could conveniently return their sample. Instructions on how to collect the sample and return the kit were also included in the mailing box (Appendix E).

Do

The next step of the PDSA cycle was to try out the test on a small scale. This step allowed for identification of problems and unexpected observations. Analysis of the data begins at this step (IHI, n.d.). Women were identified in the EHR who (1) were age 30 to 65 years, (2) do not have a current pap test or HPV result documented in their chart (3) have not had a hysterectomy, (4) are currently a patient at WCAK, and (5) must not require an interpreter. Women were contacted by phone call and asked to participate in the QI project. Women who were willing to participate were sent an online pre-survey questionnaire on potential barriers they currently face to screening. Participants were sent an Everlywell HPV self-sampling kit with a prepaid return envelope addressed to the Everlywell clinical laboratory. In addition to the self-

sampling kit, participants were mailed a disclosure letter about the QI project (Appendix B), evidence-based information regarding cervical cancer screening (Appendix E), and instructions on how to self-collect and return their sample (Appendix E). HPV self-sampling is not the standard of care in the United States currently, therefore, a disclosure was included with information to schedule regular in-person pap screening. Women were sent a reminder message through email one week and two weeks after kits were mailed out.

Due to the small-scale of the QI project, the test results were not able to be automatically integrated within the WCAK EHR, instead, women were asked in the post-survey if they completed and returned the kit. Additionally, this did not allow for the providers at WCAK to review the self-sampling results electronically. Therefore, patients were encouraged to come in for regular in-person screening regardless of if they participated in the self-sampling and regardless of the self-sampling results. The post-survey questionnaire was sent to the participants through email four weeks after the kits were sent out which included a self-reported response on their participation in the project, their experience with the self-sampling, and how likely they would be to use this method in the future (Appendix D).

Study

The third step of the PDSA cycle is to analyze the data and study the results from the small-scale implementation. During this step, the data was analyzed and summarized (IHI, n.d.). The data from the EHR review at WCAK showed that the main concern was not a lack of screening, instead, it was a lack of consistency among documentation for screening. According to the EHR, some women reported that they had been screened before but did not provide documentation of results. Other women had documentation of results of pap testing from another

clinic, but many times, these results were not easily accessible within their chart. This data showed that there is a need for self-sampling to consolidate testing and make screening more simplified and convenient for women. According to the chart review at WCAK, the number of women who had a recorded up to date pap test result within their chart was 65.9% (Appendix F).

Act

The fourth and final step of the PDSA cycle is to refine the intervention based on what was learned from the test. Appropriate modifications were made, and the next test was prepared and planned based on the data (IHI, n.d.). The goal of this QI project was to understand the acceptability of this intervention on a small scale so that it can be implemented across a larger scale in a rural Alaska OB/GYN clinic. Further discussion is needed to identify ways to make the intervention more effective and to share the results with other providers in Alaska. A new PDSA cycle can be used to make necessary changes needed to increase the effectiveness of the project.

Setting

The setting for this quality improvement project was at Women's Care of Alaska (WCAK) which is a privately owned OBGYN clinic in Anchorage, Alaska. This clinic was established in 1994 to provide obstetrical and gynecological care to women of all ages. The providers at WCAK are comprised of five physicians and four nurse practitioners and the support staff includes certified medical assistants and office staff. According to the 2010 United States Census Bureau, Anchorage, Alaska is 4.1% rural, however, WCAK provides care to many patients who travel from rural areas and from the outlying areas nearby the city of Anchorage (US Census Bureau, 2010).

Some of the services at WCAK are annual gynecological exams, including pap testing and colposcopies, pelvic pain treatment, evaluation for urinary incontinence, uterine endometrial ablation, menopause management, family planning, prenatal care, and reproductive medicine. COVID-19 has presented many challenges to WCAK including delayed care for annual exams, delayed routine pap testing, and the need to adapt a more remote approach to care. HPV self-sampling is an appropriate intervention to implement at WCAK because of the necessity for remote testing options, not only among rural populations, but for women who would prefer to stay at home, especially because of the COVID-19 pandemic.

Stakeholders

Implementation at WCAK was communicated with the nurse practitioners at the site. Key stakeholders for this project were the patients, owners of the clinic (two OBGYN physicians), the other providers at this site, and the clinic staff. The patients were the primary stakeholders because the intervention directly impacts their access to care and has the potential to increase convenience and access to screening. The owners of the clinic as well as the other providers can benefit from increased screening uptake which can lead to increased early treatment. Support and buy-in were important for effective implementation of this QI project. The nurse practitioners were consulted before and during the planning phase of the intervention to ensure clinic buy-in and appropriateness of the QI project for their patients. The clinic staff and medical assistants were also key stakeholders for this QI project because they were able to provide information to participants, schedule appointments, and direct questions to the appropriate source. With COVID-19, the clinic providers have noticed a significant number of women who did not come in for their annual wellness exam, or for their routine pap testing in the past year. This project

aims to improve routine cervical cancer screening and may be beneficial in the increasingly online approach to healthcare.

Planning the Intervention

Participants for the study were identified through the EHR at WCAK. The EHR was searched for women who (1) were 30-65 years old, (2) did not have a current Pap test or HPV result noted in their chart within the past year, (3) have not had a hysterectomy, (4) were currently a patient at WCAK, and (5) must not require an interpreter. Eligible women were notified by phone call with information about the project (Appendix C) and asked if they were interested in participating. Women were recruited until there were 14 women identified who were eligible and willing to participate. The Everlywell HPV self-sampling kit was used for this study which included easy to understand instructions and a prepaid return label. Once the 14 participants were identified, an Everlywell HPV self-sampling kit was mailed directly to the home address of each woman. Participants received a disclosure form (Appendix B) which allowed for consent to participate in the QI project. The participants were made aware that participating in this project does not replace in person pap screening, and that they were still encouraged to schedule their routine pap smear regardless of whether they chose to complete the HPV self-sampling. A study in Finland showed that a second reminder showed that screening participation increased from 72.6% to 79.2% and sending the self-sampling kit directly to the woman's home increased uptake further to 82.2% (Virtanen et al., 2015). After one week of the kits being sent out, women were sent a reminder through their email address (Appendix C). Another reminder email was sent two weeks after the kits were sent out (Appendix C).

Data was collected on the number of women who returned their completed kit in the mail within one month and on the women's personal experience with the self-sampling. Due to inability to link electronic self-sampling results with the WCAK EHR, the number of women who complete and return their kit was based on participant self-report through the post-survey.

Consent and Ethical Considerations

All participants were mailed a disclosure form which confirmed consent with participation in the project. Participants were made aware that this project did not currently replace regular in-person screening recommendations. No incentives were offered for participation. Women were informed that participation was voluntary and that they may opt out of the intervention at any time. Confidentiality and privacy were maintained throughout the project by careful security of data findings. The Everlywell self-sampling kit was sent to a CLIA-certified (Clinical Laboratory Improvement Amendments) lab therefore, the lab is required to meet high standards to obtain both state and federal certifications (Everlywell, n.d.). The kits were also reviewed and approved by independent board-certified physicians within the specific state being tested in. Lastly, the Everlywell kit is HIPAA compliant which protects patient safety and security (Everlywell, n.d.). The participant's age was obtained from the pre-survey; however, an age range was utilized to further protect patient privacy. Age ranges were grouped by age 30-39 years, 40-49 years, 50-59 years, and 60-65 years.

Timeline

The timeline (Appendix G) was developed to ensure organized and timely progression of the QI project. The timeline was followed and adjusted based on approval from the University of

Arizona Institutional Review Board. Approval from the University of Arizona IRB (Appendix A) was obtained and subsequently participants were identified.

Data Collection

A quantitative approach was used to collect data (Appendix D). Participants were sent a pre-survey questionnaire with a question on barriers that they may face that affects them from attending routine Pap testing in-person. Demographic data, including age, ethnicity, and race, were also obtained from the pre-survey. Participants were sent a post-survey questionnaire one month later with questions on their participation with the self-sampling, experience with the self-sampling intervention, and the likelihood of them using this method for cervical cancer screening in the future if given the choice. The data from the pre- and post-survey questionnaire were quantified through Likert scale and through evaluating the number of women who complete and return their self-sampling kit.

Data Analysis

The data was analyzed using descriptive statistics to score and evaluate the pre- and post-survey questionnaires and the participation rate with self-sampling. The data from the pre- and post-survey questionnaires was gathered through a Google Forms link sent to the women through their email when the self-sampling kit was mailed to them and one month later. The responses from the pre- and post-survey questionnaires were gathered through the Google Forms application. The data from these questionnaires was analyzed through graphs that were created by the Google Forms application. The multiple-choice question on the barriers to screening (Appendix D) was formatted as “check all that apply.” Likert scale results were used for two of the questions on the post-survey which were analyzed as bar charts. A “not very likely/not very

convenient" was assigned a score of zero, "neutral" was assigned a score of five, and "very likely/very convenient" was assigned a score of ten. Data on the number of women who completed and returned their kits in the mail was also collected which was based on self-report

RESULTS

Outcomes

The overall results of the QI project were positive and offer a further understanding of this promising healthcare resource. Based on the inclusion criteria, 16 patients at WCAK were identified as potential participants. The 16 patients were contacted by the PI and 14 out of 16 agreed to participate in the project. However, only 12 participants filled out the pre-survey (86%) and nine participants (64%) filled out the post survey. Of the 12 women who filled out the pre-survey (Appendix D), one participant was 50-59 years old (8.3%), five participants were 40-49 years old (41.7%), and six participants were 30-39 years old (50%). The participants were asked to select all that apply for the race that they identified as. Therefore, one participant identified as Asian (8.3%), and 12 participants identified as white or Caucasian (100%). One participant identified as Hispanic, or Latino (8.3%) and 11 participants identify as non-Hispanic or Latino (91.7%). The final question on the pre-survey was to select potential barriers that the participants face that makes attending routine pap testing challenging. Six of the participants selected "interference with childcare/work/other tasks" (50%), seven participants selected "lack of time" (58.3%), three participants selected that they do not face barriers (25%), two participants selected "reasons related to COVID-19 that delayed screening" (16.7%), and one participant selected "uncomfortable or embarrassed" (8.3%). None of the participants selected that transportation or traveling long distances was a barrier that makes attending in-person routine pap testing

challenging. The pre-survey was sent the same day that kits were sent to participants. A reminder email was sent one week (Appendix C) and two weeks (Appendix C) after the initial email.

Figure 3

Pre-survey Question 1 Results

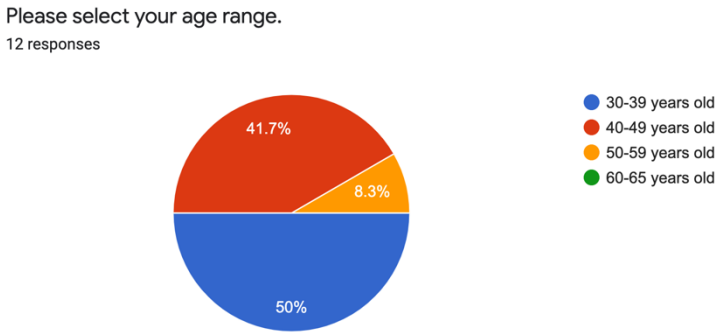


Figure 4

Pre-survey Question 2 Results

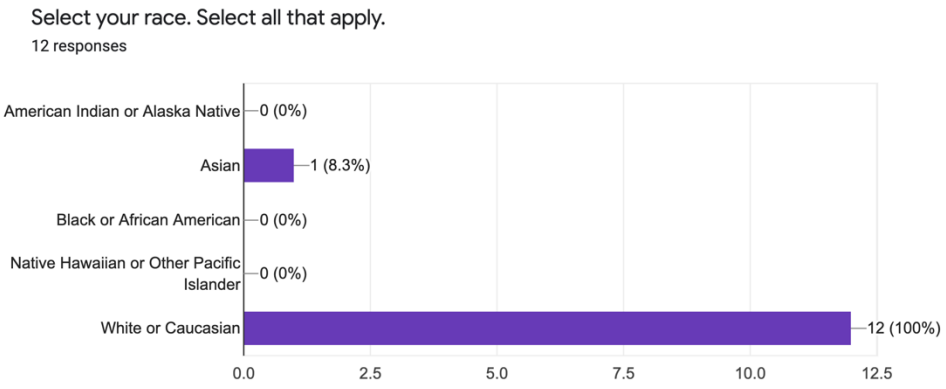


Figure 5

Pre-survey Question 3 Results

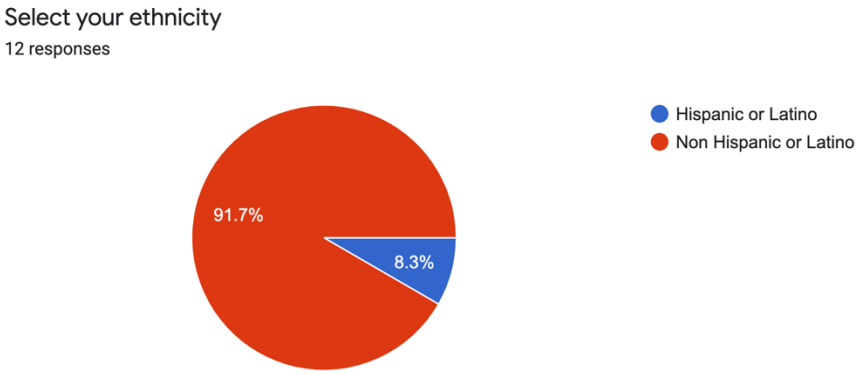
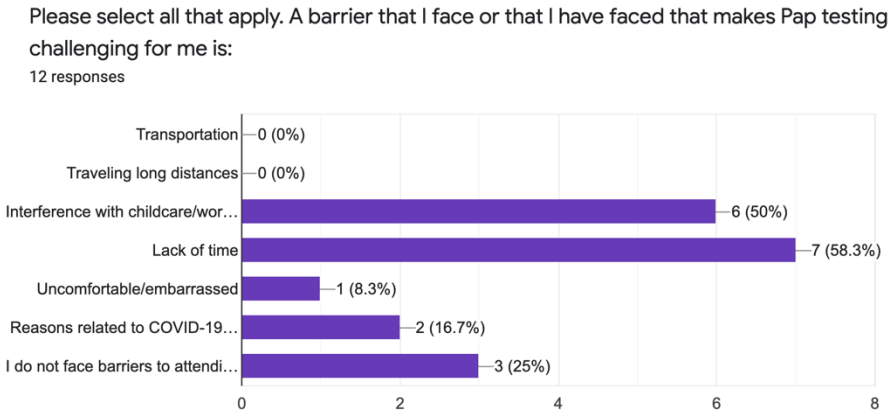


Figure 6

Pre-survey Question 4 Results



The PI sent out the post-survey four weeks after the kits were sent to participants. Nine participants responded to the post survey. Of this, eight participants reported that they completed and returned their kit in the mail (88.8%%) and one participant reported that they did not complete and return their kit in the mail (11.1%). The participants were asked on a scale of 0-10 how likely they are to use HPV self-sampling again in the future, with '0' being *least likely* and '10' being *most likely*. Four participants responded at least a '7' (44.4%), three participants

responded with a ‘5’ or ‘6’ (33.3%), and two participants responded with a ‘0’ (22.2%). The third post-survey question asked participants to answer on a scale of 0-10, how convenient was the HPV self-sampling method, with ‘10’ being *most convenient* and ‘0’ being *least convenient*. Seven participants selected a ‘9’ or ‘10’ (77.8%) and two participants selected ‘5’ (22.2%). The final question was to answer if given the choice between HPV self-sampling and in-person pap testing, which option would they choose. Seven participants chose the self-sampling method (78%), and two participants chose in-person pap testing (22.2%).

Figure 7

Post-survey Question 1 Results

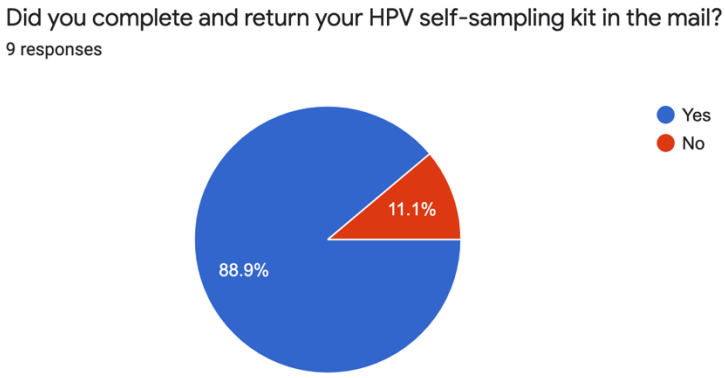


Figure 8

Post-survey Question 2 Results

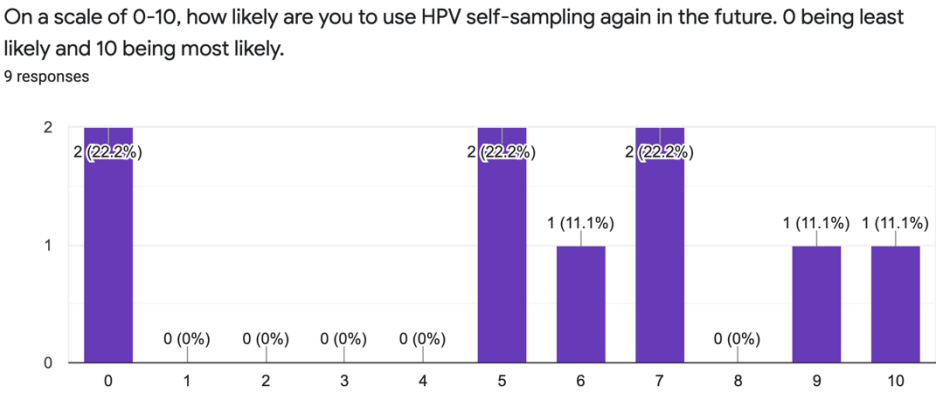


Figure 9

Post-survey Question 3 Result

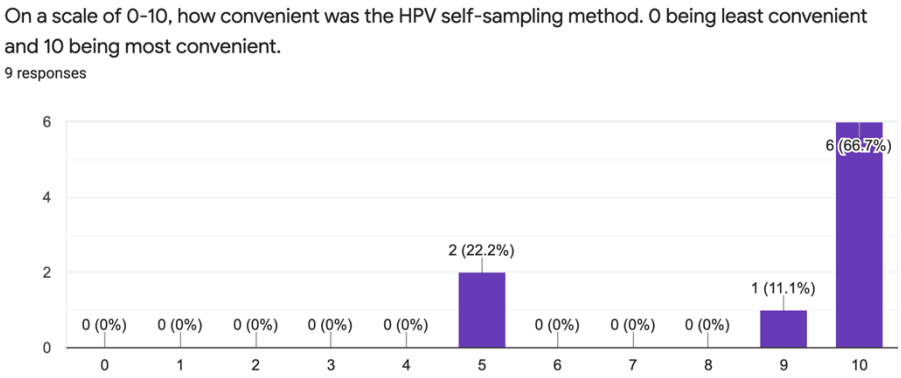
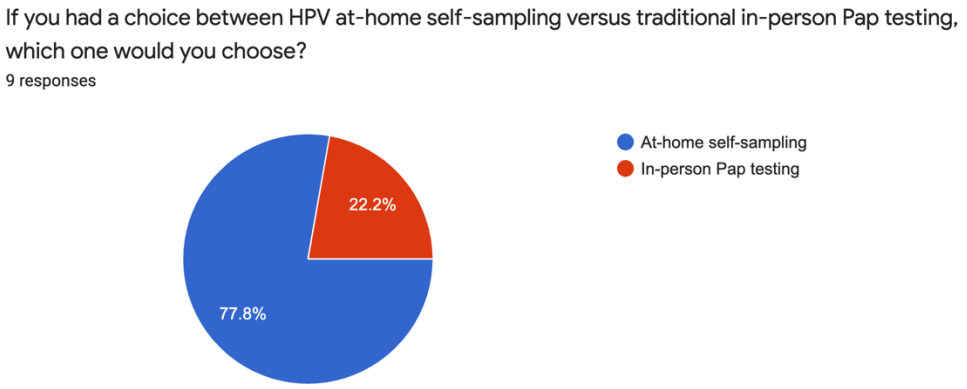


Figure 10

Post-survey Question 4 Results



An important aspect of the data analysis was to assess the post-survey results of the participants who selected "yes" to completing and returning their HPV self-sampling kit in the mail. Analyzing the post-survey data among the women who completed their kit is a better representation of the participants preference and acceptance of the self-sampling method. Therefore, among the eight women who completed and returned their HPV self-sampling kit, on a scale of 0-10 for how likely the participant would be willing to use a self-sampling method in the future, with '10' being *most likely*, one participant selected '10' (12.5%), one participant selected '9' (12.5%), two participants selected '7' (25%), one participant selected '6' (12.5%), two participants selected '5' (25%), and one participant selected '0' (12.5%%). On a scale of 0-10 on how convenient the self-sampling was, with '10' being the *most convenient*, six participants selected '10' (75%), one participant selected '9' (12.5%) and one participant selected '5' (12.5%). Among the women who completed and returned their kit in the mail, seven chose the at-home self-sampling method (87.5%) over the in-person pap testing if they were to

be given the option. Therefore, one participant would prefer in-person pap testing if given the choice (12.5%).

DISCUSSION

Summary

The purpose of this quality improvement project was to evaluate the acceptance of a self-sampling method for cervical cancer screening. The implementation process was successful, and the general response was positive. The responses received through the pre-and post-survey offer valuable data on the feasibility and acceptance of a self-sampling option. The aim of this QI project was to achieve 80% participation rate with self-sampling within one month of sending out kits to participants. Kits were sent to 14 participants and eight8 participants (57%) reported that they completed and returned their kit in the mail. Therefore, this aim was not achieved. However, this data is helpful in evaluating the acceptance of self-sampling. Over half of the participants reported that they completed and returned their kit in the mail, which is a highly positive outcome, despite the goal being 80%. Furthermore, seven out of eight of the participants who filled out the post-survey, who completed and returned their self-sampling kit, reported that they would choose self-sampling over the traditional in-person pap-testing if given the option in the future. This is a crucial result because the patients are key stakeholders. With this data, it can be inferred that most participants would likely choose self-sampling over in-person pap testing, however, there may be several women who would still prefer to attend in-person screening. This shows that it may be beneficial to offer the choice for HPV self-sampling instead of using self-sampling to replace in-person screening. The pre-survey results also showed that among the participants, there were not any women who face transportation issues or who must travel long

distances to attend in-person pap testing. Women who face these types of barriers have been shown to prefer self-sampling because of the ability to screen without having to attend an in-person visit, therefore, self-sampling may be more accepted among specific populations and subgroups (Akinlotan et al., 2017).

The results of the post-survey data show that only about half of the women would be likely to use self-sampling again in the future, however, most of the participants found self-sampling to be convenient and would choose self-sampling over pap testing if they were given the choice. These numbers support the acceptance and usability of this intervention.

Implications

The implications of this QI project are that there needs to be more research on this topic and clinical practice guidelines changes are required for widespread implementation of HPV self-sampling. The current cervical cancer screening guidelines in the United States do not include self-sampling for HPV as a recommendation, however, the guidelines do recommend primary hrHPV screening alone every five years (USPSTF, 2018). The USPSTF recommendations reflect the benefit of hrHPV testing alone, however, there requires further guidelines on self-sampling versus in-person testing. With the evidence-based research that supports the use of self-sampling for hrHPV testing, guidelines will need to be updated to reflect this method of screening.

Limitations

There were some limitations to this project that should be acknowledged. The most significant limitation of this project was that the data was completely self-reported by the participants. Therefore, it is difficult to determine the true number of participants who completed

and returned their kit because participants may not respond to the post-survey in the email, or they may not answer truthfully. Another limitation was the inability to analyze who filled out both the pre- and post-survey. Survey responses were anonymous; therefore, data could not be combined for participants for pre- and post-survey. This could have been avoided by only utilizing a post-survey instead. Additionally, the implementation for this project spanned for four weeks and data collection spanned for an additional two weeks after the post-survey was sent out. This only allowed women to fill out the pre-survey, complete and return their kit, and fill out the post-survey within a six-week timeframe. It is challenging to determine if more women would have filled out the pre- and post-survey and completed and returned their kit if given more time.

DNP Essentials Addressed

The Doctor of Nursing Practice (DNP) is the most advanced level of nursing education and requires preparation for practice which includes an expansion of scholarly and scientific knowledge and competency for improving patient care delivery and outcomes (American Association of Colleges of Nursing, 2006). The concept of a doctoral prepared nurse is not new; however, the study course has evolved significantly. The 8 DNP Essentials outline the standard fundamental elements and competencies that must be present within the curriculum to obtain a DNP degree. The DNP essentials are as follows:

1. Scientific underpinnings for practice
2. Organizational and systems leadership for quality improvement and systems thinking
3. Clinical scholarship and analytical methods for evidence-based practice

4. Information systems/technology and patient care technology for the improvement and transformation of health care
5. Health care policy for advocacy in health care
6. Interprofessional collaboration for improving patient and population health outcomes
7. Clinical prevention and population health for improving the nation's health
8. Advanced nursing practice

Doctoral education is distinguished by the completion of a final DNP project that synthesizes the studies and the nursing practice specialty of the student (AACN, 2006). The DNP project is a foundation for future scholarly practice and quality improvement (AACN, 2006). This DNP project encompasses each of the DNP essentials to varying degrees. The DNP essentials are the fundamentals of practicing as a doctoral prepared nurse practitioner. Therefore, these essentials are a guide for the PI to learn from and adapt throughout clinical practice.

Conclusions

This QI project adds helpful insight to the discussion on HPV self-sampling, however, there is more research that needs to be done to fully understand the feasibility of this resource. In conclusion, HPV self-sampling is a promising intervention that has positive acceptance among women at WCAK. Despite the limitations of this project, the implementation plan, and data from this may be used to guide future projects on this topic. Participants found self-sampling to be convenient and preferred this option over in-person pap testing. A conclusion that may be drawn from this project is that in the future, women may appreciate the option to choose self-sampling rather than in-person screening for cervical cancer.

Plan for Sustainability

Scheirer and Dearing have defined sustainability as "the continued use of program components and activities for the continued achievement of desirable program and population outcomes" (Braithwaite et al., 2020, p. 2). Sustainability requires continuous assessment and potential modification to maximize and maintain the benefits of healthcare innovation (Braithwaite et al., 2020). The key for sustainability for self-sampling would be the cost-effectiveness and buy-in from the target population. Although it is convenient for women to screen in the comfort of their home, there still requires motivation for women to complete the kit and send it back through the mail. According to this QI project, most women found self-sampling to be very convenient and would choose self-sampling over in-person pap testing if given the choice. This data is supportive of sustainability among this target population; however, the long-term sustainability may vary among different populations. Cost is another key factor for sustainability. A study by Aarnio et al. (2020) discusses the cost-effectiveness of HPV self-sampling compared to traditional pap testing. The authors of this study discussed the cost for primary screening through self-sampling compared to in-person pap testing. The total cost for screening was 241% higher for the pap smear group compared to the self-sampling group (Aarnio et al., 2020). With follow-up and treatment costs, the cost per treated woman was 45% higher in the pap smear group compared to the self-sampling group (Aarnio et al., 2020). Therefore, the cost for self-sampling is highly cost-effective. Ideally, insurance companies or organizations would cover the cost of the self-sampling kit and processing fees. An "opt-in" strategy may be a beneficial approach which would allow women to request self-sampling. This may be a potential approach to reduce waste and cost (Burger, Sy, Nygård, & Kim, 2016). The

cost effectiveness may be more or less advantageous depending on the available resources and target population; therefore, an evaluation of the target population, healthcare economy, insurance, and resources is needed before deciding on new implementation strategies.

Plan for Dissemination in Rural Communities

The setting for this project was at an outpatient clinic in an urban community of Anchorage, Alaska. The entire state of Alaska is medically underserved, additionally a significant number of the communities in Alaska are considered rural. According to the United States census, the estimated population of the state of Alaska was 731,545 people in 2019 (United States Census Bureau, 2020). Of this, it is estimated that 238,379 people were living in rural communities in Alaska (Rural Health Information Hub, 2020). This QI project shows positive acceptance of HPV self-sampling in the urban city of Anchorage. The goal for this project was to evaluate the acceptance of HPV self-sampling to eventually disseminate this promising resource among the rural Alaskan communities. There are outcomes in this project that show potential benefits among different populations and demographics, however, there are unique differences among each of the rural villages that will impact the success of implementing this intervention. Implementing this resource into a rural setting will require meticulous planning and assessment of the unique needs and resources in each individual community. Communicating closely with the local rural community members and local healthcare workers is crucial for successful dissemination. Utilizing HPV self-sampling has the potential to significantly reduce healthcare disparities and improve access to life-saving screening measures especially in areas where there are limited resources

Funding

The project was implemented at the total cost of $861. Twenty HPV self-sampling kits were purchased for $49 each. There was a 25% sale on the Everlywell website at the time of purchase, so the total cost for 20 kits was $735. Postage to send the kits to the participants was $9 each therefore, $126 total to send kits to 14 participants. The cost of implementation was paid for by personal funds of the PI (Appendix I).

APPENDIX A:

WOMEN'S CARE OF ALASKA SITE AUTHORIZATION LETTER / THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD AUTHORIZATION LETTER

Women's Care of Alaska
2741 Debarr Road, C-205
Anchorage, Alaska, 99508

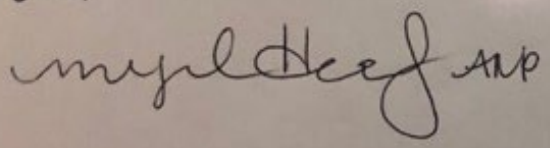
Date: June 24, 2021
University of Arizona Institutional Review Board
c/o Office of Human Subjects
1618 E Helen St.
Tucson, AZ 85721

Please note that Ms. Olivia Mills, UA Doctor of Nursing Practice student has permission of the Women's Care of Alaska clinic to conduct a quality improvement project at our facility for her project, "HPV Self-sampling to Improve Access to Cervical Cancer Screening in a Women's Health Clinic in Anchorage, Alaska."

Ms. Mills will conduct a quality improvement project at Women's Care of Alaska. She will identify potential participants through the EHR and recruit participants through phone call. She will send them a pre- and post-survey via email and an HPV self-sampling kit in the mail. Ms. Mills' activities will be completed by August 31, 2021.

Ms. Mills has agreed to provide to my office a copy of the University of Arizona Determination before she recruits participants. She will also present aggregate results to the providers at the clinic. If there are any questions, please contact my office.

Signed,



THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	July 26, 2021
Principal Investigator:	Olivia Anne Mills
Protocol Number:	2107033109
Protocol Title:	HPV Self-sampling to Improve Access to Cervical Cancer Screening in a Women's Health Clinic in Anchorage, Alaska
Determination:	Human Subjects Review not Required

Documents Reviewed Concurrently:

Data Collection Tools: *OM-2 week follow up call.docx*
Data Collection Tools: *OM-Instructions for Self-Sample.docx*
Data Collection Tools: *OM-Pre and post survey .docx*
HSPP Forms/Correspondence: *Advisor Confirmation Email.pdf*
HSPP Forms/Correspondence: *OM-Determination of Human Research (3).pdf*
Informed Consent/PHI Forms: *OM-Participant disclosure form updated.docx*
Other Approvals and Authorizations: *OM-Site Authorization .pdf*
Participant Material: *OM-Patient education.docx*
Recruitment Material: *OM-1 week Email Reminder .docx*
Recruitment Material: *OM-Phone script to recruit.docx*

Regulatory Determinations/Comments:

- Not Research as defined by 45 CFR 46.102(l): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

APPENDIX B:

CONSENT DOCUMENT (DISCLOSURE FORM)

HPV Self-Sampling to Improve Access to Cervical Cancer Screening
Principal Investigator: Olivia Mills, BSN, RN, DNP-FNP Student

The purpose of this project is to improve access to Human papillomavirus (HPV) screening at Women's Care of Alaska. HPV causes 70% of cervical cancers and precancerous lesions. Routine Pap smear testing is the traditional method for screening for cervical cancer. Self-sampling for HPV is an emerging method for cervical cancer screening that can be done privately and conveniently at-home and sent in the mail. The goal of this project is to understand barriers that women may face that prevents them from attending regular Pap testing, to understand the usefulness and acceptability of at-home HPV self-sampling, and to spread awareness on screening for cervical cancer.

To take part in this project, you will be asked to:

1. Complete a short pre-survey questionnaire via email.
2. Receive an HPV self-sampling kit in the mail.
3. Return the completed kit in the mail with the prepaid postage.
4. Complete a short post-survey via email after you have completed the kit.

It will take approximately 5 minutes to fill out the pre- and post-survey. It will take approximately 15 minutes to collect the self-sample. There are no foreseeable risks associated with participating in this project. Benefits in participation may include an increased knowledge on cervical cancer screening. Your responses are anonymous. Your name will not be collected or linked to your answers.

If you choose to participate in the project, participation is voluntary, refusal to participate will involve no penalty. You may withdraw at any time from the project. In addition, you may skip any question that you choose not to answer. By participating, you do not give up any personal legal rights you may have as a participant in this project.

Upon returning your self-sampling kit in the mail, your results will not be shared with the providers at Women's Care of Alaska. Only you will be able to see your HPV results. Your self-sampling results will not be used for this project. There will be no cost to you for participating.

HPV self-sampling for cervical cancer screening is not the standard of care in the United States, therefore, participation in this project DOES NOT replace routine Pap smear testing currently. You are encouraged to schedule your regular Pap smear testing regardless of if you choose to participate in the self-sampling or not.

The information that you provide in the pre- and post-surveys may be used for the purpose of this project. You agree to have your responses used for this project.

A range will be used to describe your age for the purpose of the project. This range will be as follows: 30-39 years old, 40-49 years old, 50-59 years old, 60-65 years old. Age, ethnicity, and race will be collected through a pre-survey via email and will be handled confidentially. If you do not wish to report your age, ethnicity, or race, you can still participate in the project.

For questions, concerns, or complaints about the project, you may contact:
Olivia Mills, BSN, RN
University of Arizona, DNP-FNP Student
oliviamills@email.arizona.edu
907-229-4345

APPENDIX C:

RECRUITMENT MATERIAL (PHONE SCRIPT TO RECRUIT PARTICIPANTS / INITIAL EMAIL TO PARTICIPANTS / ONE-WEEK AND TWO-WEEK FOLLOW-UP EMAILS TO PARTICIPANTS)

Phone Script to Recruit Participants

Hello (patient name), my name is Olivia Mills. I am a DNP student from the University of Arizona. I am calling from Women's Care of Alaska where I am completing my DNP project. I am calling you because according to your patient chart at the clinic, you do not have a current Pap test or HPV result noted in your chart. My project is on self-sampling for cervical cancer screening. Normally, you would come into the clinic for regular Pap testing to screen for cervical cancer. This can be difficult for some women so the clinic is exploring whether patients would be interested in self-screening options. Self-sampling for HPV is an emerging method for cervical cancer screening that can be done privately and conveniently at-home and sent in the mail. Currently, self-sampling is not routine practice in the United States, so you will still need to come in for a Pap test regardless of if you choose to participate in this project. If you choose to participate, I will send you a kit in the mail with some information on cervical cancer, instruction on how to collect the vaginal sample, and a disclosure form. The kit includes prepaid postage for you to conveniently return your sample through the mail. Also, if you choose to participate, I will send you a very quick pre- and post-survey questionnaire through your email. Do you have any questions or concerns? Would you like to participate in the study? If so, what is your email address and home address so that I can send you the pre- and post-survey through email and send you the self-sampling kit to your home address

Initial Email Sent to Participants

(Subject line): PARTICIPANT for HPV Self-sampling for Cervical Cancer Screening

Hello,

I hope this email finds you well. Thank you for participating in my DNP project on HPV self-sampling for cervical cancer screening. You should be receiving a self-sampling kit in the mail within the next few days. Please complete the kit and return it in the mail with the prepaid postage at your earliest convenience.

Please fill out the very brief pre-survey: (Link to online pre-survey)

I appreciate your time and help. Let me know if you have any questions or concerns!

Kindest regards,
Olivia Mills, BSN, RN
DNP Student
907-229-4345
oliviamills@email.arizona.edu

One-Week Follow up Email to Participants

(Subject line): PARTICIPANT for HPV Self-sampling for Cervical Cancer Screening

Hello,

I am following up with you regarding the HPV self-sampling project. This is a reminder to complete the self-sampling kit and return it in the mail if you have not done so already. Also, please fill out the pre-survey if you have not done so already as well. Here is the link for you to fill it out: (link to online pre-survey)

Please do not hesitate to reach out to me if you have any questions. I look forward to your participation in this project. Thank you kindly.

Best,
Olivia Mills, BSN, RN
DNP Student
907-229-4345
oliviamills@email.arizona.edu

Two-Week Follow up Email to Participants

(Subject line): PARTICIPANT for HPV Self-sampling for Cervical Cancer Screening

Hello,

This is another reminder to complete your HPV self-sampling kit and to complete the pre-survey if you have not done so already. Here is the link to the pre-survey: (link to survey)

I will be sending out a post-survey in two weeks which will conclude the project.

Thank you again for your time!

Best,
Olivia Mills, BSN, RN
DNP Student
907-229-4345
oliviamills@email.arizona.edu
.

APPENDIX D:

EVALUATION INSTRUMENTS (PRE- AND POST-SURVEY)

Pre-Survey Questionnaire

1. Please select your age range.
    a. 30-39 years old
    b. 40-49 years old
    c. 50-59 years old
    d. 60-65 years old
2. Select your race:
    a. American Indian or Alaska Native
    b. Asian
    c. Black or African American
    d. Native Hawaiian or Other Pacific Islander
    e. White
3. Select your ethnicity
    a. Hispanic or Latino
    b. Not Hispanic or Latino
4. Please select all that apply. A barrier that I face or that I have faced that makes Pap testing challenging for me is:
    a. Transportation
    b. Traveling long distances
    c. Interference with childcare/work/other tasks
    d. Lack of time
    e. Uncomfortable/embarrassed
    f. Reasons related to COVID-19 delaying screening
    g. I do not face barriers to attending Pap testing

Post-Survey Questionnaire

1. Did you complete and return your HPV self-sampling kit in the mail?
    a. Yes
    b. No
2. On a scale of 0-10, how likely are you to use HPV self-sampling again in the future.

0	1	2	3	4	5	6	7	8	9	10
unlikely				neutral					very likely	

3. On a scale of 0-10, how convenient was the HPV self-sampling method.

0	1	2	3	4	5	6	7	8	9	10
not at all convenient				neutral					very convenient	

4. If you had a choice between HPV self-sampling versus traditional in-person Pap testing, which one would you choose?
    a. HPV self-sampling
    b. In-person Pap testing

APPENDIX E:

PARTICIPANT MATERIAL (PROJECT PARTICIPANT EDUCATIONAL HANDOUT ON CERVICAL CANCER AND HPV FROM THE NATIONAL CERVICAL CANCER COALITION / EVERLYWELL HPV SELF-SAMPLING KIT INSTRUCTIONS / FINAL DEFENSE POSTER PRESENTATION)

HPV AND CERVICAL CANCER PREVENTION

WHAT IS HPV?

HPV is human papillomavirus. HPV is a common virus– more than half of sexually active men and women are infected with HPV at some time. At any time there are approximately 79 million people in the U.S. with HPV.

Some types of HPV may cause symptoms like genital warts. Other types cause cervical lesions which, over a period of time, can develop into cancer if undetected. However, most people have no symptoms of HPV infection, which means they have no idea they have HPV. In most cases, HPV is harmless and the body clears most HPV infections naturally.

HPV AND CERVICAL CANCER

According to the National Cancer Institute, more than 13,000 women in the U.S. will be diagnosed cervical cancer this year and more than 4,000 of these women will die. Most women with HPV will not develop cervical cancer, but it's very important to have regular screening tests.

Cervical cancer is preventable if precancerous cell changes are detected and treated early, before cervical cancer develops. Cervical cancer usually takes years to progress. Screening can usually catch any potential problems before they progress.

WHAT IS THE DIFFERENCE BETWEEN PAP AND HPV TESTS?

A Pap test is a test to find abnormal cell changes on the cervix (cervical dysplasia) before they have a chance to turn into cancer. A small brush or cotton tipped applicator will be used to take a sample of cervical cells. These cells are examined for abnormal cell changes. For women under 30, recommended screening is with a Pap test alone, once every three years.

An HPV test can detect "high-risk" types of HPV. "High risk" types of HPV can lead to cervical cancer and this test helps healthcare providers know which women are at greatest risk. Co-testing with a Pap/HPV test every five years or testing with the HPV test alone are both options for women ages 30 to 65.

NCCC
National Cervical Cancer Coalition
A program of the American Sexual Health Association

HPV VACCINES

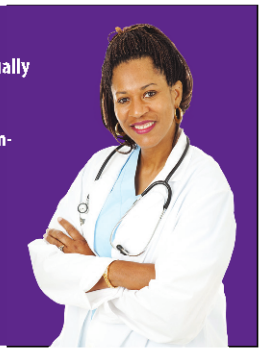
HPV vaccines can help prevent infection from both high risk HPV types that can lead to cervical cancer and low risk types that cause genital warts. The Centers for Disease Control and Prevention recommends all boys and girls get HPV vaccine at age 11 or 12. (Males are at risk for HPV and related diseases, too, so boys and young men are also recommended to be vaccinated.)

The vaccine produces a stronger immune response when taken during the preteen years. For this reason, up until age 14, only two doses are the vaccine are required. Women and men can get the vaccine up to age 45, but for those 15 and older, a full three-dose series is needed.

HPV vaccines don't protect against all types of HPV, though, so women need to continue having Pap tests and, as appropriate, HPV tests even after being vaccinated for HPV.

KEY POINTS

- **HPV is very common. Most sexually active individuals have HPV at some point.**
- **HPV infections are usually harmless and most are cleared by the body in a year or two.**
- **With regular screening (Pap and HPV tests) cervical cell changes can be found, treated (if needed), and cancer prevented.**



TAKING CHARGE OF YOUR HEALTH

A majority of women diagnosed with cervical cancer either have never had a Pap test or did not have one in the previous five years. Cervical cancer is completely preventable if precancerous cell changes are detected and treated early, before cervical cancer develops. Regular Pap tests, supplemented by HPV testing, will detect virtually all pre-cancerous changes and cervical cancers.

LEARN MORE ABOUT HPV AND CERVICAL CANCER AT WWW.NCCC-ONLINE.ORG AND WWW.ASHASEXUALHEALTH.ORG

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Everlywell kit instructions

Important Reminders

Register kit

Fill out tube

The lab **can only** process your sample if you:

- ☐ register your kit at **www.everlywell.com/register**
- ☐ fill out your information and apply Kit ID sticker to the tube

For collection:

- Do not collect specimen while menstruating.
- Do not pour preservative out of tube.
- Wait 24 hours after intercourse.
- Do not use personal lubricants to assist with collection.

Sample Collection Instructions

1

Register your kit

Visit everlywell.com/register and complete your registration. The lab cannot process your sample if this step is missed.

2

Fill out tube and apply Kit ID

Write your name and date in the specified fields on the tube. Then write your date of birth as the patient ID#. Place Kit ID sticker on the tube without covering your information.

3

Collect swab sample

Insert the swab (cotton tip) into vaginal canal and gently swirl for 30 seconds.

4

Place swab sample into tube

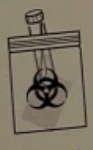
Put the swab (cotton tip downward) into the tube. Break the wand at the perforated line while leaving swab tip in the tube.

5

Seal your sample

Tightly seal cap. Wash your hands.

6



Place sample in biohazard bag

Place vaginal swab sample into the biohazard bag. Leave absorbent sheet inside.

7

Protect sample in transit

Take out return envelope and label from the bottom of the box and place biohazard bag inside. Then cover the box with the sleeve.

8

Return sample

Place the box in the return envelope and apply the shipping label provided. You're ready to ship!

What's next? →

Final Defense Poster Presentation

THE UNIVERSITY OF ARIZONA College of Nursing

HPV Self-sampling to improve access to cervical cancer screening at a women's health clinic in Anchorage, Alaska

Principal investigator: Olivia Mills, DNP-FNP Student, Committee Chair: Lisa Kiser, CNM, WHNP, Committee Members: Robin Poedel, PhD, RN, FNP-BC & Adrianne O'Brien, FNP

Abstract

Purpose: The purpose of this quality improvement (QI) project was to understand the acceptability of HPV women's health clinic in Anchorage, Alaska. **Background:** Over 70% of cervical cancer diagnoses are caused by persistent high-risk human papillomavirus infection. Regular and timely screening has been shown to reduce the prevalence for cervical cancer, however, there are barriers that may limit access to screening resources. There is emerging scholarly research on the use of HPV self-sampling for cervical cancer screening which would reduce or eliminate the need for women to attend in-person screening. **Method:** The design of this one-month project was a pre- and post-survey and a self-sampling intervention that was mailed directly to the participants. Participants were recruited through the electronic medical record at Women's Care of Alaska which is an outpatient obstetrics and gynecology clinic in Anchorage, Alaska. **Results:** Fourteen participants were sent HPV self-sampling kits. Twelve participants responded to the pre-survey and nine participants responded to the post-survey. Of the nine post-survey responses, eight of the participants completed and returned the kit in the mail. Seven out of eight of the participants who completed and returned their kit would choose self-sampling over in-person Pap testing if given the choice (87.5%). The consensus from the post-survey is that self-sampling for HPV is highly accepted. **Conclusion:** HPV self-sampling is a promising evidence-based resource to improve access to cervical cancer screening, however, it requires further research and guideline recommendations.

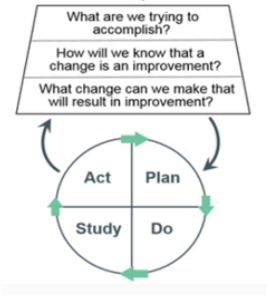
Background and Significance

- Regular and timely screening can reduce the prevalence of cervical cancer, however, there are various barriers that often affect the ability for women to access screening (Akinlotan et al., 2017).
- The CDC reports that in general, HPV is thought to be the cause of more than 90% of cervical cancers (CDC, 2020).
- Evidence supports the use of HPV self-sampling to reach underscreened women and to increase screening participation compared to traditional pap testing (Winer et al., 2019).

Purpose

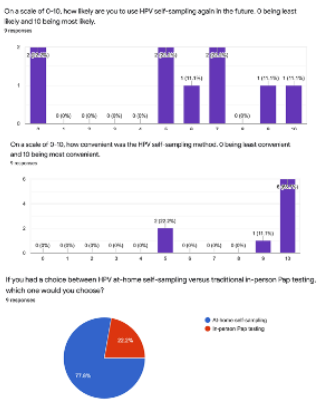
The purpose of this project was to evaluate the acceptability of HPV self-sampling for cervical cancer screening among rural Alaskan women

Model for Improvement



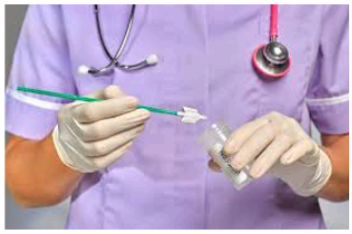
Methods

Fourteen women were recruited through the Women's Care of Alaska electronic health record to participate in the project and were sent HPV self-sampling kits, a pre-survey and then a post-survey one month later.



Results

There were 9 participants that responded to the post-survey. Of these, 8 of the participants completed and returned their kit. An important note is that 7 out of 8 (87.5%) of the participants who completed the kit responded that they would choose HPV self-sampling over in-person Pap testing if given the choice.



Discussion/Conclusions

This project shows positive acceptance to HPV self-sampling as evidenced by the convenience and the preference for self-sampling. HPV self-sampling has the potential to reduce cervical cancer screening disparities and to improve access to lifesaving screening opportunities. Further research and guidelines are needed to fully understand and implement this resource into our daily practice.

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References

APPENDIX F:

SCREENING GUIDELINES AND CHART REVIEW (AMERICAN CANCER SOCIETY AND U.S. PREVENTATIVE SERVICES TASK FORCE CERVICAL CANCER SCREENING GUIDELINES / WOMEN'S CARE OF ALASKA CHART REVIEW)

ACS and USPSTF Updated Cervical Cancer Screening Guidelines

	2012 ACS	**UPDATED 2020 ACS**	2012 USPSTF	**UPDATED 2018 USPSTF**
Age 21-24	Pap test every 3 years	No screening	Pap test every 3 years	Pap test every 3 years
Age 25-29	Pap test every 3 years	HPV test every 5 years Pap with HPV co-test every 5 years Pap test every 3 years	Pap test every 3 years	Pap test every 3 years
Age 30-65	Pap with HPV co-test every 3 years Pap test every 3 years	HPV test every 5 years Pap with HPV co-test every 5 years Pap test every 3 years	Pap test every 3 years Pap with HPV co-test every 5 years	Pap test every 3 years HPV test every 5 years Pap with HPV co-test every 5 years

Table adapted from the 2020 updated cervical cancer screening guidelines by the National Cancer Institute (NCI Staff, 2020; USPSTF, 2018).

WCAK EHR Review

Demographic		Pap test with or without HPV testing within <3 years	Pap test with or without HPV testing within 3-5 years	No Pap results in chart or Pap >5 years	Total
Age	30-39	32	4	15	51
	40-49	5	5	5	15
	50-59	5	3	9	17
	60-65	3	1	1	5
Total		**45**	**13**	**30**	**88**
Race/ethnicity	White	33	12	21	
	Hispanic/Latino	1		4	
	Black/AA	2	1	1	
	Asian	5		3	
	Native Hawaiian/Pacific Islander	4			
	AI or AN			1	
	Did not report	1		1	
Total		**58**		**30**	**88**

**Pap test in chart had to be documented under results or recorded on previous provider records that were scanned into WCAK EHR, Pap tests were not counted as documented if it was per patient verbal report.*

**AA: African American, AI: American Indian, AN: Alaska Native*

APPENDIX G:

PROJECT TIMELINE

Completion Date	Planning	Pre-Implementation	Implementation	Evaluation
May 18, 2021	Submit project proposal to committee chair.			
June 1-3, 2021	Make committee chair revisions to proposal.			
June 3, 2021	Submit revised project proposal to all committee members. Schedule Proposal Defense presentation with committee through doodle poll.			
June 22, 2021	Proposal Defense Presentation			
June 22-25, 2021	Make committee revisions to proposal.	Obtain committee approval to apply for IRB.		
June 25, 2021		Submit project proposal for IRB approval.		
August 13, 2021			Identify participants through WCAK EHR.	
August 16, 2021			Kits sent to participants home address Pre-survey emailed to participants	
August 23, 2021			1-week email reminder to participants	
August 30, 2021			2-week email reminder to participants	
September 13, 2021			Post-survey email to participants	
September 18 – October 15, 2021				Collect and analyze data.
October 15, 2021				Submit entire project to chair
November 5, 2021				Final Defense Presentation of project results.

APPENDIX H:

LITERATURE REVIEW GRID

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
2020 Aarnio, R., Ostensson, E., Olovsson, M., Gustavsson, I., & Gyllensten, U.	Cost-effectiveness analysis of repeated self-sampling for HPV testing in primary cervical screening: a randomized study	Randomized controlled trial	– Self-sampling for HPV led to 1633 more women screened and 107 more histologically diagnosed CIN2+ at a lower cost compared to traditional screening methods	– Cost effectiveness of self-sampling supported by this study
2020 Allende, G., Surriabre, P., Ovando, N., Calle, P., Torrico, A., Villarroel, J., Bossens, M., Fontaine, V., & Rodriguez, P.	Evaluation of the effectiveness of high-risk human papilloma self-sampling test for cervical cancer screening in Bolivia	Cross-sectional study	– VIA and hrHPV self-sampling were the best combination for detecting CIN2+ lesions – Cytology analysis has the poorest performance	– This study evaluated the effectiveness of hrHPV testing on self-collected samples compared to conventional cervical cytology and visual inspection – Used to identify the best combination of self-sampling screening tests
2018 Arbyn, Smith, Temin, Sultana, & Castle	Detecting cervical precancer and reaching underscreened women by using HPV testing on self-samples: updated meta-analyses	Meta-analysis	– Self-sampling similar accuracy to clinician-collected sampled when using hrHPV PCR testing – Offering self-sampling kits is generally more effective in reaching underscreened women compared to sending invitations – However, response rates highly variable among settings	– This DNP project will be done on a community in rural Alaska which is considered an underscreened population, so this meta-analysis is relevant due to the conclusion that self-sampling is more effective for reaching underscreened women compared to invitations for in-person visits
2020 Bakiewicz, A., Rasch, V., Mwaiselage, J., & Linde, D. S.	"The best thing is that you are doing it for yourself" - perspectives on acceptability and feasibility of HPV self-sampling among cervical	Qualitative study through individual semi-structured interviews	– HPV self-sampling was well-perceived and accepted, however for the method to be feasible, a nurse needed to be present	– Having positive acceptance of this intervention is crucial for effective implementation – Having a nurse present may be a barrier that may need to be addressed; however, other studies

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
	cancer screening clients in Tanzania: a qualitative pilot study		– Self-sampling may be an effective method to increase uptake of cervical cancer screening	show that women are accepting of at-home self-sampling as well which would be more impactful in rural Alaska
2018 Bergengren, L., Kaliff, M., Larsson, G. L., Karlsson, M. G., & Helenius, G.	Comparison between professional sampling and self-sampling for HPV-based cervical cancer screening among postmenopausal women	Cross-sectional study	– Postmenopausal women could be offered self-sampling devices to increase screening coverage while maintaining test quality – 83.2% of women had the same clinically relevant findings from both sampling methods (professional sampling and self-sampling) – Of the 143 participants, 119 returned the self-sample	– Statistically significant findings indicate comparable accuracy of professional-collected samples with self-collected samples
2020 Bertucci, M., Bonnet, E., Satger, L., Kreiche, A., Chappert, J. L., Loy-Morel, S., Segondy, M., Daurès, J. P., & Boulle, N.	Acceptability of vaginal self-sampling with high-risk human papillomavirus testing for cervical cancer screening: a French questionnaire-based study	Self-administered questionnaire	– Women declared high acceptability for vaginal self-sampling (81%) preferably at home (82.6%) – Acceptability was statistically higher for women older than 50 years old – No difference in acceptance according to educational level – Knowledge about cervical cancer and cervical cancer screening was significantly influence by educational level – This study confirmed that self-sampling with hrHPV testing	– High acceptance of this intervention is important as it shows that women are willing to utilize this resource – This study shows that women over the age of 50 years old were more likely to accept this intervention which is useful since the population in rural Alaska is aging

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
			is highly accepted, including underscreened women – Education about cervical cancer and screening should be a part of these programs, especially in lower-educated women	
2019 Chao & McCormack	HPV self-sampling for primary cervical cancer screening: a review of diagnostic test accuracy and clinical evidence – an update	Literature review	– Moderate to excellent agreement between self- and clinician- collected HPV samples particularly for PCR-based HPV tests	– It is important that self-sampling has similar accuracy to clinician-collected samples which is proven by this study
2020 Chatzistamatiou et al.	Acceptability of self-sampling for human papillomavirus-based cervical Ccncer screening	Nested cross-sectional survey	– Self-sampling is highly accepted – Further acceptance can be improved with proper communication of the process and its similarity with conventional screening – Large sample size (n= 13,111)	– This study emphasizes the need for proper communication and public education – Establishing trust within the community and with local providers is crucial for effective implementation
2018 El-Zein et al.	Validation of a new HPV self-sampling device for cervical cancer screening: the cervical and self-sample in screening (CASSIS) study	Randomized controlled trial	– Self-sampling using HerSwab are sensitive for detecting high-grade cervical lesions – High similarity found between self-sample and physician-sample in detecting HPV – Women expressed positive feelings toward using HerSwab	– Self-sampling is highly accepted and even preferred over physician-sampling – Comparable accuracy between self-sampling and physician-collected

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
			– Women preferred self-sampling over physician-sampling – Sensitivity for HPV detection for CIN2+ was 87.6% with HerSwab and 92.4% with physician sampling	
2020 Goldstein, A., Goldstein, L. S., Lipson, R., Bedell, S., Wang, J., Stamper, S. A., Brenner, G., Goldstein, G. R., O'Keefe, K. D., O'Keefe, S. C., O'Keefe, M., O'Keefe, T., Goldstein, A. R., & Zhao, A.	Assessing the feasibility of a rapid, high-volume cervical cancer screening programme using HPV self-sampling and digital colposcopy in rural regions of Yunnan, China	Longitudinal study	– Self-sampling allows large numbers of women to be screened rapidly and relatively inexpensively	– The cost-effectiveness and efficiency of self-sampling further strengthens the intervention – Able to test many women across variety of settings
2018 Gupta et al.	Self-sampling for human papillomavirus testing: increased cervical cancer screening participation and incorporation in international screening programs	Synthesis review of literature	– Self-sampling has been shown to equally accurate to clinician-sampling – The majority of women who have been underscreened but who tested HPV positive in self-sampling, will visit clinic for follow-up diagnosis and management – This article contains useful info on many barriers to access to screening	– Self-sampling removed many of the barriers that prevent women from participating in screening, especially in low socioeconomic and minority populations

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
2018 Harder, E., Thomsen, L. T., Hertzum-Larsen, R., Albieri, V., Hessner, M. V., Juul, K. E., Bonde, J., Frederiksen, K., & Kjaer, S. K.	Determinants for participation in human papillomavirus self-sampling among nonattenders to cervical cancer screening in Denmark	Population-based study	– Sociodemographic inequalities in women's participation in self-sampling were identified – Women with basic education or low income were less likely to participate in self-sampling compared to those with higher education and income – Nonwestern women were less likely to participate in self-sampling as well as unmarried women – Immigrants and racial or ethnic minorities less likely to accept self-sampling	– Low education/low income/minority groups have higher hates of cervical cancer disparities; however, this study shows these populations were also less likely to participate in self-sampling – This study shows that there will most likely be necessary education provided so that women will accept this intervention – Targeted approaches may be necessary to increase screening participation in this population
2018 Maza et al.	Acceptability of self-sampling and human papillomavirus testing among non-attenders of cervical cancer screening programs in El Salvador	Cross-sectional study	– Women who had not attended cervical cancer screening were accepting of self-sampling – These women felt very comfortable and confident performing HPV self-sampling – Lack of education and discomfort with male providers were reasons for not attending regular screening – Women reported high levels of satisfaction with the self-sampling experience and almost universally expressed willingness to perform the test in the future	– This is yet another study that highlights the positive acceptance of self-sampling which is a key factor in successful adoption of this intervention

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
2020 Peeters, Cornet, Devroey, & Arbyn	Efficacy of strategies to increase participation in cervical cancer screening: GPs offering self-sampling kits for HPV testing versus recommendations to have a pap smear taken - a randomized controlled trial	Randomized controlled trial	– This study showed high participation in self-sampling – Underscreened women are more likely to participate in screening compared to recommendations to participate in screening with a provider	– Teaching underscreened women is the goal of this DNP project, this study highlights the effectiveness of using self-sampling for reaching this vulnerable population
2019 Shin, Lee, Hwang, Lee, Sung, Park, & Jun	Evaluation of satisfaction with three different cervical cancer screening modalities: clinician-collected pap test vs. HPV test by self-sampling vs. HPV test by urine sampling	Longitudinal study	– Korean women more likely to report satisfaction with self-sampling compared to the traditional pap smear – Psychological distress, embarrassment, pain, anxiety, discomfort, and stress were significantly lower with self-sampling	– The satisfaction and reduction in psychological distress through self-sampling may motivate women to participate in screening
2018 Tranberg, M., Bech, B. H., Blaakær, J., Jensen, J. S., Svanholm, H., & Andersen, B.	HPV self-sampling in cervical cancer screening: the effect of different invitation strategies in various socioeconomic groups - a randomized controlled trial	Randomized controlled trial	– Large sample size (n=9,791) – All socioeconomic groups had higher screening participation with the self-sampling screening, however, western immigrant and lower socioeconomic groups seemed to benefit the most	– Participation in screening varies by socioeconomic status, this study concludes that all socioeconomic groups benefited from directly mailed self-sampling kits

Pub. Year; Author's Last Name	Title of Publication	Type of Study	Main Outcomes of Findings	Support for and or Link to Project
2018 Tranberg, Bech, Blaakaer, Jensen, Svanholm, & Andersen	Preventing cervical cancer using HPV self-sampling: direct mailing of test-kits increases screening participation more than timely opt-in procedures - a randomized controlled trial	Randomized controlled trial	– Direct mailing strategy was the most effective invitation strategy – Self sampling compared to regular cytology increases screening participation – High compliance with follow-up was also seen	– Direct mailing strategy may be used in the DNP project due to the conclusion of this study
2020 Wong, E. L., Cheun,g A. W., Wong, A. Y.,& Chan, P. K.	Acceptability and feasibility of HPV self-sampling as an alternative primary cervical cancer screening in under-screened population groups: a cross-sectional study	Cross-sectional study	– Self-sampling is a promising solution to overcome barriers of clinician-collected screening – Findings indicate that self-sampling would be feasible for an alternative to primary cervical cancer screening – Women who were under-screened or had never been screened were more likely to prefer HPV self-sampling – Positive acceptability of self-sampling – This study was used to explore the acceptability and feasibility of self-sampling in underscreened population	– Rural Alaska faces many unique barriers, self-sampling may help overcome some of these barriers – Many rural Alaskan women have never been screened or are underscreened, this study shows that self-sampling may be appropriate to improve this

APPENDIX I:

OTHER DOCUMENTS AS APPLICABLE TO THE PROJECT (BUDGET COST FOR THE QI PROJECT)

Cost for the QI Project

Item	Amount	Cost per 1 unit	Total
HPV Self-sampling kits	20	$36.75 (25% discount off $49)	$735
Postage + packaging	14	$9	$126
Total project cost			$861

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