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Evaluating the Uptake of Cotesting and Guideline Adherent Cervical Cancer Screening and Reported Barriers to Guideline Adherence in Academic and Community Practice Settings: A Mixed Methods Study

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Abstract

Evaluating the Uptake of Cotesting and Guideline Adherent Cervical Cancer Screening and Reported Barriers to Guideline Adherence in Academic and Community Practice Settings: A Mixed Methods Study

Background: Clinical practice screening guidelines recommend cotesting, a test that combines DNA Human Papillomavirus (HPV) testing with cervical cytology (also known as Pap testing) every 5-years, as a highly effective and preferred method for cervical cancer prevention among average-risk women aged 30-65. Up to date empirical data on the current uptake of this evidence-based intervention is sparse and does not allow for a complete understanding of the actual use of cotesting at the extended screening interval in practice among patients and providers in different types of practice settings. The 2012 national cervical cancer screening guidelines have further expanded in 2018 to include a third option for screening which includes primary HPV testing (testing without the use of cytology) for average-risk women 30-65 years of age, and its adoption by providers is unclear.

Purpose: The goal of this research study was to evaluate the uptake of the 2012 cervical screening guideline recommendations and obtain a comprehensive understanding of the determinants that influence cotesting uptake and guideline adherence, and explore the provider reported barriers to conducting cervical cancer screening in accordance with the guidelines. In addition, this study explored the early adoption of primary HPV testing as a third cervical screening strategy option recommended in the 2018 update of cervical cancer screening guidelines.

Methods: This explanatory sequential mixed methods study utilized a retrospective cohort design as part of the quantitative phase to analyze patient cervical cancer screening data retrieved from the George Washington (GW) Medical Faculty Associates (MFA) electronic

health record (EHR) system. Using multivariable logistic regression analysis, variables including patient age, race and ethnicity, insurance type, provider gender, specialty, degree and practice type were analyzed to determine their association with guideline adherent screening and cotesting use. Patient cervical cancer screening test type and date(s) of screening test(s) were extracted for each patient from the EHR. The interval between two negative screening tests was measured to determine if the testing had been conducted in accordance with the guideline specified screening interval defined for this study. Next, in the qualitative phase, these results were further examined with providers who conduct cervical cancer screening. Using convenience sampling methods, 7 Ob/Gyn and Primary Care providers were recruited from academic and community clinical practice sites for open-ended, semi-structured interviews to explore barriers to guideline adherence in practice and to further explicate the determinants identified in the quantitative phase of the study. Interviews were transcribed verbatim and coded using NVivo V.12 (Pro) using a deductive framework informed by The Knowledge, Behaviors, and Attitude Framework and the Consolidated Framework for Implementation Research (CFIR).

Results: One thousand patient records in the EHR were reviewed for retrospective analysis. 709 were eligible for study inclusion and 373 out of 709 were eligible for evaluation of the screening interval (i.e., guideline adherence). The overall uptake of cotesting between 2012 to 2020 was 86.3.6%. The median screening interval between two negative cotests was 36-months. 85.8% of patients were not screened in accordance with the guideline specified screening interval, with 75.1% overscreened and 10.7% underscreened. The final regression model showed that male providers had a lower odds (OR=0.31, 95%CI 0.13-0.78) of conducting cervical cancer screening within guideline specified intervals compared to females, and community practice sites had a lower odds (OR=0.15, 95%CI 0.08-0.31) of conducting screening

within guideline specified intervals compared to academic sites. For cotesting, the final model showed that patients seeing male providers for screening had a lower odds (OR=0.45, 95%CI 0.20-0.99) of receiving cotesting compared to patients seen by female providers. Patients seen by Primary Care providers or Other providers also had a lower odds (OR=0.24, 95%CI 0.12-0.50) and (OR=0.04, 95%CI 0.0003-0.39), respectively of receiving cotesting compared to patients seen by Ob/Gyn & Midwifery providers. Patients seen at community practice sites had a lower odds (OR=0.25, 95%CI 0.10-0.63) of receiving cotesting compared to patients seen at academic sites. Further exploration of these findings and barriers to guideline adherent screening were discussed in semi-structured interviews with 7 Ob/Gyn and Primary Care providers. Knowledge of current guidelines varied among different types of providers and practice settings. Provider attitude toward guidelines were driven by their past training and experience and habits. Difficulties in articulating guideline information to patients were reported as a hindrance to guideline adherence. External barriers related to patient preferences and insurance policies were reported as barriers outside the control of the provider. Provider demographic characteristics such as age and number of years in practice were discussed by the participants as potential explanations for male providers having a lower odd of conducting guideline adherent screening and cotesting when compared to females. Further, the interviewees did not prioritize following an extended 5-year screening interval per the guideline recommendations as an important piece to implementing cervical screening guidelines. The integrated results from both phases of the study demonstrated expansion and confirmation of the quantitative findings by the interviewees and provided further explication for the differences observed between gender of providers, provider specialty and the practice setting in which they reside.

Conclusion: There have been advancements in the adoption of cotesting since the issuance of the 2012 guidelines as evident by the high uptake of cotesting found in this study. Though providers mostly abide by cervical cancer screening recommendations and select the appropriate screening test, they fall short of adhering to the 5-year screening interval for cotesting and most women are overscreened. Provider characteristics such as gender, specialty, and practice setting are determinants found to influence guideline adherence and cotesting, but these are not sufficient to explain the discordant use of guidelines in practice. Barriers at the level of the health system, particularly the role of insurance and payor policies and their misalignment with current cervical screening guidelines are potential contributors to non-guideline adherent screening which result in driving up costs to the healthcare system resulting from overscreening and unnecessary testing. Multiple guidelines developed and issued on the same topic by stakeholders with different interests lends to confusion for the end-users on the recommended screening intervention to implement in practice. Finally, screening guidelines for cervical cancer prevention in the U.S. are designed to be population-based to reduce mortality and morbidity at the level of the population rather than the individual. However, delivery of population-based screening through a lack of an organized screening program or system makes screening reliant upon individual patient and provider encounters that introduce variability in the delivery of evidence-based screening interventions. To disrupt the cycle of less-than-optimal translation of cervical cancer screening guidelines in practice, changes to the current system of guideline development and delivery of cancer screening programs should be considered.

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CHAPTER 1

Introduction

Overview

The lag in translation of evidence from research to practice is evident in many areas of health research. It is known from prior work published in 2000 by authors Balas and Boren that it takes an average of 17 years for research evidence to reach clinical practice, with only a 50% uptake at best for most clinical interventions examined (Balas & Boren, 2000). The slow uptake of evidence continues to be a problem in many areas of health today, despite efforts to promote the swift dissemination and implementation of research.

In cancer prevention and control, nationally representative data on the uptake of various evidence-based cancer screening interventions in accordance with recommended national guidelines are available from United States (U.S.) population-based surveys conducted through the Centers for Disease Control and Prevention (CDC) Behavioral Risk Factor Surveillance System (BRFSS) and the National Health Interview Survey (NHIS). These self-reported data provide the most current information available on the percentage of the U.S. civilian population receiving preventive health and screening services for a variety of different cancer sites in accordance with clinical guidelines. However, several limitations are cited to assessing the uptake of guideline recommended screening tests based on self-reported surveys, questionnaires, or interviews from both patients and providers. These data tend to be less reliable than data collected from medical records and laboratory tests (Tatsas et al., 2012; Watson et al., 2017) and

different types of biases inherent in self-reports such as respondent recall-bias and social desirability-bias can threaten the validity of these data.

Surveys soliciting provider screening practice behavior often use clinical vignettes or case studies to evaluate use of guidelines and these are likely to reflect provider practice intentions and not actual behavior (Perkins et al., 2013; Roland et al., 2011; Silver et al., 2018; Yabroff et al., 2009). Thus, there is significant value and need for accessing practice-based data directly from electronic health records (EHRs) to assess the uptake of guidelines in clinical practice and their appropriate use (i.e., adherence) by providers, especially as guideline recommendations continue to evolve as new screening technologies are introduced. Studying provider behavior toward guidelines changes and its impact on practice and patients is important to better understand how screening designed for population level is translated to individual patients.

In the U.S., cancer continues to be the second most common cause of death (Heron, 2018); however, much of this burden is preventable through evidence-based interventions (Colditz et al., 2012). Cervical cancer used to be one of the most common cancers affecting women, but now ranks 14th due to a rapid decline seen after the introduction of the Papanicolaou (Pap) smear (or Pap test), also referred to as cervical cytology (American Cancer Society, 2022). Despite being a preventable cancer, cervical cancer worldwide, is the fourth most common cancer among women, and in the U.S. the second most frequent cause of cancer-related death in women aged 20-39 years. In 2019, 4,152 women died from cervical cancer, with half in their 50s or younger (Siegel et al., 2022). Most cases of cervical cancer occur among women who have never been screened or who have not been adequately screened (Melnikow et al., 2018), which may include not being screened within the previous 5 years (Curry et al., 2018; Moyer, 2012; Saslow et al., 2012). The American Cancer Society (ACS) estimates for cervical cancer in the

United States indicate that approximately 14,100 new cases of invasive cervical cancer will be diagnosed with 4,280 deaths attributed to the cancer (ACS, 2022).

Regular screening and follow-up make cervical cancer a highly preventable sexually transmitted gynecological cancer. Unlike other cancers, it is the only gynecological cancer that has highly effective primary and secondary screening strategies available. The introduction of the HPV vaccine to prevent HPV infections are primary prevention strategies targeting mostly HPV-naïve (those unexposed to the strain) populations (McGraw & Ferrante, 2014). Screening tests for secondary prevention can include a cervical cytology test (also called a Pap test or Pap smear) which collects cervical cells from a woman's cervix to identify abnormal cells that may be precancerous or cancerous caused by HPV. The Human Papillomavirus (HPV) test is a molecular-based test that looks for the presence of the virus which can cause cervical cancer. This test when combined with a Pap test is referred to as cotesting and identifies high-risk HPV and cervical changes. A Pap test and HPV test are done the same way by collecting a sample of cervical cells. Beginning in 2018, the HPV test can be used alone and is referred to as primary HPV testing (NCI, 2022).

Cervical cancer tends to occur in midlife and is most frequently diagnosed in women between the ages of 35 and 44 with the average age of diagnosis of 50 years. It rarely develops in women younger than 20 (ACS, 2022) and while declines in incidence and mortality have recently stabilized, the overall trend for cervical cancer screening test (Pap) use are declining (White et al., 2017). A NHIS survey administered in 2015 asking women about their cervical cancer screening test use found that only 21-35% of women older than 30 years received a cotest, and 81% of women aged 21-65 years received a pap test within 3 years (Watson et al., 2017).

Clinical practice guidelines exist for cervical cancer screening and provide different testing options for average-risk women based on age. These guidelines may be disseminated by primary care medical organizations, specialty societies, and medical advocacy organizations. The United States Preventive Services Task Force (USPSTF) is an independent panel of non-Federal experts in prevention and evidence-based medicine that make recommendations about clinical preventive services, including screening, counseling, and preventive medications (USPSTF, 2016). The Agency for Health Research and Quality (AHRQ) is a government-agency within the Department of Health and Human Services (DHHS) that provides administrative, scientific, technical, and dissemination support to the USPSTF. The clinical practice guidelines issued by the USPSTF are evidence-based, frequently updated, and widely used by primary care providers. Guidelines recommendations issued by the USPTF are assigned a grade based on their level of evidence, and most private insurance plans are required to cover preventive services that receive a high evidence grade of A or B without a copay (U.S. Preventive Services Task Force (USPSTF), 2019). The American Cancer Society (ACS), the American College of Obstetricians and Gynecologists (ACOG), and the American Society of Colposcopy and Cervical Pathology (ASCCP) also provide recommendations for cervical cancer screening, and these are intended to be used by primary and specialty care providers that deliver care to patients. While a lack of uniformity used to exist among the guidelines issued by these organizations prior to 2012, they became congruent when each organization issued revised guidelines in 2012.

In 2012, for the first time, USPSTF, ACS, ACOG and, ACCS issued overlapping cervical cancer screening guidelines. It was recommended that cytology testing (i.e., Pap) be initiated starting at age 21 up to age 29. Cytology is described as an analysis of the cervix in its current state with removal of cells to test for either a positive or negative presence of pre-cancer.

Cytology has low sensitivity and may miss 50% of present lesions, and a single negative test does not provide long-term reassurance that cancer will not develop (Castle et al., 2018). If results from the Pap test were normal, the next screening test would be repeated at a 3-year interval. For average-risk women ages 30-65, screening recommendations differed. This age group was recommended to undergo a combination of cytology and human papillomavirus (HPV) DNA testing every 5 years, referred to as "cotesting". Screening via cytology only at 3-year intervals was also an option, but the ACS, ACOG, and ASCCP clearly stated that cotesting was the preferred method, while the USPSTF stated cotesting was an option for women who wanted to lengthen their screening interval (Verrilli et al., 2014). Prior to 2012, the USPSTF did not recommend cotesting in this age group, but other organizations had been recommending cotesting as early as 2004, however, at shorter, 3-year intervals. The lengthened 5-year interval was only established in 2012. Women over age 65 were recommended to not receive any type of screening test.

In 2018, the USPSTF issued updated cervical cancer screening guidelines based on reviews of new evidence which evaluated screening with human papillomavirus (HPV) testing alone and concluded that harms of using this method are moderate and added it to its recommendation for women ages 30-65 years. The 2018 USPSTF recommendations for this age group now offer 3 options for screening: primary HPV testing alone every 5-years, cotesting every 5-years, or cytology alone every 3-years (Curry et al., 2018). The American College of Obstetricians and Gynecologists (ACOG), American Society of Colposcopy and Cervical Pathology (ASCCP) and the Society of Gynecologic Oncology (SGO) endorsed the 2018 USPSTF cervical screening recommendation (The American College of Obstetricians and Gynecologists, 2021). In 2020, the American Cancer Society (ACS) updates its guideline

recommending individuals with a cervix initiate cancer screening at age 25 and undergo primary HPV testing every 5 years through age 65 (as the preferred method). Cotesting every 5 years or cytology every 3 years still remain as acceptable and strongly recommended screening methods when primary HPV testing is not available (Fontham et al., 2020). The addition of a third option for cervical cancer screening by the USPSTF in 2018 provided a timely opportunity for exploration of this new test's adoption by providers in this study. However, the primary focus of this dissertation remained on the evaluation of the uptake of the 2012 guidelines, as the recommendation for primary HPV was not endorsed right away by ACS, ACOG and other medical and professional organizations and the recommendation for cotesting remained unchanged even in the updated guidelines.

Over time, a better understanding of the natural history of HPV has led to the emergence of new technologies for primary and secondary prevention of cervical cancer (Kim et al., 2015; McGraw & Ferrante, 2014). The causative link between HPV and cervical carcinoma is well established and persistent infection with certain high-risk types of HPV is necessary for cancer to develop (Denny, 2012). It is stated that "virtually all cases of cervical cancer are caused by HPV, and just two HPV types, 16 and 18, are responsible for about 70% of all cases" (National Cancer Institute (NCI), 2022). HPV testing is deemed to be more sensitive and reliable (Castle et al., 2018) for detecting precancerous lesions and cervical cancer than cervical cytology alone because it looks for DNA or RNA from certain high-risk types of HPV in samples of cells taken from the cervix (NCI, 2022). The link between an infection with a high-risk HPV type and cancer of the cervix is so strong that, "nearly all carcinomas of the cervix and the relative risk of cervical cancer associated with infection with high-risk types of HPV *is higher* than the risk of lung cancer associated with smoking" (Denny, 2012). Thus, there are several benefits of utilizing HPV testing;

earlier detection of lesions, earlier treatment, reduced incidence of cancer and cervical cancer related death, but also greater reassurance that a women's risk of cancer is low for many years which allows for screening at the extended screening intervals (i.e., 5 years with cotesting compared to 3 years with only pap) (Castle et al., 2018).

One major change in the 2012 guidelines from previous iterations was the recommendation ***against*** annual screening by any method. Less frequent screening is meant to reduce the potential for patient harm caused by over testing such as increased pain, inconvenience, and morbidity associated with excessive testing, follow-up procedures, and treatments. Additionally, the added cost and burden through unnecessary frequent and inappropriate use of cervical cancer screening should also be considered (Roland et al., 2011).

According to currently available national survey data collected by CDC, uptake of greater than 50% is reported for breast and colorectal screening tests, but there is less information about the current uptake of cervical cancer screening and the interval in which they receive the test, specifically, among women ages 30-65 that are recommended to receive cotesting every 5-years. Most existing data available on the use of cervical screening tests were collected and reported prior to 2012 using national surveys and focused on the use of cytology screening (i.e., Pap tests), not cotesting. One example are data available from 2006. At that time, ACOG, ACS, and ASCCP recommended cotesting for women ages 30-65 at 3-year intervals. The CDC administered a Cervical Cancer Screening Supplement (CCSS) to the National Ambulatory Medical Care Survey (NAMCS) to obtain national data on providers' self-reported cervical screening practice. While approximately 50% of providers reported (self-reports) ordering a cotest, only 14% of providers would follow the 3-year screening interval for the next test. The remaining would rescreen annually, although, this practice was not recommended (Roland et al.,

2011). Only recently, the question about the use of HPV testing was asked in a national population-based survey (Watson et al., 2017). In 2015, the NHIS collected data from women about receiving HPV screening with their most recent Pap test; however, the wording of the question did not allow women to specify if the HPV test was given for some other reason or at another time, which would not necessarily indicate that they received a cotest. This survey reports one-third (or 21-35%) of women older than 30 years received a cotest. However, many women (17%) reported not even knowing whether they had an HPV test and may have confused a Pap or cotest with a pelvic examination (Watson et al., 2017) weakening the reliability of these data.

One other source of data, and perhaps the best estimate we have to ascertain cervical cancer screening use in practice, particularly cotesting use in the United States, is from the New Mexico HPV Pap Registry (NMHPVPR) database, a population-based, state-wide registry established in 2006 to evaluate cervical cancer screening delivery for New Mexico residents (Castle et al., 2021; Cuzick et al., 2021; Cuzick et al., 2015). These data are based on laboratory reports from women screened in New Mexico between 2007-2019, and thus is an empirical assessment of screening practice, and more reflective of actual test use. Data in 2007 showed that only 5.2% of women ages 30-65 received cotesting, but, increased to 19.1% in 2012, the same year multiple organizations revised their guidelines and unequivocally recommended cotesting at 5-year intervals (Cuzick et al., 2015). The increased uptake of cotesting indicated slow but steadily increasing adoption in practice. An update to these data were published by Cuzic et al (2021) and showed that cotesting uptake rose to 84.3% in 2019 among women aged 30–64 years old. The largest increase in cotesting occurred in 2013 and 2015, reflecting the introduction and adoption of new clinical guidelines. More NMHPVPR data in 2021 were published evaluating cervical screening usage trends to report on guideline adherence observed between 2008 to 2019

for women aged 21-64 years (Cuzick et al., 2021). These data showed that between 2008 to 2019, there was a decline in the annual number of screening cytology tests with or without HPV (145,281 in 2008 to 72,957 in 2019) and an increase in the median screening interval between screening tests (15.0 to 39.0 months) in women 30-64 years (Cuzick et al., 2021). The percentage of women screened decreased two-fold for all ages, and there was a concomitant increase in the median screening interval from 1.5 years in 2008 to approximately 3.5 years in 2019. There was an increasing trend across time for women to be screened at intervals longer than those recommended. Only 12.7% of women with an antecedent negative cotest received cervical screening at the recommended 5-year interval. Most of the population was overscreened, although the percentage of overscreening for cotesting did decrease from 2013 to 2019.

One health system in Baltimore, MD has been conducting ongoing surveillance of cervical cancer screening patterns, specifically cotesting since 2004 (Phelan et al., 2011; Tatsas et al., 2012). In 2018, a study was published that used the John Hopkins University (JHU) hospital Pathology database to analyze cotesting use and screening intervals between 2006-2013 (Silver et al., 2018). It demonstrated that the uptake of cotesting within this system increased steadily starting in 2009 (33.3%) to 2013 (78.3%), but there was not sufficient follow-up post 2012 to determine if this increase was sustained nor was the study designed to evaluate the 2012 guidelines. At the time the study began, the pre-2012 guidelines recommended that women 30 years or older with a normal screening test be re-screened in 2–3 years if screened by cytology alone, or in 3 years if screened by cotesting (the 5-year interval was recommended beginning in 2012). It compared the length of screening interval by patient age, race, and insurance to evaluate determinants associated with appropriate application of recommending screening intervals (i.e., adherence) in clinical practice over time. Differences in adherence to cotesting and the

recommended screening interval by age, race, and insurance status were observed, however, the study was not able to determine the multi-level determinants that may be driving these differences or the cause, as the study did not qualitatively assess patient or provider knowledge, attitude, and preferences toward cotesting or the barriers to the uptake of the guidelines. It was concluded by the author of this study that "fidelity of evidence-based screening interventions is not uniform across populations" (Silver et al., 2018) and further research to understand why differences exist and what is driving them is needed.

Although guidelines recommending cotesting at longer intervals for women ages 30-65 have been in effect since 2012, the reported uptake is low (Cuzick et al., 2015; Watson et al., 2018; Watson et al., 2017) and few studies have been conducted shortly after the introduction of these guidelines for continued surveillance of data on cotesting adoption and the determinants that influence cotesting uptake and adherence to the extended screening interval in practice. Some studies conducted on cervical cancer screening guideline adherence demonstrate barriers to cotesting uptake and a lack of adherence to guidelines at the individual patient/provider, organization, and system level (MacLaughlin et al., 2011; Perkins et al., 2013; Silver et al., 2015; Silver et al., 2018; Teoh et al., 2015). This research aimed to identify the different determinants that influence screening practice and explain through a mixed methods research design, providers reported barriers to cervical cancer screening guideline adherence. This study is one of the few to use a mixed methods design to investigate cervical cancer screening guideline uptake after 2012, specifically focused on the use of cotesting and the extended 5-year guideline specified interval for women aged 30-65 years old. The knowledge gained from this research will inform current understanding of barriers to uptake and adherence to evidence-based cervical cancer screening guidelines as reported by providers of different genders, degrees, specialties and practice types. It

will also help explain the discordance between research, policy and practice as it relates to populations based cervical cancer screening. Recommendations from this study will help inform future research that seeks to eliminate guideline discordance screening practice and interventions for addressing system level barriers that inhibit guideline concordant screening.

Statement of the Problem

Prior studies published found that cervical cancer screening practice is not consistent with current screening guideline recommendations, reflecting a wide array of screening intervals, infrequent use of cotesting, and even overuse of screening (Hawkins et al., 2013; Kim et al., 2015; Roland et al., 2011; Yabroff et al., 2009). A lack of adherence to recommended cervical cancer screening guidelines have been reported by patients and providers residing within different practice settings. Exploration of patient, provider and practice level characteristics can help explain their influence in driving differences in screening practice. While the recommendation to screen women ages 30-65 with cotesting at extended (5-year) intervals has existed since 2012 and is the preferred recommendation of multiple professional and medical organizations, our knowledge of the current uptake of this screening intervention in clinical practice is limited and barriers to adherence to the extended screening interval are not well explored in the literature. This gap in our knowledge must be addressed so strategies can be designed and implemented to enhance use of screening guidelines as intended for the benefit of providers and patients and ultimately increasing the use of evidence-based practice and providing improvements in cervical cancer at a population health level. Based on the literature reviewed, it is expected this dissertation study may have similar results that find shorter screening intervals indicating overscreening.

Purpose and Research Questions

The purpose of this study is to quantitatively evaluate the uptake of cotesting, a combined Pap and HPV test, in practice since 2012 and whether cervical cancer screening is conducted in accordance with extended (5-year) screening interval among women ages 30-65 seen for routine primary cervical cancer screening in diverse clinical practice settings; and to identify patient, provider, and practice level determinants associated with reported screening practice. To better understand the reported screening practice and determinants associated with uptake of cotesting and guideline adherent screening observed, this study aims to further explore these results through semi-structured interviews with providers from academic and community settings. In addition, this study will explore the adoption of primary HPV testing as a third option for screening as recommended in the 2018 update of the guidelines. Insight into the actual uptake of guideline recommendations in practice and barriers limiting providers from conducting guideline adherent screening will add to our understanding of guideline adoption and identify areas of improvement within the GW Medical Faculty Associations (MFA) health system. Future studies may utilize information from this study to inform their own assessment of guideline use in practice and the development of interventions to overcome barriers to guideline adherent screening and accelerate adoption of new or updated evidence-based guidelines.

The following research questions will be addressed:

1. Beginning in 2012, what is the reported uptake of cotesting, (cytology (Pap test) plus human papillomavirus (HPV testing), among average-risk women aged 30-65 eligible to receive routine cervical cancer screening within an urban-based clinical practice setting? (Quantitative)

2. What is the screening interval between two negative cotests for women receiving routine cervical cancer screening? (Quantitative)
3. What are the patient, provider and practice determinants associated with guideline adherent screening interval and cotesting use? (Quantitative)
4. How do providers in different practice settings describe multilevel barriers to guideline adherence? (Qualitative)
5. What are the knowledge, attitudes, and preferences of providers toward the adoption of primary HPV test (without concurrent cytology) as another option for cervical cancer screening as recommended by the updated 2018 cervical cancer screening guidelines? (Qualitative)
6. How are determinants associated with cotesting uptake and guideline adherence explained by providers in practice conducting cervical cancer screening? (Mixed)

Translational Nature of Study

The cotest is an example of an evidence-based cervical cancer screening intervention that crosses through all parts of the biomedical research translational continuum beginning from basic science (T1 chasm) to clinical application (T2 chasm), but faces barriers to bridging the last translational chasm; to achieve adoption of cervical cancer screening guidelines in practice (T3 chasm) (Drolet & Lorenzi, 2011). Without appropriate use of screening guidelines by providers to benefit patients, translation in practice is not achieved and delays progress toward public health impact (T4). More importantly, it prohibits the ability to gain additional knowledge that feeds into a process of "reciprocal translation" (Drolet & Lorenzi, 2011), a feedback loop that will ultimately make its way back to T1 and pave the way for new discoveries that improve cervical cancer screening. By addressing both the T3 and T4 chasms in this study, we will

understand the patient, provider and practice level determinants that influence the uptake of cervical screening guidelines in clinical practice, and barriers to guideline adherence that impact provider behavior to use population-based screening guidelines. This study's findings may provide direction to design future intervention strategies to address this problem at the system level and bridge into the T4 chasm.

Statement of Potential Impact

This study has the potential to inform the continued research and surveillance of cancer prevention and control efforts at the population level. There are 3 *Healthy People 2020* objectives directly related to cervical screening and cancer of the cervix (Centers for Disease Control and Prevention, 2020):

- Objective C4: reduce the death rate from cancer of the uterine cervix
- Objective C10: reduce rates of invasive uterine cervical cancer
- Objective C15: increase the proportion of women who receive a cervical cancer screening based on the most recent guidelines.

This final objective is important, as the data has been limited to only reporting on the use of Pap testing, though the 2012 and 2018 guidelines include HPV testing in addition to Pap testing for women ages 30-65. Thus, adherence to guidelines by patients, providers, and the health system is an important consideration in measuring the uptake of cervical cancer screening. This study aims to fill in this knowledge gap and provide greater context and explanation around how much screening is getting done, and if it is conducted in accordance with national guidelines. Since this study is being conducted shortly after the release of the revised 2018 USPSTF guidelines for cervical cancer screening, it will also provide an early understanding of

provider perceptions toward the adoption of primary HPV testing and guide future research using implementation strategies to stimulate its acceptance and uptake.

Theoretical Foundation and Conceptual Framework

The Knowledge to Action Cycle (KTA) promulgated by Graham and colleagues (2006) provides a conceptualization for moving evidence informed by research into practice. The KTA cycle, with its two components, begins with creating knowledge (represented by the funnel) in the Knowledge Creation phase and then moves to putting it in use or application, illustrated in the Action Cycle . For cervical cancer screening, it can be argued that knowledge has been created, as the evidence for screening with a combination of cytology and HPV testing (i.e., cotesting) every 5-years led several professional organizations to issue screening guidelines that included cotesting as an option for screening women ages 30-65. However, it has not successfully been moved into practice (i.e., action or use) as evidenced by the lack of reliable data on its uptake and adherence to the extended screening interval by providers and patients. To complete the action cycle, barriers to knowledge use by providers will be assessed within the context of a complex system of healthcare using The Knowledge, Behaviors, and Attitude Framework of Cabana (Cabana et al., 1999). Acknowledging, however, that barriers may occur beyond the individual provider level, external barriers in the outer setting that affect lack of uptake and adherence to guideline recommendations will be evaluated using the Consolidated Framework for Implementation Research (CFIR) by Damschroder et. al. (2009).

Summary of the Methodology

This study used a mixed methods approach with quantitative and qualitative research methods to understand patient, provider and practice determinants associated with the uptake of cotesting as a method for cervical cancer screening, guideline adherent screening intervals, and

provider reported barriers to guideline adherent screening in academic and community clinical practice settings. A mixed methods approach to conducting this research was used because it allowed for a more complete understanding about the research problem (Creswell, 2015). Additionally, a pragmatic epistemology which used both quantitative and qualitative approaches to collect data provided added strength from each to answer the research questions. The use of real-world data obtained from clinical practice EHRs in this study lends to a pragmatic worldview drawing on employing "what works" utilizing diverse approaches and objective and subjective knowledge to address the research problem (Creswell & Plano Clark, 2011).

This study specifically employed an explanatory sequential design which began with a quantitative strand to collect and analyze EHR data, and then transitioned to a qualitative phase to conduct provider interviews to explain the quantitative results (Creswell, 2015). The qualitative inquiry was built from the quantitative results and the researcher determined based on the quantitative findings what questions to explore through semi-structured interviews with providers to better understand provider reported barriers to guideline adherent screening.

The quantitative phase of the study utilized EHR data from new or established patients seen for annual well woman examination between 2008-2020 at the George Washington University (GW) Medical Faculty Associates (MFA) Ob/Gyn and Primary Care academic and community Clinics located across Washington, DC, Virginia, and Maryland. This time period allowed for at least a 10-year evaluation. The selected patient cohort provided a retrospective evaluation of the uptake of cotesting between 2008-2020 among women aged 30-65, and whether screening intervals were followed in accordance with the 2012 guidelines (i.e., guideline adherence). A query using Current Procedural Terminology (CPT) Codes in the Allscripts® Electronic Health Record (EHR) system was used to retrieve a list of patient records for any

female that presented for a routine preventive care visit. The dataset provided to the researcher included the patient's age, race and ethnicity, smoking status, insurance, date(s) of screening visit, date(s) of cervical screening test, provider name, and practice name and location. After a random sample of 1,000 patients were selected from the 49,050 list of potentially eligible patients, additional data were extracted by the researcher from the EHR manually which included the last two screening tests (if available, otherwise only one screening test date and type was recorded), the type of screening test(s) conducted, test dates and test results. Any patient with abnormal cervical screening results was excluded. Descriptive statistics were used to describe the study population, median screening interval between two screening tests, percentage of the sample that was guideline adherent and percentage of sample that was over and underscreened. The patient, provider and practice level determinants were analyzed to perform multivariable logistic regression to determine whether any variables were associated with uptake of cotesting and guideline adherent screening. Data were analyzed using IBM SPSS Statistical Software version 28 IBM Corporation, Armonk, NY.

The qualitative phase of the study began after the quantitative phase was completed and the results analyzed. It built off the quantitative findings to explore provider perceptions of the quantitative results and reported barriers to conducting guideline adherent cervical cancer screening. Individual and paired semi-structured interviews with up to 10 to15 providers were planned, but due to the COVID-19 pandemic, recruitment of clinicians was very challenging, and the final number of participants was seven. Using the information obtained from the interviews, the researcher comprehensively addressed the knowledge gap in understanding why certain patient, provider and practice level determinants influenced how cervical screening guidelines

are used in practice, and the barriers to adherence as reported by academic and community Ob/Gyn and Primary Care providers who practice in diverse clinical settings.

Participants for qualitative interviewing were selected using a convenience sampling technique. The development of an interview guide for the individual and paired interviews was guided by Cabana's Knowledge, Behaviors, and Attitude Framework (Cabana et al., 1999) to assess knowledge, attitudes, external barriers to conducting guideline adherent screening. Cabana's framework and constructs from CFIR (Damschroder et al., 2009) that address the outer setting informed the analysis of the qualitative data. Interviews ranged from 30-60 minutes in length and were conducted in-person and via WebEx video conferencing.

Interviews were recorded, transcribed verbatim, and coded by the researcher and a second coder using a deductive approach (Patton, 2015) guided by Cabana and CFIR constructs to describe barriers that relate to knowledge, attitude, and external factors. Themes emerging from codes were used to define and interpret relationships between existing concepts emerging from textual data (Saldana, 2016).

Limitations & Delimitations

Several limitations to this study must be acknowledged. The EHR query inadvertently included data from new and established patient visits through July 2019. Since the study did not have a full year of data included in the query for 2019, it did not capture the complete population of women that presented for cervical cancer screening in 2019. This likely explains the large reduction in number of total screening tests seen in 2019 (Table 4) compared to previous years.

Another limitation was that analysis was not done by clinic type for the community practices and any clustering effect by clinic could not be adjusted for. This limits our ability to generalize the findings beyond the targeted practice setting and account for any practice wide

differences based on where they were located, particularly in the community. By conducting only provider interviews, this study missed an opportunity to gather information from other important stakeholders in the health system such as patients, insurance providers, and practice administrators. These interconnected system level influences may impact outcomes and should be studied in future research.

In 2018, when this study was initiated, the uptake of cervical cancer screening using only Pap testing was reported to be the highest in D.C. of any other state within the United States, with 84.8% of women ages 21-65 reporting a Pap test within the last 3-years (CDC, n.d.). It is possible that this may have also reflected a higher rate of cotesting adoption in D.C. and we selected a biased study population who had already adopted cotesting and would report high uptake in the dissertation study. The 2018 USPSTF guidelines that were issued at the time this dissertation study began provided a third, new option for cervical cancer screening for women aged 30-65 years old using primary HPV testing, but the uptake of the HPV test alone could not be measured in this study, as it was too soon after guidelines changed to assess its adoption by providers. However, the addition of primary HPV was timely for this study and allowed exploration of perceptions of providers to understand their current preferences and potential future adoption of primary HPV testing as it becomes more widely accepted.

Definition of Key Terms

Adherence. Relates to the content and dose of the intervention, *i.e*., has the content of the intervention – its 'active ingredients' – been received by the participants as often and for as long as it should have been" (Carroll et al., 2007).

Cervical Cancer. Cancer that forms in tissues of the cervix (the organ connecting the uterus and vagina). It is usually a slow-growing cancer that may not have symptoms but can be

found with regular Pap tests (a procedure in which cells are scraped from the cervix and looked at under a microscope). Cervical cancer is almost always caused by human papillomavirus (HPV) infection (National Cancer Institute (NCI), 2022).

Clinical Practice Guidelines. Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice, 1990).

Confirmation. In mixed methods, refers to the fit of the data when the findings from both types of data confirm the results of the other (Fetters et al., 2013).

Cotest. A procedure in which a human papillomavirus (HPV) test and a Pap test are done at the same time to check for cervical cancer. The HPV test looks for DNA or RNA from certain high-risk types of HPV in samples of cells taken from the cervix. The Pap test checks for cervical cancer cells and cell changes that may lead to cervical cancer. The same cell sample may be used for both the HPV test and the Pap test. Women aged 30 to 65 years may have HPV/Pap cotest every 5 years. Cotesting is more likely to find abnormal cells or cervical cancer than a Pap test alone is. Also called Pap/HPV cotest (National Cancer Institute, n.d.-b).

Determinants. The conditions for the successful implementation of innovations to healthcare organizations. These "determinants" are factors that facilitate or impede actual change (Fleuren et al., 2004).

Discordance. In mixed methods research, refers to the fit of the data when the qualitative and quantitative findings are inconsistent, incongruous, contradict, conflict, or disagree with each other (Fetters et al., 2013).

Expansion. In mixed methods research, refers to the fit of the data when the findings from the two sources of data diverge and expand insights of the phenomenon of interest by

addressing different aspects of a single phenomenon or by describing complementary aspects of a central phenomenon of interest (Fetters et al., 2013).

Fit. The "fit" of data integration refers to coherence of the quantitative and qualitative findings (Fetters et al., 2013).

Guidelines. Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Their successful implementation should improve quality of care by decreasing inappropriate variation and expediting the application of effective advances to everyday practice (Cabana et al., 1999).

Implementation. The process of putting to use or integrating new practices within a setting (Nilsen, 2015).

Human Papillomavirus (HPV). A type of virus that can cause abnormal tissue growth (for example, warts) and other changes to cells. Infection for a long time with certain types of human papillomavirus can cause cervical cancer. Human papillomavirus may also play a role in some other types of cancer, such as anal, vaginal, vulvar, penile, and oropharyngeal cancers. Also called HPV (National Cancer Institute, n.d.-a).

Primary HPV DNA Testing. A cervical cancer screening technology used to test for HPV strains associated with cervical cancer. HPV testing has been used for primary screening, cotesting with cytology, and follow-up testing of positive cytology results (reflex HPV).

Pap Test. A procedure in which a small brush or spatula is used to gently remove cells from the cervix, so they can be checked under a microscope for cervical cancer or cell changes that may lead to cervical cancer. A Pap test may also help find other conditions, such as infections or inflammation. It is sometimes done at the same time as a pelvic exam and may also

be done at the same time as a test for certain types of human papillomavirus (HPV). Also called Pap smear and Papanicolaou test (National Cancer Institute, n.d.-c).

Screening. Checking for disease when there are no symptoms. Since screening may find diseases at an early stage, there may be a better chance of curing the disease. Examples of cancer screening tests are the mammogram (for breast cancer), colonoscopy (for colon cancer), and the Pap test and HPV tests (for cervical cancer). Screening can also include doing a genetic test to check for a person's risk of developing an inherited disease (National Cancer Institute, n.d.-d).

Translation. The transformation of knowledge through successive fields of research from a basic science discovery to public health impact—a complex process that requires both research (e.g., bench-work and clinical trials) and non-research activities (e.g., implementation) (Drolet & Lorenzi, 2011).

Uptake. Defined as the action to try or employ an innovation or evidence-based practice. Adoption also may be referred to as "uptake." Adoption could be measured from the perspective of provider or organization. Can be used to measure the adoption of evidence-based guidelines (Proctor et al., 2011).

CHAPTER 2

Literature Review

Introduction

In the United States, cancer continues to be the second most common cause of death (Heron, 2018); however, much of this burden is preventable through evidence-based interventions (Colditz et al., 2012). Cervical cancer, also known as carcinoma of the cervix, is a highly preventable form of gynecological cancer. It tends to occur in midlife and most frequently diagnosed in women between the ages of 35 and 44 (American Cancer Society, 2022). Cervical cancer used to be one of the most common cancers affecting women, but now ranks 14th due to a rapid decline seen after the introduction of the Papanicolaou (Pap) test (Fowler et al., 2022). Worldwide, cervical cancer is the third most common cancer diagnosis among women and the second most frequent cause of cancer-related death, accounting for nearly 300,000 deaths annually (Binagwaho et al., 2019). The American Cancer Society (ACS) estimates for cervical cancer in the United States indicate that approximately 14,100 new cases of invasive cervical cancer will be diagnosed with 4,280 deaths attributed to the cancer (American Cancer Society, 2022). Regular screening and follow-up make cervical cancer a highly preventable sexually transmitted gynecological cancer, particularly if detected at an early stage (Nelson et al., 2009). Most cases of cervical cancer occur among women who have never been screened or who have not been adequately screened (Melnikow et al., 2018), which may include not being screened within the previous 5 years (Curry et al., 2018; Moyer, 2012; Saslow et al., 2012). It is believed

that “nearly all cervical cancer deaths could be prevented if women and their healthcare providers adhered to screening recommendations and follow-up treatment” (Nelson et al., 2009).

Background on Cervical Cancer

Cervical cancer begins in the cells lining the cervix, an area connecting the uterus to the vagina (ACS, 2022). This cancer develops gradually with normal cells of the cervix showing pre-cancerous changes that form into cancer. It is estimated that there may be a 10-to-20-year lag between pre-cancer and cancer to develop (World Health Organization (WHO), 2014). Cervical cancer is one of the very few cancers where a precursor stage (pre-cancer) lasts many years before becoming invasive cancer, providing ample opportunity to screen, detect, and treat pre-cancer to avoid progression to cancer (WHO, 2014).

Pre-cancerous changes are described as cervical intraepithelial neoplasia (CIN), squamous intraepithelial lesion (SIL), and dysplasia. The Pap test is used to detect these changes as a part of routine cervical cancer screening to catch pre-cancerous changes before they develop into cancer (American Cancer Society, 2020a). CINs are graded by the proportion of abnormal epithelium. CIN grade 1 indicates an active human papillomavirus (HPV) infection and these lesions are considered low grade with a high spontaneous regression rate; these lesions are generally not treated. CIN grade 2 is often considered a high-grade lesion but has a spontaneous regression rate of up to 40% and may indicate a benign HPV infection (Perkins et al., 2013). CIN grade 3 lesions have the highest likelihood of progression to invasion and are universally treated (Sawaya & Huchko, 2017). There are two main types of cervical cancers: squamous cell carcinoma and adenocarcinoma. Most (9 out of 10) cervical cancers are squamous cell (American Cancer Society, 2020b)

The Human Papillomavirus (HPV), the most common sexually transmitted infection (STI) (Centers for Disease Control and Prevention, 2022), is implicated as the causative agent in cervical cancer. HPV infections are common; the US Centers for Disease Control and Prevention (CDC) estimates that nearly all sexually active women are exposed to HPV over their lifetimes, but most infections (~90%) are transient, and undetectable within one or two years (Saslow et al., 2012). There are over 100 different types of HPV, and most of them are ***not*** associated with cervical cancer. Persistent or chronic infection with one or more of the high-risk (cancer-causing or oncogenic) types of HPV: HPV 16 and 18 accounts for at least 70% of all cervical cancer cases reported throughout the world (World Health Organization (WHO), 2022).

Pap Testing. Since the 1950s until the 2000s, the use of the Pap test (i.e., cytology), was "touted as one of the most effective cancer prevention measures to date" (Perkins et al., 2013). A Pap test looks for abnormal cells on the cervix that could turn into cancer over time. Since its introduction, the United States (U.S.) has seen a decline in cervical cancer incidence and mortality by more than 70% (Safaeian et al., 2007). Following guidelines to screening at 1 to 3-year intervals with cytology did lead to dramatic declines in cervical cancer rates, but the discovery that that HPV is a necessary precursor for nearly all cases of cervical cancer, and an increased understanding of the association between HPV and cervical cancer risks, led to the development of newer screening methods which have the potential to decrease cervical cancer rates even further (Felix et al., 2016).

HPV Testing. The HPV DNA test can identify an HPV infection by detecting the presence of HPV DNA or other molecular markers of HPV infection in cells taken from the cervix. An HPV test looks for the virus that can cause abnormal cells on the cervix. The Food and Drug Administration (FDA) approved the Roche Cobas® HPV Test in 2011 for use in

conjunction with or as a follow-up to a Pap test for routine cervical cancer screening (The ASCO Post, 2014). Prior to 2011, the HPV DNA test was approved for clinical use only for women ages 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology test results to determine the need for referral to colposcopy. More recently in 2014, the use of the test was expanded and approved for use in women 25 years and older, as a first-line primary cervical cancer screening test to detect high risk HPV, including genotyping for 16 and 18 (The ASCO Post, 2014).

Cotesting. When an HPV test and a Pap test are done at the same time to check for cervical cancer, this is referred to as cotesting. The two tests function differently, but when cotesting is performed, cells from the same specimen are used for detecting abnormal cells and the HPV infection. The use of a single specimen reduces any variability in testing evaluation and enhances cotesting consistency (Evantash, 2017). Using the HPV test, which has the highest sensitivity when combined with the Pap (i.e., cotesting) optimizes diagnosis of high-grade CINs (McGraw & Ferrante, 2014). Evidence from long-term prospective cohort studies and randomized clinical trials show that DNA testing for HPV is "substantially more sensitive than cervical cytology" for detecting CIN2 and CIN3 and cancer (Katki et al., 2011). Pap testing alone has a low degree of sensitivity with a single cycle of screening and while that sensitivity increases over several cycles, undetected disease may be progressing (Hoffmann-La Roche Ltd., 2022). It is estimated that **1 in 10 women** who are positive for HPV 16 and/or 18 have high-grade cervical disease that is missed by cytology (Wright et al., 2011). A negative HPV test in conjunction with negative cervical cytology (cotesting) provides greater assurance that a woman's risk of cancer is low, specifically, "cohort studies and trials suggest that women's risk of CIN3 or cancer after a negative test for HPV is very low for 5 years" (Katki et

al., 2011). Such studies helped support the regulatory approvals and clinical guideline changes incorporating routine testing for HPV in conjunction with cervical cytology (cotesting). The value of cotesting and compelling evidence demonstrating it as a superior strategy has been suggested by other recent studies (Blatt et al., 2015; Felix et al., 2016; Zhou et al., 2016).

Evidence-Based Cervical Cancer Screening Guidelines

Prevention of cervical cancer can be achieved through routine cervical cancer screening tests in accordance with recommended screening guidelines. In the U.S., annual screening using Pap testing remained the norm for many decades following its introduction, but in 2012, professional and medical societies revised their guidelines and reached consensus in their recommendations to incorporate HPV testing with the Pap test, referred to as cotesting. The emergence of unified recommendations that could be followed by all practitioners is one approach to following evidence-based practice (Darwish-Yassine et al., 2015) and achieving quality healthcare.

In 2012, the American Cancer Society (ACS), the American College of Obstetricians and Gynecologists (ACOG), the American Society of Colposcopy and Cervical Pathology (ASCCP), and the United States Preventive Services Task Force (USPSTF) issued updated cervical cancer screening guidelines for average-risk women (Figure 1). Average-risk women are defined as "women with no prior diagnosis of CIN2 or a more severe lesion or cervical cancer (CIN2+), women who are not immunocompromised (e.g., infected with human immunodeficiency virus [HIV], and women with no in utero exposure to diethylstilbestrol" (Sawaya & Huchko, 2017). The updated guidelines were based on a thorough review of the latest evidence, concluding that harms from unnecessary follow-up of regressive disease outweighs the benefits (Moyer, 2012; Saslow et al., 2012) and screening more frequently than every 3- years confers small additional

Figure 1

Summary of Cervical Cancer Screening Guidelines by Organization (2002-2012) (Verrilli et al, 2014)

	Organizations					
Screening guidelines	American Cancer Society (ACS) 2002 [7, 13]	US Preventative Services Task Force (USPSTF) 2003 [6]	American Congress of Obstetricians and Gynecologists (ACOG) 2003 [14]	American Congress of Obstetricians and Gynecologists (ACOG) 2009 [5, 15, 16]	US Preventative Services Task Force (USPSTF) 2012 [3]	ACS/ASCCP and ACOG 2012 [4, 17]
Screening start age	3 y after start of vaginal intercourse; no later than age 21	3 y after start of vaginal intercourse; no later than age 21	3 y after start of vaginal intercourse; no later than age 21	Age 21, regardless of onset of vaginal intercourse	Age 21, regardless of onset of vaginal intercourse	Age 21, regardless of onset of vaginal intercourse
Screening interval for women <30 y	Annually with conventional cytology or every 2 y with liquid cytology	Every 3 y	Annually	Every 2 y	Every 3 y	Every 3 y
Screening interval for women ≥30 y	Every 2–3 y (after 3 consecutive negative tests) or every 3 y with Pap and HPV DNA testing (pending approval in 2003)	Every 3 y; no use of HPV DNA testing	Every 2–3 y with Pap and HPV DNA testing	Every 3 y with Pap and HPV DNA testing (following 3 consecutive negative screens)	Every 3 y without HPV DNA testing (preferred); every 5 y with HPV DNA testing	Every 5 y with HPV DNA testing (preferred); every 3 y without HPV DNA testing
Age to stop screening	Age 70 y	Age 65 y	No specific end date	Age 65–70 y with 3 consecutive negative screens	Age 65	Age 65

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reductions in cancer risks, and incurs substantially more screening harms, including false positive testing and colposcopies (Sawaya & Huchko, 2017).

2012 Cervical Cancer Screening Guidelines. The recommendation to screen women annually using any strategy was no longer endorsed and no screening should begin before the age of 21 (regardless of sexual history) and should cease at age 65 if certain criteria are met. It recommended cytology (Pap) testing alone at 3-year screening intervals for women ages 21-29 years (HPV testing is not recommended due to the high prevalence of HPV infection in this age group), and for women ages 30-65 years, cytology alone at 3-year intervals or cotesting at 5-year intervals (U.S. Preventive Services Task Force (USPSTF), 2012). According to Haas et al. (2015), “these revisions signaled an important transition in screening guidelines from a one size

fit all approach (e.g., screen every woman every year) to a more individualized approach based on personal risk and prior screening results" (p.53).

The ACS, ACOG, and ASCCP specifically cited cotesting as the ***preferred method***, and Pap testing as ***acceptable*** (Verrilli et al., 2014). While the USPSTF did not cite cotesting as the "preferred" method in its recommendation, it stated that cotesting was an option for women who wish to extend their screening interval (U.S. Preventive Services Task Force (USPSTF), 2012). Longer screening intervals decreased unnecessary detection of transient HPV yet still maintained low cancer rates (Verrilli et al., 2014). The addition of HPV testing to cytology allows stratification of women with normal cytology and negative HPV tests into a particularly low-risk group allowing a safe extension of the screening interval (Sawaya & Huchko, 2017). Since the updated guidance, research demonstrates that providers have shown inconsistent application of the USPSTF guidelines (Haas et al., 2016)

Update of Previous USPSTF Guidelines. In 2018, the USPSTF issued a revision to its 2012 guidelines with the major change recommending screening every 5 years with primary HPV testing alone as an alternative to screening every 3 years with cytology among women aged 30-65 years (U.S. Preventive Services Task Force (USPSTF), 2018). Cotesting was also still an option for women ages 30-65 at 5-year intervals. Primary screening with HPV testing was not part of the 2012 recommendations issued by the USPSTF or any of the other professional organizations. However, in 2014, the FDA approved the Roche Cobas® HPV test for a primary screening indication (The ASCO Post, 2014) and in 2015 the ASCCP and the Society of Gynecologic Oncology (SGO) issued interim guidance recommending primary HPV screening starting at age 25 as an alternative to cytology alone or cotesting (Huh et al., 2015). With more screening options now available, the new guidelines are stated to "emphasize the importance of

patient-provider shared decision-making process to assist women in making an informed choice about which screening method is most suitable for them" (Perron, 2018).

Current Screening Practice. With multiple options available for women to get screened, it is not well-established which tests are currently used in practice and if providers and patients are being adherent to recommended screening guidelines and the extended screening intervals. Studies conducted after the release of the 2012 guidelines to evaluate cervical screening practice found discordance with screening guidelines, reflecting a wide array of screening intervals, infrequent use cotesting, and overuse of screening, contributing to non-evidence-based screening practices which may potentially increase risks to patients, add to patient distress, and contribute to rising costs of health care (Felix et al., 2016; Hallett & Gerber, 2018; Hawkins et al., 2013; Kim et al., 2015). Despite the length of time passed since the revised guidelines were issued, clinical practice has been slow to change (Hawkins et al., 2013).

Adherence to Cancer Screening Guidelines. As stated by Chubak and Hubbard (2016) adherence has several dimensions because cancer screening recommendations are usually multifaceted. Typically, recommendations include guidance on the age to start and stop the screening, the type of screening test and the ages, and the frequency (i.e., interval) between tests. A person may be adherent to some aspects of cancer screening recommendations but not to others. Measurement of adherence can help predict long-term effectiveness of screening interventions, explain differences in screening outcomes across settings, and identify areas for improvement or intervention (Chubak & Hubbard, 2016).

The evidence for the importance of incorporating HPV testing with Pap is sound, but whether this is being followed in routine practice following 5-year screening intervals is needed. Clinicians report that their practice is influenced by clinical practice guidelines, but studies

suggest limited adherence and divergent screening practices (Darwish-Yassine et al., 2015). Two studies (King et al., 2014; Teoh et al., 2015) conducted to evaluate adherence to the 2012 cervical screening guidelines found poor adherence, with providers specifically overscreening patients between 21-65 years of age (King et al., 2014). Much of these data rely on provider and patient self-report through cross-sectional survey and case study vignettes which reflect provider or patient intention rather than actual practice behavior.

One study (Perkins et al., 2013) surveyed U.S. Obstetricians-Gynecologists to examine attitudes, practice patterns, and barriers related to HPV vaccination and cervical cancer screening guidelines recommended by ACOG. The study was conducted prior to the issuance of the 2012 revised guidelines recommending an extended screening interval for women ages 30-65 years using cotesting. It provided an opportunity to address the question of guideline adherence among specialty providers from a nationally representative sample and evaluated the uptake of the ACOG 2009 guidelines recommending cotesting at 3-year intervals for women ages 30-65 which had not been done before. Due to the long time it takes for guidelines to be adopted in practice, the study of the 2009 guidelines was thought to be helpful in predicting the uptake and obstetrician-gynecologists' behavior related to the forthcoming 2012 guidelines. The study found that only half of providers adhered to the 3-year screening interval for cotesting, and most physicians continued to recommend annual Pap even though it was not recommended more often than every 2-3 years after 3 consecutive normal pap tests. Provider adherence to guidelines was associated with determinants such as gender, geographic region, and practice type and overall demonstrated limited use of current guidelines and potentially signaled very slow uptake and adherence to 2012 guidelines. Similarly, another study (Corbelli et al., 2014) was conducted at the University of Pittsburgh using a web-based survey of residents and attending physicians in

four primary care specialties to assess the extent to which providers follow the 2009 ACOG guidelines. Differences in adherence to guidelines were found by specialty provider group and significant overutilization of cervical cancer screening in women regardless of age. As found in other studies, providers did not adhere to current guidelines, and barriers to this behavior needed to be addressed (Corbelli et al., 2014).

Another study surveying national healthcare providers on their use of cervical cancer screening tests and how they align with current guidelines was conducted by the Michigan Public Health Institute and the Michigan Cancer Consortium's Cervical Cancer Committee in 2010, a time when cervical cancer screening guidelines were not standardized; organizations issued multiple conflicting recommendations, sometimes even contradicting one another (Darwish-Yassine et al., 2015). These differing guidelines and inconsistent delivery in practice lead to variability in the methods applied for screening patients. However, even when recommendations among the various organizations aligned, there was an apparent lack of consensus among providers regarding adherence to established guidelines for Pap testing. A lack of unified guidelines pre-2012 led providers to disregard published guidelines and clearly contributed to the lack of consensus among providers in performing screening tests. Patients were tested differently based on the providers' screening practices and demonstrated cervical cancer screening disparities between and among the 4 provider groups participating in the survey. ACOG guidelines were reported as the most common guidelines used by providers, but only under half (48.8%; 145 of 297 providers surveyed) of the general medicine/family practice providers reported consistently following ACOG guidelines, compared with 80.7% (447 of 591 providers surveyed) of the OB/Gyns. At the time this study was conducted, ASCCP guidelines recommended that HPV testing should only be conducted on women younger than 30 years as a

triage for Pap results that indicate ASCUS; and cotesting should only be performed for women 30 years or older. However, practice was discordant with these recommendations. 14.7% (65 of 443) of the Ob/Gyns and 33.7% (87 of 258) of the midwives ordered HPV as a screening test (Pap/ cotesting) in most or all (76%–100%) of their women younger than 30 years.

The use of evidence-based guidelines for cervical cancer screening was also tested in a single facility in the Veterans Administration (VA) in a study conducted by Hallet & Gerber (2018). In 2014, using a retrospective chart review of women ages 21-65, the researchers evaluated HPV tests ordered with Pap testing to determine concordance of HPV ordering with screening (USPSTF) guidelines. The study demonstrated 68% of eligible HPV tests evaluated to be ***guideline discordant*** with potential overuse of HPV testing with no documented reason for why HPV testing was performed.

Guideline adherence was also assessed among practicing gynecologists in the Pacific Northwest in a study conducted by Verrilli, Winer and Mao (2014). The study was specifically conducted to understand screening practice and uptake of the 2012 guidelines and identify reasons that the guidelines may not be followed. As done in prior studies, the study used an online survey based on self-reported screening practice which may overestimate adherence rates and not reflect true practice behavior. Although 52% of providers reporting adhering to or planned to adhere to new guidelines, only 38% reported screening patients younger than 30 every 3-years as currently recommended. Most physicians reported the use of HPV testing in conjunction with a Pap test (cotesting) for women aged 30 years and older, but also stated they would repeat the exam every 3-years on women with negative results which is consistent with 2009 ACOG, not 2012. 32% of physicians moved to a 5-year screening interval after a negative

Pap/cotest result, consistent with 2012 guidelines. Differences in adherence were also found by provider practice type (academic *versus* private practice).

Uptake of Cotesting. Tracking of screening practice patterns and evaluating the uptake of cotesting at 5-year intervals since the issuance of the 2012 guidelines in the United States has not been well documented in the literature. Most studies reporting use of cervical cancer screening tests rely on provider and patient self-report from survey data or response to case vignettes and not actual testing practice data from clinical practice settings, limiting the utility of these data provide an accurate assessment of the use of evidence-based practice in the real world.

Uptake Using Population-based Data. Population-level data for cervical cancer screening test use in accordance with recommended guidelines are collected through national surveys conducted by the CDC. These nationally representative data are collected through the National Health Interview Survey (NHIS), a cross-sectional household survey conducted in person in English or Spanish and representative of the civilian, non-institutionalized U.S. population. The data collected on cervical cancer screening test use is limited, as it only asks about cytology testing (Pap) use among women ages 21-65 without a hysterectomy within the last 3-years. Receiving a Pap test in accordance with a 3-year interval is considered to be up to date with current screening guidelines (USPSTF). However, USPSTF screening guidelines provide an option for cotesting in women ages 30-65, which is not a question routinely asked in the survey. In 2015 (Watson et al., 2017), the NHIS assessed the use of cotesting and added a question for the first time to determine if an HPV test was given with the most recent Pap. While 81.1% of women aged 21-65 reported receiving a Pap test within 3-years, in accordance with recommendations, only 1/3 (21-35%) of these women reported having a cotest at their most recent screening. Although cotesting is only recommended for women 30 years and older, 38.2%

of 21-29 also reported receiving a cotest, which is discordant with USPSTF guidelines. Since the HPV question was only added in 2015, the survey cannot be used to examine trends in the use of cotests for recommended screening (Watson et al., 2017).

A study published in 2015 (Cuzick et al., 2015) provided population-based data for utilization of routine cotesting screening procedure between 2007-2012 using the New Mexico HPV Pap Registry. At the time of its publication, no other population-based data were available to examine utilization of HPV testing in the United States. This study reports cotesting utilization increasing from 5.2% in 2007 to 19.1% in 2012. The largest increase occurred between 2011 and 2012 (55.1%).

A limited number of studies conducted in health systems of various types and sizes have evaluated the uptake of cotesting and screening intervals in accordance with 2012 guidelines using clinical practice data from health care claims data, electronic medical health records or other primary laboratory or administrative based data sources. One example is a retrospective cohort study conducted between September 2013 and January 2014 at the University of California Davis Medical Center, to assess guideline adherence rates of cotesting for cervical cancer screening among family medicine and Ob/Gyn physicians. Of women eligible to receive cotesting, 62.4% of family medicine and 71.9% of OB/Gyn practitioners performed cotesting. It was noted that over time, the proportion of patients cotested increased (Einck & Cansino, 2016).

Health Claims Data. Health claims data is another source of information that can provide rates of use of cervical cancer screening tests among populations with access to private insurance. A study (Watson et al., 2018) examined cervical cancer screening during 2005-2013 among private commercially insured women ages 18-65 to understand recent trends in screening, including cotesting. Overall, screening rates were declining over time, and data showed a lower

prevalence of cervical cancer screening than self-reported data on test use suggested (Gamble et al., 2017; Watson et al., 2018). Cotesting uptake was highest throughout the entire period for women aged 30–39, ranging from 7.5% in 2005 to 44.4% in 2014. Trends in cotesting prevalence for women aged 40–49 and 50–65 years were similar to those in women aged 30–39, although prevalence of cotesting was lower in the two older age group (Watson et al., 2018).

Laboratory and Administrative Data. The Johns Hopkins University (JHU) academic medical center is a large health system that has been tracking cervical testing patterns over time and long before the use of cotesting at 5-year intervals became a universal recommendation endorsed by multiple professional organizations. Two studies (Phelan et al., 2011; Tatsas et al., 2012) assessed screening practices based on cytology and HPV specimens submitted to the cytopathology laboratory for analysis. The studies showed slow uptake of cotesting, a lack of adherence to screening intervals (3-years), and rates of cotesting varying by clinic. More recently, a study by Silver et al. (2018) analyzed the use of cotesting and screening intervals between 2006-2013 using specimen data from the Hopkins cytopathology laboratory, allowing for limited data on cotesting post 2012 guidelines to be evaluated. The study found a steady increase in cotesting beginning in 2009 (33.3%) to 2013 (78.3%), but the study did not evaluate beyond 2013 to determine if the increase in uptake was maintained several years after the issuance of the new guidelines. In addition to evaluating the adoption of cotesting and recommended screening intervals in clinical practice settings within JHU, the study described the yearly uptake of cotesting by patient characteristics such as age, race, and insurance status and found differences that require further exploration to understand how these factors influence the uptake of the guidelines.

While there have been a small number of studies attempting to describe the uptake of cotesting based on the 2012 guidelines, the literature suggests that most of these studies are limited and do not provide robust data. Further, without continued surveillance of cervical cancer screening practice obtained in real-world settings, we cannot gain an understanding of the current uptake of cotesting and whether extended intervals are followed despite the issuance of comprehensive guidelines endorsing its use by multiple organizations.

Frameworks for Barriers to Guideline Adherence

The gap between evidence-based guidelines for cervical cancer screening and actual use in practice can be explained by an understanding of barriers that exist within a complex system in which multiple stakeholders involved in cancer screening reside. Achieving an understanding of the barriers impeding translation of evidence-based practice and contributing to the gap can lead to interventions that effect change toward optimal practice and better care.

Several frameworks can guide in the identification and assessment of barriers that may exist at various levels of the health system. The Knowledge, Behaviors, and Attitude Framework (Cabana et al., 1999) focuses on the individual physician level and was developed based on a comprehensive systematic review. It emphasizes that there may be a variety of barriers to guideline adherence that need to be considered. Using this framework in this study will allow for in-depth exploration of factoring limiting provider adherence to guidelines. However, recognizing that barriers can occur beyond the individual provider-level, select constructs using the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) which include five major domains; the intervention, inner setting, outer setting, the individuals involved, and the process by which implementation occurs will be included. CFIR emphasizes the context in which the implementation occurs and will be key in the analysis of barriers that

reside outside the provider level, such as the individual patients, the organization or setting where screenings occur, and the health system which includes external policies, mandates, and regulations that may impede or advance uptake and adherence.

Individual-Level. Barriers to guidelines adherence can occur at the patient or provider level. Among average-risk women ages 30-65 eligible to receive a cervical screening test, barriers to screening can impede receiving cotesting, extending screening intervals, or both. Some studies (Roland et al., 2011) suggest patient lack of knowledge about cervical cancer screening, HPV and its relation to cervical cancer as a barrier to guideline adherence. Some patients desire more frequent care and demand shorter screening intervals (Lee et al., 2011). They also have a higher perceived risk of cervical cancer and skepticism about costs associated with screening. A variety of demographic, psychological and social factors can also contribute to patients' adherence to guidelines (MacLaughlin et al., 2011). Some practical barriers such as financial, access to healthcare, work schedules that create difficult scheduling time off work can impede attendance at screening appointments even among those who hold positive attitudes toward screening (MacLaughlin et al., 2011). Among providers, barriers can include lack of guideline knowledge, awareness, and lack of agreement with guidelines (attitude) (Cabana et al., 1999). A study in Norway cited that characteristics of the provider, such as male gender may be a barrier for some women in certain sociocultural subgroups who prefer a female practitioner conducting the screening test (Leinonen et al., 2017).

Organizational-Level. The organizations in which providers work and patients seek care can also serve as a barrier. Time limitations during appointments, patients moving in and out of the healthcare system making it difficult to ascertain where and when the last screening was done

and obtaining results, and problems within the electronic/information technology system making customized reminders in electronic health records a challenge to use (MacLaughlin et al., 2011).

Minorities and Underserved Women. Cervical screening rates among minority women tend to be lower and there is higher incidence and mortality compared to white women. African-American women in particular report inadequate knowledge as a main barrier to cervical cancer screening. Emotional barriers and fear of the exam and feelings of unconscious bias and racism are also commonly cited barriers that prevent women from adhering to guidelines (Nardi et al., 2016). The patient-provider relationship is especially important and can serve as a barrier for uninsured immigrant woman if they feel distrust and have not had exposure to screening prior to coming to the U.S.

Conceptual Frameworks

Knowledge to Action Cycle. The issuance of evidence informed guidelines is referred to as "third-generation" knowledge in the KTA process, as during this last phase of knowledge creation, knowledge tools or products such as guidelines, decision aids and rules, and care pathways (Graham et al., 2006) are generated. These tools and products are intended to influence what stakeholders do and to meet stakeholders' knowledge or informational needs, facilitating the uptake of knowledge. Given the lack of existing information on the current uptake of 2012 cervical screening guidelines, further inquiry is likely needed to create more knowledge, before moving into action. As noted by Graham et al. (2006), "local and external knowledge creation or research can be integral to each action phase" (p.21). Thus, using this framework to determine the magnitude of the problem (the actual uptake of guidelines in practice and guideline adherence as measured by screening interval) in the local context (within the urban clinical

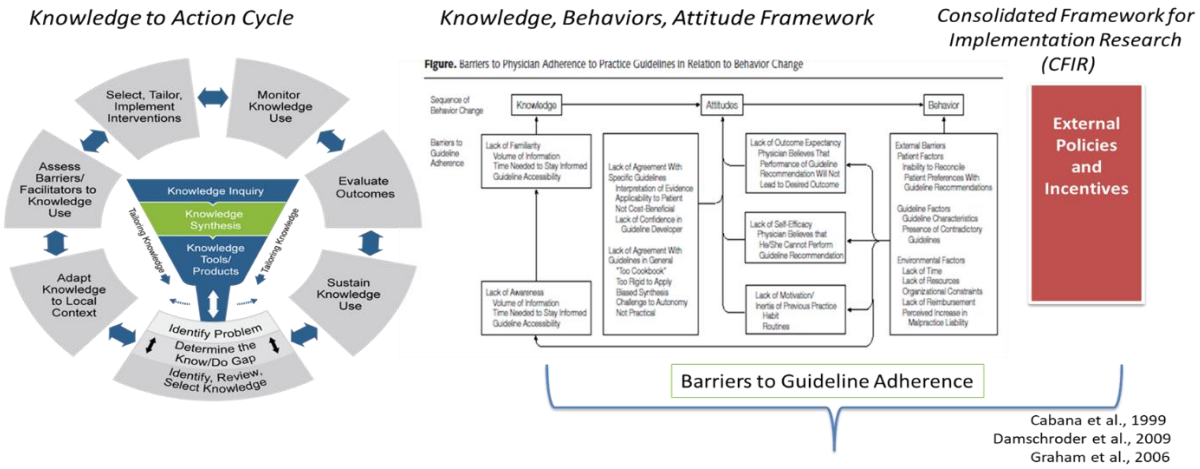
practice settings) would need to be determined and any barriers to its use prior to assessing knowledge use in practice and moving along the action phase of the cycle.

Physician Barriers to Guideline Adherence. Another guiding frameworks from the literature will identify key constructs that may serve as barriers to the use of guidelines by providers and inform the development of the interview guide and the analysis in the qualitative phase of the study. The Knowledge, Behaviors, and Attitude Framework is a model that describes, an ideal, general mechanism of action for physician barriers to guideline adherence (Cabana et al., 1999). Cabana's framework will be the guiding framework used to categorize barriers and facilitators to guideline adherence and uptake of cotesting as reported by providers during the semi-structured interviews.

CFIR. The CFIR includes five major domains (the intervention, inner and outer setting, the individuals involved, and the process by which implementation is accomplished) which will provide important constructs that will be used to guide the analysis of qualitative data around barriers that present beyond the individual provider-level (Damschroder et al., 2009). Figure 2 is a conceptual framework for this study that illustrates the use of these combined frameworks.

Figure 2

Study Conceptual Framework



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CHAPTER 3

Research Methodology

Overview

The goal of this dissertation research study was to evaluate determinants that influence cotesting uptake and guideline adherence, and explore the provider reported barriers to conducting cervical cancer screening in accordance with the guidelines. In addition, this study explored the adoption of primary HPV testing as recommended in the 2018 update of the guidelines. This was addressed through the following research questions:

- Beginning in 2012, what is the reported uptake of cotesting, cytology (Pap test) plus human papillomavirus (HPV) testing, among average-risk women ages 30-65 eligible to receive routine cervical cancer screening within an urban-based clinical practice setting? (Quantitative)
- What is the screening interval between two negative cotests for women receiving routine cervical cancer screening? (Quantitative)
- What are the patient, provider and practice determinants associated with a guideline adherent screening interval and cotesting use? (Quantitative)
- How do providers in different practice settings describe multilevel barriers to guideline adherence? (Qualitative)
- What are the knowledge, attitudes, and preferences of providers toward the adoption of primary HPV test (without concurrent cytology) as another option for cervical

cancer screening as recommended by the updated 2018 cervical cancer screening guidelines? (Qualitative)

- How are determinants associated with cotesting uptake and guideline adherence explained by providers in practice conducting cervical cancer screening? (Mixed)

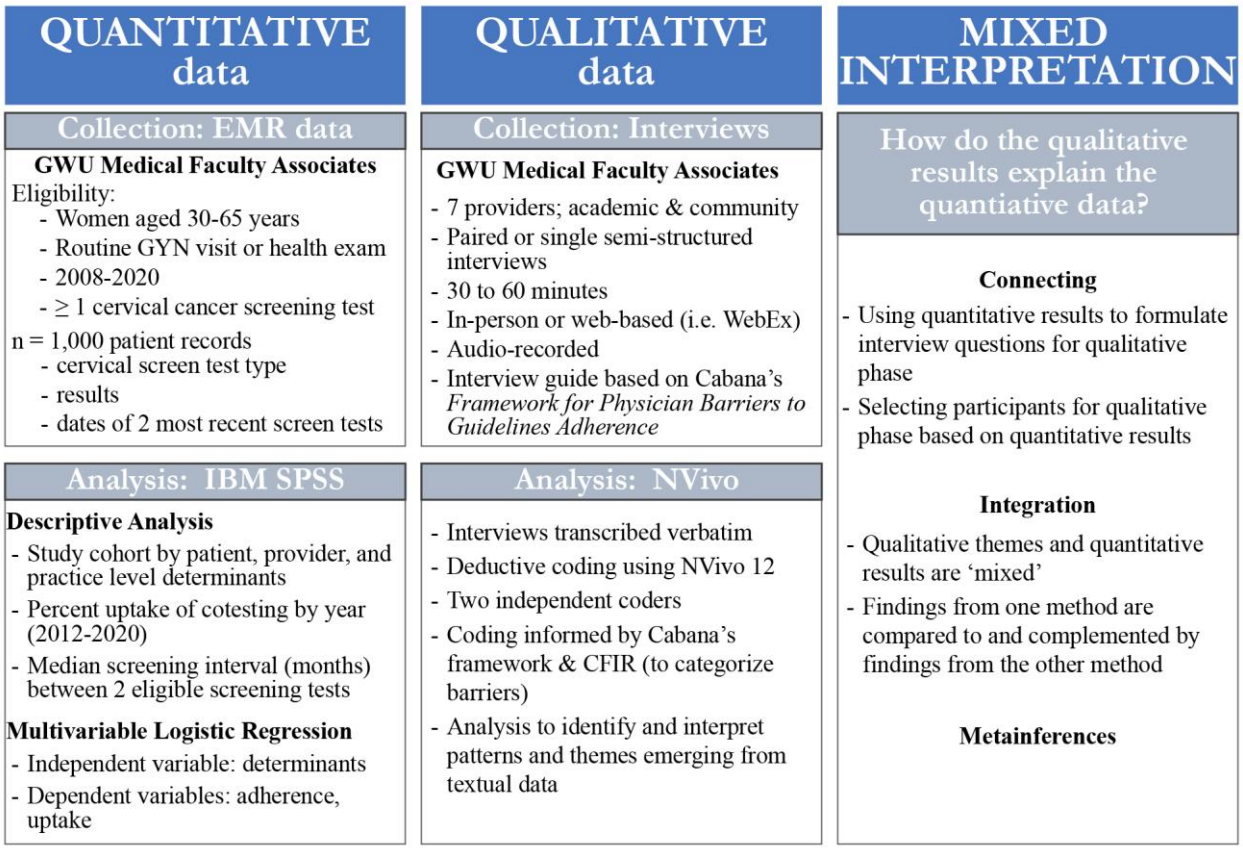
The study was designed utilizing a pragmatic research paradigm as it relied on both objective (quantitative EHR data) and subjective knowledge (qualitative interviews) obtained from real-world clinical practice settings to understand how cervical screening guidelines were implemented in practice. A pragmatic ontology acknowledges that reality is influenced by a variety of factors in real-world settings (Creswell & Plano Clark, 2011). This approach allowed for a more comprehensive understanding of the various patient, provider and practice level determinants that influenced the use of cotesting and guideline adherent screening and then further explored how providers viewed these findings and the barriers to actual use of guidelines in practice. This chapter provides detailed description of the methods and procedures that were used to conduct this study.

Study Design

This mixed methods research study employed an explanatory sequential design beginning with a quantitative phase (QUAN) to quantify the reported uptake of cotesting since the issuance of the 2012 guidelines, the level of guideline adherent screening, and finally the relationship of patient, provider and practice determinants that influence guideline adherent screening and use of cotesting. The second phase of the research was a qualitative study (QUAL) informed by the

Figure 3

Explanatory Sequential Mixed Methods Design



quantitative findings and through provider interviews provided a more nuanced and deeper understanding of why providers use or don't use guidelines as prescribed and the barriers that inhibit adherence to the extended screening interval.

In the first phase of the study, the QUAN strand was carried out as a retrospective cohort study to analyze patient level cervical cancer screening data obtained from the Allscripts® EHR system used by the GW MFA health system. The second phase was qualitative in nature and used single and paired interviews with providers to explore barriers to guideline adherence implementation and the adoption of primary HPV testing. Finally, the

independent results from the QUAN and QUAL analyses were integrated to answer the mixed research question. See Figure 3 for study design.

Research Setting and Study Population

The population for this study included average-risk women who were seen by primary care or Ob/Gyn providers for routine preventive care within the GW Medical Faculty Associates (MFA) outpatient, non-profit physician-led practice group. Average-risk women are defined as those women without high-risk medical conditions or abnormal screening histories, and without evidence of hysterectomy with removal of the cervix for benign indications.

The GW MFA practice offers 52 medical and surgical specialties and providers are members of The School of Medicine and Health Sciences faculty. It employs over 2,150 employees. The GW MFA is located within Washington, DC which has one of the lowest uninsured rates of any state, 3.7% (KFF, 2021), and was reflected by the high rates of insured patients included in this study. The MFA has a network of community-based practices in DC, Maryland and Virginia, including GW Immediate and Primary Care clinics. Patients whose data were analyzed for this study were seen at the GW MFA site in Washington, DC by a Primary Care or Ob/Gyn specialist provider (referred to as academic practice site), or at one of the affiliated community sites in DC, Virginia or Maryland (referred to as community site). There were a total of 23 community practice sites from across DMV included in this study. Providers interviewed for the qualitative study were recruited from GW academic and community sites, but due to difficulties with recruiting GW MFA affiliated providers, two Ob/Gyn providers were recruited from outside of GW and practiced at community sites within the DC, Maryland and Virginia (DMV).

Quantitative Strand

The objective of the quantitative research strand was to evaluate cervical cancer screening data using EHR data to quantify the uptake of cotesting that had occurred within the GW MFA health system since the issuance of the 2012 guidelines and to assess guideline adherence and determinants associated with each of these outcomes. Using a retrospective chart review, a sample of women with cervical cancer screening data available in the Allscripts® EHR system were selected to analyze uptake, adherence and determinants associated with these outcomes.

Research Questions and Hypothesis

The quantitative strand addresses the following three questions:

1. Beginning in 2012, what is the reported uptake of cotesting, cytology (Pap test) plus human papillomavirus (HPV) testing, among women ages 30-65 eligible to receive routine cervical cancer screening within an urban-based clinical practice setting?
2. What is the screening interval between two negative cotests for women receiving routine cervical cancer screening?
3. What are the patient, provider and practice determinants associated with guideline adherent screening interval and cotesting use?

The overarching hypothesis was that uptake of cotesting would show a gradual increase after 2012 guideline issuance as this was a finding in other studies assessing uptake of cotesting (Silver et al., 2018). Patient level factors related to age, race and ethnicity and insurance were expected to influence uptake of cotesting, and a shorter than 5-year screening interval, indicating overscreening, may be observed among the study population.

Data Source

The Allscripts® EHR system used by the MFA was the primary data source from which all quantitative data were collected, reviewed, and analyzed. The student researcher worked alone to extract, review and analyze the data with oversight by a clinician (JK) working in the Department of Obstetrics and Gynecology at the MFA, who is also a member of the dissertation committee.

The study began with a request to the MFA Information Technology (IT) staff by the researcher for data on all women between the ages of 30-65 who had presented for a routine preventive care visit with at least one cervical screening test in the EHR between 2012-2018. The following CPT codes were used to conduct the query:

```
99395 (established patient well visit age 18-39)
99396 (established patient well visit age 40-64)
99385 (new patient well visit 18-39)
99386 (new patient well visit 40-64)
```

The query retrieved all established and new female patients between the ages 18–65-years that presented to an MFA clinic between 2012 -2018 for at least one clinic visit which included a cervical cancer screening result. Since it was not possible to run a query in Allscripts® to retrieve patients who were only between the ages of 30-65 years, the researcher was given patient data not meeting the study age criteria and these data were excluded during the data cleaning process and evaluation of study eligibility prior to randomization for obtaining the final study sample.

For each patient record, the patient's medical record number (MRN), name, date of birth (DOB), race, ethnicity, insurance name, smoking status, last appointment date, second to last appointment date, last cervical screening test date and time, second to last cervical screening test date and time (if done), performing provider name, and department which represented the practice location/department were retrieved as part of the dataset. The type of cervical cancer

screening test that the patient received, and the result of that test could not be provided by the query in Allscripts®. These data were manually extracted by the researcher from the EHR once the sample was randomized to select only patient records that were eligible for study analysis. All data were provided to the researcher in an excel spreadsheet that was password protected and only the researcher and clinician overseeing the project had access to. The patient's name was immediately deleted from the data file upon receipt. The MRN was a second patient identifier and was immediately removed from the excel file to deidentify the data and replaced with a unique study patient identification number (ID) created by the researcher. A file linking the MRN with the study patient ID were kept in a password protected file from separate from the research data file accessible to the researcher. This file linking the MRN to the patient ID was deleted after completion of the study analysis.

Data Cleaning and Coding

The raw data file with the queried patient records had to be cleaned and coded to prepare for analysis. This part of the research process took 18 months to complete (July 2019-December 2020). Access to the MFA building where the EHR data were kept was limited due to the COVID-19 pandemic and contributed to the long delay in completing this part of the process. The data file was large and included 103,296 rows of patient data. There were multiple rows of data for the same patient because if the patient had two appointments, each appointment would appear on a separate row. This led to duplicated data that had to be deleted. There were also patients that had one or more fields of missing data such as DOB, race and ethnicity, insurance name, or provider or department where they were seen. In order to work with a dataset with as much complete data as possible and reduce non-response bias in the results, a decision by the researcher and dissertation committee was made to remove records with more than one field of

missing data. Others with only a single missing data field, were kept in the dataset, and indicated as missing in the analysis. After a single patient record row was created for each patient and records with multiple missing data fields were removed, the excel data file was ready for further review with 81,792 unique patient records.

Coding of select variables was done on 81,792 patient records. The following fields were included in the dataset:

- Patient Unique Study ID
- DOB
- Patient Insurance
- Patient Race and Ethnicity
- Patient Smoking Status
- Provider Gender*
- Provider Specialty*
- Provider Degree*
- Department/Practice*
- Last screening test date (referred to as “last”)
- Second to last screening test date (referred to as “prior”) (if available)
- Patient Age at last screening test visit*
- Patient Age at prior to last screening test visit*

Some of these data were provided to the researcher as part of the queried dataset, others (see those with an asterisk) were manually entered by the researcher as part of the data coding and categorization process. Data coding in the context of this dissertation research study referred to taking each individual insurance type, each provider name and each department where the screening was conducted and putting it into a category by which the analysis would be conducted. This step was necessary so that analysis on the determinants specified for the logistic regression could be run in SPSS.

Coding Insurance Names. The data pulled from Allscripts® for the insurance field consisted of at least 385 unique insurance names that had to be coded into 1 of 4 categories: Public, Private, Self-Pay, or Other. There were many patient records that had a value entered for the insurance name that could not be classified as public, private or self-pay and was categorized as other. Often, a single insurance name was spelled in multiple different ways in the EHR and the researcher had to go through all variations of an insurance name to decipher the insurance name captured so it could be appropriately coded. The researcher worked with a clinician in the Ob/Gyn department who is also a dissertation committee member (JK) to verify coding and categorization and for input on any insurance names that were not easily categorized.

Coding Providers. The name of the provider who conducted the screening test was a data field for each patient record. When the data file was organized to have each patient's data on a single row, a decision was made to only capture the provider's name who conducted the last screening test. This meant that a patient with two screening tests performed by different providers would only capture a single provider. The researcher took a random sample of a few patient records to determine how this approach affected the data. In almost all cases that were reviewed, even when a patient saw two different providers for screening, the gender, specialty and degree of both providers were almost always the same. This gave assurance that it would be unlikely to have any effect on the data analysis for the provider level determinants.

To code each provider by gender, specialty and degree, the student researcher conducted a google search to retrieve information about the provider. There were at least 578 unique providers that had to be identified. Since all providers were from within the GW MFA system, some practicing providers at the MFA could be found by accessing their profile on www.gwdocs.com. However, in cases where a provider was no longer practicing at the MFA or

had been a resident or fellow at the time the test was conducted was harder to trace. Finding a picture or other information online about the provider was important in helping classify the gender of the provider. For provider specialty, each provider was coded as Ob/Gyn, Primary Care, or other. For provider gender, each provider was coded as male or female and provider degree was coded as MD/DO, PA, NP, or other. The researcher and MFA clinician on the dissertation committee worked closely to categorize all providers in the dataset and reach agreement on the coding of each provider's data.

Coding Department/Practice. Finally, each patient record had a field named Department which identified the location of where the patient was seen for the cervical cancer screening test. There were a total of 23 unique community clinic locations. Each location name was recoded and categorized into 1 of 2 categories: Academic Practice or Community Practice. The student researcher received verification of coding of the practice sites from the clinician dissertation committee member who was familiar with the EHR data and the community practice locations where GW MFA providers saw patients.

Study Eligibility Criteria. Once data for the 81,792 patients were coded, the study eligibility criteria for randomization was assessed to only include patient records meeting the following study inclusion criteria:

- Female between the ages of 30-65 at the cervical screening test visits(s)
- Routine gynecological visit or routine health maintenance exam visit at any George Washington (GW) Medical Faculty Associates (MFA) practice site
- At least one cervical screening test conducted between 2012-2019

Upon applying these criteria, 32,742 patient records had to be removed due to being ineligible for randomization based on the following exclusion criteria:

- Under age 30 or over age 65 at the last screening visit
- Missing cervical cancer screening test date
- Patient seen at a non-GW academic or GW community practice site

Of these, 29,032 patient records were missing cervical cancer screening test dates therefore it was unclear if they had been seen for screening or not. 1,324 patient records indicated the patient was seen at a clinic that was not a GW academic or GW community site. There were 2,033 patients that were under 30 at their last screening visit and 2,033 that were over the age of 65 at their last screening visit.

Sampling Method and Sample Size

The resulting dataset of the eligible 49,050 records was imported into SPSS and these data represented the study population from which the random sample was drawn.

Sample Size. There is little formal guidance on calculating sample size for studies conducting retrospective chart reviews (Johnston et al., 2019), and no agreed upon method in the literature on sample size calculation when using logistic regression for analysis in multivariable models (Bujang, 2021; Bujang et al., 2018; Hsieh et al., 1998; Peduzzi et al., 1996). The approach used for this study was guided by Bujang et al (2018) which is specifically recommended for non-experimental studies with large population sizes that involve logistic regression in the analysis. Bujanag et al (2018) recommended a minimum sample size of 500 was necessary to derive statistics that can represent the parameters in the targeted population. For this study, approximately 2% (or 1,000 patients) were chosen as a reasonable sample. This doubled the minimum sample size of 500 and also took into consideration the feasibility (i.e., time and effort)

of manually extracting EHR data for this number of patient records and achieving a sufficientlylarge sample to meaningfully address the research question (Johnston et al., 2019).

Sampling Method. A stratified sampling technique was used so that the researcher could maintain the distribution observed in the population and minimize overrepresentation in any category. In SPSS, the 49,050 records were divided into strata based on patient age, race and ethnicity, insurance, provider specialty, gender, degree and practice type.

Data Collection

EHR Data Extraction and Review. Once the random sample of 1,000 records were identified, the first 500 out of 1,000 records for manual data extraction were selected. Data for the second 500 patients were extracted after data extraction for the first 500 records were completed and reviewed by the dissertation committee. Data extraction was conducted in this stepwise fashion because the dissertation committee met to review and discuss the descriptive data analysis for the first 500 patient records so that they could weigh in on the distribution of patient and provider determinants and also the testing group distributions (e.g., one cotest versus two cotest, etc.) and the number of patients that were excluded. The committee's check of these data prior to completing the full data extraction was utilized to ensure the methods for data extraction were properly followed and to confirm that the sample of 1,000 patient records for the study would be sufficient.

For each patient drawn from the random sample, the student researcher searched the Allscripts® EHR system by medical record number (MRN). Once the EHR was found, the student searched the patient's record for at least one cervical screening test date and laboratory confirmed result. The type of test (pap or pap plus HPV test), date test was conducted, and result of the test were recorded on a data collection spreadsheet kept by the researcher. For patients

who had more than one cervical screening test in the EHR, the student researcher recorded the last two cervical screening test types, dates and results in the spreadsheet for the screening interval analysis. Each patient's medical history and provider clinical visit notes were reviewed carefully to assess study eligibility for the analysis after data for that patient had been extracted. Only asymptomatic women, and not those undergoing evaluations for symptomatic gynecological disease were included. Women with any pathological findings, or those who underwent any diagnostic or treatment related procedures for cervical dysplasia were excluded. Patient records meeting the following criteria were excluded from the analysis:

- Laboratory confirmed positive HPV test result
- Laboratory confirmed atypical squamous cells of undetermined significance (ASCUS) with or without HPV negative result
- Any test sample that is unsatisfactory for evaluation
- Clinician documented history of past abnormal cervical screening test results (i.e., irregular pap, HPV infection/HPV positive/ASCUS) even if all cervical screening tests conducted at MFA are normal
- Clinician documented history of cervical dysplasia (i.e., CIN1, CIN2, CIN3, LGSIL, HGSIL)
- Clinician documented history of colposcopy, cervical biopsy, or Loop Electrosurgical Excision Procedure (LEEP)
- Total hysterectomy (i.e., no cervix)

The student researcher had a clinician (EW) from the MFA Ob/Gyn Department verify accuracy of the data that had been recorded for 5% of the sample.

The data extraction spreadsheet contained two separate tabs; a tab for the eligible records required for the analysis and a second tab for the ineligible records. For the eligible records, the following key IVs and DVs were included in the study analysis:

- Patient insurance
- Patient race and ethnicity
- Patient age at last screening test
- Patient smoking status
- Provider gender
- Provider specialty
- Provider degree
- Department/practice
- Testing type
- Prior test (Yes/No/NA)
- Prior test date
- Last test (Yes/No/NA)
- Last test date
- Testing interval in months (if applicable)
- Guideline Adherent? (Yes/No/NA) (if applicable)
- Cotesting Uptake? (Yes/No)

For the ineligible records, the following key variables were included in the study descriptive analysis:

- Patient Insurance
- Patient Race and Ethnicity

- Patient age at last screening test
- Patient Smoking Status
- Provider Gender
- Provider Specialty
- Provider Degree
- Department/Practice

Preparation for Data Analysis. Once cervical screening test data extraction for 1,000 patients were completed, the student researcher prepared a final analytic file in Excel that would be imported into SPSS for the planned analyses. Each patient record in the file was coded as either 1 (evaluable) or 2 (excluded). The testing status for the evaluable records were coded as 1 (one cotest only), 2 (two cotests), 3 (one cotest and pap), 4 (two paps), and 5 (one pap only). The test year (s)for these records were also recorded as prior test and/or last test. For evaluable records with 2 test dates, a screening interval between the prior and last test was calculated in months using an excel formula. Finally, each record with a screening interval was coded as 0 (No) or 1 (Yes) to describe if the test was conducted within the specified guideline adherence screening interval for the study.

Data Analysis

Descriptive Analysis. Data were analyzed IBM SPSS Statistical Software Version 28. The first stage of the analysis included running descriptive statistics to summarize key characteristics that describe the study sample whose data are being used for this dissertation project. All independent variables (IVs) were categorical with the exception of age which was recoded from a continuous variable to a categorical variable. Frequency counts for patient age group, insurance, race and ethnicity, smoking status, provider specialty, degree, gender and

practice type were summarized to show the distributions for the included, excluded and total sample as displayed in Table 1. Chi-square tests were performed on all independent variables to determine whether the evaluable and excluded samples were statistically different.

Cotesting Uptake. Research question #1 was designed to evaluate the reported uptake of cotesting in the study sample that occurred between 2012-2020. First, frequencies in SPSS were tabulated by year to get the total number of all cervical screening tests conducted for the study sample of 709 patients between 2012-2020 (denominator). Then, for each year, the total number of cotests extracted from the EHR were tabulated (numerator). These data were entered into a table in Microsoft Excel and a calculation was done by dividing the number of cotests for each year by the total number of cervical screening tests to get the proportion of cotests by year. The overall uptake of cotesting was calculated by adding up the total number of cotests conducted between 2012-2020 and dividing it by the total number of all cervical screening tests. These data are shown in Table 4 in Chapter 4.

Screening Interval between Tests and Guideline Adherence. Research question #2 focused specifically on evaluating the length of the screening interval between two negative cotests for patients in the study. The calculation of the screening interval was conducted only for patient records with 2 screening tests and thus those with only a single cotest or a single pap were excluded from this analysis. A formula in excel was setup to calculate the number of months between variable "prior test" date and "last test" date. Using the screening interval calculated, an evaluation of guideline adherence was made by the researcher guided by the study specific operationalization of the 2012 recommended screening interval for pap and cotesting.

Operationalizing Screening Interval and Screening Level. The 2012 cervical screening guidelines specify a 3-year (or 36-month) screening interval for cervical cytology (i.e.,

paps) and 5-year (or 60-month) screening interval for cervical cytology plus HPV testing (i.e., cotesting). The researcher and dissertation committee acknowledged that a more flexible approach to applying the screening interval would be suitable for this study given meeting a stringent 36-month or 60-month length of time between screening tests would be difficult and not reflective of what happens in actual clinical practice. In this study, the researcher and dissertation committee agreed to operationalize a screening interval which considered adequately screened if a screening test conducted within a plus or minus 6-month interval of the guideline (e.g., for pap, between 2.5–3.5-year intervals, or cotest between 4.5–5.5-year intervals). Any records with a screening test conducted outside of these screening intervals would be coded as underscreened or overscreened variable in SPSS. The operationalization of guideline adherence is summarized in Figure 4.

Figure 4

Operationalization of Screening Interval for Cytology and Cotesting

Screening Test	2012 Guideline Recommendations for Screening Interval	Screening Interval Applied to this Study	Not Guideline Adherent and Screening Level
Cytology (Pap)	Every 3-years (36-months)	Every 2.5 to 3.5 years (30-42 months) Guideline Adherent	if less than 30 months (under screened) or greater than 42 months (over screened)
Cotesting (Cytology+HPV)	Every 5-years (60-months)	Every 4.5 to 5.5 years (54-66 months) Guideline Adherent	if less than 54 months (under screened) or greater 66 months (over screened)

Multivariable Logistic Regression. Research question #3 was designed to determine the patient, provider and practice determinants associated with the guideline adherent screening interval and cotesting use and this was best addressed by conducting a multivariable logistic regression. Guideline adherence and cotesting were the two DVs evaluated in this study. There

were 7 IVs included in the model; patient age, patient insurance, patient race and ethnicity, provider specialty, provider degree, provider gender and practice type. In SPSS, we ran a backward Wald logistic regression to conduct two separate analyses for each of the DVs. Using this analytic technique all 7 IVs and 1 DV were included in the regression model. P-values of 0.05 were set as the threshold for variable elimination from a model. The first model for guideline adherence was run and six models were produced. The same method was followed for cotesting, and five models were produced. The final models for each dependent variable showing the significant variables were selected.

Sensitivity Analysis for Overscreening and Underscreening (non-guideline adherent). To take a closer look at the non-guideline adherent group, a sensitivity analysis was conducted to determine the predictors for the odds of overscreening compared to underscreening. In SPSS, we ran a backward Wald logistic regression to find the IVs associated with overscreening and underscreening. P-values of 0.05 were set as the threshold for variable elimination from a model. Seven models were produced; the final model showing the significant variable(s) associated with overscreening was selected.

Qualitative Strand

The second phase of this dissertation study was designed to follow-up on the quantitative results from the first phase to understand the provider perspective around cervical screening guideline use and adherence in practice. The purpose of this phase of the research was to be able to learn through the voice of the providers using individual and paired semi-structured interviews, the factors they believe to be driving their screening behavior and what barriers they describe to implementing current cervical screening guidelines. This qualitative inquiry was guided by Cabana's Knowledge, Behaviors, and Attitude Framework (Cabana et al., 1999) to

assess knowledge, attitudes and external barriers to conducting guideline adherent screening and what they perceived to be the barriers to implementing guidelines.

Research Questions

Specifically, this qualitative study addressed the following two research questions:

4. How do providers in different practice settings describe multilevel barriers to guideline adherence?
5. What are the knowledge, attitudes, and preferences of providers toward the adoption of primary HPV test (without concurrent cytology) as another option for cervical cancer screening as recommended by the updated 2018 cervical cancer screening guidelines?

Sample Size

The challenges to conducting research with providers during a global pandemic impacted the final number of participants recruited for the study. As described by Patton (2015), sample size for data collection in qualitative research is dependent upon the richness of the data, the depth and breadth of information sought, and the available time and resources. The original sample size for this qualitative study aimed to recruit 10 to 20 providers or until data saturation would be reached. However, given the challenges faced in recruiting providers, the study completed with seven providers because it adequately addressed the goals of this study.

Qualitative Research Procedures

In qualitative research, the research process is emergent, as the initial prescribed plans for research may shift or change after the researcher enters the field (Creswell, 2013). In this dissertation study, there were changes made to the study procedures, sampling and recruitment plan and sample size due to the challenges of conducting research during the COVID-19 pandemic.

Following the completion of the quantitative data collection and analysis, the researcher prepared a brief 10-minute presentation summarizing the main results from the quantitative study (Appendix A). Individual and paired interviews with any Ob/Gyn and Primary Care provider willing to spare 30 to 60 minutes in person or over web-based video conferencing were scheduled. Prior to the scheduled interview, a study information sheet (Appendix B) was sent to the interviewee via email to review. At the start of each interview, the student researcher reviewed the purpose of the research, its voluntary nature, procedures, and risks in detail. Signatures were not required, as written consent was waived for this exempt study. The interviews began with a brief 10-minute presentation by the student researcher and then transitioned to a discussion with the interviewees guided by a flexible interview protocol and supplemented by follow-up questions, probes and comments. Interviews lasted between 30 and 60 minutes.

Participant Recruitment and Sampling

The study used a convenience sampling method because it allowed selection of participants based on accessibility, ease and speed. Though this is typically not a preferred approach because "most readily available sources of data are not likely to be the most informative sources" (Staller, 2021), the study was able to recruit a diverse range of participants which included both genders, different specialties, and practice affiliation.

An MFA clinician (JK) who is also a member of the dissertation committee served as a gatekeeper to assist with study recruitment. Interested individuals were asked to contact the student directly if they were interested in participating. The student researcher also attended a virtual meeting of the DC Chapter of The American College of Obstetricians and Gynecologists (ACOG) to share the study details and provided her contact information for any providers interested in participating. Participation in the study was incentivized and lunch was provided for

the paired interview that was held in-person and $50 Amazon gift cards were provided to those who participated virtually. Through the study gatekeeper, seven providers contacted the student, and all participated in the study. Five out of seven participants were current MFA employees, and two providers were from outside the MFA health system.

Study Setting

The study conducted all interviews using a virtual web-based videoconferencing option except for the first interview, which was a paired interview held in-person at the MFA building in Washington, DC with Ob/Gyn providers.

Data Collection Instruments

A semi-structured interview guide was developed and questions were guided by Cabana's Framework (Cabana et al., 1999) (Appendix C). A mini recording device was used to record the in-person interviews in addition to using otter.ai (https://otter.ai/), an automated meeting note capture software. The interview was transcribed in the Otter system, and the researcher made edits by listening to the recording to clarify what had been captured. The file was deleted after the transcript was finalized. Those interviews conducted over WebEx were recorded using the online platform and a transcription of the interview was produced in WebEx. The same process was followed to listen to the recording and make edits to fix any errors. The audio file was deleted after transcription was completed. Transcriptions were saved in a password-protected folder that only the researcher had access to. The files were deleted after they were uploaded to NVivo and saved to Box.

Data Source and Collection

All interviews were conducted by the student researcher for consistency and to minimize interview to interview variation with the exception of the first paired interview that was held in

person. For the in-person interview, a fellow student (SG) in a different THS PhD cohort volunteered her time to assist the student researcher with logistics and notetaking during the interview. She was also given the opportunity to ask probing questions and asked a couple of questions toward the end of the interview. The in-person interview at the MFA was conducted in a private conference room in the building that had been reserved for this purpose. A sign-in sheet was used to record attendance. This interview was audio recorded using a mini-portable tape recorder and Otter.ai as the back-up source. The two interviews conducted over WebEx included audio with video that was recorded. A link to access the WebEx meeting was provided in advance to the interviewees. One single interview was conducted over the telephone and recorded using a tape recorder and otter.ai. Participants were given an opportunity to review the study information sheet in advance of the scheduled interview and the researcher allowed time for questions prior to starting the interview. Everyone was reminded that the interview was being recorded and the recording would not be made available to anyone. No follow-up interviews with any participants were required.

Data Analysis

Once transcription of the interviews was reviewed and edited, they were uploaded into NVivo V.12 (Pro) to begin the manual coding process by the student researcher. No participant identifiers were recorded on the transcript. Transcripts were labeled as interview 1, interview 2, interview 3, and interview 4. A THS PhD student (LC) served as the peer reviewer and assisted with coding and did independent coding of all four interview transcripts in a Word document. Coding by two coders was conducted to ensure there was intercoder agreement. Coding was an iterative process whereby the student researcher and peer reviewer went through an initial coding cycle with the first interview transcript to reach agreement on how to apply codes using the

conceptual frameworks. A second cycle of coding was conducted to identify any codes that emerged that may not have been identified as a barrier or facilitator to guideline adherence but important to capture to address provider experience with cervical screening guidelines. The codebook was created in NVivo V.12 (Pro), and final codes were reviewed by the Dissertation Chair. Some reorganization of codes was done after the discussion.

Coding was conducted using a deductive approach guided by Cabana's Knowledge, Behaviors, and Attitude Framework (Cabana et al., 1999) and The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). As described by Cabana, "factors limiting adherence through a cognitive component were considered barriers affecting knowledge, through an affective component were considered barriers affecting attitude, and through a restriction of physician ability (i.e., external) were considered barriers affecting behavior" (Cabana et al., 1999, p.1459). External barriers described by Cabana could be patient related factors, guideline related factors or environmental factors. Specifically, in this study there were additional external barriers to physician guideline adherence related to health system or financial factors that were truly outside the provider's influence and did not fit with the Cabana framework. The outer setting domain described by CFIR which included External Policies and Incentives as a construct addressed these health system barriers (Damschroder et al., 2009). Barriers identified were grouped by three Categories derived from the two frameworks that were used for analysis. Once categories and codes were organized, the student researcher applied thematic analysis to define themes that illustrated the main ideas within each category. Themes were discussed with peer reviewer (LC), and the dissertation committee. Finally, integration of results from the interviews and EHR screening data were done to answer the overarching mixed methods research question (Creswell, 2013).

Trustworthiness and Rigor

A peer from the PhD cohort (LC) assisted the student researcher in reviewing interview transcripts, coding, reviewing, and updating the code book, identifying patterns and categories, and themes. The Dissertation Chair provided input on the initial and final codes. Finally, members of the dissertation committee were called upon to review interview summaries, qualitative themes, and provide feedback. Using more than one person to look at the data and analysis and compare similarities and differences provided a form of *investigator* triangulation (Patton, 2015) and helped minimize researcher bias and provide clarification of interpretation.

A strength of this study is using a mixed methods approach which allows for an additional form of data triangulation to ensure credibility by combining quantitative and qualitative findings. Triangulation of EHR data with interview transcripts helped enhance the integrity of the findings between two different data sources. Any inconsistencies or conflicting findings were evaluated during the qualitative interviews to provide a more detailed understanding of these divergent results.

Mixed Methods Analytic Approaches

Once data collection and analyses for the QUAN and QUAL strands were completed, the mixed methods research question could be addressed as to how the QUAL results helped explain the QUAN results. The mixed methods research question addressed in this study was (6) How are determinants associated with guideline adherence and use of cotesting explained by providers in practice conducting cervical cancer screening?

Zheng and Creswell (2013) state, “health services researcher can achieve “mixing” through combining, connecting, and embedding data, or through a combination of any of these approaches.” In this study, data from QUAN and QUAL studies were connected to answer the

mixed research question (Zhang & Creswell, 2013). Guided by Creswell and Plano Clark (2011), connecting is an analytic procedure that can be used when data are collected in a sequential explanatory study. There are two ways in which this technique was applied in the methods phase for data collection. First, the questions in the interview guide for the semi-structured interviews were formulated based on the QUAN results. According to Zhang and Creswell (2013), the key point of "mixing" using this approach is to interpret how one method builds on other methods. Connecting was also demonstrated through the sampling frame (Fetters et al., 2013) when some providers for interviews (i.e., those that worked in the GW MFA academic or community practice sites) were selected from the population of participants whose data were analyzed in the quantitative phase. The sample of providers were also selected based on the determinants found to be significantly associated with guideline adherent screening and cotesting as well as those determinants that were not associated with the outcomes. Using this approach, the participants were asked to explain their thoughts on why these patterns were seen.

Integration is the final step commonly used in mixed methods analysis when data from two strands are collected separately and are integrated together to build the final analysis and gain new insights (Guetterman et al., 2015). In this study, data from the QUAL and QUAN strands were explained as a narrative and in a joint display in which a QUAL theme was used to explain the QUAN results. A joint display analysis was used as a visual means to draw new insights beyond what was gained from the separate QUAN and QUAL results (Guetterman et al., 2015) and helped optimize the understanding of the mixed findings. The joint display analysis was an iterative process which began with identifying themes, patterns and anomalies in the results based on the findings of both data sets. Then, numerical data from the quantitative analysis and textual data from the qualitative analysis was selected to integrate. These data were

then compared and contrasted to illustrate expansion, confirmation or discordance between the QUAL and QUAN data (Fetters et al., 2013).

Ethical Considerations

This study required Institutional Review Board (IRB) review from the GWU Office of Human Research and was deemed to be research that is exempt from IRB review under DHHS regulatory category .104(d)(4)(iii). The quantitative phase of the research was conducted only using records from GW MFA did not require researchers to have direct interaction or contact with human participants but did require access to pre-existing, identifiable data which contained personally identifiable information (PII). Though no identifiable information were extracted from the EHR, there was a way to link the Study ID number to the patient medical record number, so data can be cross checked and verified.

Other human participant concerns related to accessing patient data from the MFA. The researcher was required to complete HIPAA training through MFA compliance, the HIPAA workforce member agreement, and MFA User Confidential Agreement in order to gain access to the medical record system of the MFA. CITI training was also required and completed by the researcher.

Privacy and confidentiality risks exist with the use of de-identified data that could potentially be linked back to participants' medical records and identify the name, age, gender of those whose EHR data were analyzed. Only the researcher extracting data had access to medical record numbers and the study ID link. This information was stored in a password-protected folder accessible only to the researcher. The names or any other identifying information were not provided to anyone outside of the research team nor will be mentioned in any publications related to this research. It is expected that publications will name the locations (city/state) where

the patients, providers, and practice sites were located and describe the setting, but without naming the actual practice sites.

For the qualitative piece of the research study, IRB reviewed and approved the research as exempt category 2. A waiver of written informed consent was sought, and the study provided an information sheet to participants prior to the start of the study. The study information sheet included details regarding audio recording and storage of data for future use. No identifiable information was included in the interview transcripts. Each interviewee was assigned a study ID and only basic demographic information such as age, gender, specialty, degree, practice type and years in practice were collected about the participant.

There are possible risks to participating in a qualitative study that must be acknowledged.

Psychological Risks.

It is not expected that any of the interview questions asked by the researcher caused psychological distress, but providers may not feel comfortable being open and transparent with the researcher about their opinions and habits for screening women for cervical cancer using clinical guidelines. If any questions cause discomfort, the participants did not have to answer them.

Social Risks.

There is a potential social risk to providers if they share information about their organizational practice or culture and barriers to guideline adherent screening that could be perceived as negative by their peers or others at higher level in the organization if become aware of their participation in the study. Though there is a very low chance of this occurring, participants were made aware that their participation could potentially be viewed as negatively reflecting on them or their own organization.

CHAPTER 4

Results

Introduction

This chapter provides the separate results of the quantitative and qualitative strands of this explanatory sequential research study and the final integrated results of both approaches to address the mixed methods design.

Quantitative Results

In the quantitative strand of the study, descriptive statistics and multivariable logistic regression analyses were used to analytically address the following three research questions:

- Research Question #1: Beginning in 2012, what is the reported uptake of cotesting, (cytology (Pap test) plus human papillomavirus (HPV)) testing among average-risk women aged 30-65 eligible to receive routine cervical cancer screening within an urban-based clinical practice setting?
- Research Question #2: What is the screening interval between two negative cotests for women receiving routine cervical cancer screening?
- Research Question #3: What are the patient, provider and practice determinants associated with guideline adherent screening interval and use of cotesting?

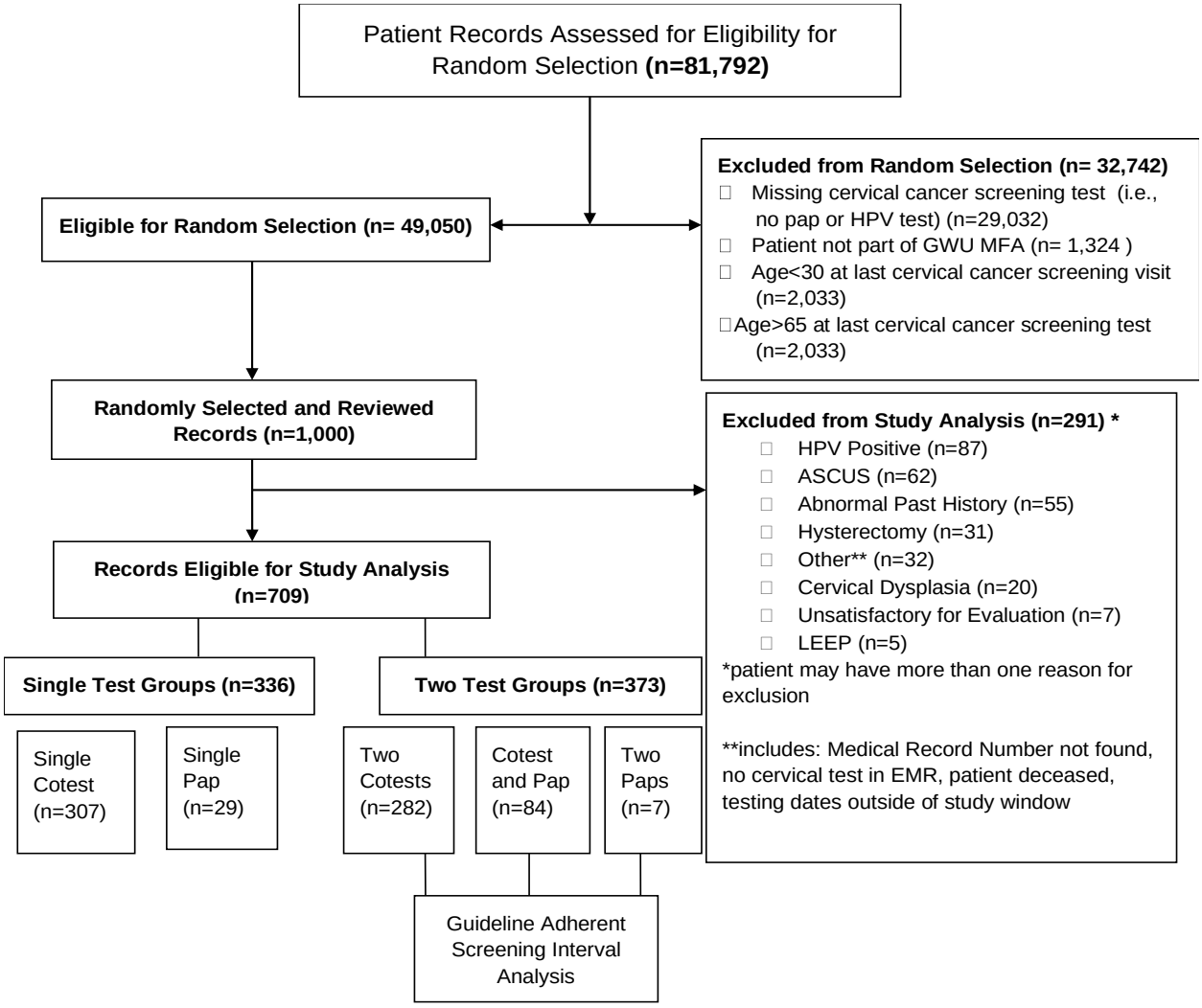
The George Washington (GW) Medical Faculty Associates (MFA) Allscripts® electronic health record (EHR) system was the data source for the quantitative study. The dataset included 81,792 women between the ages of 18-65 who presented for an established patient or new patient well women visit to a GW MFA Ob/Gyn or Primary Care provider between January 2012 to July

2019. Of these women, 49,050 were deemed eligible for study inclusion. One thousand (or approximately 2%) patient records were randomly selected from 49,050 eligible records and analyzed using descriptive analysis on determinants related to the patient: patient age, race and ethnicity, smoking status, and insurance type. Provider level determinants which included provider gender, provider specialty, provider degree, and practice type were also analyzed.

All 1,000 patient records were reviewed in the Allscripts® EHR system to extract every cervical screening test (pap and cotest) the patient had conducted in the MFA system. These data were used to analyze the uptake of cotesting. Only the most recent two cervical screening tests, if available were used to conduct the screening interval analysis. If only one test date for a patient was available in the EHR, this test information was still extracted. The patient's most recent cervical cancer screening test (referred to as the "last" test) and the test conducted prior to the most recent (referred to as the "prior" test) was reviewed. The test date(s), type of test(s), and results of the test(s) were recorded. Patient medical history and provider clinical notes were reviewed to look for any existing or past abnormalities that would make the patient ineligible for the study. Of the 1,000 patient records reviewed, 291 patient records (29%) were excluded, and 709 (71%) were deemed eligible for inclusion in the study for the multivariable logistic regression analysis. Figure 5 summarizes the study sample allocation and reasons for patient record exclusions.

Figure 5

Study Sample Allocation



Demographics

Patient and Provider Characteristics. Descriptive analysis of patient demographics are presented (Table 1) for the full study sample (n=1,000), the evaluable sample (n=709) and the excluded sample (n=291). The evaluable patient sample was predominantly white non-Hispanic females (52.9%) in the 30-39 age group (37.1%), non-smoking (82.9%) with private insurance (88.4%).

The majority of providers in the evaluable sample were MD/DO (89.1%), female (75.6%) and Ob/Gyn/Midwifery specialty (67.7%). More patients were seen at community practice sites (59.5%) than academic practice sites (40.5%).

Chi-square tests were performed on all independent variables to determine whether the evaluable and excluded samples were statistically different. Race and ethnicity between the samples was statistically different, $X^2 = 31.7$; $p<0.001$. A lower percentage of Black non-Hispanic participants were included (28.6%) relative to the percentage excluded (43.6%) Practice type was also different between both groups and was statistically significant, $X^2 = 6.82$; $p<0.01$. A lower percentage of patients seen by academic practice sites were included (40.5%) relative to the percentage excluded (49.5%).

Table 1

Patient and Provider Characteristics

	Included (n=709)		Excluded (n=291)		Total (n=1,000)	
Characteristics	n	%	n	%	n	%
Patient Age Groups						
30-39	263	37.1	125	43.0	388	38.8
40-49	203	28.6	82	28.2	285	28.5
50-59	178	25.1	61	21.0	239	23.9
60-65	65	9.2	23	7.9	88	8.8
Patient Race and Ethnicity^{+}						
White and Non-Hispanic	375	52.9	124	42.6	499	49.9
Black and Non-Hispanic	203	28.6	127	43.6	330	33.0
Hispanic	78	11.0	21	7.2	99	9.9
Asian and Non-Hispanic	50	7.1	18	6.2	68	6.8
Other*	3	0.4	1	0.3	4	0.4
Patient Insurance						
Public	79	11.1	38	13.1	117	11.7
Private	627	88.4	251	86.3	878	87.8
Missing	3	0.4	2	0.7	5	0.5
Patient Smoking Status						
Non-Smoker	600	84.6	229	78.7	829	82.9
Smoker	109	15.4	62	21.3	171	17.1
Provider Gender						
Female	536	75.6	213	73.2	749	74.9
Male	173	24.4	78	26.8	251	25.1
Provider Specialty						
Ob/Gyn & Midwifery	506	71.4	197	67.7	703	70.3
Primary Care	198	27.9	88	30.2	286	28.6
Other**	5	0.7	6	2.1	11	1.1
Provider Degree						
MD/DO	632	89.1	255	87.6	887	88.7
Other***	77	10.9	36	12.4	113	11.3
Practice Type $^{++}$						
Academic	287	40.5	144	49.5	431	43.3
Community	422	59.5	147	50.5	569	56.9

* Other includes American Indian or Alaska Native Non-Hispanic and Hawaiian Pacific Islander Non-Hispanic;
Other includes Medical Genetics, Palliative Care and Women's Health; * Other includes PA NP, and CNP Certified Nurse Midwife; $^{+}X^2$=21.70, $p<0.001$ $^{++}X^2$=6.82, $p<0.01$

Patient Testing Group. Women screened for cervical cancer in accordance with 2012 guidelines must be between the ages of 30-65 and receive either a pap (i.e., cervical cytology) every three years or a cotest (i.e., cytology plus HPV test) every 5 years. In this study of 709 eligible patients, 307 patients (43.3%) received a single cotest, 282 (39.3%) received two cotests, 84 (11.8%) received a pap at one visit and a cotest at the other visit, 29 (4.1%) received a single pap, and 7 (1.0%) received two paps.

Patient Characteristics by Cotested versus Not Cotested. Differences in patient characteristics such as patient age, race and ethnicity, insurance type, and smoking status by those that received at least one cotest compared to patients who did not receive any cotest were analyzed. Table 2 provides a summary of patient age, race and ethnicity, insurance and smoking status by testing group. The percentage of cotesting across patient age groups was similar, with the 40-49 and 60-65 age groups having the highest percentage of patients receiving at least one cotest, 96.6% and 96.9%, respectively when compared to the other two age groups. When age groups were compared to evaluate which group did not receive any cotesting, the 30-39 age group had the highest percentage (6.8%), while the 60-65 had the lowest percentage (3.1%) of not receiving any cotest compared to other age groups. Asian Non-Hispanics had the highest percentage of cotesting (98.0%) compared to all other racial and ethnic groups in the study. Hispanics had the highest percentage of patients not receiving any cotesting (12.8%) followed by Black and Non-Hispanic patients receiving no cotest (6.8%).

Age. Patients fell into one of four age groups: 30-39, 40-49, 50-59 and 60-65. Testing status was examined by age group to understand the types of cervical cancer screening tests patients in each group received. The 30–39-year-old group received the highest percentage of single cotests (53.2%), and single pap (6.1%) compared to all other age groups which meant

these women only had a single test in the EHR and never returned to GW MFA for a second cervical cancer screening test. The 50–59-year-old group had the highest percentage of two cotests conducted (48.3%) followed by the 60–65-year-old group (47.7%). This oldest age group also had the highest percentage of receiving a two-test combination of pap with cotesting (18.5%) compared to all other age groups. As patient age increased, there was a pattern seen of increasing percentage of patients receiving two cotests and decreasing percentage of single cotests conducted. Overall, the lowest uptake of cotesting was found in the 30-39 age group (93.2%) and highest uptake in the 60-65 age group (96.9%).

Race and Ethnicity. When testing groups were compared by race and ethnicity, Black non-Hispanic patients received the highest percentage (43.3%) of two cotests compared to all other racial groups. Asian non-Hispanic (54.0%) and Other which included American Indian or Alaska Native non-Hispanic and Hawaiian Pacific Islander non-Hispanic (66.7%) received the highest percentages of single cotesting compared to the other race and ethnicity groups. Hispanics received the lowest percentage of two cotests (28.2%) but the highest percentages of combination testing with pap and cotesting (17.9%) and single pap (12.8%) compared to all other groups.

Insurance. A similar percentage of public and private insured patients received single cotests, 43.0 and 45.0, respectively. However, those with private insurance received a higher percentage of two cotests (40.5%) compared to those with public insurance (32.9%).

Smoking Status. Patients identified as non-smoker or smoker had similar distributions in the single cotest group, 43.7% and 41.3 %, respectively. A slightly higher percentage of smokers (45.9%) compared to non-smokers (38.7%) received two cotests and two paps (2.8 % and 0.7%, respectively).

Table 2

Eligible Patient Characteristics by Testing Group (n=709)

Characteristics	Single Cotest n (%) 307 (43.3)		Two Cotest n (%) 282 (39.3)		One Cotest and Pap n (%) 84 (11.8)		Two Paps n (%) 7 (1.0)		Single Pap n (%) 29 (4.1)		Cotested		Not Cotested	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Cotesting Groups						*No Cotesting Groups*							
Patient Age Groups														
30-39	140	53.2	75	28.5	30	11.4	2	0.8	16	6.1	245	93.2	18	6.8
40-49	81	39.9	90	44.3	25	12.3	2	1.0	5	2.5	196	96.6	7	3.4
50-59	66	37.1	86	48.3	17	9.6	3	1.7	6	3.4	169	94.9	9	5.1
60-65	20	30.8	31	47.7	12	18.5	0	0	2	3.1	63	96.9	2	3.1
Patient Race and Ethnicity														
Hispanic	32	41.0	22	28.2	14	17.9	0	0	10	12.8	68	87.2	10	12.8
Black, Non-Hispanic	82	40.4	88	43.3	20	9.9	2	1.0	11	5.4	190	93.6	13	6.4
White, Non-Hispanic	164	43.7	156	41.6	43	11.5	5	1.3	7	1.9	363	96.8	12	3.2
Asian, Non-Hispanic	27	54.0	15	30.0	7	14.0	0	0.0	1	2.0	49	98.0	1	2.0
Other*	2	66.7	1	33.3	0	0	0	0	0	0	3	100.0	0	0
Patient Insurance														
Public	34	43.0	26	32.9	12	15.2	2	2.5	5	6.3	72	91.1	7	8.9
Private	273	43.5	254	40.5	71	11.3	5	0.8	24	3.8	598	95.4	29	4.6
Missing			2		1						3			
Patient Smoking Status														
Non-Smoker	262	43.7	232	38.7	78	13.0	4	0.7	24	4.0	572	95.3	28	4.7
Smoker	45	41.3	50	45.9	6	5.5	3	2.8	5	4.6	101	92.7	8	7.3

Includes American Indian or Alaska Native Non-Hispanic, and Hawaiian Pacific Islander Non-Hispanic

Provider Characteristics and Practice Type by Testing Group

Provider and Practice Characteristics by Cotested versus Not Cotested. Table 3 provides a breakdown for each provider characteristic and practice type by testing group. Differences by provider characteristics who cotested compared to providers who did not cotest show a slightly higher percentage of female providers (95.3%) compared to male providers (93.6%). A higher percentage of male providers (6.4%) compared to female providers (4.7%) did not cotest. Differences by provider specialty show that 96.8% of Ob/Gyn & Midwifery providers cotested, the highest compared to Primary Care providers (90.4%) and Other specialties (80.0%). The academic practice sites cotested more (97.6%) compared to community Practice sites (93.1%).

Table 3

Provider Characteristics and Practice Type by Testing Group (n=709)

Characteristics	Single Cotest n (%) 307 (43.3)		Two Cotest n (%) 282 (39.3)		One Cotest and Pap n (%) 84 (11.8)		Two Paps n (%) 7 (1.0)		Single Pap n (%) 29 (4.1)		Cotested n (%)		Not Cotested n (%)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
	Cotesting Groups						*No Cotesting Groups*							
Provider Gender														
Female	246	45.9	206	38.4	59	11.0	5	0.9	20	3.7	511	95.3	25	4.7
Male	61	35.3	76	43.9	25	14.5	2	1.2	9	5.2	162	93.6	11	6.4
Provider Degree														
MD/DO	264	41.8	255	40.3	80	12.7	6	0.9	27	4.3	599	94.8	33	5.2
Other*	43	55.8	27	35.1	4	5.2	1	1.3	2	2.6	74	96.1	3	3.9
Provider Specialty														
Ob/Gyn &Midwifery	201	39.7	221	43.7	68	13.4	2	0.4	14	2.8	490	96.8	16	3.2
Primary Care	103	52.0	60	30.3	16	8.1	4	2.0	15	7.6	179	90.4	19	9.6
Other**	3	60.0	1	20.0	0	0	1	20.0	0	0	4	80.0	1	20.0
Practice Type														
Academic	144	50.2	118	41.1	18	6.3	1	0.3	6	2.1	280	97.6	7	2.4
Community	163	38.6	164	38.9	66	15.6	6	1.4	23	5.5	393	93.1	29	6.9

* Other Provider Degree includes Physician Assistant (PA), Nurse Practitioner (NP)and Certified Nurse Midwife (CNM)

** Other includes Medical Genetics, Palliative Care and Women's Health

Cotesting Uptake. Research question #1 addressed the reported uptake of cotesting among average-risk women aged 30-65 eligible to receive routine cervical cancer screening within an urban-based clinical practice setting. For the evaluable study sample of 709 participants, all screening tests for each patient found in the EHR conducted between 2012-2020 were analyzed to measure the uptake of cotesting. A total of 1,113 screening tests were conducted for 709 patients. Of this sample, 673 out of 709 patients (94.9%) received at least one cotest.

Proportion of Cotesting Use by Year. To calculate the proportion of cotesting conducted by year starting in 2012, the number of cervical cancer screening tests for 709 patients were analyzed as shown in Table 4. For each year, the total number of cotests conducted were divided by the total number of cervical cancer screening tests. This study found the overall uptake of cotesting between 2012-2020 was 86.3%. A steady increase in the percentage of patients cotested is seen starting in 2012 with 68.7% cotested and ending at 97.3% in 2020.

To determine whether the observed increase in percentage of women receiving cotesting year to year was significant, a chi-square test for trend was conducted and $X^2 = 46.9$; $p < 0.001$ which showed a statistically significant increase in cotesting over time.

Table 4

Proportion of Cotests Conducted by Year for Evaluable Sample (n=709) 2012-2020*

Year	Number of cervical screening tests conducted (n=1,113) **	Total number of cotests (n=961)	% cotested +
2012	67	46	68.7%
2013	81	65	80.3%
2014	103	81	78.6%
2015	139	115	82.7%
2016	151	129	85.4%
2017	219	194	88.6%
2018	195	178	91.3%
2019	83	80	96.4%
2020	75	73	97.3%

*Cotesting uptake was analyzed only for the evaluable sample

**Includes all pap tests and cotests found in EMR for every evaluable patient record.

+Chi Square Test for Trend: $X^2=46.89$, $p<0.001$

Screening Interval. The 2012 cervical screening guidelines specified a 3-year (or 36-month) screening interval for cervical cytology (i.e., paps) and 5-year (or 60-month) screening interval for cotesting (i.e., cervical cytology plus HPV testing). In this study, we applied a modified screening interval for evaluating the number of months between two negative screening tests. A flexible screening interval such as the one used in this study is still within the guideline recommended interval and is more reflective of real-world clinical practice.

Research Question #2 evaluates the screening interval between two negative cotests for women receiving routine cervical cancer screening. Three hundred seventy-three patients out of 709 (52.6%) had two negative cervical screening tests in the Allscripts® EHR system that were eligible for evaluation of the screening interval. Two hundred eighty-two, 75.6% of the sample were two cotests. The median screening interval between two negative cotests was 36-months, lower than the recommended 60-months by the 2012 guidelines and also lower than the threshold set for this study as seen in Table 5. In addition to two cotests, some patients had other combinations of two negative cervical cancer screening tests that we could measure the screening interval for. Eighty-four (22.5%) of tests were a combination of cotest and pap and had a median screening interval of 23.5 months. The third group of two cervical tests consisted of those that had two pap tests (1.8%) and this group had a median screening interval of 17-months, which is shorter than the recommended 36-months by the 2012 guidelines and also lower than the threshold set for this study at 30-42 months. Table 5 summarizes screening intervals for each of the test groups.

Table 5

Cervical Screening Interval, Adherence and Screening Level by Testing Status (n=709)

Testing Status Group	Total Included n (%)	Screening Interval (months)					Guideline Adherent (n=373)		Screening Level (n=373)		
		Mean	Median	Min	Max	Std. Dev	Yes n (%)	No n (%)	Over n (%)	Under n (%)	Within interval† n (%)
Single Cotest*	307 (43.3)										
Two Cotests	282 (39.8)	39.4	36.0	3.0	122.0	19.8	39 (13.8)	243 (86.2)	214 (75.9)	29 (10.3)	39 (13.8)
One Cotest and Pap	84 (11.8)	26.4	23.5	9.0	81.0	15.1	13 (15.5)	71 (84.5)	60 (71.4)	11 (13.1)	13 (15.5)
Two Paps	7 (1.0)	19.0	17.0	11.0	34.0	8.1	1 (14.3)	6 (85.7)	6 (85.7)	0 (0)	1 (14.3)
Single Pap*	29 (4.1)										
							53 (14.2)	320 (85.8)	280 (75.1)	40 (10.7)	53 (14.2)

*Single test groups not included in screening interval, guideline adherence and screening level analysis (n=336)
† ±6 months

The screening interval in months was further analyzed by patient race and ethnicity, age, and insurance type to look for any differences in screening interval months that may be present. No differences in screening interval months were observed by patient age group or insurance type. A Kruskal-Wallis test was conducted to explore differences in interval months across racial groups. Results showed screening interval months for Asian Non-Hispanic patients (21.5 months) is significantly shorter ($p<.001$) when compared to White Non-Hispanic (36.0 months) and Black Non-Hispanic (34.5 months). As shown in in Table 6, this racial group was consistently overscreened, as 100% of Asian Non-Hispanic patients in the two-test group were overscreened.

Race and Ethnicity. Guideline adherence by race and ethnicity was analyzed to look for any differences in screening levels (overscreening, underscreening, and within interval) by racial categories as seen in Table 6. One hundred percent of Asian Non-Hispanic and Other which include American Indian, or Alaska Native were overscreened followed by 80.6 % of Hispanics. Black Non-Hispanic had the lowest percentage of overscreening (67.4%) compared to other racial groups, but the highest percentage (15.5%) of underscreening. This group also had the highest percentage (17.3%) of screening within the correct screening interval compared to all other racial groups.

Table 6

Cervical Screening Test, Interval, and Level by Race and Ethnicity (n=373)

Evaluable (n=373)		Testing Group (n=373)			Screening Interval Months (n=373)					Screening Level (n=373)		
		n (%)	n (%)	n (%)								
Race and Ethnicity	n (%)	Two Cotests	Single Cotest w/Pap	Two Paps	Mean	Median	Min	Max	Std. Dev	Over	Under	Within interval†
Hispanic												
All races	36 (0.10)	22 (61.1)	14 (38.9)	0 (0)	31.3	27.5	12.0	81.0	17.2	29 (80.6)	1 (2.8)	6 (16.7)
Non-Hispanic												
White	204 (54.7)	156 (76.5)	43 (21.1)	5 (2.5)	37.1	36.0	3.0	111.0	18.7	154 (75.5)	22 (10.8)	28 (13.7)
Black	110 (29.5)	88 (80.0)	20 (18.2)	2 (1.8)	38.4	34.5	9.0	122.0	22.1	74 (67.4)	17 (15.5)	19 (17.3)
Asian	22 (0.06)	15 (68.2)	7 (31.8)	0 (0)	23.0	21.5	10.0	53.0	10.9	22 (100.0)	0 (0)	0 (0)
Other*	1 (0.003)	1 (100.0)	0 (0)	0 (0)	27.0	27.0	27.0	27.0	27.0	1 (100.0)	0 (0)	0 (0)

* Includes American-Indian or Alaska Native Non-Hispanic

\+ Kruskal-Wallis test showed screening interval months for Asian and Non-Hispanic is significantly shorter (p<.001) when compared to White and Non-Hispanic and Black and Non-Hispanic

† ±6 months

Guideline Adherent Screening Interval

Patients in the two-test groups were eligible to be evaluated for guideline adherent screening interval. Guideline adherence is based on receiving a cervical screening test within the appropriate study defined screening interval (Figure 4). Three hundred seventy-three patients were eligible for guideline adherence evaluation based on their study screening interval.

In this study, 53 out of 373 patients (14.2%) were guideline adherent. The remaining 320 patients, or 85.8% were not screened in accordance with guidelines, with 280 out of 373 (75.1%) overscreened and 10.7% underscreened.

Testing Group. Further review of these data by testing group found that overscreening occurred in 85.7% of patients in the two-pap group, 75.9% of patients in the two cotest group, and 71.4 % of patients in the combination of pap and cotest group. The two cotest group had the lowest percentage (13.8%) of screening that occurred within the correct screening interval compared to the other two test groups. When guideline adherence rates are compared by test group, they all fall close to the overall guideline adherence of 14.2% and non-guideline adherence of 85.8%.

Age. Patients were also compared by age group to look for any differences in guideline adherence by this predictor. Only 11.6% of the 60–65-year age group was guideline adherent, the lowest of any age group. This age group was also overscreened the least (69.8%), but underscreened the greatest (18.6%) when compared to all other age groups. The 40-49 age group was the most guideline adherent when compared to the overall rate, with 16.2% of patients in this age group receiving guideline adherent cervical cancer screening and it was also the most guideline adherent group compared to all other age groups. The 50-59 age group was overscreened the most (85.8%) and higher than the overall 75.1% overscreening rate. This

group was also underscreened the least (6.6%) compared to all other age groups and was also much lower than the study average for underscreening. In Table 7, a breakdown for each age group is provided.

Table 7

Cervical Screening Interval, Adherence and Screening Level by Patient Age (n=373)

	Total Included (n=373)	**Screening Interval Months (n=373)**					**Guideline Adherent (n=373)**		**Screening Level (n=320)**		
Patient Age Group	n (%)	Mean	Median	Min	Max	Std. Dev	Yes† n (%)	No n (%)	Over n (%)	Under n (%)	Within interval† n (%)
30-39	107 (43.3)	33.6	34.0	3.0	91.0	17.9	15 (14.0)	92 (86.0)	81 (75.7)	11 (10.3)	15 (14.0)
40-49	117 (39.8)	37.7	34.0	10.0	122.0	20.9	19 (16.2)	98 (83.8)	84 (71.8)	14 (12.0)	19 (16.2)
50-59	106 (2.4)	36.4	36.0	11.0	84.0	18.7	14 (13.2)	92 (86.8)	85 (80.2)	7 (6.6)	14 (13.2)
60-65	43 (9.4)	37.1	34.0	12.0	111.0	21.5	5 (11.6)	38 (88.4)	30 (69.8)	8 (18.6)	5 (11.6)
							53 (14.2)	320 (85.8)	280 (75.1)	40 (10.7)	53 (14.2)

†±6 months

Multivariable Logistic Regression Analyses to Determine Predictors of Guideline Adherent Screening Interval and Cotesting Uptake

The last research question investigated the relationship between the patient, provider, and practice level determinants with guideline adherent screening interval and cotesting use. Two separate multivariable logistic regression analyses were conducted to address this question.

Predictors of Guideline Adherent Screening Interval. For the first outcome of guideline adherence, six regression models were generated. Table 8 displays the odds ratios and confidence intervals for all variables. In Model 6, the final model, provider gender ($p<0.001$) and practice type ($p<0.001$) were determinants found to be associated with guideline adherent screening interval. A test for interaction between provider gender and practice type was explored, but no significant interaction was found between these variables, suggesting that each variable is an independent main effect.

Table 9 provides the results the detailed breakdown of the final regression model. Provider gender was a dichotomous variable with females set as the reference group. The results indicated that male providers had 0.31 lower odds of conducting cervical cancer screening within the specified screening intervals (95%CI, 0.13-0.78) compared to females. Practice type was also a dichotomous variable with academic set as the reference group. The results indicated that community practice sites had 0.15 lower odds of conducting cervical cancer screening within the guideline specified screening intervals (95%CI, 0.08-0.31) compared to academic sites.

Table 8

Multivariable Logistic Regression Models Predicting Adherence to Cervical Cancer Screening interval per the 2012 Guidelines (n=373)

Variables	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)
Patient Age	0.94 (0.67–1.32)					
Patient Insurance	1.21 (0.45 - 3.27)	1.22 (0.45 -3.30)				
Patient Race and Ethnicity	0.86 (0.57 – 1.30)	0.87 (0.58 - 1.31)	0.86 (0.57 – 1.29			
Provider Degree	1.57 (0.64 – 3.88)	1.57 (0.64 – 3.87)	1.56 (0.64 – 3.84)	1.49 (0.61-3.64)		
Provider Specialty	1.58 (0.81 – 3.09)	1.55 (0.80 - 2.99)	1.55 (0.80 - 2.99)	1.50 (0.78 - 2.89)	1.42 (0.74 - 2.70)	
Provider Gender	0.37 (0.14 – 0.94)	0.37 (0.14 - 0.93)	0.36 (0.14 - 0.93)	0.35 (0.14 - 0.90)	0.33 (0.13 - 0.81)	0.31^{+} (0.13 - 0.78)
Practice Type	0.18 (0.09 - 0.37)	0.18 (0.09 - 0.37)	0.18 (0.09 - 0.37)	0.18 (0.09 - 0.37)	0.17 (0.08 - 0.34)	0.15^{+} (0.08 - 0.31)

$^{+}$ $p<0.001$

Table 9

Final Logistic Model of Significant Predictors of Adherence to Screening Interval

	Total (n=373)
Variables	Odds Ratio (95% CI)
Provider Gender ($p<0.01$)	
Female	1.0
Male	0.31 (0.13–0.78)
Practice Type ($p<0.001$)	
Academic	1.0
Community	0.15 (0.08–0.31)

Sensitivity Analysis of Predictors for Overscreening and Underscreening (non-guideline adherent). As noted above, provider gender and practice type were significant predictors of guideline adherence. To further explore the association of determinants with non-adherence (i.e., over screening and underscreening), a sensitivity analysis was conducted. Results from a multivariable logistic regression indicated that practice type was a significant predictor of overscreening. In particular, the patients who saw providers from community practices had 3.86 times higher odds (95%CI, 1.94-7.70) of overscreening than those who saw providers at academic practices. No other determinants were significant predictors of overscreening.

Predictors of Conducting Cotesting. To evaluate predictors for cotesting, a second multivariable logistic regression model was run producing five regression models. See Table 10. In Model 4, four variables were associated with cotesting: patient age (p=0.054), provider gender (p<0.05), provider specialty (p<0.001) and practice type (p<0.01). Model 5 included all the above variables except patient age which was removed manually from the model before running the logistic regression because it was only borderline significant, and we wanted to test whether the

Table 10

Multivariable Logistic Regression Models Predicting Cotesting Use (Uptake) (n=373)

Variables	Model 1	Model 2	Model 3	Model 4	Model 5
	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)	Odds Ratio (95% CI)
Provider Degree	1.25 (0.34 – 4.64)				
Patient Race and Ethnicity	0.94 (0.67 - 1.32)	0.93 (0.66 – 1.30)			
Patient Insurance	1.89 (0.75 - 4.79)	1.89 (0.74 - 4.77)	1.93 (0.77 – 4.86)		
Patient Age	1.48 (1.01– 2.18)	1.49 (1.01 - 2.19)	1.50 (1.02 - 2.20)	1.46 (1.00 – 2.14)	
Provider Gender	0.49 (0.22 - 1.10)	0.48 (0.21 - 1.07)	0.47 (0.21 - 1.06)	0.44^{+} (0.20 – 0.97)	0.45^{+} (0.20 – 0.99)
Provider Specialty	0.22 (0.11 - 0.46)	0.23 (0.11- 0.47)	0.22 (0.11 - 0.45)	0.21^{+++} (0.11 - 0.43)	0.23^{+++} (0.12 – 0.46)
Practice Type	0.25 (0.10 - 0.61)	0.25 (0.10 - 0.60)	0.24 (0.10 - 0.58)	0.25^{++} (0.10 - 0.60)	0.26^{++} (0.11 – 0.63)

$^{+}p < 0.05$
$^{++}p < 0.01$
$^{+++}p < 0.001$

other three variables remained significant after removing age. Differences between Model 4 and Model 5 related to the relationship of age with cotesting. Patient age was the only patient level factor that was associated with a dependent variable in the study, however the P-value for age was 0.054 suggesting it was a borderline significant predictor for cotesting. The remaining determinants that showed an association in Model 4 and Model 5 were related to provider and practice characteristics (i.e., provider gender, provider specialty, practice type).

All determinants that showed an association for both models were further explored in Table 11 to understand their influence on cotesting. Since age was only included in Model 4, the

effect of each age category was explored. The 40-49 age group had 3.20 higher odds (95%CI, 1.25-8.19) of cotesting when compared to the 30-39 age group (reference group). The odds of cotesting for the 50-59 age group were 1.83 times higher (95%CI, 0.78-4.31) than the 30-39 age group (reference group). The eldest age group, 60-65 years old, had 3.87 times higher odds (95% CI, 0.84-17.9) of cotesting than the 30-39 years old (reference group), the youngest age group. For provider gender, the odds of cotesting were 0.44 lower (95% CI 0.20-0.97) for patients seeing male providers when compared to females (reference group). The odds of cotesting for patients seen by Primary Care providers was 0.19 (95%CI, 0.09-0.41) and 0.03 for Other providers (95%CI, 0.003-0.36) lower compared to patients seen by Ob/Gyn & Midwifery providers (reference group). Patients seen at community practice sites had 0.25 lower odds (95%CI, 0.10-0.60) of receiving cotesting compared to patients seen at academic sites (reference group).

When age was not included in the model, as seen in Model 5, the odds of the remaining three variables remained roughly the same (see Table 11). Patients who were seen by male providers for cervical cancer screening had 0.45 lower odds (95%CI, 0.20-0.99) of receiving cotesting compared to patients seen by female providers. The odds of cotesting for patients seen by Primary Care providers was 0.24 (95%CI, 0.12-0.50) and 0.04 for Other providers (95%CI, 0.0003-0.39) both lower compared to patients seen by Ob/Gyn & Midwifery providers. Patients seen at Community practice sites had 0.25 lower odds of receiving cotesting (95%CI, 0.10-0.63) compared to patients seen at Academic sites.

Table 11

Details of Final Logistic Model of Significant Predictors of Cotesting (Uptake) for Model 4 and Model 5

	Model 4	**Model 5**
Variables	Odds Ratio (95% CI)	Odds Ratio (95% CI)
Patient Age *(p* =0.054)		
30-39	1.0	
40-49	3.20 (1.25–8.19)	
50-59	1.83 (0.78–4.31)	
60-65	3.87 (0.84–17.9)	
Provider Gender *(p* <0.05)		
Female	1.0	1.0
Male	0.44 (0.20–0.97)	0.45 (0.20-0.99)
Provider Specialty (*p*<0.001)		
Ob/Gyn &Midwifery	1.0	1.0
Primary Care	0.19 (0.09–0.41)	0.24 (0.12-0.50)
Other*	0.03 (0.003–0.36)	0.04 (0.003-0.39)
Practice Type *(p*<0.05)		
Academic	1.0	1.0
Community	0.25 (0.10–0.60)	0.25 (0.10-0.63)

*includes Medical Genetics, Palliative Care and Women's Health

The relationship between age with provider gender, provider specialty and practice type was explored further to look for any patterns that may suggest a relationship between age and these variables. While no significant interaction was found between age and the other three variables, there was an interesting pattern seen between age and provider specialty that was statistically significant (X^2=19.6; p<0.01). As seen in Table 12, a higher percentage of patients in the 30-39 age group were seen by an Ob/Gyn/Midwifery provider (81.0%) compared to patients in the other age groups who ranged between 63.1% (40-49 and 60-65 age groups) and 69.7% (50-59 age group). The distribution of patients by age in the primary care group also show differences with 18.3% of the 30-39 age group seen by this specialty compared to 29.8% (50-59 age group), 36.0% (40-49 age group) and 36.9% for 60-65 age group.

Table 12

Patient Age Distribution by Provider Specialty Group

	Ob/Gyn/Midwifery		Primary Care		Other*	
Provider Specialty	n	%	n	%	n	%
Patient Age Groups						
30-39	213	81.0	48	18.3	2	0.8
40-49	128	63.1	73	36.0	2	1.0
50-59	124	69.7	53	29.8	1	0.6
60-65	41	63.1	24	36.9	0	0.0

Qualitative Results

The qualitative study sought to explain the findings of the quantitative study and address the following research questions:

- Research Question #4: How do providers in different practice settings describe multilevel barriers to guideline adherence?
- Research Question #5: What are the knowledge, attitudes, and preferences of providers toward the adoption of primary HPV test (without concurrent cytology) as another option for cervical cancer screening as recommended by the updated 2018 cervical cancer screening guidelines?

Demographics

Provider Characteristics. Seven Ob/Gyn and Primary providers practicing in the Washington, DC metropolitan area agreed to participate in either individual or paired interviews. This research was deemed exempt (Exemption 2) by the GWU Institution Review Board (IRB), and no documentation of written consent was required. Prior to proceeding with the interviews, the participants were provided a study information sheet to review (Appendix B). The first interview was conducted in-person and the remaining 3 interviews were conducted over WebEx

video conferencing and by phone. Providers participating were closely balanced in gender and practice affiliation with 4 females and 3 males, and 4 from Academic and 3 from Community practice sites. All female providers worked in Academic practice and all male providers in Community practice. There were more Ob/Gyn (5/7), and most providers (4/7) had been in practice between 10-20 years. Ob/Gyn providers worked in Academic and Community Practice sites and Primary Care providers only in Academic. Table 13 provides characteristics of providers who participated in the interviews.

Table 13

Characteristics of Providers Interviewed

	Total (n=7)
Characteristics	n
Provider Gender	
Female	4
Male	3
Provider Specialty	
Ob/Gyn&Midwifery	5
Primary Care	2
Provider Degree	
MD/DO	6
Other	1
Practice Type	
Academic	4
Community	3
Number of Years in Practice	
<10 years	1
10-20 years	4
21-30 years	1
>30 years	1

*Other includes Family Nurse Practitioner (FNP)

Interviews

Three interviews were conducted in pairs and one with a single provider. The average interview duration was 50 minutes with a range from 39 to 65 minutes. The first paired interview conducted with Academic Ob/Gyn providers occurred in-person at the Medical Faculty Associates (MFA) in Washington, DC, while the other three interviews were conducted over WebEx video conferencing and by telephone. The longest interview was a paired interview with the Academic Primary Care providers lasting one-hour and five minutes, and the shortest was a paired interview with the Academic Ob/Gyn providers lasting 39 minutes.

Analytical Frameworks

The Knowledge, Behaviors, and Attitude Framework (Cabana et al., 1999) is focused on describing physician barriers to guideline adherence according to their effect on physician knowledge, attitudes or behavior. A deductive approach using categories from this framework were used to map barriers reported by the interviewees. Categories of barriers from the Cabana framework include Knowledge, Attitude, and External. The Consolidated Framework for Implementation Research (CFIR) by Damschroder et al. (2009) was a second framework utilized to capture any barriers that were not described by Cabana's framework but emerged during the interviews. The outer setting domain described by CFIR which includes External Policies and Incentives as a construct addresses these additional barriers. Additionally, demographic characteristics of the providers (i.e., gender, age, specialty) involved in the delivery of screening taken from CFIR emerged as important factors to consider in making sense of driving provider behavior toward adherence to guidelines.

Table 14 displays codes, categories and themes that emerged from the interviews. Within each category of barriers, 1-2 overarching themes emerged to illustrate how providers described

from their own experience barriers to guideline adherence. The following five themes were identified as barriers:

1. Guideline familiarity is dependent on type of provider and organizational setting.
2. Provider attitude toward guideline adherence is driven by their past training, experience, and habit.
3. Provider discomfort with articulating guideline information to patients is a hinderance to guideline adherence.
4. Patient preferences drive provider testing behavior.
5. Insurance policies are not designed to promote guideline adherence among patients and providers.

In addition to these five themes that explained barriers to provider adherence to guidelines, one additional theme emerged related to *provider demographic characteristics*, particularly provider age and number of years in practice, but was not stated by the interviewees as a barrier. Of note, provider age, gender, ethnicity, and specialty are not part of the Cabana framework because the framework is only focused on barriers that can be changed by an intervention. However, age, and numbers of years in practice were mentioned by interviewees as important factors they believed drove screening behavior and could be used to explain the association of gender with conducting guideline adherent screening and cotesting in the quantitative strand.

Table 14

Qualitative Categories and Themes

Categories	Deductive Codes	Themes
Knowledge Barriers	**Lack of Familiarity of Guideline** **Lack of Awareness of Guideline**	*Guideline familiarity is dependent on type of provider and organizational setting.*
Attitude Barriers	**Cervical Screening Guideline Related**: Lack of Agreement with Guidelines, Lack of Agreement with Interpretation of Evidence, Lack of Agreement with Applicability to Patient, Not Practical **Lack of Motivation/Inertia of Prior Practice:** Habit or Routine (Including Provider Training) **Lack of Outcome Expectancy**: Physician Belief that Performance of Guideline Recommendation will not Lead to Desire Outcome **Lack of Self-Efficacy**	*Provider attitude toward guideline adherence is driven by their past training, experience, and habit.* *Provider discomfort with articulating guideline information to patients is a hindrance to guideline adherence.*
External Barriers	**Health System Factors**: Insurance or Payor Related, Lack of Guideline Dissemination or Education to Patient, Misalignment of Insurance Policies and Guidelines, Perceived Increase in Malpractice Liability **Environmental Factors:** Organizational and Practice Level Factors; EHR System Barrier, Lack of Organizational Constraints (freedom to practice), Lack of Oversight and Quality Checking, Lack of Time, Overwhelmed by Multiple Demands in Practice	*Patient preferences drive provider testing behavior.* *Insurance policies are not designed to promote guideline adherence among providers and patients.*

	Financial Factors: Financial Loss or No Financial Advantage; Lack of Incentive to Follow Guidelines **Patient Related Factors**: Inability to Reconcile Patient Preferences with Guideline Recommendations. Lack of Understanding of Guideline by Patient; Patient Belief Regarding Lack of Harm from Annual Screening, Patient Lacks Awareness of National Guidelines, Patient Unaware of when Last Screening was Done, Preserving Patient Provider Relationship, Provider Perception of Patient's Willingness to Learn about Changing Guidelines **Patient Characteristics:** Age, Race and Ethnicity, Risk Factors for Cervical Cancer (Smoker, no HPV vaccination), SES Factors (Education, Income, Insurance)	
Demographic Characteristics*	**Provider Characteristics**: Provider Age, Number of Years in Practice	*Provider demographic characteristics explain the gender differences found in the quantitative study.*
*not reported as a barrier		

Knowledge Barriers

As defined by Cabana, "factors limiting adherence through a cognitive component were considered barriers affecting knowledge" (Cabana et al., 1999). In order to correctly apply guideline recommendations to patients, providers must first know the guideline exists and then the content it entails in order to apply it. Figure 6 summarizes the 2012 cervical cancer screening guideline recommendations by age and test type.

Figure 6

Summary of 2012 Cervical Screening Guideline Recommendations by Age and Test

Age/Patient Type	Screening Test	Screening Interval
21-65	Cytology (Pap Test)	Every 3 years
30-65	Cotesting (Pap Test + HPV Test)	Every 5 years
Under 30	Cotesting or HPV testing alone is not recommended	Not applicable
Under 21	Not recommended	Not applicable
Over 65 with adequate prior screening	Not recommended	Not applicable
Women with hysterectomy	Not recommended	Not applicable

Theme #1: *Guideline familiarity is dependent on type of provider and organizational setting.* Knowledge barriers could signal lack of familiarity with guidelines and/or lack of awareness that guidelines exist. All providers interviewed were aware of the 2012 cervical cancer screening guidelines and acknowledged their existence. Although keenly aware of the guidelines, Primary Care providers and those from Ob/Gyn Community practice settings lacked familiarity with some of the details of the guideline recommendations. This was captured through responses that illustrated providers unable to correctly state the guideline content, questioning what the

guidelines recommended, or citing outdated evidence that was no longer relevant to the guidelines under discussion.

> I think many of the pap smears that are done are actually unreliable and inaccurate. And in medicine, a positive test is more valuable than a negative one. And I think in a lot of cases when pap smears are done, somehow the cells just are not collected properly. And the transformation zone is not always sampled. (Community Ob/Gyn, MD, Male)

> I use the HPV as a reflex. There are some patients who may have had a history of HPV and so for those probably, we do the cotesting routinely. (Community Ob/Gyn, MD, Male)

> Because it might save the patient from having an abnormality that would have been undetected if we hadn't done the pap test. So, I normally do them yearly. (Community Ob/Gyn, MD, Male)

Most, but not all Ob/Gyn providers had a strong familiarity of the guidelines and knew the details of the recommendations including the age group for which cotesting was recommended for and recommended against, and the correct screening interval between two negative cotests. Primary Care providers that were interviewed showed casual familiarity with guidelines, and sometimes incorrectly stated the guideline content and their application to patients in practice.

> If they change a partner, we do a pap test. Isn't it recommended in the guidelines that you need to be doing another pap smear? (Academic Primary Care, MD, Female)

Differences in familiarity of guidelines between providers from academic compared to community settings was acknowledged to exist by the interviewees. Academic Ob/Gyn providers felt strongly that providers in community settings do not take the time to keep up with changing guidelines or have the time to spend with patients explaining the guidelines.

> You have to know enough about it to explain why it's the right thing to not screen and you have to have the time to do that. And so that's going to be an Academic provider because a community provider either doesn't know or knows but doesn't have time to put a fight. And just like it's just faster to do it. (Academic Ob/Gyn, Female, MD)

Attitude Barriers

The affective component of Cabana's Framework included barriers related to the provider's attitude such as inertia of previous practice and lack of self-efficacy which inhibit provider adherence to guidelines (Cabana et al., 1999).

Theme #2: *Provider attitude toward guideline adherence is driven by their past training, experience, and habit.* All providers cited their perceived attitude toward guidelines as the inability to overcome the inertia of previous practice. This could be in the form of their medical training, experience in their respective practice setting (i.e., academic or community) or habits and routine which are difficult to break/change. Ob/Gyn and Primary Care providers who

completed their training less than 20 years ago were similar in their views and understanding of the 2012 guidelines due to the timing of their medical training.

> Your autopilot is what you've always done and it's harder for that change. If you learned it in the newer guidelines, or it was closer to when you learned it, it's easier to transition to newer guidelines. (Academic Ob/Gyn, MD, Female)

Some providers from community settings shared that colleagues within their practice were not following current cervical cancer screening guidelines and this was not a surprise to them. They explained that many doctors trained during a time when the understanding of cervical cancer as an HPV driven disease process was not fully understood, and HPV testing was not part of the screening guidelines. Providers who had been out of training longer and in practice before the current guidelines were issued, stated that they were more apt to continue screening the way they had been doing over the course of their careers, and would also be unable to adopt the newest screening method as recommended in the 2018 guidelines which included primary HPV testing (without concurrent cytology). Lacking motivation to stay up to date with changing guidelines stemmed from their inability to break old habits according to providers interviewed.

> But I think it's sometimes harder to change the way you practice to some extent than it is easier to just stick with something that works. (Community Ob/Gyn, MD, Male)

All providers working in community settings that were interviewed were cognizant that each provider within a practice may practice differently depending on when they trained, and they expressed that this was acceptable behavior.

> We all kind of follow the beat of our own drummer. I have three partners. One is right out of residency, so everything is according to what she was taught when she was a resident. Then I have a partner who's been in practice for eight years, and a partner whose been in practice for 25 years, who practices more like I do. And so, each of us practice with a different style. I mean, it's just that we don't all agree that we all have to do something a certain way. (Community Ob/Gyn, MD, Male)

This flexibility in style of practice in community settings was described as a barrier to guideline adherence by both academic and community providers. Contrary to community providers, providers from academic settings stated that they believed most providers they worked with practiced screening similarly despite prior training and habit and followed guidelines because this is what was expected in an academic medical setting. Community providers shared a similar view and also thought that academic providers were more likely to follow guidelines because there is an expectation for them to practice in the same way, whereas community providers have more freedom to practice the way they want.

> I think in academic facilities, you're more apt to follow guidelines that are sort of, recommended that all the providers adhere too, and I think there's a little bit more in a community setting, um what's the right word? A little bit more freedom to sort of practice in a little bit of a different fashion and not necessarily follow guidelines strictly. (Community Ob/Gyn, MD, Male)

Additionally, interviewees pointed out that because some providers had been doing annual pap smears over the course of decades, it was difficult for them to switch to newer guidelines and explain to patients that screening must be done less frequently. Providers

emphasized that patients were not willing to listen to them and follow the new guidelines because just like providers have developed habits guiding how they practice, so have the patient populations they screen.

> And I think there's just sort of this entrenched thought that annual exam to pap smear, annual exam to pap smear, that if you're not even doing the pap smear portion like, why am I even coming in to see you for an exam. (Community Ob/Gyn, MD, Male)

> The patient population matters. Particularly my private practice, you know, there were providers that retired when I started and, I'll freely admit there are patients that were like, in their 70s, who were getting mad that I wasn't doing annual pap smears on them because it had been done for the prior 5 decades. These patients were told they were high risk for whatever reason, and essentially getting over tested like, every 6 months from a previous provider they had been seeing. (Community Ob/Gyn, MD, Male)

> There's a little bit less of a desire to stay up to date and change your practice methods based on guideline changes. I mean, to some extent, you do kind of get into habits. Um, and those habits sort of stick with you and the way you practice through time if you're not really staying up to date. (Community Ob/Gyn, MD, Male)

Theme #3: *Provider discomfort with articulating guideline information to patients is a hinderance to guideline adherence.* Academic Ob/Gyns providers shared a strong sense of confidence in their ability to explain cervical screening guidelines to patients and the evidence which supported less frequent screening and the addition of HPV testing to the pap smear

(cotesting). These providers admitted that many times they got pushback from patients who insisted they want to get a pap even if they are not due for one at that visit, but they felt that if a provider took the time to explain that frequent testing would not reduce their risk of getting cervical cancer, some patients were willing to listen and agree to not get screened.

> So not only do you have to understand the guidelines, but you have to be willing to put in the time and energy to explain that to the patient. (Academic Ob/Gyn, MD, Female)

One Primary care provider that was interviewed shared that in her experience, patients coming to academic medical centers for their healthcare seem to be more willing to listen to the provider's recommendations, so it is not as difficult to have a conversation about the guidelines in comparison to what she had experienced when she worked in the community previously. On the contrary, most community Ob/Gyns interviewed stated that they find it difficult to have conversations with patients who are in the habit of getting annual screenings that they were not due for at that visit or if the provider told them they would not need a screening test at the next annual visit. Providers repeatedly stated that patients often misinterpreted their recommendation to not get a cervical cancer screening test with meaning they do not have to return for an annual gynecological visit at all which includes many other necessary health screenings and evaluations.

Also, due to the variability in how providers in a single community practice may follow guidelines, providers find it difficult to have conversations with patients about less frequent cervical cancer screening, if the patient has been seeing a different provider in that practice that does not follow guidelines.

> There are 2 providers that still do pap smears on women **every single** year. And if somehow, in some way, one of my patients lands in that individual's queue, then that patient's going to get a pap smear. When I see patients of those providers in my schedule, then the discussion needs to be had. Then it gets a little bit hairy because it's like, 'well, I've been doing this X Y, and Z for the past however many years. And suddenly now you're telling me that I don't need this.' It gets a little bit awkward. (Community Ob/Gyn, MD, Male)

All providers admitted that sometimes the difficulty in explaining and trying to convince the patient that they do not need a screening test as well as the time that this can take, is a huge hindrance to guideline adherence.

> So, I say to them, 'we want to see you every year'. And, we do have patients, where we recommend that they not have a Pap test after a visit. And I'll have to tell you, **it's kind of hard to explain why they don't need a Pap test**. (Community Ob/Gyn, MD, Male)

External Barriers

There are barriers beyond the provider's knowledge and attitude that can limit their ability to perform the guideline recommended behavior. External barriers are important to consider because "despite adequate knowledge and attitudes, external barriers can affect a physician's ability to execute recommendations" (Cabana et al., 1999, p.1461). In this study, patient related factors which include patient preference and health system factors which include insurance/payor policies stood out as main external drivers for lack of guideline adherence by providers. While patient related factors are a component of Cabana's framework, health system

factors, specifically insurance/payor related are not. These barriers were evaluated using the outer setting domain of CFIR, which includes a construct to evaluate external policies and regulations which can be a barrier to effective implementation (Damschroder et al., 2009). Provider demographic characteristics such as the provider's age and years of experience in practice were also brought up during the interviews as explication for the association of provider's gender with the study outcomes.

Theme #4: *Patient preferences drive provider testing behavior.* All providers interviewed shared that sometimes they had no choice but to give the patient what she wanted (i.e., the pap that was not needed) even if it was going against screening recommendations. Providers stated that they must think about the downstream consequences of not meeting the patient's expectations for the visit and the impact this could have on the practice and their relationship with the patient.

> I think most of the people in our practice who get over screened is because its patient driven. I would say 99.999% of it is patient driven. Because our providers here know they are not supposed to test them. (Academic Ob/Gyn, MD, Female)

> I rarely if ever do a pap early. But that's what's like I'm weighing in my head to say if she thinks she is getting poor care from me. Is that going to spill over into other care that she's getting by me? And so maybe we just do it. (Academic Ob/Gyn, MD, Female)

Community Ob/Gyns were particularly concerned that patients may translate a provider not performing a screening test to receiving poor care and may not return to the practice in the future, resulting in financial loss.

> If we start to lose patients, because essentially, we're trying to educate them and that is something that they're not used to, and they just don't want to believe those guidelines, in the end we could potentially be losing patients. And, if you're going to lose patient because you don't want to give them what they want, then that's a huge impact. (Community Ob/Gyn, MD, Male)

All providers shared that most patients have an expectation to receive a pap test when they see a gynecologist for a routine wellness check and there is a disconnect on the part of the patient in understanding what a pap test really does.

> They sort of think that we're not treating them properly. It's like patients are conditioned to think that when they come in, they're going to have a Pap test. (Community Ob/Gyn, MD, Male)

Additionally, patients do not understand the difference between a “pap” compared to a “pap + HPV” test which is what is referred to as the cotest. Most patients also have no awareness of national guidelines according to providers interviewed. One provider explained that when a patient over 30 years of age tells a provider that they want a “pap” they usually don’t understand what they are asking for. The patient is not aware that they should be receiving additional laboratory testing to screen for HPV as a part of the screening and this is the component of the screening test which allows them to wait a longer period between screenings in the absence of abnormal results. Even when providers stated they have tried to explain the latest cervical cancer screening recommendations to cotest every 5-years to patients, the patients often insisted that since testing is safe and their insurance will pay for it annually, they preferred to get tested at each visit. Most providers interviewed noted that often patients who are asking for cervical

cancer screening (i.e., pap) are incorrectly assuming they are getting screened for sexually transmitted diseases (STDs) like chlamydia or gonorrhea.

> I mean half the patients that want the test don't know the difference between the tests and cytology. They associate pap testing with somehow, you're going to tested for chlamydia also. So, they say, 'test me, I want it.' I've seen that in my practice. (Academic Primary Care, MD, Female)

Providers in academic practice shared that despite their best efforts at times to convince the patient that they don't need a pap, the time it can take to have that conversation with the patient and to properly explain the reasons is not always worthwhile as it can further frustrate patients who may feel alienated and not taken care of by the provider which may sacrifice the doctor patient relationship.

> If the patient feels alienated or you're not taking care of them by not doing the pap, it's also 'Am I sacrificing a doctor patient relationship and trust over this and is it worth it?' (Academic Primary Care, MD, Female)

Providers unanimously expressed that the annual well women visit includes much more than screening for cervical cancer, but if patients are told the pap is not needed, they may skip the annual visit and the opportunity to have the doctor check for breast cancer, ovarian cancer and discuss menopause.

> They kind of equate going to gynecologists with having a Pap test. And I think when we tell them that they don't need to come in for a pap test they take that to mean but we don't need to come in at all. (Community Ob/Gyn, MD, Male)

Theme #5: *Insurance policies are not designed to promote guideline adherence among providers or patients.* From a health system perspective, insurance policies and their payment structures which continue to pay for unnecessary screening were reported as a barrier for providers to follow the current cervical screening guidelines. Providers pointed out that although screening guidelines for cervical cancer have evolved over the years, insurance carriers have not changed their reimbursement practice to align with the updated guidelines that call for using HPV testing and less frequent screening.

Providers interviewed shared that patients know that their insurance plans will pay for annual screening and use this as a reason to request testing even when they are told by the provider that it is not needed. Patients also don't feel that getting screened for cervical cancer is harmful or invasive like other cancer screenings, so that coupled with the insurance willing to pay screening that is not needed promotes lack of guideline adherence.

> And when you try to explain it to them, I'll say the great majority of time, when I start to break things down, the question would be, 'well, if insurance is going to cover it, I'm just going to come back whether it's 1 year or 2 years or whatever.''' (Community Ob/Gyn, MD, Male)

> I tell them what the guidelines are unfortunately, they'll say, 'well, you know what, my insurance has been paying for the past 30 years, it's not dangerous for me', and I can tell them whatever I want but they'll still request to have it done sometimes. (Community Ob/Gyn, MD, Male)

Providers, whether in academic or community practice stated that they do not get any additional reimbursement for doing cervical cancer screenings, so there is no financial incentive

driving their screening behavior. However, during the interview with academic providers, they shared their understanding of how community practice providers were reimbursed for screening and they believed those providers were incentivized to not follow guidelines because they got paid for paps.

> When you think about incentives, right? If a private doctor out in the middle of wherever, who's just doing Paps, because Paps are a procedure that they get paid for. There's no incentive not to do that. (Academic Ob/Gyn, MD, Female)

This was found to be untrue when speaking to community providers who confirmed that there is zero financial reimbursement for conducting the screening test since it is the laboratories that get paid for the test, not the providers.

> There is s like zero actual financial reimbursement for actually doing a Pap smear. We don't own our lab. (Community Ob/Gyn, MD, Male)

> We don't get paid for Pap tests at all, we don’t get paid for providing that service. You don't get paid at all for doing a Pap test. We don't get paid for performing it. You don't get paid for the interpretation of it. We don't get paid for calling the patient and discussing over the phone. The only thing we would get paid for would be if it were abnormal, and then they'd have to come back for a colposcopy or further discussion about treatment. (Community Ob/Gyn, MD, Male)

Community providers interviewed felt strongly that the cost to the healthcare system because of misaligned insurance policies and guidelines had to be addressed. This would need to begin with insurance companies refusing to pay for testing not in accordance with guidelines.

These providers acknowledged that in the current healthcare system, insurance companies are not concerned with who needs a pap or who does not and therefore just pay for all screenings whether cytology or cotest, thereby reducing their risk to miss paying for something that was necessary.

> Insurers would stop paying for Paps that were done inappropriately, that would also help. (Academic Ob/Gyn, MD, Female)

> If insurance carriers did like a cost analysis of this- if you extrapolate that over the entire population, like, the millions of dollars saved by not having to do an unnecessary Pap smear- if you put a dollar amount to that, it will raise the eye of insurance companies saying, 'hey, you know what? This isn't being done, number one, and we should stop paying for it'. (Community Ob/Gyn, MD, Male)

Preference for Adoption of Primary HPV Testing

Adoption of the primary HPV test which is done without concurrent cytology was recommended as the newest, third option for cervical cancer screening in the updated 2018 cervical cancer screening guidelines. The adoption of this testing method was discussed with the interviewees and addresses the second research question of the qualitative study to assess provider knowledge, attitude and preference for adoption of this test.

All Ob/Gyn providers that were interviewed shared their thoughts around the primary HPV test. Some had briefly tried offering this test in their practice while others were unsure if it was ever used in their practice.

> I tried for a little while to offer only HPV testing to my patients when that guideline changed and, um, I don't think I had a single patient that took me up on it. Their thought process is 'how do I know that my pap smear is normal if you're not doing

it?' 'Well, you don't actually need to have that information if your HPV test is negative.' But it's just such a shift in thinking. (Community Ob/Gyn, MD, Male)

All providers had knowledge of the testing option, mostly demonstrating awareness that it was part of the newer guidelines but may have lacked familiarity as no one delved into a detailed discussion during the interviews about the evidence supporting the addition of the test as part of the updated guidelines. They all agreed, however, that this test was not broadly utilized in their practice settings.

We are not using it in my practice. I don't know when I would potentially be adopting that personally. (Community Ob/Gyn, MD, Male)

One provider from a community practice stated it would be a great disservice to patients for providers to use primary HPV testing as it assumes the test was collected and analyzed properly and that is just not true in the real world. Cervical screening tests, in his opinion, are highly unreliable and to only rely on the results of the HPV test without cytology, is not something he would recommend doing.

I would NEVER recommend THAT [referring to primary HPV test]. NEVER. I just think it's just something that helps make insurance companies more profitable, but I don't think it does anything useful for patients and I think it's assuming that the test was collected properly, that it was analyzed properly. Everything along the way is an assumption that you're getting a very reliable, accurate results, and I just don't think that's true in the real world. (Community Ob/Gyn, MD, Male)

Another provider from a different community practice shared his reluctance for using this test because he had a few cases recently where the HPV test was negative with abnormal cytology which led to more testing and further follow up found cervical dysplasia. This is an example where without the cytology piece of the test, the HPV testing along would have missed finding evidence of disease. Another provider interviewed had a similar experience to this and this information further validated the clinical importance of doing the pap with HPV testing (i.e., cotesting). In general, the providers' attitude toward the HPV test was that its utilization would not lead to the desired outcome of reliably detecting cervical abnormalities. All of these providers believed their personal experience as a clinician is a major consideration for the type of cervical screening test they decide to offer patients. Providers seemed to have a strong sense of comfort with using cotesting over HPV testing and did not show enthusiasm or have preference for adopting this new screening method at this time.

> There's a certain amount of truth to your own personal experience as a physician, as a clinician, that helps you determine how you want to offer these tests to patients. (Community Ob/Gyn, MD, Male)

Barriers and Facilitators to Guideline Adherent Screening

The interviews with providers generated an analysis of barriers and facilitators to guideline adherent cervical cancer screening which nicely fit within the Cabana framework. Under knowledge, providers from academic practice cited that they believed some providers may lack an understanding of the guidelines by not knowing the details which can be a barrier to adherence. A potential facilitator may be that the current cervical screening guidelines were described to be easy to follow which further facilitates translation of knowledge and implementation in practice. When discussing attitude as a barrier to guideline adherence,

providers' lack of self-efficacy is a barrier, but a potential facilitator of this barrier was described as providers' agreement with the guidelines and guideline evidence. Lastly, under external barrier and facilitators, patient preference is a barrier to guideline adherence because providers must go against guidelines to fulfil the patient's request for screening. However, a facilitator to this barrier is patient education which can help increase patient understanding of guidelines and lessen the amount of patient preference driving provider screening behavior. Table 15 summarizes barriers and facilitators found related to knowledge, attitude, and external factors.

Table 15

Barriers and Facilitators to Guideline Adherence

Category	Barriers	Facilitators
Knowledge	**Understanding and knowing details of the guidelines** "From the provider's perspective, first you have to know what the guidelines are. Then there's the **know the details of why the guidelines are the way they are** because there's plenty of people who come in and say, 'I want a pap', I want a pap every year', or 'I do a pap every year', and so you have to know enough about it to explain why it's the right thing to not screen."(Academic Ob/Gyn, MD, Female)	**Providers find cervical screening guidelines easy to follow** …So many guidelines that can be confusing. You know which part is confusing? It's what do with ASCUS or CIN1, CIN 2 or anything like that. But, with regular pap screening guidelines there is no confusion." (Academic Primary Care, MD, Female)
	"A person [patient] is saying, 'I want this kind of this screening' or 'I want to decrease my risk for cervical cancer', or 'we're supposed to be doing this test.' I think it's **if you don't understand the guidelines enough to explain why you are not doing it.** (Academic Ob/Gyn, MD, Female)	"You have to know what the new guidelines are and get used to them and like you just do it like autopilot." (Academic Ob/Gyn, MD, Female)
Attitude	**Providers lack self-efficacy** "I say to them, 'we want to see you every year'. And, we do have patients, when we recommend that they not have a Pap test after a visit. And I'll have to tell you, it's kind of hard to explain why they don't need a Pap test." (Community Ob/Gyn, MD, Male) "It creates a little bit of a weird dynamic because there are different methods of practicing." (Community Ob/Gyn, MD, Male) "Initially it was hard to convince people that 'oh, my God, 5 years no pap!" (Academic Primary Care, MD, Female)	**Providers demonstrate agreement with guideline/guideline evidence** "I think the screening guidelines are very appropriate. The nature of them being very stepped, there's a very stepped approach to the guidelines and I think there's also a lot of evidence around the nature of the HPV infection for a couple of things. For one, we understand it and the how slowly it can invade the general lower genital track. So, we have a better understanding of why 5 years is appropriate in young women or in 30 plus year old women… But we, I think have a much better idea of why 5 years is satisfactory. We didn't see a change in cervical cancer incidence when we were doing it annually. So, I think the guidelines are very appropriate." (Academic Primary Care, FNP, Female)

External	**Patient preference trumps guidelines** “I tell them what the guidelines are and unfortunately, they'll say, ‘well, you know what, my insurance has been paying for the past 30 years, it's not dangerous for me.’ And I can tell them whatever I want but they'll still request to have it done sometimes.” (Community Ob/Gyn, MD, Male) “There are certainly patients for whom like, if it's been three years and they're like,’ I really want a pap and I have this new partner and I'm really nervous about it.’” (Academic Ob/Gyn, MD, Female) “When you tell a patient that they can wait 5 years between their pap smears they sort of look at you sideways. Like, ‘really is that actually healthy and safe?’ Sometimes there's a request from a patient to actually follow a more frequent testing schedule that's not in accordance with the guidelines.” (Community Ob/Gyn, MD, Male) “I would let the patient decide how they wanted to proceed. So that is definitely an instance where I could end up over testing because they're choosing a pap when they don't need it.” (Community Ob/Gyn, MD, Male) “Patients can often drive the ordering.” (Academic Primary Care, FNP, Female)	**Providers take time to educate patients on guideline recommended testing** “You have to know enough about it to explain why it's the right thing to not screen and you have to have the time to do that. And so that's going to be an academic provider.” (Academic Ob/Gyn, MD, Female). “Usually, it’s a little bit of education. I'll tell them the guidelines are every 5 years. I'll say, ‘you know, it can be done more frequently if you choose to, but you run the risk of being over treated and having unnecessary follow up tests that you wouldn’t otherwise need.’ You know, try and explain to them a little a little bit of the timeline for HPV infection and what our thoughts are in terms of how that'll actually result in abnormal paps or cervical cancer and reassure them that every 5 years is actually safe and okay.” (Community Ob/Gyn, MD, Male) “But, again, there's opportunity for a teaching a patient right there and subsequently I have rarely found them to say, ‘well, I still want the pap and the cotest.’” (Academic Primary Care, FNP, Female)

Mixed Methods Results

Integration of the results from the QUAN and QUAL strands addressed the final mixed methods research question in this explanatory sequential mixed methods study. Research Question: #6: How are determinants associated with guideline adherence and cotesting explained by providers in practice conducting cervical cancer screening? A joint display was used to visually show the qualitative results as explanatory of quantitative findings (Table 16).

The qualitative themes, *"guideline familiarity is dependent on type of provider and organizational setting*" and "*provider demographic characteristics*" explained the quantitative finding that determinants such as provider gender, practice setting, and provider specialty that described the type of provider were associated with cotesting and guideline adherence. Specifically, for gender, males providers had a lower odds of conducting guideline adherent screening compared to females and the majority of interviewees shared that these differences were likely driven by the age of the provider, rather than their gender. They explained that most Ob/Gyns that have been in practice longer tend to be older aged (e.g., 60-70 years old) males and have been observed to be slower in adopting cotesting and following current guidelines with extended screening intervals. This explanation of quantitative findings about gender differences demonstrated *expansion of* data and offered an additional angle to help explain why the gender of the provider influenced use of cotesting and guideline adherence. The organizational setting, or practice type, is another variable that described the type of provider and was found to be associated with cotesting and guideline adherent screening. The quantitative results showed that community providers had a lower odds of conducting guideline adherent screening compared to academic providers. The interviewees explained that this was a finding that was expected and not surprising to them as they noted providers who are in community practice tend to have more

flexibility and freedom to practice as they choose whereas academic providers are more apt to follow recommendations. This data integrations demonstrates *confirmation* of the QUAN and QUAL results. Finally, the third variable that described the provider type is the provider specialty. In the quantitative study, the provider's specialty was associated with conducting cotesting and showed that primary care providers had a lower odds of conducting cotesting compared to Ob/Gyn & Midwifery providers. Primary care providers interviewed acknowledged that they could miss ordering a cotest due to difficulties in locating the order in the EMR and explained that because primary care providers were responsible for taking care of so many different clinical issues, being on top of cervical cancer screening was not their primary focus. Ob/Gyn providers expanded on these results by explaining that as specialty providers they have greater knowledge and familiarity of cervical screening guidelines because that is what they spend most of their time doing and learning about. They agreed with primary care providers' explanation that it was not possible for providers to keep up to date with changing guidelines in many different clinical areas so it was understandable why non-specialty providers could miss ordering certain tests. These explanations by the interviewees demonstrated *confirmation* and *expansion* of the quantitative data.

Table 16

Joint Display

Qualitative Theme: *Guideline familiarity is dependent upon type of provider and organizational setting*		
Provider gender		**Fit of data integration**
Male providers have a lower odds of guideline adherence and cotesting compared to female providers	I wouldn't be surprised if there was an age variance amongst the practitioners… within my own practice, a lot of the older providers definitely were much slower to pick up cotesting.	Expansion
	Females, but really, it's age of female. I'm saying that because in Ob/Gyn there's so many more women. So, not all men, but more of the men are, I'm going to call them "leftover men", like they've been Ob/Gyns for a long time. I think that's the factor, not that they're male.	
Practice type		
Community providers have a lower odds of guideline adherence and cotesting compared to academic providers	The difference in screening between academic and community practice sites does not surprise me.	Confirmation
	So, you have to know enough about (the guidelines) to explain why it's the right thing to not screen and you have to have the time to do that. And so that's going to be an academic provider, because a community provider either doesn't know or knows but doesn't have time to put a fight. And just like it's just faster to do it.	
Provider specialty		
Primary Care providers have a lower odds of cotesting compared to Ob/Gyn providers	It's harder to keep up with newer guidelines. So, you keep up with newer guidelines in your own specialty.	Confirmation/Expansion
	Sometimes it's just an EMR ease, you know. So, I'm not surprised. I'm not surprised at all.	
	I'm sure there are primary care things that I'm doing wrong, but the primary care doctors are doing right. Because it's not my like, the thing I'm spending the most time on…learning about.	

CHAPTER 5

Discussion

Introduction

As described in the literature review of this dissertation, provider use of evidence-based screening guidelines for cervical cancer prevention have been reported to be inconsistent with screening recommendations for average-risk women aged 30-65. Since their issuance, current empirical data on the uptake of 2012 cervical cancer screening guidelines by providers specifically to the recommendation to screen women aged 30-65 using cotesting within the extended 5-year screening interval have not been well explored in the literature, limiting our understanding of the uptake and adherence to these guidelines in practice. It is well established that screening recommendations are not optimally translated into practice and reasons for why this may be happening must be explored and addressed to move toward improvements in care for patients and reducing costs in the healthcare system. Using quantitative and qualitative data, the purpose of this mixed-methods research study was to evaluate the extent to which cotesting was being used by providers in the George Washington (GW) Medical Faculty Associates (MFA) since the issuance of the 2012 cervical screening guidelines, to assess adherence to the extended 5-year screening interval, and to identify the patient, provider and practice determinants associated with cotesting uptake and guideline adherence. To obtain a more complete understanding of cervical cancer screening practice, providers were interviewed for their insights

on the current cervical screening guidelines and the barriers that prevent them from following recommendations. The following research questions were addressed:

1. Beginning in 2012, what is the reported uptake of cotesting, (cytology (Pap test) plus human papillomavirus (HPV testing), among average-risk women aged 30-65 eligible to receive routine cervical cancer screening within an urban-based clinical practice setting?
2. What is the screening interval between two negative cotests for women receiving routine cervical cancer screening?
3. What are the patient, provider and practice determinants associated with guideline adherent screening interval and cotesting use?
4. How do providers in different practice settings describe multilevel barriers to guideline adherence?
5. What are the knowledge, attitudes, and preferences of providers toward the adoption of primary HPV test (without concurrent cytology) as another option for cervical cancer screening as recommended by the updated 2018 cervical cancer screening guidelines?
6. How are factors associated with cotesting uptake and guideline adherence explained by providers in practice conducting cervical cancer screening?

This chapter will discuss the major findings, limitations, and translational impact of this dissertation study. It will also suggest recommendations to consider for future research that can address cervical cancer screening guideline uptake and adherence in clinical settings.

Major Findings of the Dissertation

Cotesting Increased

This study was conducted using practice-based data from patient electronic health records (EHRs) to evaluate the uptake of cotesting since issuance of the 2012 cervical cancer screening guidelines. This study was able to provide an objective assessment of screening in practice compared to prior studies that have relied on self-reported surveys without laboratory confirmed testing, claims data, or clinical vignettes to estimate uptake of cotesting (Perkins et al., 2013; Roland et al., 2011; Silver et al., 2018; Yabroff et al., 2009).

Since the issuance of the 2012 screening guidelines recommending cotesting for women aged 30-65 as the preferred screening method, the data showed that cotesting was adopted at a high rate by providers in the GW MFA health system with 94.9% of the study sample receiving at least one cotest. This indicates that this was a highly cotest adherent population.

Adoption of cotesting at GW MFA showed a gradual increase over an eight-year period as it increased from 68.7% of patients receiving a cotest in 2012 to 97.3% in 2020. This upward trend indicating increased cotesting was statistically significant, and we would expect the proportion of cotesting to remain high at GW MFA in 2021 and beyond compared to pap testing (without HPV testing). The increased use of cotesting further signals another important change in cervical cancer screening practice which is the movement away from providers conducting annual pap testing, which is no longer recommended by any organization issuing cervical cancer screening guidelines.

The increased trend in cotesting uptake was similar to a hospital-based study conducted in Olmstead County, Minnesota which showed an increasing adoption of cotesting from 10.0% in 2007 to 60.8% in 2016 (MacLaughlin et al., 2019). This dissertation study, however, showed

an even higher proportion of cotesting in 2016 (85.4%) compared to Olmstead County in 2016, suggesting a faster rate of adoption. The New Mexico HPV Pap Registry (NMHPVPR), a population-based surveillance system for cervical cancer screening and outcomes in the state of New Mexico also recently reported an update on the trends observed in the use of cotesting among women aged 30-64 from 2008 to 2019 (Castle et al., 2021). In 2012, NMHPVPR reported 19.1% of women had received cotesting, and this increased to 84.3% in 2019. These upward trends in cotesting use suggest cotesting adoption was achieved across various health systems since the issuance of the 2012 guidelines. This finding was further validated in the qualitative interviews conducted with providers in this study who all (with the exception of one provider) stated that cotesting was the *only* test they *ever* used for women aged 30-65 because they knew it was within the recommended cervical screening guidelines.

When cotesting uptake was compared by age groups, the NMHPVPR found a slightly higher cotesting uptake in 2019 in the younger age groups (85.5% at ages 30-39 years, 85.2% at 40-49 years and 82.5% at 50-64 years). In another study (Wright et al., 2021) evaluating women who were recently screened for cervical cancer, 37.8% received cotesting. When compared to women aged 30–39 years, the prevalence of cotesting was also lower among older women aged 40-65. The dissertation study showed a very different result from these two studies. In the dissertation study, when cotesting uptake was compared by age, the youngest age group had the lowest uptake (93.2%) but an increase in uptake occurred with increasing age and the oldest age group aged group (60-65) had 96.9% uptake of cotesting. This finding in the dissertation study was surprising because in contrast to the literature and to what was learned in the qualitative interviews in this study, older patients who may be seeing older aged providers more often get annual pap testing and not cotesting.

The 30-39 year age group in the dissertation study with the lowest uptake of cotesting also included a higher percentage of Black and Non-Hispanic women (30.0%) relative to other age groups and Black and Non-Hispanics had the second lowest uptake of cotesting (93.6%) compared to other racial groups in this study. Also, it is possible that the COVID-19 pandemic contributed to gaps in screening that may have impacted this younger age group more than others from not being able to return for in-person visits for screening/care thereby reducing the number of screening tests in this age group.

Results for the uptake of cotesting found in this study compared to other studies that have studied cotesting uptake since the issuance of the 2012 screening guidelines show similar trends in increased uptake, suggesting the findings of this study are robust. A study (Goding Sauer et al., 2020) using 2016 Behavioral Risk Factor Surveillance System (BRFSS) data looked at geographic and sociodemographic differences in cervical cancer modalities and found that the prevalence of cotesting in the District of Columbia (DC) was higher (49.9%), than the national estimate. Additionally, Northeastern and Western states had a higher prevalence of cotesting than Midwestern and Southern states. They also found that cotesting was more common among those with higher levels of education and younger women. Further, the Northeastern states reported having a higher proportion of college-education women. Related to the women's age, they speculated that younger women may be more likely than older women to accept cotesting and its longer screening interval (Saraiya et al., 2018). The findings from these studies related to sociodemographic differences and cotesting uptake in the Northeastern U.S. may help explain the high rate of cotesting occurring in D.C which resides in the Northeastern part of the U.S. Level of education for the women in our study was not data that was collected or analyzed but could also help explain the uptake of cotesting. Overall, the results from this dissertation study suggest that

the use of cotesting has proven to be a well-established screening method that has been adopted by providers in a health system in D.C. similarly to cohorts of women in other geographic locations such as Minnesota and New Mexico. Results from several earlier studies that were conducted about the adoption of cotesting (MacLaughlin et al., 2019; Silver et al., 2018; Watson et al., 2018) suggested there was early adoption for this method of screening. The findings of this dissertation study confirmed that the early adoption that began since 2012 was sustained.

Extended 5-Year Screening Interval

Screening guidelines are multifaceted and *adherence* to guidelines means to adhere to all aspects of the recommendation, not to only certain components. Cervical cancer screening guidelines include the age to start and stop the screening, the type of screening test and the age for which it is recommended, and the frequency (i.e., interval) to follow between tests. The extended 5-year screening interval which is recommended for women receiving cotesting is an important component of the 2012 cervical cancer screening guidelines for women aged 30-65. It is not sufficient for providers to select only parts of screening guidelines to utilize. In addition to choosing the correct test, providers must also screen at the recommended interval. Non-adherence to guideline recommended screening intervals leads to over or under use of screening and downstream physical, psychological and medical consequences, as well as significant costs to the healthcare system (Kamineni et al., 2022; Wright et al., 2021). The limited data describing the rates of provider adherence to the 5-year screening interval in the literature (MacLaughlin et al., 2011; Perkins et al., 2013; Silver et al., 2015; Silver et al., 2018; Teoh et al., 2015) contributed to a lack of knowledge around provider screening practice since the issuance of the 2012 guidelines and was an important research question addressed by the dissertation study. The

dissertation study also addressed the question of the actual screening interval that was occurring for patients om the GW MFA system with two negative cotests and found the median screening interval of 36.0 months (or 3-years) between cotests. This shortened interval is *more frequent* than the modified, study defined guideline recommended interval for appropriate screening of 60-months (or 5-years) plus or minus 6-months set for this study and suggests overscreening. This finding was not surprising because providers interviewed in this study expressed that patients often requested more frequent screening and providers were compelled to comply with patient requests. It was also felt that waiting 5-years felt "too long" between tests and 3-years was a "more comfortable" interval and easier to remember for providers and patients. There is no benefit to more frequent screening as shown by modeling studies that indicate that performing screening tests more frequently than every 3 years for cytologic examination or every 5 years for HPV-based testing is associated with significantly increased rates of colposcopy with little association with the incidence of cervical cancer (Wright et al., 2021). Only 13.8% of women who underwent cotesting in the dissertation study were adherent to the study defined screening interval of 54-66 month (or 4 year and 6 months to 5 year and 6 months) which was similar to the findings from the NMHPVPR in 2019 which reported 13% of women aged 30-64 underwent cotesting at the recommended 5-year screening interval (Castle et al., 2021). These findings emphasize that not all components of cervical cancer screening guidelines are being adopted by providers, particularly the screening interval which is contributing to overscreening.

Overscreening

This study found that 85.8% of patients screened outside of guidelines and 14.2% were screened in concordance with guidelines. The rate of screening outside of guidelines found in the study was *higher* than reports from prior studies which found that 40% of providers performed

cervical cancer screening outside of guidelines (Haas et al., 2016). It was initially hypothesized that overscreening would occur in this study and this was found to be true based on the results of this study that showed that 75.1% of the study sample was overscreened. Again, this rate of overscreening was higher when compared to results of national surveys which indicated that overscreening is common, with 50-65% of women overscreened (Franklin et al., 2020). Providers interviewed in this study articulated that overscreening is the norm in their practice and essentially "everyone [referring to providers] does it", despite knowing what the guidelines recommend.

Harms of Overscreening

The harms of cancer screening must not be overlooked as there should be consideration for patient and provider-level harms but also harms to the system level, such as financial or other costs to the health system through screening inefficiencies or waste (Kamineni et al., 2022; Wright et al., 2021). Harms caused to individual patients by overscreening contribute to overtreatment of lesions and a cascade of additional tests and procedures for transient infections or low-grade abnormal findings, psychological stress, and adverse pregnancy outcomes including preterm birth (Kamineni et al., 2022; Wright et al., 2021). These subsequently contribute to harms at a system level through increased healthcare costs (Lee et al., 2022). The economic consequences to the health care system of performing testing that is minimal benefit to the patient cannot be dismissed (Wright et al., 2021).

Individual level harms were clear and acknowledged by providers interviewed in this study- but system level harms were not discussed. Screening decisions are individual level decision made between providers and patients. This individual level decision making contributes to the complexity of applying formulaic screening guidelines that are designed for population

level implementation but being applied differently based on the provider or patient preference. Providers cannot apply a "one size fits all" approach to screening and must weigh the "tradeoffs between competing benefits and harms, and risks of different options for managing the disease, clinical applicability and context, values and preferences of those of whom the recommendations are provided (providers, patients, and developers), organizational needs and costs, and implementation feasibility" (Kastner et al., 2015). Qualitative interviews with providers emphasized that there can be financial consequences to the practice if providers start to lose patients because they refuse to provide them with a pap test that they feel they should receive at their annual visit. Despite providers taking time during clinic visits to explain testing options based on current screening guidelines, some patients still want to receive annual screening because that is what they believe is needed during a preventive care, especially since insurance plans will not deny coverage for annual pap. These practical issues to implementing guidelines should be addressed during the guideline development process because this step can help predict and try to ameliorate these practical issues to increase compliance and uptake.

Multilevel Barriers to Overscreening in Community Practices

To dig deeper into understanding what factors in this study may have been driving overscreening, a sensitivity analysis was conducted and found that the odds of overscreening were 3.86 times higher for patients seen at community practices compared to academic sites. The study did not delve into practice characteristics to determine what specifically about community practices might be driving this behavior, however, the discussion of multilevel barriers to guideline adherence with providers does give some insights into explaining this finding within the context of this study.

At the individual level, providers delivering cervical cancer screening within community practices perceived screening to be more heterogeneous. They based the decision to screen on individual women preferences and their own perceptions of the necessity of screening, which influence whether screening is conducted, the mode of testing and the frequency. The provider's lack of knowledge of guidelines can serve as a barrier to adherence because knowing the details of when to start or stop screening based on the patient's age, the mode of testing, and how often to screen can be ignored. This is especially true in community practices who do not have institutional pressure to stay up to date with changing guidelines nor an expectation for all providers to follow guidelines in the same way. It was acknowledged by many community providers interviewed in this study that it was acceptable for providers to practice the way in which they felt comfortable. Their practice habits were developed when they were trained, and the habits they had developed which were difficult to change. Other individual level provider demographic characteristics, such as the provider's age, could also influence knowledge of guidelines. Some of the providers interviewed believed that older aged providers who have been practicing over a long period of time, will stay with their old practice behavior, such as annual screening, even though guidelines have changed and now recommend against annual screening. There was an interesting pattern that emerged from the qualitative data that suggested the longer the provider had been in practice, the less familiarity of guideline content they showed. While data on provider age and numbers of years in practice were not collected and analyzed as part of the quantitative dataset, it is possible that the age and years in practice of providers between academic and community practices differed and community practices were comprised of older aged providers. This could potentially offer a possible explanation for why in this study community practices reported a higher odds of non-guideline adherent screening (i.e.,

overscreening/underscreening) which also relates to lack of guideline knowledge and being driven by their past training and habits, as suggested by the qualitative results.

At the organizational level, within community practices, it was reported that lack of institutional constraints or "freedom to practice" could also be a barrier to guideline adherence and subsequently lead to overscreening. Academic practices were described to be "more strict" and there was an expectation for providers to practice in the same way, with lesser flexibility and variability across providers. Academic practices (or academic medical centers) combine research, education and patient care and may have access to more resources and cutting-edge technologies than community practices. These differences between academic and community practice settings influence provider behavior and the way screening and preventative care is delivered to individual patients and subsequent health outcomes.

The role of system level barriers, particularly the role of insurance plans/payor policies and their misalignment with current cervical screening guidelines are potential contributors to overscreening. For cervical cancer screening, insurance carriers have not updated their reimbursement policies to match guidelines that no longer recommend annual screening. This leaves providers with minimal financial disincentive to perform more frequent testing. Some patients desire to be more frequently tested because they know insurance covers annual screening and they don't believe the screening test (although not needed) will result in any direct harm, physical or otherwise. There is also fear that an abnormality may be missed with less frequent screening. Providers also find it easier just to perform the screening if the patient asks for it rather than spending time to educate them about why the test is not needed due to limited time during a clinic visit. Some providers interviewed shared that they have observed patients disengage from all gynecological care when screening intervals are extended. Patients think that

if they don't need to be seen for "a pap", they don't need to be seen by the provider at all. This may lead to missed pelvic exams, breast exams, and other important evaluations.

Overuse of screening is expensive for the health care system (Sawaya et al., 2015) because it increases the potential for unnecessary exams and procedures. However, this is not at the forefront of discussions within organizations and at the system level. In a study examining overscreening in women under 21 and over 65, the estimated cost of unnecessary healthcare expenditures for Pap testing using $50 per pap test outside of expenditures for office visits or other costs was $545,900. While this figure does not account for those within the 30-65 age range that may be overscreened, it does give an indication for the excessive and unnecessary spending that can be reduced with better policies for cervical cancer screening at the system level.

Influence of Determinants on Guideline Adherent Screening Interval and Cotesting

Whether or not average-risk women aged 30-65 received cotesting and additionally pap or cotesting that was guideline adherent (i.e., conducted within the appropriate study defined screening interval), could be influenced by multilevel determinants at the patient, provider or practice levels.

There are other studies that have been conducted in cancer and cardiology that are similar to this dissertation study and have tried to identify determinants that influence guideline adherence. A recent study (Haas et al., 2022) evaluated variations in cervical cancer screening using cotesting compared to pap that are influenced by multiple levels such as the individual, provider, clinic/facility, and healthcare system using administrative health data from three diverse health systems. They posit, "the choice of a particular screening test is generally made by the provider but may be influenced by factors from multiple levels…" Another study by McKinlay et al (2007) also studied provider adherence but for coronary health disease (CHD)

diagnostic and treatment guideline used by primary care providers. They evaluated the influence of patient attributes (age, gender, race, socioeconomic status) and physician characteristics (gender and years of clinical experience) on CHD guideline adherence. While we acknowledge there are some differences in evaluating screening versus diagnostic and treatment guidelines, the findings from this study extend the results of this dissertation study focused on screening and corroborate some of the findings.

In this dissertation study of cervical cancer screening, no patient-level determinants (age, race and ethnicity, insurance) were found to be significantly associated with cotesting or guideline adherent screening which is somewhat consistent with the findings of Haas et al (2022) that found patient age, race, risk status and insurance were generally less strongly associated with receipt of cotesting. McKinlay and colleagues (2006) found the patient's gender and age to be influential to how providers applied guidelines, but not the patient's race. In the dissertation study, however, patient's age showed a borderline significant P-value (p=0.054) in the multivariable regression model for cotesting, suggesting there was some relationship of the patient's age with receiving cotesting. When this relationship was explored further, we found that the oldest age group (60-65) had the highest odds (OR=3.87) of cotesting compared to the youngest age group (30-39). There was a pattern of increasing odds of receiving cotesting from age ranges 40-49 (OR=3.20) to 50-59 which dipped to slightly lower odds (OR=1.87) but still higher when compared to the youngest age group (30-39). This result may have been indicative of older patients in this study staying within the GW MFA healthcare system and consistently returning for follow-up care. Qualitative interviews with Ob/Gyns in the dissertation study also stated that that they believed that patients who presented to care regularly are often the ones that get screened more by providers, and older patients, in their experience demonstrated this

behavior more than younger patients. In a study conducted by Franklin et al (2020) evaluating overscreening, they also found that "patients highly engaged with the health system are easy to reach and may be more amenable to preventive health measures." Lastly, a patient's age is criteria that should factor into the provider's recommendations for the screening strategy since age to start or stop screening must be considered when choosing a screening modality. However, providers may unknowingly be screening some age groups more or less frequently based on their own biases for guideline adoption (McKinlay et al., 2007).

Other significant determinants that influenced cotesting in this study were provider gender, practice type, and provider specialty. Guideline adherence was also associated with provider gender and practice type. Specifically, male providers had a lower odds of conducting cotesting as well as screening withing the guideline adherent screening interval. This finding was surprising and one that providers in the qualitative study did not agree with. Male gender was thought to *not* be the driver for having a lower odds of conducting cotesting and guideline adherent screening, but rather it was the age of the provider driving this association. Age of the provider was not collected in the dissertation study and could not be analyzed. When McKinlay and colleagues (2006) evaluated provider gender in their study, their findings did *not* show a main effect by physician gender related to guideline adherence, unlike our study that *did* find an association by provider gender. However, McKinlay and colleagues (2006) did find that the physician's level of experience was significantly associated with provider guideline adherence. In general, providers in McKinlay and colleagues' study were older/more experienced and were more likely to inquire about symptomatic factors and order more testing compared to less experienced physicians. This does suggest that perhaps there may be a correlation of provider age with years of experience, though provider age was not collected in their study so this can

only be speculated. One other important finding from McKinlay and colleagues study that corroborated results from the dissertation study was that less than 50% of physicians would only adhere to 2/3 of the specific recommendations. This finding helps explain what was learned from our study which is that while providers may be adherent to the age and type of screening test recommended by guidelines, they do not adhere to the recommended screening interval component of the guidelines, demonstrating partial guideline adherence.

Practice Type and Organizational Level

The practice type in this dissertation study was associated with both cotesting and guideline adherent screening interval and closely relates to what is described in other studies as the organizational/clinical level (Haas et al., 2022). Community practices had a lower odds of cotesting and screening within recommended screening intervals compared to academic practice. Community practices also had a higher odds of overscreening compared to academic practice. While we did not explore characteristics at the clinic level to be able to explain what practice variations may have contributed to these effects, this finding is consistent with Haas and colleagues (2022) that also found that clinic/facility and system level factors were associated with receiving cotesting across three diverse health systems. These findings illustrate that the influence of organizational characteristics and system level policies drive differences in how cervical cancer screening gets adopted, more than individual patient factors. In qualitative interviews with providers in this study, they acknowledged organizational level and system level barriers as a hinderance to providing guideline concordant screening which supports what is learned from Haas and colleagues (2022).

Delays in Adopting Primary HPV Testing

This study was designed to evaluate the uptake and adherence to the 2012 guideline recommendations but the release of revised 2018 cervical cancer screening guidelines by USPSTF and several professional and medical organizations provided an opportunity to explore its early adoption with providers interviewed in this study. In 2018, 6-years after the 2012 cervical cancer screening guidelines were issued, an updated version was released to include a third, new option of primary HPV testing every 5 years for average risk women aged 30–65 years. Cotesting was still recommended every 5 years, and Pap testing every 3 years. While an added option for primary HPV testing provides patients and providers more choice to choose a screening test, it also adds to the growing complexity and confusion of having too many screening options within guidelines which have become entangled due to constant revisions and issuance by multiple organizations. Providers are faced with managing the multiplicity of clinical guidelines from various professional organizations and staying abreast of changes in these guidelines (Thompson et al., 2020). During the period in which this dissertation study was conducted, the GW MFA academic and community providers had not implemented primary HPV testing for cervical cancer screening, so the results of this study are not impacted by the updated guidelines.

All Ob/Gyn providers interviewed in this dissertation study were aware of the new screening option for primary HPV testing but not enthused about its implementation in their practice. Some non-GW MFA affiliated community providers interviewed stated they had tried offering it to their patients briefly, but patients resisted and questioned how a test that was *not* collecting a pap could ensure they were no abnormalities that were missed. Despite providers explaining why the primary HPV test was sufficient without cytology and safe, patients were not willing to accept it. One provider shared a recent experience with a patient who tested negative

on HPV but an abnormal pap with further testing revealed cervical dysplasia. This experience diminished the provider's confidence in adopting the primary HPV test. In general, providers strongly believed that their own personal experience as a clinician is a major consideration for the type of cervical screening test they decided to offer patients, despite guideline recommendations. Another provider stated he believed that cervical testing is highly unreliable and just relying on HPV testing without cytology is not safe nor something he would *ever* recommend to his patients. This provider still did annual pap testing and only offered reflex HPV testing which was highly discordant with current guidelines. This behavior signaled a lack of agreement with the latest guideline recommendations for primary HPV testing. Although providers did not delve into discussion around the evidence that was used by guideline makers to generate this new recommendation for screening, there was not any disregard or disagreement voiced for the data that led to the new recommendation. Providers were mostly concerned with missing an abnormality that could lead to cancer if cytology was not performed with the HPV test. Providers were also unclear about how to transition patients from cotesting which still included a pap to a test that did not include that component and how to have that discussion. Overall, discussion around adoption of primary HPV testing with providers suggested they would be delaying or not adopting primary HPV testing since cotesting remained an acceptable screening option per the guidelines. Providers were in agreement that they will continue to screen patients with the test that they are most comfortable delivering, whether guideline concordant or not.

Implementing guidelines requires providers to balance multiple competing interests. This includes individual patient preferences, their own clinical experience, habits, and knowledge on top of organizational constraints of time, resources, and multiple demands in practice. These are

embedded in a complex and fragmented system of care with misaligned policies that drive payment and reimbursement and do not incentivize guideline concordant cervical cancer screening.

Limitations

This research has several limitations which may impact the results of this study. First, for the quantitative study, the use of EHR data for research, incomplete cervical screening data for 2019, and inability to account for clinic level clustering. Second, the COVID-19 pandemic which began in March 2020 also severely impacted the originally designed qualitative portion of the study and contributed to some major changes in its execution due to limited access to research participants during a pandemic. Third, the sample selection for the qualitative study was small and only recruited providers limiting this study to a single stakeholder perspective to understanding the research problem.

Data Collection and Analysis

While the use of EHR data for conducting objective research for large population-based studies such as this one is ideal, there are real challenges to accessing, retrieving, manipulating and cleaning these data to prepare for research. It is important to keep in mind that these data are intended for clinical care, and have limitations in quality, accuracy, or completeness. There may be errors in the EHR we did not account for that could affect research results.

This study was conceptualized in 2018 to evaluate cervical cancer screening conducted at the GW MFA between 2012-2018, a 6-year period. When the query was run to retrieve all cervical screening visits for this period by the information technology (IT) staff at GW MFA, it inadvertently included screening visits through June 2019. While including data for 2019 in the study was not the issue, the query only captured 6-months of screening visits that had occurred in 2019 thereby underreporting the actual number of screening visits for 2019 through

December 2019. This likely explains the large reduction in number of screening tests for 2019 compared to previous years.

The practice site was found to be important determinant associated with guideline adherent screening and cotesting. There were 23 community sites represented in this study, but the analysis for determinants could not be done at the clinic level which did not allow us to understand any practice wide variations based on location of the clinics. Our understanding of community site practice behavior in this study could have been enhanced if the data were analyzed at the clinic level.

While the study sample size was robust, it was not generated to account for subgroup analysis which if done, could have allowed the study to look for differences in outcomes by different patient or provider factors. This lack of analysis may have added additional valuable information about the determinants associated with the study outcomes.

Lastly, there was an opportunity to evaluate guideline adherence screening for women under 30 or over 65 who received cotesting in this study to provide a more comprehensive assessment of screening practice in the GW MFA health system and enhance the results of this study. This was outside the scope of this research study but presents an opportunity for future analyses with these data. Other research studies have found that women aged 25-29 for whom ***only*** cytology screening is recommended were screened by cotesting (Castle et al., 2021), which is ***not*** guideline adherent screening. This finding suggests that there may also be more non-guideline adherent screening being conducted in the GW MFA health system that could be explored.

COVID-19 Global Pandemic Impact on Preventive Screening

Disruption to preventive care services during the COVID-19 pandemic must be acknowledged because of the impact it had on patients returning for screening visits, affecting

cervical cancer screening uptake, and screening intervals evaluated in this study. Cervical cancer screening tests reported in 2020 were likely lower than those in the pre-pandemic period because of social distancing requirements, patients fearful of going to health care facilities and Primary Care and Ob/Gyn providers prioritizing caring for sick or pregnant patients over routine preventive screenings. Patients may have lengthened their screening intervals by skipping a screening test that was due in 2020. It is also possible that some patients in this study that had only a single healthcare visit with a cervical cancer screening test in the EHR may not have had an opportunity to return for future health care visits due to the disruptions to healthcare caused by the pandemic in 2020.

Qualitative Study Changes. The original qualitive study was designed to interview providers and patients across two health systems but could only recruit providers from one health system. The inclusion of two health systems and patients was intended to provide a richer inquiry into the barriers to cervical cancer screening and also triangulate data collected from the providers, however this was not possible, and this study converted to a small pilot study in single health system with only providers. The original sample size goal was to get 15-20 participants, but this became impossible during the pandemic. First, patients were removed from the study design and only providers were included. Participating in research during a public health emergency was a low priority for busy clinicians who were overworked and burnt out, so recruitment was another challenge. The study switched to convenience sampling, which was the most expeditious way to recruit, but may have introduced researcher bias into the sampling technique. A maximum sample size of 7 was reached and this was smaller than anticipated. We also were not able to recruit any females from community practices and males from academic practices to interview which does lend to some gender imbalance between the

practice site providers interviewed. Lastly, by interviewing only providers, this study offers a single perspective on barriers to guideline adherent cervical cancer screening which may be biased toward patients and practice leaders who were not part of the research design. Transferability of results from the qualitative study must be done with caution as they may not apply to other similar health systems.

Member checking is a technique used in in qualitive research to enhance the trustworthiness of the study and enhance credibility of the results. The study had originally planned to send each interviewee their interview transcript to check for accuracy and resonance with their experience. Due to time limitations, this step was not done and is acknowledged as a limitation to the study.

Translational Impact

This study was designed to evaluate both the T3 and T4 chasms; implementation of population-based cervical cancer screening guidelines by individual providers to assess adoption in practice (T3) and progress toward population health impact (T4). Knowledge gained from this study addressed the question of uptake and found cotesting was a highly adopted method for screening in the GW MFA health system, as recommended by the 2012 cervical cancer screening guidelines. However, we also identified some deficiencies in complete translation of guidelines in practice which confirmed that while cotesting was a guideline recommended cervical cancer screening test being used by providers for screening women aged 30-65, it was not being delivered to patients in accordance with the 5-year screening interval. This demonstrated partial adherence to aspects of cancer screening recommendations including the age and test type, but not to the frequency (i.e., interval) of testing. This lack of adherence was explained by providers to result from barriers related to provider knowledge of guidelines, attitude toward guidelines

and external barriers related to insurance/payor policies outside of the provider's control at the system level. Barriers at the system level impede bridging the chasm from T3 to T4 and require translational researchers to focus efforts on designing system level interventions to effect change at the individual and organizational levels that promote non-guideline adherent screening. Additionally, new knowledge that was gained from this study relates to how guideline development for future cervical cancer screening could be improved by incorporating implementation feasibility in the guideline development process. The process of reciprocal translation (Drolet & Lorenzi, 2011) and a feedback loop is necessary to address guideline development to reevaluate T3 to understand why providers are not screening as recommended by guidelines. Moving cancer screening in the U.S. away from opportunistic screening toward an organized screening approach will help align population-based screening guidelines with the goal of achieving better health at the population level and ultimately bridging T3 to T4 for complete translation across the biomedical research continuum.

Recommendations

Prevention and early detection of cervical cancer through screening using evidence-based guidelines is a shared goal among providers and their patients. It is also a critically important outcome for healthcare systems trying to balance quality care with rising costs and spending, minimizing risk and maximizing benefit of screening strategies alongside national experts in prevention and evidence-based medicine who are responsible for evaluating the latest research evidence and making recommendations. Guidelines, when applied appropriately, have the potential to facilitate the implementation of evidence into practice, support clinical decision making, influence public policy (Kastner et al., 2015) and improve population health outcomes. However, the results of this dissertation study suggest that these potential benefits may not be consistently

achieved under the current system for guideline implementation as evident by the low rates of guideline adherent screening, and reluctancy of providers to implement cervical cancer screening systematically despite national recommendations. There are and will continue to be unintended consequences that result from applying an individualized level approach to cervical screening guideline implementation which - despite being generated using the best available evidence - lacks feasibility and practicality for its end-users. This study proposes considering implementation feasibility as part of the guideline development process and introducing system level interventions to address barriers to population-based screening. A movement toward organized screening without multiple versions of guidelines on the same topic to guide the future of the next generation of cervical cancer screening in the U.S. is recommended.

Addressing Implementation Feasibility in the Guideline Development Process

There are some obvious gaps in our process for how national population-based guidelines are developed and implemented in the U.S. which may be potentially contributing to the lack of adoption and acceptance by providers who are the intended audience for their use. Under the current guideline development process for screening, data from randomized controlled trials conducted under well controlled conditions are used to generate evidence for the efficacy of the screening intervention. Moving this evidence for use into real-life settings requires understanding the end-user (patient, providers, organizational leader) in conjunction with the various influences that will impact the implementation of the screening intervention, however, the emphasis seems to be more toward ensuring guideline credibility rather than implementability. Other research being done in this area using the AGREE-REX tool (Florez et al., 2020) reports, “high-quality clinical practice guideline (CPG) processes, although necessary, are not always sufficient to yield individual CPG recommendations that are clinically credible and implementable.” Screening

guidelines for cervical cancer screening have not been fully implemented as evident by the results of this study's qualitative work. This aspect, which was referred to as *guideline implementability* (Kastner et al., 2011; Shiffman et al., 2005) is described as "the perceived characteristics of guidelines that predict the relative ease of their implementation." Characteristics demonstrating a lack of guideline implementability were addressed by the conceptual framework, *The Knowledge, Behaviors, and Attitude Framework* (Cabana et al., 1999) used in this study to assess barriers to guideline adherence through provider interviews. While most providers did agree with the evidence supporting the use of cotesting and the extended screening interval, they made screening decisions that were individualized to the patient using the method or interval which they thought was best, driven by inertia of their previous practice, training and education, patient's preference, competing demands for time, balance of risk and benefit, and insurance policies, payment structures, and the organizational context in which they deliver care. Many times, this was not concordant with guideline recommended screening. Without any overarching screening policies at the organization or system level to mandate a uniformed approach to screening, providers are left to apply individual decision making to screening which has led to an overwhelming amount of non-guideline adherent screening as seen in this study. These practical issues may be accounted for during the guideline development process so that the end-users of the guidelines do not continue to remain in a cycle of delivering guideline discordant screening to patients in practice and guidelines are developed with feasibility of implementation in mind.

Too Many Cervical Cancer Screening Stakeholders and Guidelines

Numerous stakeholders are involved in the development and use of cancer screening guidelines which lends to multiple guidelines existing for the same disease with differences

between guideline recommendations. This variability between guidelines contributes to confusion among the end-users who are implementing guidelines, less cost-effectiveness and poor-quality screening due to over and under screening. For cervical cancer screening in the U.S., guidelines are issued by the following *7 key player organizations* which consist of government agencies, clinical specialty societies, disease-specific societies, and international organizations. Private organizations such as Kaiser Permanente also have an internal organization dedicated to guideline development for preventive and chronic care conditions, which includes cervical cancer (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, 2011).

- American Cancer Society (ACS)
- American Congress of Obstetrics and Gynecology (ACOG)
- American College of Physicians (ACP)
- American Society of Clinical Pathology (ASCP)
- American Society of Colposcopy and Cervical Pathology (ASCCP)
- U.S. Preventive Services Task Force (USPSTF)
- World Health Organization (WHO)

These guidelines vary in the degree to which they are based on existing evidence, and they can be influenced by the underlying interests of the issuing organization. Organizations follow different policies for their conflict of interest of members who are part of guideline committees and review and rating of evidence. Some rely on systematic reviews like the USPSTF, while others draw upon consensus statements, expert opinions, literature reviews or conferences/meetings. They differ in the number of resources for guideline development and have varying experience. With so many entities with differing interests, opinions, and audiences

issuing guidelines on a single topic like cervical cancer screening, there is no surprise that there is variability in uptake and adherence to cervical screening guidelines across patients, providers, organizations, and health systems. As suggested by the findings of this study, screening is dependent on the provider you see and where they practice, as these are strong determinants for uptake and adherence to cervical screening guidelines. This lack of uniformity in the delivery of screening practice drives differences we see in uptake and adherence. While cervical cancer screening guidelines in 2012 across all organizations did become congruent for a short period, this is no longer the case since there were guideline updates issued in 2018. As an example, the ACS issued updated cervical cancer screening guidelines in 2020 recommending initiating primary HPV screening at *age 25* every 5 years through age 65 as the preferred option (Fontham et al., 2020). In contrast, ACOG and ASCCP issued a statement to adopt USPSTF's guideline which added the third option for primary HPV testing starting at *age 30* every 5 years through age 65. Women under 30 are still recommended to have cytology screening every 3 years (Kaiser Permanente, 2021). Kaiser Permanente updated its cervical screening guidelines in 2021 and has made primary HPV screening the preferred option for patients every 5 years starting at age 30 through 64, with a reflex Pap if the HPV test results are positive. Women 65 or older are *not* recommended any cervical cancer screening if they had adequate prior screening and are not otherwise high risk. Women under 30 are recommended Pap testing every 3 years, and those women 25 and over should get a reflex HPV test if they have an abnormal pap (Kaiser Permanente, 2021). These are some recent examples of differences in screening guidelines that exist currently, and many more may exist for management of abnormal screening and treatment guidelines for cervical cancer. If screening guidelines are for improving the health at a population level, the next generation of cervical cancer screening guidelines should work toward

promulgating a single, harmonized guideline endorsed by multiple organizations. Organizations should also be clear and transparent with patients and providers on the screening guideline they endorse if they are selecting to follow one out of the many differing versions on the same topic.

A challenge that must be acknowledged, particularly for primary care providers who have responsibility for providing care to patients with a range of health conditions and comorbidities is the difficulty in juggling a multitude of guidelines. This can serve as a barrier to a physician's behavior to recommend, deliver, and accept guideline concordant screening. The complexity of providing comprehensive care while adhering to all necessary screening and prevention guidelines and time constraints during clinical encounters adds to the complexity of addressing this problem at an individual provider or patient level.

Organized Screening versus Opportunistic Screening

The Kaiser health system is an example of an *organized system* of screening in the U.S. in which the organization holds central responsibility for the screening process which includes eligibility, quality assurance, follow-up and evaluation (Miles et al., 2004). All Kaiser centers implement the same guidelines to reduce provider and organizational variability in guideline delivery. This is a key feature of an organized screening program as well as the focus on reducing mortality and morbidity at the level of the population, rather than the individual. In the U.S., cancer screening is predominantly *opportunistic* (aside from a few organized programs within certain health plans like Kaiser) because it depends on individual patients to request screening or their providers to recommend it. There are no formal decisions on whether to screen, who to screen with what test and the screening interval that should be performed. As stated by Miles and colleagues (2004), "most screening in the U.S. depends on a confluence of interests between individuals and their primary care providers during health care encounters."

This reiterates that cervical cancer screening that occurs in the U.S. is siloed and not part of a model with a common system of oversight. This introduces the variability in screening performance because there is no monitoring by a larger system, either at the organizational or health system level. Individual providers deliver screening how they feel is best. We acknowledge, as others have (Sivaram et al., 2018) that the U.S. health system lacks the needed infrastructure needed for such types of organized programs. They require heavy investments in health personnel, screening invitations, reminder screening and follow-up, tracking and follow-up of results which would require a major restructure of the current healthcare system to implement nationally. While screening recommendations are not mandates, or currently delivered as part an organized system or national program, it is still important to take steps that could help us move toward delivery of unified screening guidelines for cervical cancer screening. Additionally, evaluations by individual organizations of their screening policies and practices to minimize ineffective delivery of screening that does not benefit patients, providers, organizations or even the system should be prioritized by organizational leaders. At the health system level, the detrimental effects of overscreening and unnecessary costs consumed by insurance plans could be quantified balancing patient harm and maximizing efficient use of resources. The impact of screening guidelines on population health will become more evident once we begin to see change that trickle from the organizational up to the larger system level for screening.

Conclusion

This study provides us with new knowledge on the current uptake of cotesting among providers in a single health system in Washington, DC since the issuance of the 2012 cervical cancer screening guidelines recommending its use for average-risk women aged 30-65. There have certainly been advancements in the adoption of cotesting since 2012 as evidenced by the

high rate of uptake achieved in this study and several others (Cuzick et al., 2021; MacLaughlin et al., 2019). Although cotesting adoption is relatively high in this health system, we found that it is not conducted in accordance with the extended 5-year screening interval, resulting in 75.1% of the study population getting overscreened. Guideline adherence and use of cotesting can be promoted or impeded by the type of provider and practice in which the screening takes place. Providers and practice settings in the U.S. reside within a large, complex and fragmented health system without an organized approach to population-based screening and this can have detrimental effects on the delivery of cervical cancer screening at the individual patient, organization and system levels. Barriers driven by external factors outside the provider's control must be addressed starting at the organizational level through development of processes and policies for cancer screening that will reduce variability in how guidelines are delivered to patients. Addressing only individual level provider knowledge and attitude toward guideline adherence will not be sufficient to improve rates of over and under screening until there are changes made to policies that dictate insurance and reimbursement at the system level.

This study highlights the complexities of delivering guideline concordant cervical cancer screening in clinical practice. It provides recommendations for researchers and policy makers to consider around the next set of cervical cancer screening guidelines that should consider incorporating elements of implementation feasibility in the guideline development process. Promulgating a single, unified guideline endorsed by multiple stakeholders that can be adopted across different providers and organizations, and a movement toward an organized screening approach at the organizational level should be considered. Continuing to operate using our current processes for guideline development and delivery without consideration of the impact on

the harms of inefficient screening practice will keep the cycle of less-than-optimal translation in practice going.

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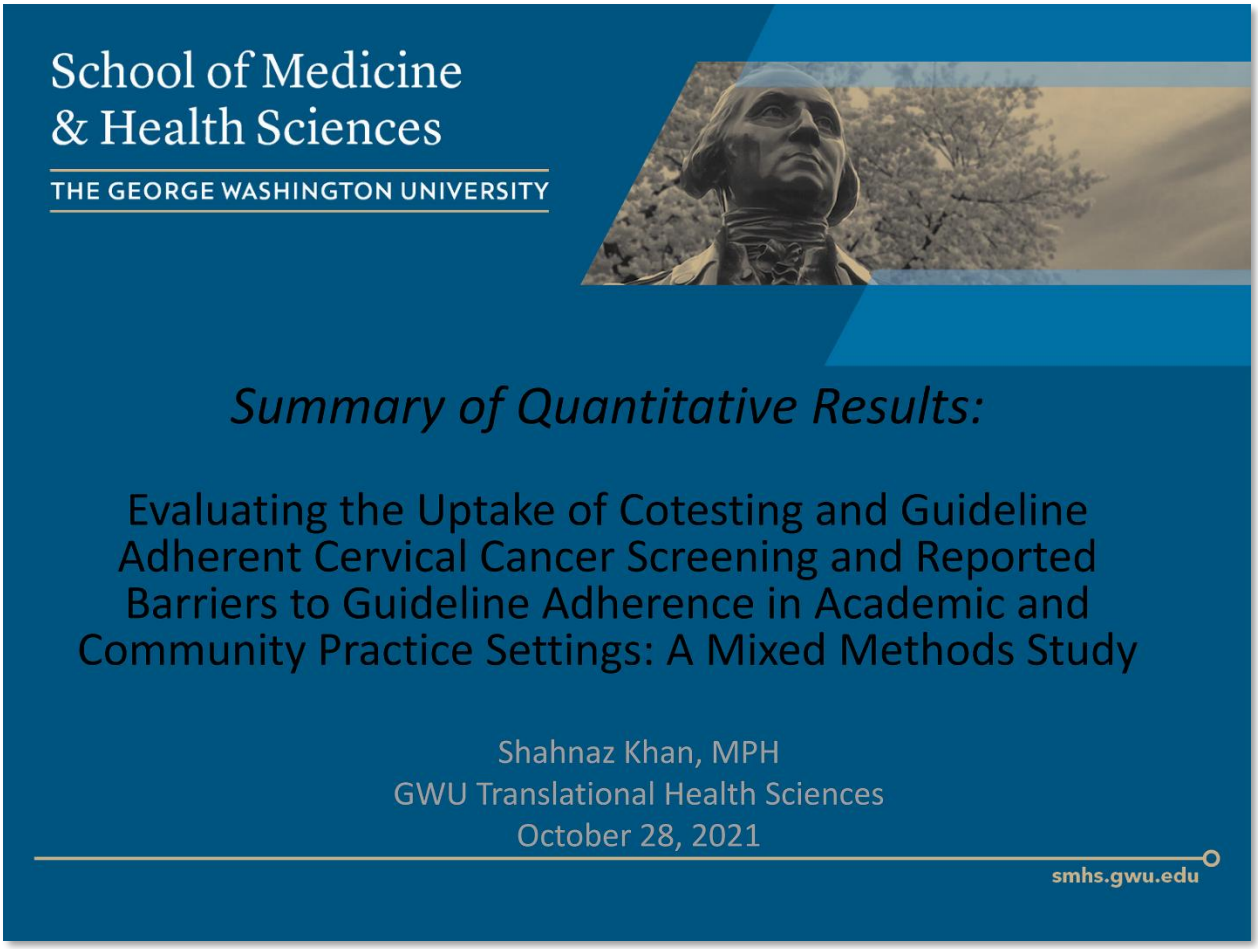
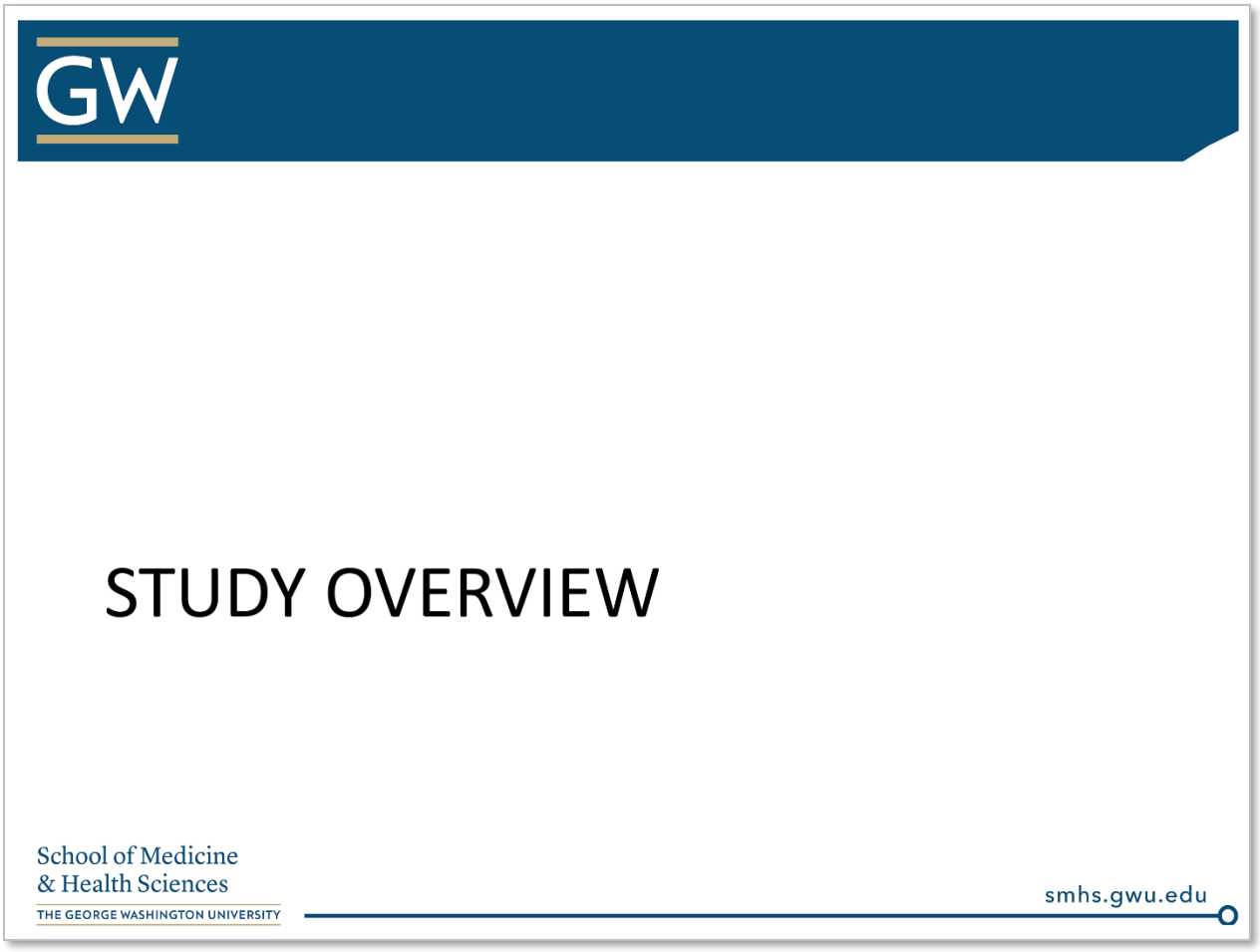
Appendix A

Slide Show: Summary of Quantitative Results for Focus Group



Slide 1 (Title Slide)


GW
STUDY OVERVIEW
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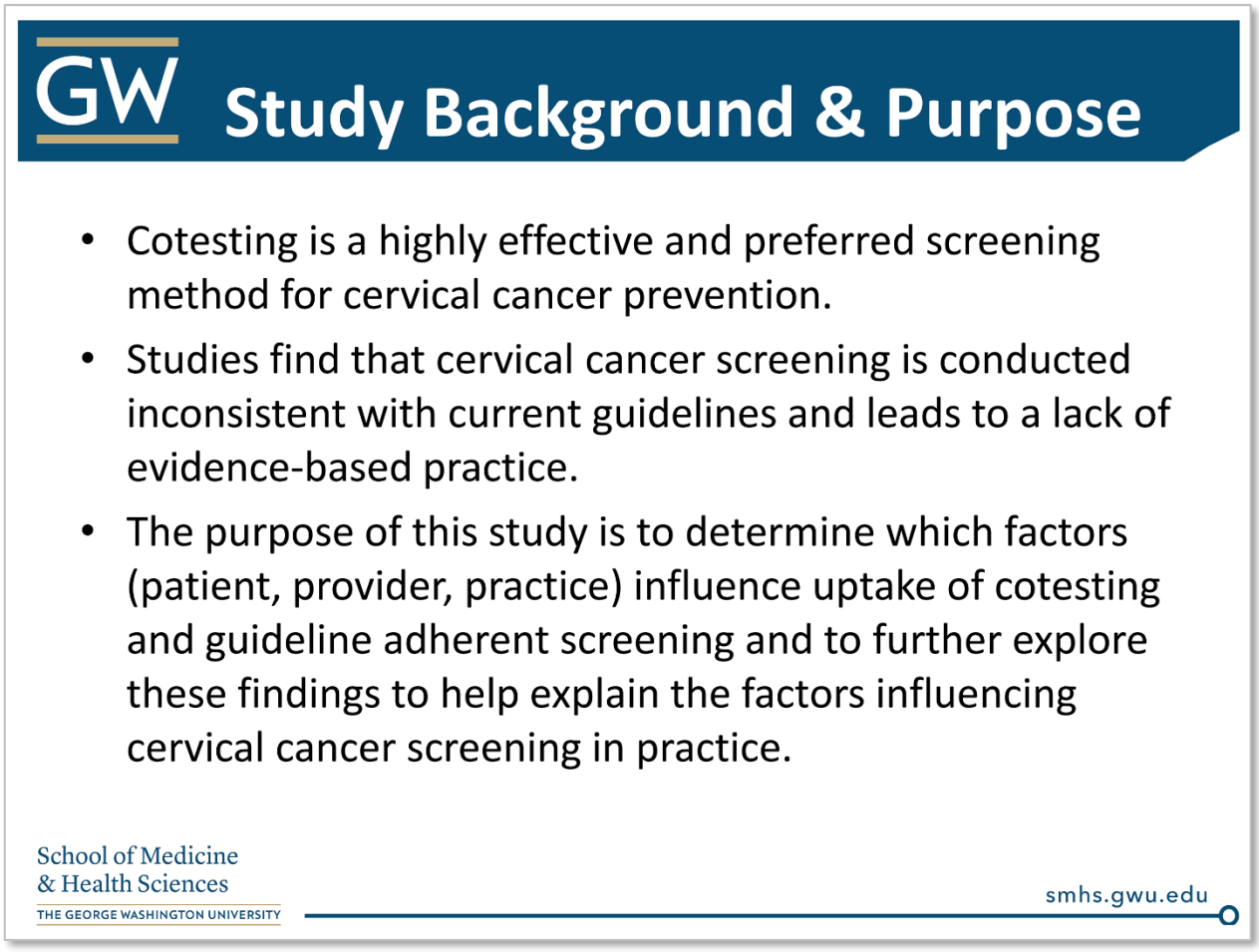
Slide 2


Study Background & Purpose
Cotesting is a highly effective and preferred screening method for cervical cancer prevention.
Studies find that cervical cancer screening is conducted inconsistent with current guidelines and leads to a lack of evidence-based practice.
The purpose of this study is to determine which factors (patient, provider, practice) influence uptake of cotesting and guideline adherent screening and to further explore these findings to help explain the factors influencing cervical cancer screening in practice.
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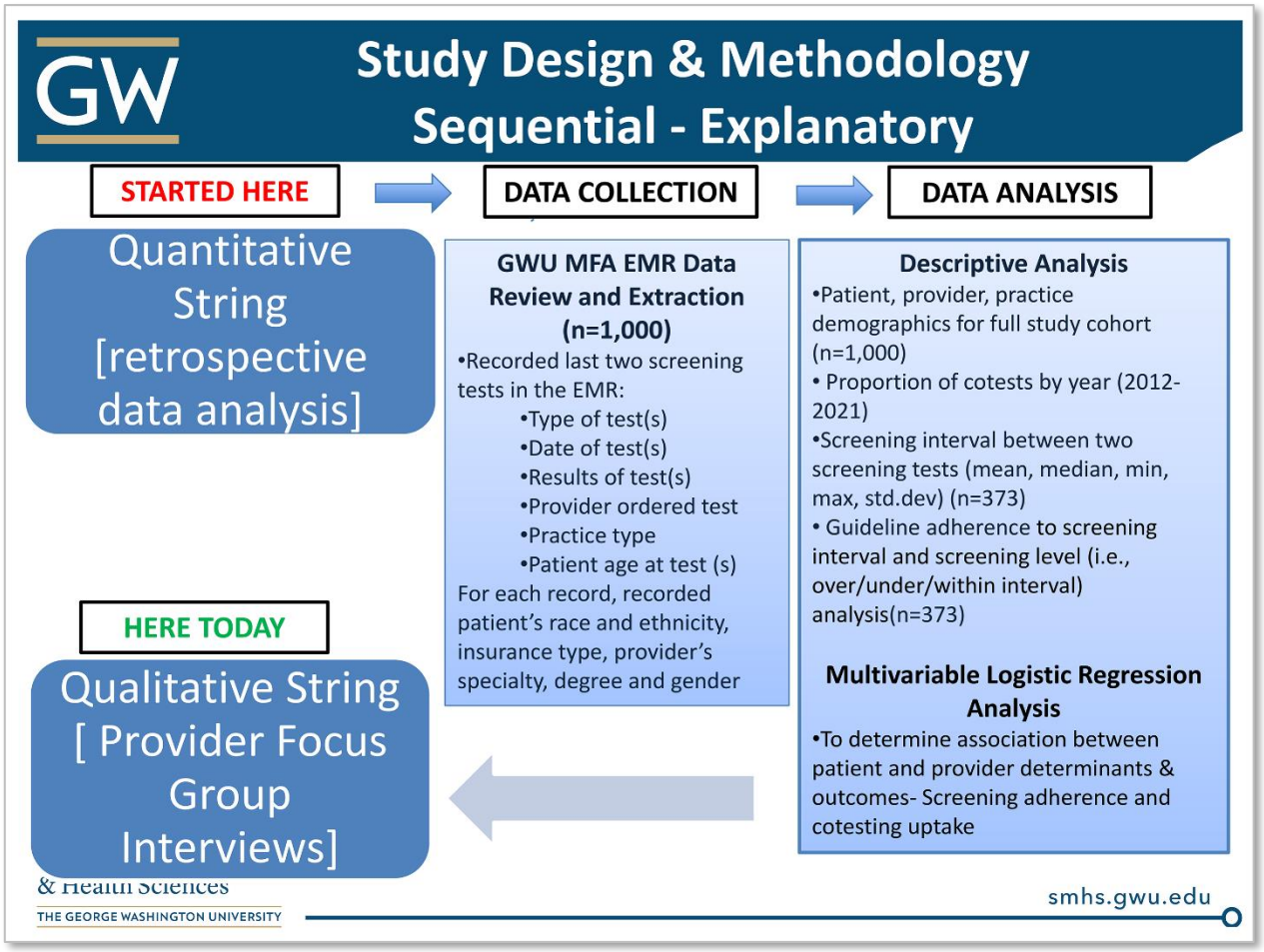
Slide 3


Study Design & Methodology
Sequential - Explanatory
STARTED HERE
DATA COLLECTION
DATA ANALYSIS
Quantitative String [retrospective data analysis]
GWU MFA EMR Data Review and Extraction (n=1,000)
•Recorded last two screening tests in the EMR:
•Type of test(s)
•Date of test(s)
•Results of test(s)
•Provider ordered test
•Practice type
•Patient age at test (s)
For each record, recorded patient's race and ethnicity, insurance type, provider's specialty, degree and gender
Descriptive Analysis
•Patient, provider, practice demographics for full study cohort (n=1,000)
• Proportion of cotests by year (2012-2021)
•Screening interval between two screening tests (mean, median, min, max, std.dev) (n=373)
• Guideline adherence to screening interval and screening level (i.e., over/under/within interval) analysis(n=373)
Multivariable Logistic Regression Analysis
•To determine association between patient and provider determinants & outcomes- Screening adherence and cotesting uptake
HERE TODAY
Qualitative String [Provider Focus Group Interviews]
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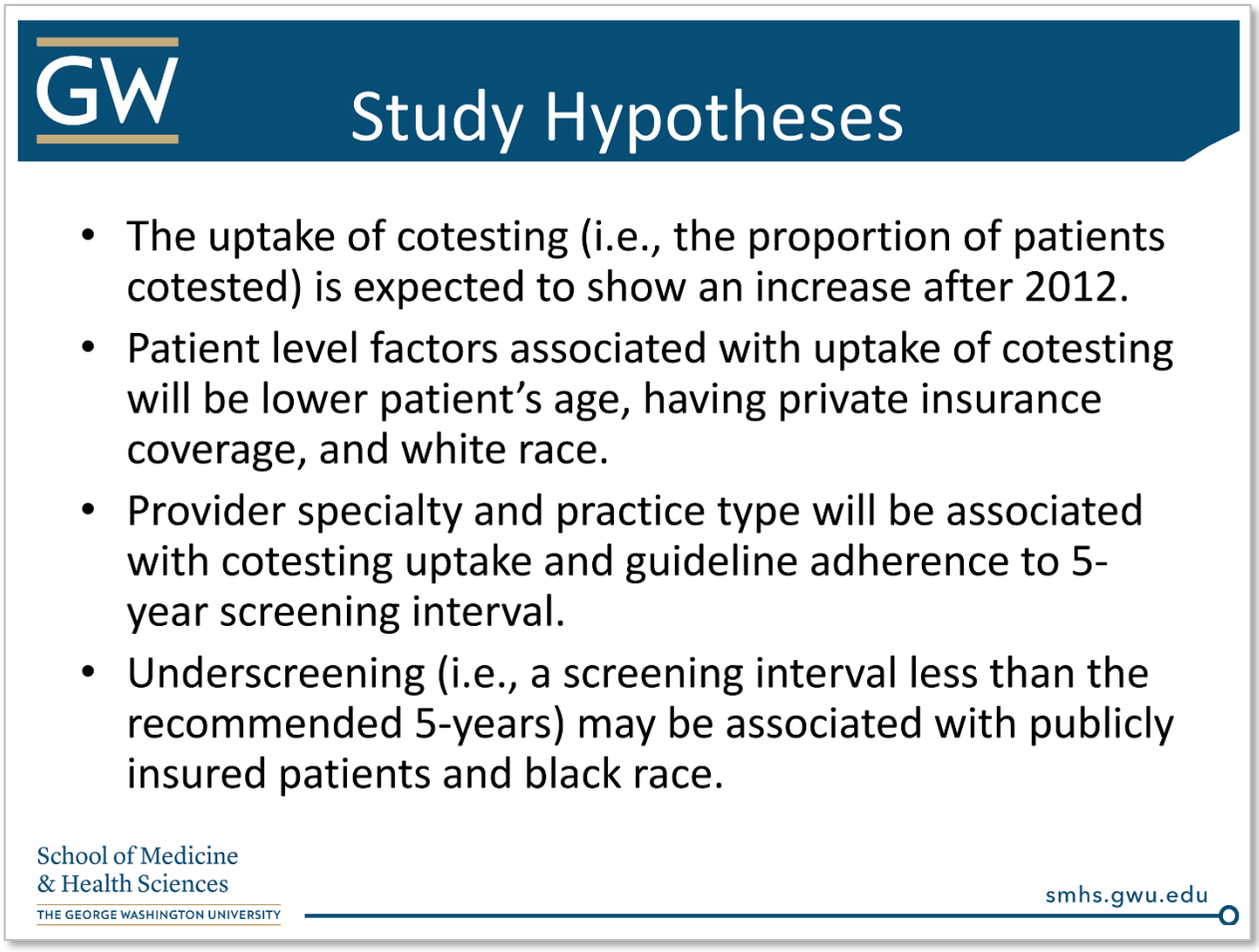
Slide 4


GW
Study Hypotheses
• The uptake of cotesting (i.e., the proportion of patients cotested) is expected to show an increase after 2012.
• Patient level factors associated with uptake of cotesting will be lower patient's age, having private insurance coverage, and white race.
• Provider specialty and practice type will be associated with cotesting uptake and guideline adherence to 5-year screening interval.
• Underscreening (i.e., a screening interval less than the recommended 5-years) may be associated with publicly insured patients and black race.
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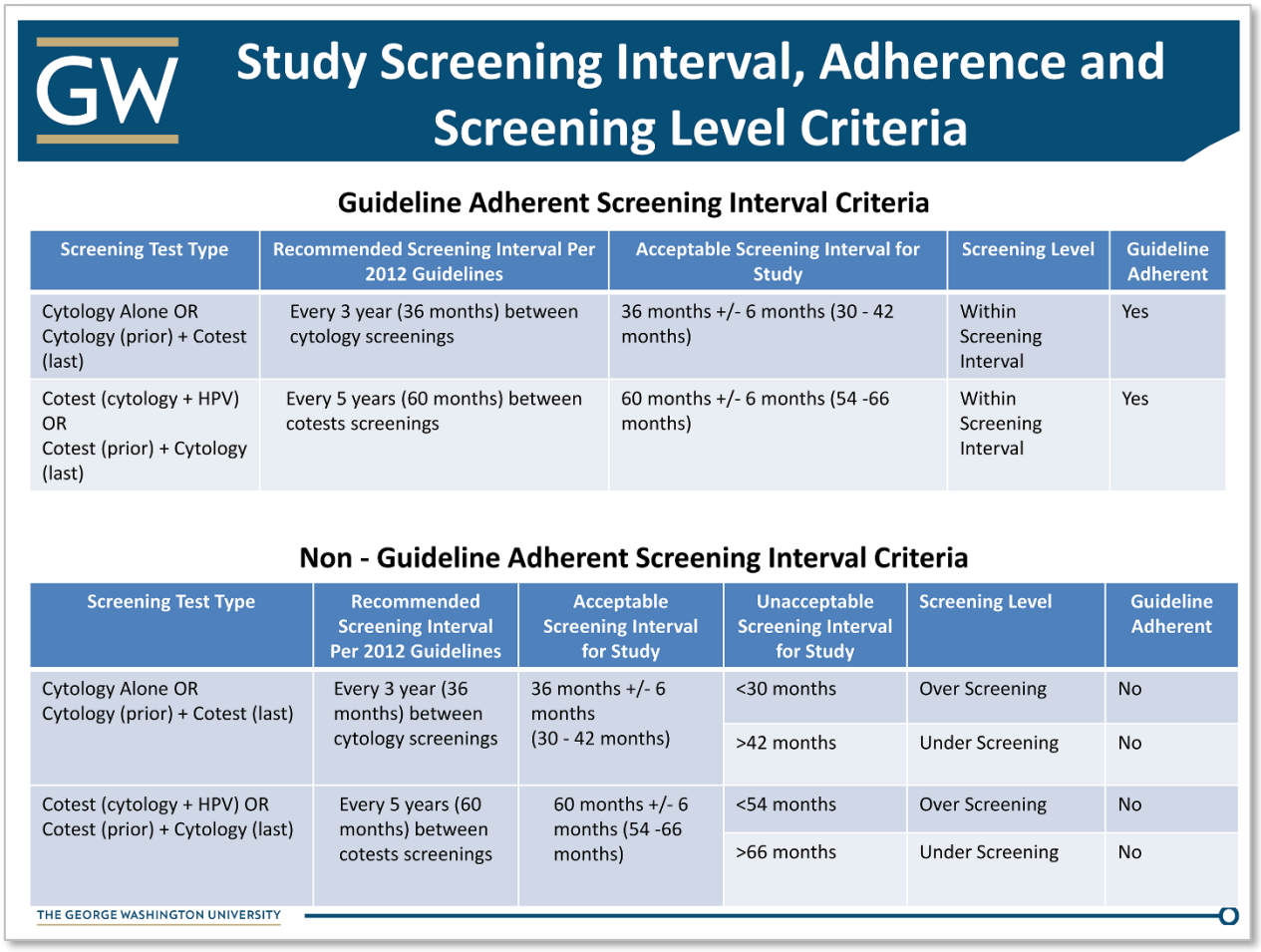
Slide 5.


Study Screening Interval, Adherence and Screening Level Criteria
Guideline Adherent Screening Interval Criteria
Screening Test Type
Recommended Screening Interval Per 2012 Guidelines
Acceptable Screening Interval for Study
Screening Level
Guideline Adherent
Cytology Alone OR Cytology (prior) + Cotest (last)
Every 3 year (36 months) between cytology screenings
36 months +/- 6 months (30 - 42 months)
Within Screening Interval
Yes
Cotest (cytology + HPV) OR Cotest (prior) + Cytology (last)
Every 5 years (60 months) between cotests screenings
60 months +/- 6 months (54 -66 months)
Within Screening Interval
Yes
Non - Guideline Adherent Screening Interval Criteria
Screening Test Type
Recommended Screening Interval Per 2012 Guidelines
Acceptable Screening Interval for Study
Unacceptable Screening Interval for Study
Screening Level
Guideline Adherent
Cytology Alone OR Cytology (prior) + Cotest (last)
Every 3 year (36 months) between cytology screenings
36 months +/- 6 months (30 - 42 months)
<30 months
Over Screening
No
>42 months
Under Screening
No
Cotest (cytology + HPV) OR Cotest (prior) + Cytology (last)
Every 5 years (60 months) between cotests screenings
60 months +/- 6 months (54 -66 months)
<54 months
Over Screening
No
>66 months
Under Screening
No
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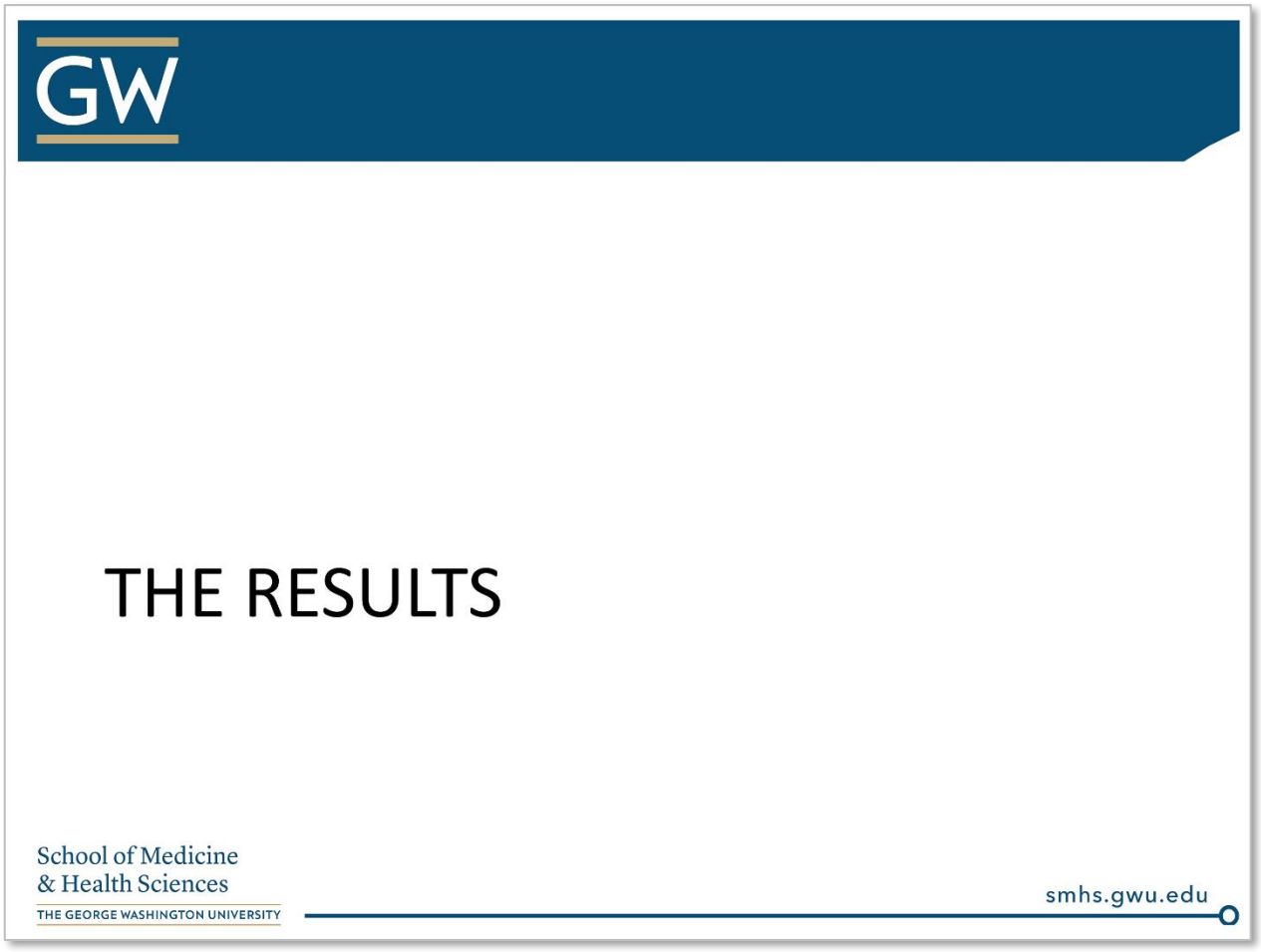
Slide 6.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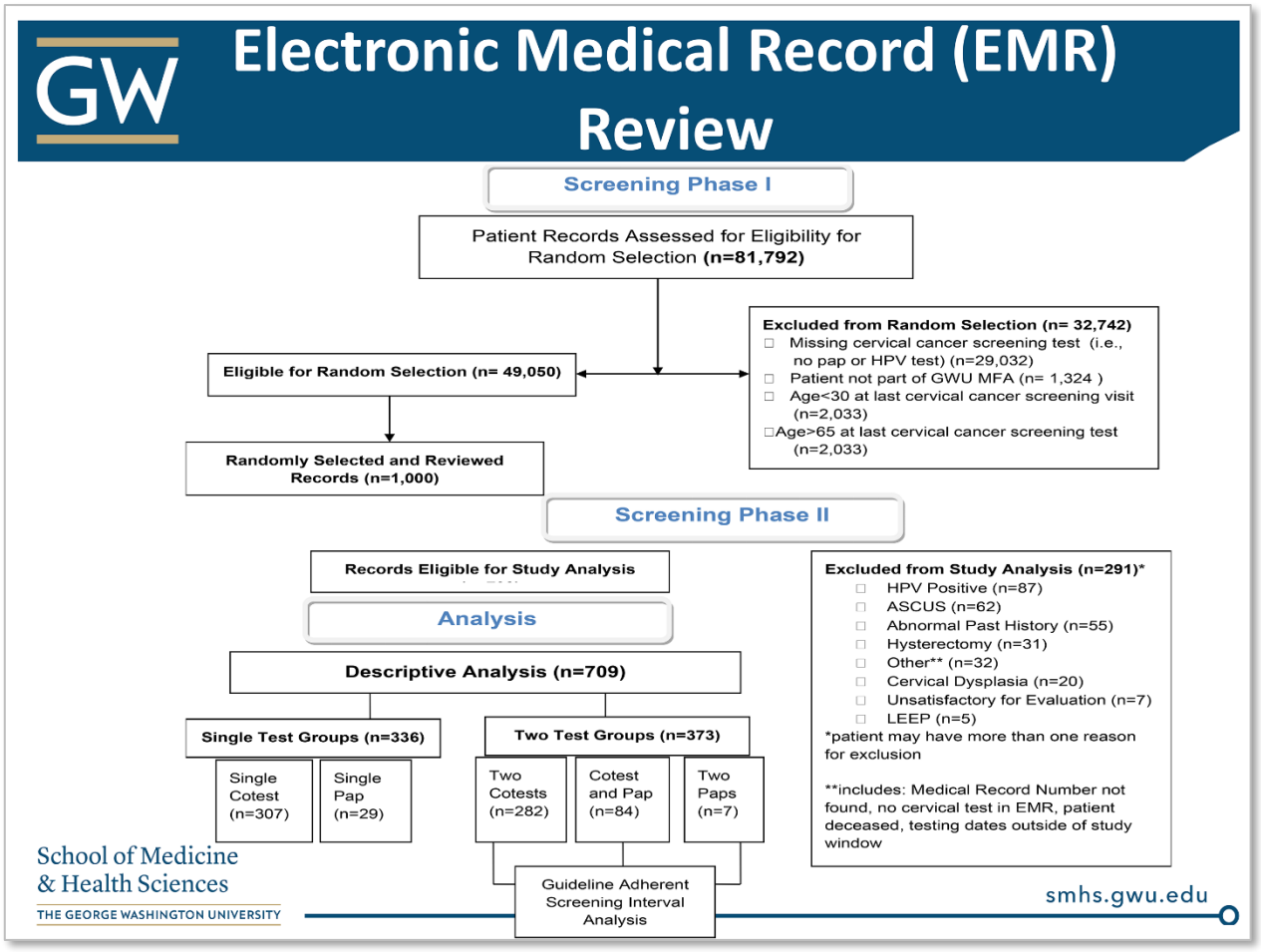
Slide 7.


Electronic Medical Record (EMR) Review
Screening Phase I
Patient Records Assessed for Eligibility for Random Selection (n=81,792)
Excluded from Random Selection (n= 32,742)
Missing cervical cancer screening test (i.e., no pap or HPV test) (n=29,032)
Patient not part of GWU MFA (n= 1,324)
Age<30 at last cervical cancer screening visit (n=2,033)
Age>65 at last cervical cancer screening test (n=2,033)
Eligible for Random Selection (n= 49,050)
Randomly Selected and Reviewed Records (n=1,000)
Screening Phase II
Records Eligible for Study Analysis
Excluded from Study Analysis (n=291)*
HPV Positive (n=87)
ASCUS (n=62)
Abnormal Past History (n=55)
Hysterectomy (n=31)
Other** (n=32)
Cervical Dysplasia (n=20)
Unsatisfactory for Evaluation (n=7)
LEEP (n=5)
*patient may have more than one reason for exclusion
**includes: Medical Record Number not found, no cervical test in EMR, patient deceased, testing dates outside of study window
Analysis
Descriptive Analysis (n=709)
Single Test Groups (n=336)
Two Test Groups (n=373)
Single Cotest (n=307)
Single Pap (n=29)
Two Cotests (n=282)
Cotest and Pap (n=84)
Two Paps (n=7)
Guideline Adherent Screening Interval Analysis
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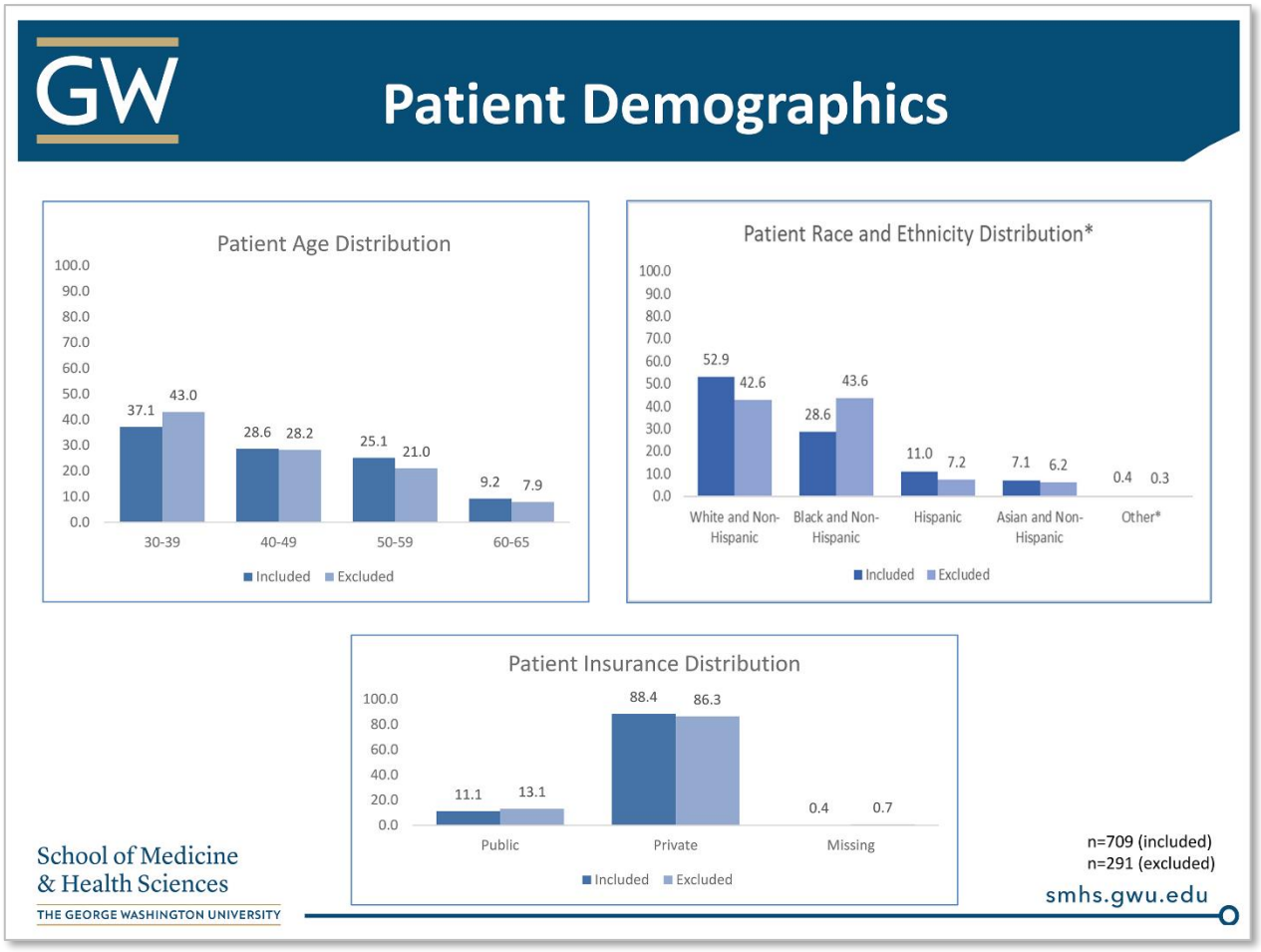
Slide 8.


Patient Demographics
Patient Age Distribution
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90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
37.1
43.0
28.6
28.2
25.1
21.0
9.2
7.9
30-39
40-49
50-59
60-65
Included
Excluded
Patient Race and Ethnicity Distribution*
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
52.9
42.6
28.6
43.6
11.0
7.2
7.1
6.2
0.4
0.3
White and Non-Hispanic
Black and Non-Hispanic
Hispanic
Asian and Non-Hispanic
Other*
Included
Excluded
Patient Insurance Distribution
100.0
80.0
60.0
40.0
20.0
0.0
11.1
13.1
88.4
86.3
0.4
0.7
Public
Private
Missing
Included
Excluded
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n=709 (included)
n=291 (excluded)
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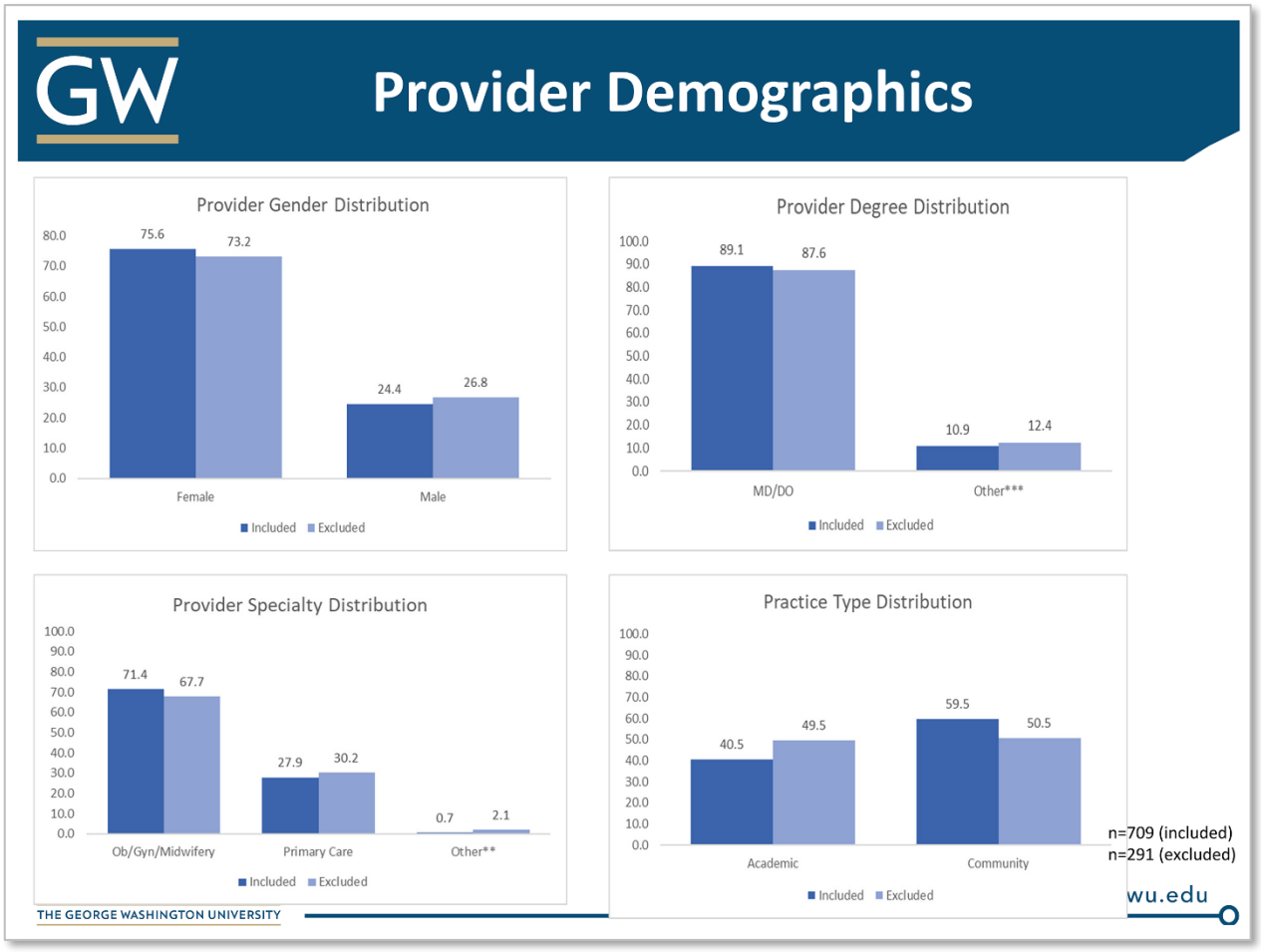
Slide 9.


Provider Demographics
Provider Gender Distribution
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70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
75.6
73.2
24.4
26.8
Female
Male
Included
Excluded
Provider Degree Distribution
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
89.1
87.6
10.9
12.4
MD/DO
Other***
Included
Excluded
Provider Specialty Distribution
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
71.4
67.7
27.9
30.2
0.7
2.1
Ob/Gyn/Midwifery
Primary Care
Other**
Included
Excluded
Practice Type Distribution
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
40.5
49.5
59.5
50.5
Academic
Community
Included
Excluded
n=709 (included)
n=291 (excluded)
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Slide 10.

Proportion of Cotesting 2012-2021

*Proportion of Cotests Conducted by Year for Evaluable Sample (n=709)**

Year	Number of cervical screening tests conducted (n=1,030) **	Total number of cotests (n=913)	% cotested
2012	52	38	73.1%
2013	65	54	83.1%
2014	83	67	80.7%
2015	119	102	85.7%
2016	143	124	86.7%
2017	207	187	90.3%
2018	186	172	92.5%
2019	83	80	96.4%
2020	75	73	97.3%
2021	17	16	94.1%

*cotesting uptake was analyzed only for the evaluable sample
**includes pap tests and cotests for every evaluable patient record

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Slide 11.

Screening Interval, Adherence and Level by Testing Group

Testing Status / Group	Total Included (n=709) n (%)	Screening Interval Months* (n=373) Mean	Median	Min	Max	Std. Dev	Guideline Adherence* (n=373) Yes n (%)	No n (%)	Screening Level (n=373) Over Screened n (%)	Under Screened n (%)	Within interval ±6 months n (%)
Single Cotest*	307 (43.3)										
Two Cotest	282 (39.8)	39.4	36.0	3.0	122.0	19.8	39 (10.5)	243 (65.1)	214 (57.4)	29 (7.8)	39 (10.5)
Single Cotest First then Pap	17 (2.4)	21.7	14.0	12.0	81.0	18.1	0 (0)	17 (4.6)	16 (4.3)	1 (0.3)	0 (0)
Pap First then Single Cotest	67 (9.4)	27.6	25.0	9.0	73.0	14.2	13 (3.5)	54 (14.5)	44 (11.8)	10 (2.7)	13 (3.5)
Two Paps	7 (1.0)	19.0	17.0	11.0	34.0	8.1	1 (0.3)	6 (1.6)	6 (1.6)	0 (0)	1 (0.3)
Single Pap*	29 (4.1)										
							53 (14.3)	320 (85.8)	291 (75.1)	40 (10.8)	53 (14.3)

*Screening interval, guideline adherence and screening level analysis excludes single test groups (n=336)

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Screening Interval and Level by Race and Ethnicity

Group	Evaluable (n=373)	Testing Group (n=373)			Screening Interval Months (n=373)					Screening Level (n=373)		
	n (%)	n (%)	n (%)	n (%)						n (%)	n (%)	n (%)
Race and Ethnicity		Two Cotests	Single Cotest w/Pap*	Two Paps	Mean	Median	Min	Max	Std. Dev	Over Screened	Under Screened	Within interval ±6 months
White and Non-Hispanic	204 (54.7)	156 (76.5)	43 (21.1)	5 (2.5)	37.1	36.0	3.0	111.0	18.7	154 (75.5)	22 (10.8)	28 (13.7)
Black and Non-Hispanic	110 (29.5)	88 (80.0)	20 (18.2)	2 (1.8)	38.4	34.5	9.0	122.0	22.1	74 (67.38)	17 (15.5)	19 (17.3)
Hispanic	36 (0.10)	22 (61.1)	14 (38.9)	0 (0)	31.3	27.5	12.0	81.0	17.2	29 (80.6)	1 (2.8)	6 (16.7)
Asian and Non-Hispanic	22 (0.06)	15 (68.2)	7 (31.8)	0 (0)	23.0	21.5+	10.0	53.0	10.9	22 (100.0)	0 (0)	0 (0)
**Other	1 (0.003)	1 (100.0)	0 (0)	0 (0)	27.0	27.0	27.0	27.0	27.0	0 (0)	1 (100.0)	0 (0)

*Combined single first cotest with pap and single second cotest with pap groups
**includes American-Indian or Alaskin Native Non-Hispanic
+ Kruskal-Wallis test showed screening interval months for Asian and Non-Hispanic is significantly shorter (p<.001) when compared to White and Non-Hispanic and Black and Non-Hispanic

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Slide 13.

Predictors of Guideline Adherent Screening

- Provider Gender and Practice Type are significant predictors of guideline adherent screening.
  - Compared to female providers, male providers have a lower odds of conducting guideline adherent cervical cancer screening
  - Compared to academic providers, community providers have a lower odds of conducting guideline adherent screening

Table 9

Final Logistic Model of Significant Predictors of Adherence to Screening Interval

	Total (n=373)
Variables	Odds Ratio (95% CI)
Provider Gender ($p<0.01$)	
Female	1.0
Male	0.31 (0.13–0.78)
Practice Type ($p<0.001$)	
Academic	1.0
Community	0.15 (0.08–0.31)

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Slide 14.

Predictors of Cotesting Uptake

- Provider Gender, Provider Specialty and Practice Type are significant predictors of cotesting uptake
  - Compared to female providers, male providers have a lower odds of conducting cervical cancer screening using a cotest
  - Compared to academic providers, community providers have a lower odds of conducting cervical cancer screening using a cotest
  - Compared to Ob/Gyn and Midwifery specialists, Primary Care providers and Other specialties have a lower odds of conducting a cotest

Table 11

Details of Final Logistic Model of Significant Predictors of Cotesting (Uptake) for Model 4 and Model 5

	Model 4	Model 5
Variables	Odds Ratio (95% CI)	Odds Ratio (95% CI)
Patient Age (p <0.05)		
30-39	1.0	
40-49	3.20 (1.25–8.19)	
50-59	1.83 (0.78–4.31)	
60-65	3.87 (0.84–17.9)	
Provider Gender (p <0.05)		
Female	1.0	1.0
Male	0.44 (0.20–0.97)	0.45 (0.20-0.99)
Provider Specialty (p<0.001)		
Ob/Gyn &Midwifery	1.0	1.0
Primary Care	0.19 (0.09–0.41)	0.24 (0.12-0.50)
Other*	0.03 (0.003–0.36)	0.04 (0.003-0.39)
Practice Type (p<0.05)		
Academic	1.0	1.0
Community	0.25 (0.10–0.60)	0.25 (0.10-0.63)

*includes Medical Genetics, Palliative Care and Women's Health

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Summary of Findings

- ✓ Cotesting use **steadily increased** after the issuance of 2012 cervical screening guidelines.
- ✓ The screening interval for **cotesting** is **three years** which is inconsistent with the recommended five-year interval.
- ✓ The screening interval for screening with **cytology** is **17-months** which is inconsistent with the recommended three-year interval.
  - ✓ The screening interval is **shortest (21.5 months) for Asian Non-Hispanics** when compared to White non-Hispanic and Black non-Hispanic groups. All were **overscreened**.
- ✓ The **majority** of patients are **overscreened** (75.1%)
- ✓ **No patient level factors** (age, insurance or race and ethnicity) are associated with cotesting or guideline adherence.
- ✓ **Only provider level factors (**provider's gender, practice type) **are associated** with guideline adherent testing
  - ✓ **Male** providers and **community** practice sites have a **lower odds** of conducting guideline adherent screening compared to female providers and academic practice sites
- ✓ **Only** provider level factors (practice type, provider's gender and specialty) **are associated** with cotesting
  - ✓ **Male** providers and **community** practice sites have a lower odds of conducting cotesting compared to female providers and academic practice sites
  - ✓ **Primary care providers** have a lower odds of conducting cotesting compared to Ob/Gyns and Midwives

Slide 16

Appendix B

Study Information Sheet for Participation in a Research Study

Title of Study: Evaluating the Uptake of Cotesting and Guideline Adherent Cervical Cancer Screening and Reported Barriers to Guideline Adherence in Academic and Community Practice Settings: A Mixed Methods Study

IRB #: NCR191123

Principal Investigator Name: Philippus Jan Van der Wees, PhD

Version Date: September 15, 2021

You are invited to participate in a research study under the direction of Dr. Van der Wees of the Department of Clinical Research and Leadership, George Washington University (GWU). Taking part in this research is entirely voluntary. The status of your employment will not, in any way, be affected should you choose not to participate or if you decide to withdraw from the study at any time. A total of 15 providers from the GW MFA clinical practice sites may participate in this research study.

Further information regarding this study may be obtained by contacting Shahnaz Khan at kshahnaz@gwmail.gwu.edu; a Doctoral Student in the GWU Translational Health Sciences Program in the Department of Clinical Research and Leadership who has designed this research under the direction of the Principal Investigator. Dr. Jennifer Keller is a Co-Investigator on this project and may also be able to provide further information about this study at jkeller@mfa.gwu.edu.

The purpose of this study is to understand the provider perspective on the observed cotesting rates and guideline adherent testing patterns analyzed using electronic medical record data from the MFA academic and community clinical practice sites. This study will gain further

insight to understand provider knowledge, attitudes and preferences for cotesting and the extended 5-year screening interval for women ages 30-65, as first recommended in 2012, and what are the perceived barriers to implementing cervical screening guidelines.

What are the reasons you might choose to volunteer for this study?

You will have a unique opportunity to learn about your site's cervical screening practice data and use these findings for ongoing quality improvement initiatives.

What are the reasons you might not choose to volunteer for this study?

You may not be interested in knowing how your site and its providers use evidence-based guidelines to screen patients for cervical cancer or you do not have time to devote to this research.

If you choose to take part in this study, you will participate in a virtual focus group interview using a video conferencing platform such as Zoom or WebEx and the session will be recorded. The focus group will be moderated by Shahnaz Khan, the doctoral student researcher on this project.

If you choose to participate, you will spend between 60-75 minutes one time in connection with this study. The first 15 minutes of your participation will consist of listening to a brief presentation by the student researcher to learn the results from an analysis conducted using MFA practice site cervical screening data to measure uptake of cotesting and factors that influence uptake and guideline adherent screening. After practice data have been presented, you will be guided by the moderator to discuss how you perceive the findings and what may be some reasons for these observed results. You may refuse to answer any of the questions and you may stop your participation in this study at any time.

Possible risks or discomforts you could experience during this study include: loss of confidentiality or discomfort with sharing your perspective in a large group setting about provider screening behavior and use of evidence-based guidelines and/or barriers to guideline implementation.

During the focus group discussions, while we cannot guarantee the confidentiality of the discussion, we request that all present respect the group by not repeating what is said, outside the group.

Every effort will be made to keep your information confidential, however, this cannot be guaranteed. No names will be associated with quotes that might be used in presentation of results. If results of this research study are reported in journals or at scientific meetings, the people who participated in this study will not be named or identified. The audio recordings and the associated transcript of the focus group interviews will not be labeled with individually identifiable information. Only the student researcher will have access to the audio/video recording of the focus group interview and the recording will be destroyed (i.e., deleted) upon completion of the analysis which is expected to be within 3-months of the focus group meeting.

You will not benefit directly from your participation in the study. The benefits to science and humankind that might result from this study are: increasing our knowledge and understanding of the use of evidence-based guidelines for prevention of cervical cancer within an urban healthcare setting, and this has the potential to impact the quality of care for patients at the MFA.

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research participant.

Your willingness to participate in this research study is implied if you proceed and type "Yes" in the chat box.

*Please keep a copy of this document in case you want to read it again. A signature is not required on this form.

Appendix C

Interview Guide

1. What surprised you most about the quantitative results?
    a. What did the results show about cotesting uptake and adherence that you expected to see or not to see?
    b. Tell me more about why you did or did not expect to see this?
    c. Do you think these results indicate further research is needed to increase cotesting uptake and guideline adherence at your site?

- If yes: What are some ways you think this can be done?
- If no: Or are you satisfied and think these data don't indicate any improvements screening practice are needed?

  [Probe further on certain responses given to get others to validate or disagree with what has been stated].

2. Do you agree with the current (i.e., 2012) cervical screening recommendation to cotest women ages 30-65 years and the extended 5-year screening interval? Why or why not?

3. What characteristics of a patient influence your decision for the type of screening test to administer to a patient? (i.e., Race, Age, SES, insurance type, clinical history, other)

4. What other (non-patient) factors drive your decision to cotest or not to cotest a patient? What about cotesting using the 5-year extended interval? OR
    a. Is patient preference driving testing decisions? If yes, is this most of the time, sometimes, never?

5. In your opinion, what are some barriers you as a provider face in following cervical cancer screening guidelines?

- [Probe with lack of familiarity, lack of awareness, lack of agreement with specific guideline, patient factors, patient preferences, guideline factors, environmental factors]

6. Are you aware of the updated 2018 cervical cancer screening guidelines issued by USPSTF recommending primary HPV testing alone in women ages 30-65 years? If yes, do you use? Do patients request you to conduct HPV testing? [only if there is time]

Appendix D:

Guideline Adherence Checklist

- Female between the ages of 30-65 years AND
- Received two routine cervical cancer screening tests
    - Test 1 (last) may be either via cytology (pap smear) or a cotest with negative results AND
    - Test 2 (prior) may be either via cytology (pap smear) or a cotest with negative results
- Screening Interval Criteria:
    - Cytology: If Test 1 and Test 2 are both negative cytology
        - Interval between two tests is 2.5 to 3.5 years (30-42 months) = YES to Guideline Adherence
    - Cotesting: If Test 1 and Test 2 are both negative cotests
        - Interval between two tests is every 4.5 to 5.5 years (54-66 months) = YES to Guideline Adherence