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Primary and Secondary Prevention of Cervical Cancer Among Ethnically Diverse and Low-Income Populations

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Primary and Secondary Prevention of Cervical Cancer Among Ethnically Diverse and Low-Income Populations

A dissertation submitted in partial satisfaction of the requirements for the degree Doctor of Philosophy in Health Policy and Management

by

Narissa Jennifer Nonzee

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ABSTRACT OF THE DISSERTATION

Primary and Secondary Prevention of Cervical Cancer
Among Ethnically Diverse and Low-Income Populations

by

Narissa Jennifer Nonzee
Doctor of Philosophy in Health Policy and Management
University of California, Los Angeles, 2018
Professor Roshan Bastani, Chair

Cervical cancer prevention has undergone significant changes over recent decades. Evolving evidence and practices have shifted towards upstream prevention, less frequent screening, and more conservative follow-up. Understanding how these changes have been adopted among ethnic minority and low-income populations, groups disproportionately impacted by cervical cancer in the U.S., is important to optimizing prevention strategies. In three distinct studies, this dissertation advances evidence on adherence to recommendations for primary prevention (human papillomavirus (HPV) vaccination) and secondary prevention (early detection) of cervical cancer among high-risk populations.

The first study assesses changes in adolescent HPV vaccination following vaccine approval in the U.S., using two cycles of population-based survey data from Los Angeles County. Between 2007 and 2011, ethnic and income differences in parental HPV vaccine awareness diminished, and HPV vaccine uptake rates markedly increased among older

adolescent girls and those with access barriers. Yet, five years after vaccine approval, overall only half of adolescent girls had initiated vaccination.

The second study evaluates adoption of evidence-based guidelines for management of abnormal screening tests among young women, using four years of administrative claims data from California's Medicaid family planning program. A difference-in-differences approach was used to estimate the impact of updated guidelines on receipt of a colposcopy, a procedure that could lead to potential harmful interventions. Among a sample of low-income, predominantly Hispanic women, results suggested the guideline was associated with a 2-fold reduction in colposcopies for young women relative to a comparison group, which has implications for reducing future risk of adverse obstetric outcomes.

Given provider recommendations can influence patient adherence, the third study explores provider communication around cervical cancer screening and follow-up recommendations, including lengthened screening intervals. Semi-structured interviews were conducted among safety net providers in Southern California. Findings revealed that clinicians perceived explaining the rationale for guidelines, in addition to addressing patient emotions, uncertainty, and preferences, facilitated patient understanding and acceptance of recommended care.

Collectively, these studies highlight opportunities to maximize the benefits of primary prevention and early detection strategies, while minimizing the harms of unnecessary intervention, among high-risk populations.

The dissertation of Narissa Jennifer Nonzee is approved.

Beth Ann Glenn-Mallouk

Gerald F. Kominski

Anna-Barbara Moscicki

Roshan Bastani, Committee Chair

University of California, Los Angeles

2018

For my parents and grandparents

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LIST OF ACRONYMS

ACIP	Advisory Committee for Immunization Practices
ASCCP	American Society for Colposcopy and Cervical Pathology
ASC-H	Atypical Squamous Cell – cannot exclude High Grade Squamous Intraepithelial Lesion
ASCUS	Atypical Squamous Cells of Undetermined Significance
CI	Confidence Interval
CIN	Cervical Intraepithelial Neoplasia
CPT	Current Procedural Terminology
DID	Difference-in-differences
EWC	Every Woman Counts
FPACT	Family Planning Access Care and Treatment Program
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
HEDIS	Healthcare Effectiveness Data and Information Set
HPV	Human Papillomavirus
HSIL	High Grade Squamous Intraepithelial Lesion
LACHS	Los Angeles County Health Survey
LEEP	Loop Electrosurgical Excision Procedure
LSIL	Low Grade Squamous Intraepithelial Lesion
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NCI	National Cancer Institute
NIS-Teen	National Immunization Survey – Teen
OR	Odds Ratio
OSHPD	Office of Statewide Health Planning and Development
Pap test	Papanicolaou test
USPSTF	United States Preventive Services Task Force

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Chapter 1

Introduction

1.1 Overview of Dissertation

Ethnic minorities, immigrants, and uninsured women bear an unequal burden of cervical cancer in the United States. Primary and secondary prevention strategies provide opportunities to mitigate these disparities. Over the past 15 years, the landscape of cervical cancer prevention has undergone major changes. In 2006, the prophylactic human papillomavirus (HPV) vaccine was introduced in the U.S., and routine vaccination was recommended for girls ages 11-12 years. Uptake among adolescent girls remains suboptimal nationally, however, and thus does not obviate the need for adequate cervical cancer screening, regardless of vaccination history. Pap testing has reduced cervical cancer incidence and mortality and, for decades, annual testing was recommended. In 2012, guidelines were updated to extend screening intervals among adult women and conservatively manage precancerous lesions among young women in particular. Among high-risk groups and vulnerable populations with historically lower rates of Pap testing, balancing the risks of under-screening against potential harms of unnecessary intervention presents a public health challenge.

The overall objective of this dissertation is to explore facilitators of adherence to cervical cancer prevention recommendations among high-risk populations. This first chapter describes disparities in cervical cancer care and outcomes, current clinical practice guidelines, the conceptual framework guiding this research, and the contribution of studies included in this dissertation. The following three chapters present distinct studies examining guidelines developed for different stages along the cervical cancer progression continuum: HPV vaccination, cervical cancer screening, and follow-up of abnormal screening test results. The

first study uses two cycles of a population-based survey to evaluate changes and disparities in HPV vaccination among adolescents in Los Angeles (LA) County, the most populous county in the U.S. The second study explores the impact of guideline changes on cervical cytology management, using longitudinal administrative and claims data from the largest publicly funded family planning program in the nation. Given increasing complexity of cervical cancer screening guidelines, the final study explores provider communication about screening and management recommendations and patient preferences, drawing from in-depth interviews with safety net providers. The final chapter synthesizes findings and discusses implications for health services research and future work.

1.2 Background

1.2.1 Terminology

Over recent decades, a greater understanding of the natural history of HPV and cervical carcinogenesis has enabled opportunities to intervene during more distinct stages along the continuum of cervical cancer progression. In this dissertation, the term “primary prevention” is defined as interventions to prevent exposure to risk factors for cervical cancer (e.g., HPV vaccination), and “secondary prevention” is defined as interventions for early detection of pre-cancerous cervical lesions and intervention prior to disease onset (e.g., cervical cancer screening, treatment of pre-cancerous lesions). Additionally, the term “Pap test” and “cervical cytology test” are used interchangeably in chapters to refer to cytology-based screening. A Pap test involves collection of a sample of cervical cells that are analyzed under a microscope for cellular abnormalities. A colposcopy may be recommended following an abnormal test, which entails using a magnifying instrument to observe cellular changes in the cervix, and is often performed with a biopsy procedure to remove tissue from abnormal areas. The process of determining whether an abnormal Pap test should be triaged to colposcopy is referred to as “management of abnormal cytology” or “management” for brevity in this dissertation.

1.2.2 Racial/ethnic and socioeconomic disparities in cervical cancer health outcomes

Cervical cancer, a preventable disease, impacts an estimated 13,000 newly diagnosed women and claims over 4,200 lives annually in the U.S.[1] Widespread Pap testing has led to a dramatic decline in cervical cancer incidence and mortality in the U.S.,[2,3] but some populations remain disproportionately burdened by the disease: poor, racial/ethnic minority, immigrant, and inadequately screened women.[1,4-7] Over half of all new cervical cancer cases occur in women who have never or rarely been screened.[6] Despite narrowing ethnic disparities over the past two decades,[8] the incidence rate among Hispanics is 40% higher than non-Hispanic whites (9.1 vs. 7.0 per 100,000, respectively) and the highest among major racial/ethnic groups,[1,7] and the mortality rate for African Americans is two-fold that of non-Hispanic Whites (10.1 vs. 4.7 per 100,000, respectively).[4] These differences can be explained, in part, by poor access to health care services, including Pap testing, follow-up after an abnormal test result, and treatment of pre-cancerous lesions and invasive cervical cancer.

1.2.3 Disparities in cervical cancer screening impacts poor and racial/ethnic minorities

Poor and racial/ethnic minority women remain at risk for inadequate cervical cancer screening.[9-11] In 2015, 64% of uninsured women versus 87% of privately insured and 68% of recent immigrants versus 85% of U.S.-born women were appropriately screened for cervical cancer (i.e., at least one test within the past three years).[9] Women with lower educational attainment, lower incomes, and those who lack a usual source of care are also less likely to be adequately screened.[9] Consistent with historical trends, Asians have the lowest screening rates (76%) compared to all other racial groups.[9,12,13] In California, Hispanics and Asian/Pacific Islanders comprise 38% and 14% of the population, respectively, and represent two of the most rapidly growing immigrant populations in the U.S.[14] Additionally, within Hispanic and Asian sub-groups, significant variation in screening uptake has been identified.[13,15]

1.2.4 HPV vaccine offers opportunity to fill screening gaps

Since the 1940's, Pap testing has served as the clinical reference standard for prevention, but the approval of the prophylactic HPV vaccine in 2006 made primary prevention tangible. HPV has been accepted as the primary causal agent of cervical cancer. Persistent infection with at least one of approximately 15 types of high-risk HPV is responsible for almost all (99%) cervical cancers.[16] All three available vaccine formulations protect against two HPV types (16 and 18) responsible for almost 70% of cervical cancers in the U.S. The 9-valent vaccine further extends protection to 5 more HPV types, covering an additional 10-15% of cervical cancers.[17] Studies suggest the vaccine is working. In the U.S., reductions in surrogate outcomes such as oncogenic HPV type prevalence and high-grade cervical lesions have been observed.[18,19] The Advisory Committee for Immunization Practices (ACIP), a federal advisory committee, has recommended routine HPV vaccination at ages 11-12 years for girls since 2006 and for boys since 2011.[20] While initial guidelines recommended a 3-dose schedule, revised recommendations lowered required number of shots to two doses for adolescents under age 15 years. After a decade since HPV vaccine introduction in the U.S., however, initiation rates among teens hover around 66%, and only 49% of teens have received all recommended doses.[21]

1.2.5 Changing landscape of cervical cancer prevention and guidelines

As knowledge about the epidemiology of cervical cancer has advanced and tools have allowed for better risk stratification, clinical practice guidelines have correspondingly adapted. In 2012, the U.S. Preventive Services Task Force (USPSTF) and other leading professional health organizations endorsed several changes in cervical cancer screening guidelines.[22-25] The most notable paradigm shift was the lengthening of cervical cytology testing intervals from annually to every 3 years for women ages 21-65 years, with the option to extend screening to every 5 years with HPV co-testing for women ages 30-65 years. The guidelines also increased the age at

which to begin screening to 21 years and lowered the age at which to discontinue screening to 65 years. More recently, in 2018, the USPSTF added yet another modality to the menu of screening options: primary HPV testing alone every 5 years for women ages 30-65 years.[26]

Furthermore, clinical practice has shifted towards more conservative management of pre-cancerous cervical lesions, particularly among young women. In 2012, the American Society of Colposcopy and Cervical Pathology (ASCCP) recommended cytological observation of minimal abnormalities instead of direct referral to colposcopy for women ages 21-24 years, owing to an overall net harm of intervention among this age group.[22] Invasive cervical procedures have been associated with greater risk of negative obstetric outcomes (e.g., future premature delivery, low birth-weight infants) and psychological distress.[27-32] Cervical cancer rates are also extremely low among this age group (1.4 per 100,000 women),[33] and although young women have high rates of HPV infection, the majority will clear through natural immunity and pre-cancerous lesions are likely to regress.[34-36] Thus, the harms of invasive cervical procedures were found to outweigh the mortality benefit and also deemed costly and unnecessary. Since the ASCCP convened in September 2012 to develop consensus guidelines, the revised recommendations are commonly referred to as the "2012" guidelines; however, the guidelines were not published until March 2013.[22]

1.2.6 Provider adherence to cervical cancer screening and management guidelines

Primary and secondary prevention tools hold great promise, but their potential can only be realized with adequate uptake. Barriers to guideline implementation are multi-factorial and far-ranging. At the provider level, reasons include lack of awareness or knowledge,[37] attitudes towards guidelines (e.g., trust in clinical appropriateness),[38,39] perception of patient preferences for screening,[37,39-42] concern about unintended consequences,[40,41,43] as well as variation in provider experience and training.[38,44,45] Provider behavior may also be influenced by organizational factors, such as financial incentives to screen more frequently, constrained

practice resources, malpractice concerns, and limited time to adequately explain guideline changes to patients.[39,41,42,46] These conditions may be exacerbated in safety net settings with high staff turnover, inconsistent training, fragmented patient care and insurance coverage along the screening, follow-up, and treatment continuum. Studies to date have been mostly limited to privately insured women and non-ethnic minorities. Further research is needed within the health care safety net setting, given their role in delivering care to vulnerable populations at high risk for developing cervical cancer.

1.2.7 Current challenges in implementing cervical cancer prevention guidelines

Evolving cancer prevention strategies and guidelines created new opportunities to reach underserved populations, but with new guidelines came new challenges to implementation. Adolescent HPV vaccination expanded prevention approaches, but it also meant shifting implementation to the pediatric setting, decision-making to caregivers, and public health messaging to increase awareness among a larger population at risk of infection. Changes in screening guidelines increase choices and reduce patient touch points, but also place additional responsibility on providers to disseminate information to their patients in an understandable way that is consistent with patient values and preferences. This responsibility may be greater for those serving lower-literate and lower-educated populations, and patient education standards for cervical cancer screening in particular are not well delineated in the literature. Finally, conservative management confers a net benefit for patients, provided patients return for repeat cytology. Providers in safety net settings serving populations who are less engaged with the health care system must therefore also consider the risks of failure to return. This dissertation explores some of these issues.

1.3 Dissertation Objectives

Overall, this dissertation aims to explore adherence to primary and secondary cervical cancer prevention recommendations among ethnically diverse and low-income populations. In three distinct studies capturing prevention guidelines that target different stages along the cervical cancer progression continuum, this project examines: 1) how HPV vaccination among adolescents changed in the initial years following HPV vaccine approval in the U.S.; 2) how follow-up of abnormal cervical cancer screening tests differed for young women following issuance of updated consensus guidelines; and 3) how providers communicate revised cervical cancer screening and management recommendations with patients and address patient preferences.

1.4 Study Setting

This project is conducted within two settings in California: Los Angeles County (Study 1) and California's Family Planning Access Care and Treatment Program (Family PACT), the state's Medicaid family planning program (Studies 2 and 3).

1.4.1 Los Angeles (LA) County

The first study focuses on primary prevention of cervical cancer and is set in LA County, the most populous county in the U.S., home to over 10 million residents. The cervical cancer incidence rate in LA County exceeds the national rate (7.7 versus 7.2 per 100,000, respectively)[47,48] and is highest among Latinos and Southeast Asian subgroups (Vietnamese, Thai/Cambodian/Hmong/Laotian).[49] Furthermore, the cervical cancer death rate is approximately 2.5 times higher in LA County than the U.S. (3.0 vs. 1.2 per 100,000, respectively) and disproportionately impacts African American and Latina women (4.1 and 3.1 per 100,000, respectively, versus 2.6 per 100,000 for Whites).[47] The demographic profile of

adult women in the county is ethnically diverse (46% Latino, 14% Asian, 9% African American, 30% White), over-representing ethnic subgroups disproportionately impacted by cervical cancer.[47] Additionally, 46% of adult women are foreign-born, 38% speak another language other than English, 25% have less than a high school education, and 27% have household incomes less than 100% of poverty.[47] As described earlier, these vulnerable populations are at greatest risk for inadequate cervical cancer screening, lending greater importance to the success of primary prevention. Over 1 million adolescents (approximately half girls) in LA County are age-eligible for HPV vaccination.[50] Given the demographic diversity and elevated cervical cancer burden in LA County, it represents an ideal geographical setting to evaluate disparities in HPV vaccination among adolescents.

1.4.2 California's Family Planning Access Care and Treatment Program (Family PACT)

The second and third studies focus on secondary cancer prevention and are set in Family PACT, California's Medicaid family planning program. California's Medicaid program is called Medi-Cal. The California state legislature established Family PACT in 1996, recognizing the importance of empowering reproductive health decisions and the cost-effectiveness of reducing unplanned pregnancies.[51] Family PACT was funded by the state general fund from 1996 to 1999 and received additional support from the Centers for Medicare and Medicaid Services (CMS) under a Medicaid Section 1115 Waiver demonstration project from 2000 to 2010. In 2011, California transitioned Family PACT to a State Plan Amendment (SPA), retroactive to 2010, which eliminated the need to renew the waiver at regular intervals.

Family PACT is the largest publicly funded family planning program in the nation, accounting for over half of all beneficiaries in the U.S. The program comprises a network of over 2,000 affiliated private and public providers for eligible low-income (≤200% FPL), uninsured or underinsured women and men who do not qualify for traditional Medicaid—regardless of immigration status. Unlike California's full-scope Medicaid program, this limited benefits

program supports family planning and family planning-related services such as cervical cancer screening and diagnostic tests. In 2014, Family PACT provided nearly triple the number of cervical cancer screening tests as screening and diagnostic services combined in California's breast and cervical early detection program (approximately 200,000 vs. 70,000 clients, respectively). Currently, Family PACT serves over 1 million low-income California residents who are predominantly Latino (64%), immigrants, and sexually active, populations at higher risk for HPV infection and cervical cancer.[52] Family PACT providers therefore present important "medical homes" to reach vulnerable groups disproportionately impacted by cervical cancer. In California, Hispanic and poor women are at increased risk of preterm birth.[53,54] Moreover, almost all Family PACT female clients (97%) are of reproductive age and seeking family planning services, making it a fitting setting to study trends in potential overtreatment, given the important clinical consequences among this age group.

1.5 Conceptual Framework

Figure 1.1 depicts the conceptual framework guiding the overall dissertation. It illustrates how factors at the individual, provider, health care system, and community levels impact adherence to cervical cancer prevention guidelines. The term "individual" refers to the medical decision-maker: adult women for cervical cancer screening or caregivers of adolescents for adolescent HPV vaccination. This framework incorporates constructs from existing health behavior and implementation frameworks that explain determinants of behavior and translation of evidence-based guidelines into practice.[55-57] Although the dissertation does not examine all constructs outlined in Figure 1.1, they are described below for context.

Individual Level. At the individual level, socio-demographic characteristics may impact propensity to seek and attitudes towards preventive care. For example, increasing age may coincide with greater perceived susceptibility to infection or disease, and race/ethnicity could

reflect cultural attitudes, beliefs, and trust in the health care system. Inadequate or lack of health care coverage can also limit engagement with the health care system and access to recommended services. An individual's medical history (e.g., Pap test history, HPV status) could furthermore impact their perceived need for care. Finally, awareness and knowledge, as well as literacy and health literacy, may impact individual understanding of and self-efficacy to engage in behaviors. Together, these factors can shape patient preferences for recommended care.

Provider Level. Several provider factors also impact adherence to guidelines. For example, providers' medical education and practical experience can increase their knowledge, ability, and confidence to implement evidence-based guidelines. Prior patient experiences can also influence providers' risk perception, attitudes towards and acceptability of clinical practice guidelines, and subsequent decisions to adhere to them. Providers can directly impact patient adherence as well, since the quality of their communication and relationship may increase patient knowledge, trust, and acceptance of recommended care.

Health Care System Level. The environment in which providers practice and individuals receive care is another source of influence. The system's structure (e.g., size, staffing) could affect ease of guideline adoption and implementation. The organization's prioritization of cervical cancer prevention may help to establish a climate and culture of quality improvement, and increase investments in resources (e.g., trainings, infrastructure, clinical decision supports) to improve guideline adoption and implementation across providers within the organization. Furthermore, system guidelines (e.g., clinic protocols, workflow processes) may help to routinize and streamline processes for vaccination, screening, and follow-up. Incentives and rewards (e.g., reimbursements, recognition) may also extrinsically motivate providers to deliver guideline-concordant care.

Community Level. Finally, community resources may indirectly impact adherence to preventive care guidelines through individuals, providers, and the health care system. For instance, social interactions may influence subjective norms and affect an individual's likelihood

of obtaining preventive care. Structural characteristics (e.g., public transportation) and environmental barriers (e.g., travel distance) may impact an individual's access to clinics and ability to complete recommended care. Moreover, neighborhood economic conditions may affect provider availability and establishment of safety net clinics at the provider and health care system levels and availability of social programs that enable patients to seek care at the individual level.

1.6 Dissertation Aims

Guided by this multi-level framework, this dissertation examines adherence to strategies for primary prevention of cervical cancer (HPV vaccination) and secondary prevention of cervical cancer (cervical cancer screening and management) among high-risk populations, primarily ethnic minority and low-income women.

The specific aims for each study are as follows.

Study 1. To compare changes and disparities in HPV vaccine awareness among parents of adolescents and to compare changes and disparities in HPV vaccine uptake among adolescent girls between 2007 and 2011, using population-based survey data

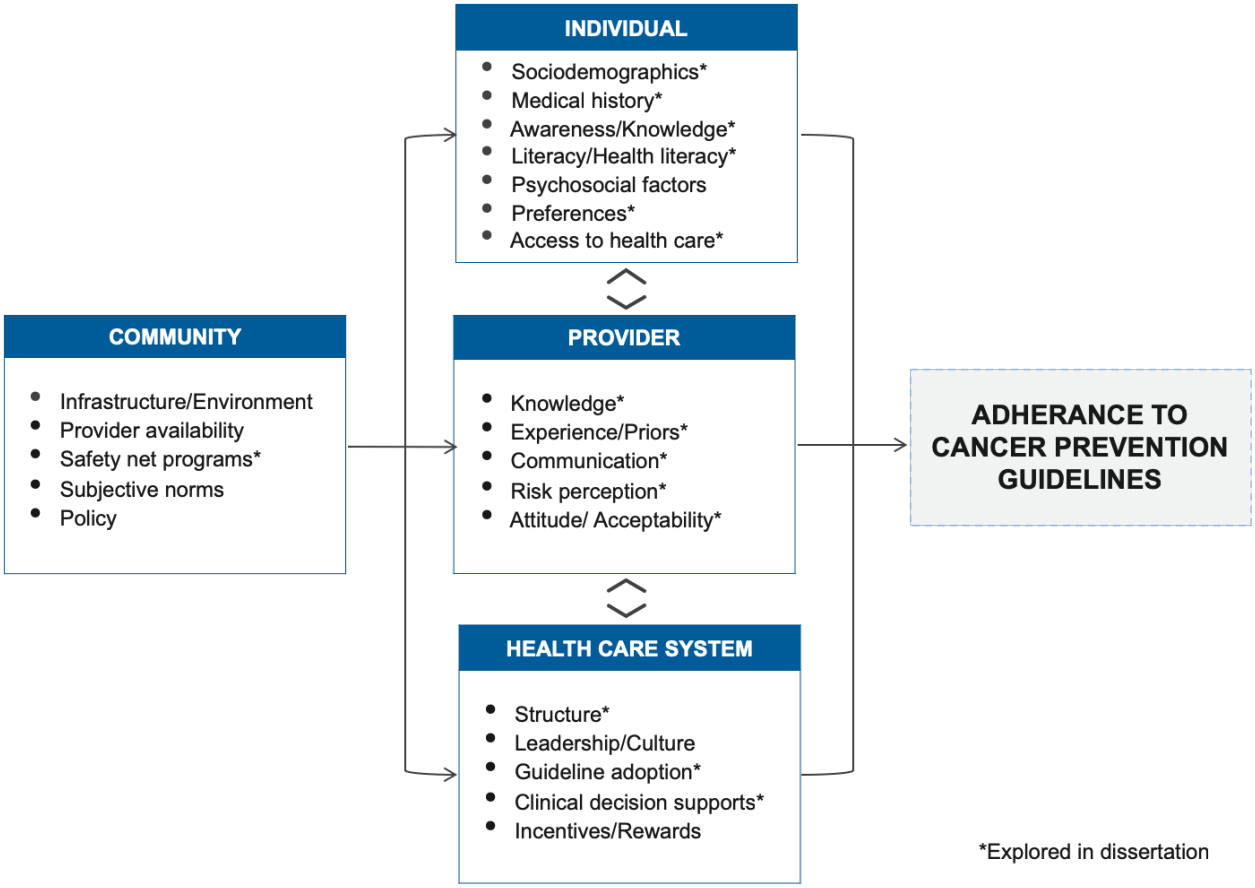
Study 2. To evaluate the impact of the 2012 cervical cytology management guidelines on colposcopy procedures among young women, using quantitative administrative and claims data

Study 3. To explore how providers communicate with patients about the 2012 cervical cancer screening and management guidelines and address patient preferences, using in-depth semi-structured interviews

1.7 Contribution to Research

This dissertation extends knowledge about uptake of cervical cancer prevention strategies among ethnically diverse and low-income populations during a period of significant changes in the field. First, it not only contributes generalizable knowledge about primary and secondary prevention, but also directly informs local efforts and policies for the counties and publicly funded programs in which the studies are conducted. Second, there is a lack of empirical evidence on the impacts of recent clinical practice changes to management of abnormal screen findings, particularly among uninsured women with well-documented barriers to follow-up. Research on monitoring care for abnormal cytology often relies on lengthy prospective data collection, but this project leverages longitudinal administrative and publicly available data to evaluate organization-level impacts and account for both individual and provider-level characteristics. Third, this project uses primary data collection to elicit provider perspectives on communication with patients, whereas existing research largely reflects patient perspectives. Understanding the provider perspective is important to informing interventions that are both accepted by providers and that can be feasibly integrated into clinical practice. Together, results from these studies will help to inform future efforts to improve patient and provider adherence to cervical cancer prevention strategies among ethnically diverse and undeserved communities.

Figure 1.1 Conceptual Framework for Adherence to Cervical Cancer Prevention Guidelines



Cervical cancer prevention outcomes explored in this dissertation include human papillomavirus vaccination (individual = caregiver for adolescent HPV vaccination), cervical cancer screening, and management of abnormal cytology

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Chapter 2

Disparities in Parental Human Papillomavirus (HPV) Vaccine Awareness and Uptake among Adolescents

2.1 Abstract

Background. The Advisory Committee for Immunization Practices (ACIP) recommends routine human papillomavirus (HPV) vaccination for adolescents. We evaluated changes in HPV vaccine awareness among parents of adolescent boys and girls (ages 13-17 years) and HPV vaccine uptake (≥1 dose) among girls (ages 13-17 years) in an ethnically and socioeconomically diverse county.

Methods. We analyzed two cycles of a population-based survey in Los Angeles County conducted in 2007 and 2011. Survey-weighted data and multivariable logistic regression analyses were used to evaluate rates and correlates of parental HPV vaccine awareness (n=3,647) and HPV vaccine uptake among girls only (n=1,779), controlling for parent and child demographic characteristics and access factors.

Results. Between 2007 and 2011, parental HPV vaccine awareness moderately increased from 72% to 77% overall, with significant increases among mothers, Latinos, and respondents with daughters and Medi-Cal insured children. In 2011, lower likelihood of parental awareness was associated with male gender, older age, less education, Asian/Pacific Islander ethnicity, and having a son. HPV vaccine initiation among daughters nearly doubled from 25% in 2007 to 48% in 2011, and girls who were older, uninsured, and had access-related barriers showed the largest improvements. In 2011, daughters who were younger and who had older and African American parents were at risk for low vaccine uptake.

Conclusions. Efforts to increase HPV vaccine awareness and coverage are needed. Initiatives targeting parents of boys and younger adolescents, culturally relevant information, and awareness about access to vaccination may help to reduce identified disparities.

2.2 Introduction

The approval of the human papillomavirus (HPV) vaccine marked a significant advancement for cancer prevention. The quadrivalent HPV vaccine was licensed in the United States. in 2006, and the bivalent and 9-valent formulations were approved in 2009 and 2014, respectively. These vaccines protect against 66-81% of cervical cancers and the majority of other HPV-associated cancers.[1] Since the vaccine's introduction in the U.S., population-level reductions in oncogenic HPV type prevalence and high-grade cervical lesions attributable to the vaccine have been observed.[2,3] Given ethnic and socioeconomic disparities in the incidence of cervical and other HPV-associated cancers,[4-6] ensuring equitable coverage—particularly among younger adolescents prior to HPV exposure—remains a critical public health strategy to mitigating cancer health disparities.

The Advisory Committee for Immunization Practices (ACIP) has recommended routine HPV vaccination at ages 11-12 years for girls since 2006 and for boys since 2011, with catch-up vaccinations through age 26 years for females and age 21 years for males. In 2015, however, coverage rates for teenage girls and boys only reached 63% and 50%, respectively, in the U.S. and 67% and 59%, respectively, in California.[7] Prior studies have identified facilitators to adolescent HPV vaccination, including parent and adolescent race/ethnicity, parental awareness and knowledge, child age, health insurance status, health care utilization, and physician recommendation.[8-11] Many, however, included limited ethnic subpopulations or non-random samples, and few assessed correlates over time. Given nationwide variation in vaccination coverage,[7] it is furthermore important to explore predictors at local levels to appropriately target interventions.

To address these gaps, we analyzed two cycles of a large, ethnically diverse population survey in Los Angeles (LA) County, California, the most populous county in the U.S., where cervical cancer incidence and death rates have exceeded national averages.[12,13] Using a large, ethnically diverse population-based survey, we compared (1) HPV vaccine awareness among

parents of adolescent girls and boys (ages 13-17 years) between 2007 and 2011 and (2) HPV vaccine uptake (≥1 dose) among girls (ages 13-17 years) over this same period. We hypothesized an increase in parental HPV vaccine awareness and vaccine uptake among adolescent girls between 2007 and 2011. Following ACIP's HPV vaccine recommendation for girls in 2006, information dissemination by health care providers and the media is expected to increase parental awareness about the HPV vaccine. As increased awareness could lead to increased knowledge and social acceptability of the vaccine, providers may be more willing to recommend and parents may be more willing to accept vaccination for their children. We also hypothesized that differences in outcomes between racial/ethnic and age groups would narrow between 2007 and 2011, as a result of potential dissipation of stigma around sexually transmitted infections.

2.3 Methods

2.3.1 Data Source

This study is nested in the Los Angeles County Health Survey (LACHS), a periodic, population-based telephone survey that collects information on demographics, health conditions, health behaviors, and access to health care among adults and children in LA County. Our study focused on findings from the child surveys, which compile data from a representative sample of non-institutionalized children (ages 0-17 years), collected in 2007 and 2011. The Los Angeles County Department of Public Health's Institutional Review Board approved the survey.

2.3.2 Data Collection

Detailed descriptions of the LACHS methodology have been reported previously.[14-16] Briefly, a sample of LA County households was random digit dialed, and surveys were completed with the parent or primary caregiver (referred to as parent hereon for brevity) of a selected child ages 0-17 years in that household. In 2011, cellular telephone numbers were added to the sampling

frame to improve survey coverage. Computer-assisted telephone interviews were conducted in six languages (English, Spanish, Cantonese, Mandarin, Korean, and Vietnamese) between April and December 2007 for the 2007 survey and between June 2010 and June 2011 for the 2011 survey. Overall sample sizes for 2007 and 2011 child surveys were 5,728 and 6,013, and response rates were 15% and 20%, respectively. For this study, we restricted analyses to parents with children ages 13-17 years, comparable to the age range monitored in the National Immunization Survey – Teen (NIS-Teen). The final sample included 1,783 and 1,864 respondents from 2007 and 2011, respectively (**Figure 2.1**).

2.3.3 Data Measures

Outcomes. Primary outcomes included parental HPV vaccine awareness and adolescent HPV vaccine uptake. A statement about HPV and the cervical cancer vaccine or HPV shot (or Gardasil in the 2007 survey) for girls (and boys in the 2011 survey) introduced HPV survey questions. Awareness was measured with a question asking parents whether they had ever heard of a vaccine to prevent HPV and cervical cancer; awareness was defined as having heard of the vaccine. Aware parents with children ages 9-17 years were then asked whether their children had received any HPV shots and how many. For unaware parents, we assumed their children received no shots. HPV vaccine uptake was defined as having received at least one shot.

Explanatory variables. Other measures, informed by literature and prior work,[17-19] included parental and child demographics and child's access to health care. Survey questions used to assess each measure are outlined in **Appendix 2.1**, and variable construction in final models is described below.

Parental demographic factors included age (18-39, 40-49 vs. ≥50 years), gender (male vs. female), race/ethnicity (Latino, African American, Asian/Pacific Islander vs. White), education (less than high school, high school, some college or trade school vs. college or post

graduate degree), household income (0-99% federal poverty level (FPL), 100%-199% FPL, 200%-299% FPL vs. 300% or above FPL), language used most at home (English, Spanish vs. other languages), and birthplace (foreign-born vs. U.S.-born).

Child demographic factors included age (by year) and gender (male vs. female). Child's race/ethnicity and socio-economic status were assessed but not reported due to their strong correlation to corresponding parental characteristics. We also measured several health care access indicators among children, including health insurance status (California's Children's Health Insurance Program called Healthy Families/Healthy Kids, Medicaid called Medi-Cal, private vs. no insurance), having a regular source of care (yes vs. no), and difficulty in accessing medical care (yes vs. no). The survey categorized race and ethnicity using a mutually exclusive hierarchical system,[20] and a Markov chain Monte-Carlo method was used to impute missing values for household income. All other variables had limited missing data, and no imputation was performed.

2.3.4 Statistical Analysis

All statistical analyses employed weighted data to account for design effects. We conducted descriptive analyses to assess study population characteristics and outcomes. For unadjusted analyses, we examined 95% confidence intervals [CI] between years, and non-overlapping CIs were considered statistically significant ($p<0.05$). For adjusted analyses, we employed logistic regression, calculated adjusted odds ratios [aOR] and 95% CIs, and stratified analyses by parent gender. Because the vaccine was not approved for boys in 2007 and only a small number (≈10%) of boys received the vaccine in 2011, vaccine uptake was modeled only among girls (n=888 in 2007 and n=891 in 2011; **Figure 2.1**). We evaluated statistical significance using the Wald test, and p-values were two-sided. All analyses were performed in SAS 9.3 (SAS institute, Cary, NC).

2.4 Results

2.4.1 Study sample

Table 2.1 presents weighted percentages and 95% CIs for sample characteristics. Respondent characteristics in 2007 (n=1,783) and 2011 (n=1,864) were comparable. About half of parents were lower-income (<200% FPL) and had less than a college education. Reflecting the ethnic diversity of LA County, over 75% of parents identified as an ethnic minority (about 55% Latino, 10% African American, and 10% Asian/Pacific Islander), approximately 56% were foreign-born, and 37% spoke mostly Spanish at home. Due to changes in respondent selection, proportionally more men were included in 2011 compared to 2007 (26% vs. 4%, respectively). In both years, about half of respondents' children were female, half privately insured, and ages were equally distributed.

2.4.2 Parental HPV vaccine awareness

Table 2.2 presents weighted percentages and multivariable logistic regression results for parental HPV vaccine awareness. Overall, parental HPV vaccine awareness moderately increased from 72% (95% CI 69-74%) in 2007 to 77% (95% CI 74-80%) in 2011. Significant increases were observed among mothers, Latinos, and respondents with daughters or Medi-Cal insured children. Among mothers only, additional subgroups revealed significant increases, including among those who were younger, less-educated, foreign-born, lower-income, mostly spoke Spanish, and whose children had greater ease accessing medical care and a regular source of care (data not shown).

In adjusted analyses, many subgroup differences were no longer significant, including for lower household income, Latino and African American race/ethnicity, and other primary language. In 2011, however, lower parental awareness remained associated with Asian/Pacific Islander ethnicity and lower education. Specifically, Asian/Pacific Islander parents had 58% lower odds of being aware of the vaccine, relative to Whites (aOR 0.42, 95% CI: 0.20-0.86).

Fathers also remained significantly less likely than mothers to report awareness, albeit to a lesser magnitude (aOR 0.39 vs. aOR 0.19 in 2007 and 2011, respectively), while the difference between parents with sons compared with daughters widened (aOR 0.32 vs. aOR 0.55 in 2007 and 2011, respectively). Additionally, in 2011, younger versus older parents were more likely aware.

2.4.3 HPV vaccine uptake among girls

Weighted percentages and multivariable logistic regression results for HPV vaccine uptake for girls are displayed in **Table 2.3**. Overall, HPV vaccine uptake doubled between from 25% in 2007 (95% CI: 21-28%) and to 48% in 2011 (95% CI: 42-53%). Daughters who were older, uninsured, and had difficulty accessing medical care or no regular source of care exhibited the largest significant improvements. For example, there was a 35 percentage-point (300% relative) increase in uptake among uninsured girls, rising from 12% in 2007 to 47% in 2011. Daughters with no regular source of care exhibited a 42 percentage-point (435% relative) increase, climbing from 10% in 2007 to 51% in 2011.

In adjusted analyses, education was the only factor associated with HPV vaccine initiation in 2007. Compared to parents with a college education, those with some college or trade school education were less likely to have a vaccinated daughter (aOR 0.52, 95% CI: 0.31-0.88). In 2011, poor vaccine uptake was associated with younger child age (13-14 years), and parent correlates included African American race, moderate-income level (200-299% FPL), and older age. African American vs. White parents had 64% lower odds of having a vaccinated daughter (aOR 0.36, 95% CI: 0.15-0.89).

2.5 Discussion

In 2007 and 2011, approximately three in four parents were aware of the HPV vaccine in LA County. Awareness rates among parents in our sample with specifically daughters paralleled national estimates (85%),[21] but were higher than those reported among girls in California and high-risk communities in LA County (ranging from 53% to 60%).[18,19,22,23] Although rates of HPV vaccine uptake among girls nearly doubled from 2007 to 2011, coverage only reached 48% in 2011, lower than national (53%) and state (65%) NIS-Teen estimates.[24] Notably, population composition and survey methodology may explain some of these differences in vaccination estimates. For example, LA County has a greater proportion of Latino, low-income, and foreign-born residents than California and the U.S. Additionally, the NIS-Teen vaccination coverage estimates were based on parental report and provider verification of teen vaccination history, whereas the LA County survey relied on solely parental report, which has been associated with net underreporting.[25]

Our findings importantly highlighted subpopulations for outreach. The persistent gender disparities underscore the need for targeting both fathers and mothers and promoting the vaccine's direct benefits for both boys and girls. National surveys conducted around the same time as our 2011 survey similarly identified disparities in awareness between mothers and fathers and revealed even lower rates of awareness among parents with pre-teen and teenage sons (55%) than parents with sons in our study (69%).[26,27] Differences in parental awareness by child gender may reflect slow dissemination of HPV vaccine approval for boys and physicians' reluctance to recommend it for boys.[28] Furthermore, stagnantly low awareness among Asian/Pacific Islanders, who historically have had the poorest rates of cervical cancer screening, raises concerns.[29] Asian parents who had heard of the vaccine, however, were as likely as White parents to vaccinate their daughter. In contrast, despite awareness rates comparable to White parents in 2011, African American respondents were significantly less likely to have vaccinated daughters. These results suggest promoting awareness may be an effective strategy

for Asians, but alone may be an insufficient approach for some African American parents. Identifying modifiable facilitators that narrow the gap between awareness and action, such as trust in healthcare providers,[30] merit continued exploration.

Older teens also made greater coverage gains than younger teens, consistent with prior research.[31] In addition to parental refusal, research has shown that providers may feel less urgency to recommend the vaccine to younger adolescents.[32] Given well-documented impacts of providers' recommendation on parental decisions to vaccinate their children[23,33-35] and superior immune response in younger children, interventions encouraging providers' strong endorsement of HPV vaccination and its cancer prevention benefit among younger adolescents are needed.[36] A recent study found a provider recommendation strongly endorsing HPV vaccination, its cancer prevention benefit, and same-day vaccination was associated with over nine times higher odds of HPV vaccine initiation.[36] Moreover, recent changes to ACIP recommendations from a three-dose to a two-dose schedule for adolescents before age 15 years strengthen the rationale for initiating HPV vaccination in younger adolescents.

Interestingly, traditional access-related barriers did not predict poor vaccine receipt among girls, potentially owing to several safety net programs in LA County and the federal Vaccines for Children program. In LA County, for example, the Children's Health Outreach Initiative helps to fill gaps in insurance coverage for children, which may have played a role in initial engagement with the health care system. The 3-fold increase in uptake among uninsured daughters may also reflect early impacts of community health center expansions and delivery system reforms to California's safety net occurring around the same time. Other unmeasured potential influences beyond access, such as behavioral and psychosocial determinants and provider recommendation, warrant further study. Furthermore, our results may underestimate uptake because we categorized children with unaware parents as unvaccinated. Parents may have not recalled the HPV vaccine if co-administered with other adolescent vaccinations. Also,

vaccines are accessible at school-based clinics in California and, moving forward, it is important to remember that state legislation permits adolescent HPV vaccination without parental consent.

Study limitations are acknowledged. First, cross-sectional data limit causal inferences. Second, the 2007 sampling frame did not include residents who solely used cellular telephones, often younger and lower-income people.[37] To mitigate potential bias, we adjusted survey weights to account for noncoverage of cellular-only households. Third, similar to other population-based surveys, measures were self-reported, and surveys had low response rates. Self-reported HPV vaccination rates, in particular, may be underestimated,[38] though likely non-differentially between survey years. Also, non-response does not necessarily introduce substantial biases into survey estimates.[39,40] Finally, findings may not be generalizable to all populations, but may inform other diverse communities. Despite these limitations, this study's major strength includes use of a large, complex population-based survey with an ethnically and socioeconomically diverse sample and two years of data.

In conclusion, improvements in HPV vaccine awareness and uptake are needed. Emphasis on routine provider recommendation for all age-eligible boys and girls, integration of culturally relevant information, and greater awareness about access to the vaccine regardless of insurance remains critical. The inclusion of HPV vaccination as a HEDIS® performance measure for boys and girls and reduction in recommended number of doses for younger adolescents may further facilitate improvements in coverage and completion. More recently, the Food and Drug Administration (FDA) approved expanded use of the HPV vaccine for adults ages 27 to 45 years. Whether ACIP will subsequently revise guidelines and insurance companies will cover vaccination for this age group remains to be seen. One possible unintended consequence of expanding use for older adults, however, could include a reduction in parental urgency to vaccinate their children during adolescence. Thus, continued monitoring of HPV vaccine awareness and uptake, for boys and girls, is important to understanding impacts of incremental efforts to increase and promote equitable coverage.

Table 2.1 Sample Characteristics (n=3,647)

	2007	2011
	N[a] (Weighted %[b])	N[a] (Weighted %[b])
Overall	1,783 (100)	1,864 (100)
Parent Characteristics		
Gender		
Female	1,711 (96.3)	1,363 (74.4)
Male	72 (3.7)	501 (25.6)
Age Group (years)		
18-39	442 (26.0)	347 (29.7)
40-49	877 (50.1)	899 (47.4)
50 or over	452 (23.9)	609 (22.9)
Race/Ethnicity[c]		
White	503 (24.6)	598 (23.9)
Latino	924 (54.9)	896 (55.7)
African American	130 (11.0)	159 (10.4)
Asian/Pacific Islander	206 (9.6)	181 (10.1)
Education		
Less than high school	542 (32.2)	486 (29.8)
High school	299 (18.3)	308 (20.3)
Some college or trade school	410 (23.3)	388 (20.5)
College or post graduate	512 (26.2)	662 (29.3)
Household Income (% FPL)[d]		
0-99% FPL	619 (36.6)	435 (31.0)
100%-199% FPL	394 (23.7)	424 (25.5)
200%-299% FPL	205 (10.6)	218 (12.1)
300% or above FPL	565 (29.1)	787 (31.4)
Primary Language		
English	1,007 (56.6)	1,130 (56.3)
Spanish	613 (37.7)	583 (37.4)
Other	118 (5.7)	124 (6.4)
Country of Birth		
Foreign born	989 (56.9)	947 (55.7)
US born	784 (43.1)	906 (44.3)
Child Characteristics		
Gender		
Female	888 (49.6)	891 (48.2)
Male	895 (50.4)	973 (51.8)
Age (years)		
13	315 (20.6)	295 (18.3)
14	352 (22.3)	338 (20.6)
15	356 (18.1)	366 (18.5)
16	407 (20.4)	429 (21.7)
17	353 (18.7)	436 (21.0)
Insurance[e]		
Healthy Families/Healthy Kids	238 (13.1)	267 (16.2)
Medi-Cal	432 (26.2)	380 (28.1)
Private	932 (50.0)	1,086 (48.4)
No insurance	166 (10.8)	113 (7.3)

Difficulty Accessing Medical Care		
Yes	262 (16.6)	211 (14.1)
No	1,471 (83.4)	1,625 (85.9)
Have Regular Source of Care		
Yes	1,618 (90.5)	1,770 (94.8)
No	161 (9.5)	90 (5.2)

[a] Unweighted frequency; numbers might not add up to 1,783 (2007) or 1,864 (2011) due to missing data
[b] Percentages were adjusted for sampling weights.
[c] Only Whites, Latinos, African Americans, and Asians/Pacific Islanders were included in the analysis.
[d] Based on U.S. Census Federal Poverty Level (FPL) thresholds at the time of interview
[e] Healthy Families/Healthy Kids is California's Children's Health Insurance Program. Medi-Cal is the state's Medicaid program.

Table 2.2 HPV Vaccine Awareness among Parents of Adolescents Aged 13-17y (n=3,647)

	2007		2011	
	% (95% CI)	Adj. OR (95% CI)[a]	% (95% CI)	Adj. OR (95% CI)[a]
Overall	72 (69-74)	--	77 (74-80)	--
Parent Characteristics				
Gender				
Female	72 (70-75)	Ref	82 (78-85)†	Ref
Male	56 (41-70)	0.19 (0.09 - 0.37)*	63 (56-70)	0.39 (0.25 - 0.62)*
Age Group (years)				
50 or over	73 (68-78)	Ref	69 (62-76)	Ref
40-49	72 (69-76)	1.09 (0.74 - 1.59)	80 (76-84)	1.70 (1.01 - 2.87)*
18-39	70 (65-75)	1.44 (0.94 - 2.21)	79 (72-85)	2.08 (1.09 - 3.94)*
Race/Ethnicity				
White	90 (87-94)	Ref	87 (83-91)	Ref
Latino	65 (61-69)	0.50 (0.28 - 0.90)*	75 (70-79)†	0.91 (0.45 - 1.85)
African American	74 (64-84)	0.39 (0.19 - 0.79)*	86 (79-93)	0.81 (0.37 - 1.77)
Asian/Pacific Islander	59 (51-67)	0.33 (0.15 - 0.72)*	61 (49-72)	0.42 (0.20 - 0.86)*
Education				
College or post graduate	84 (80-88)	Ref	84 (80-89)	Ref
Some college or trade school	81 (77-86)	0.97 (0.55 - 1.72)	83 (77-89)	0.59 (0.32 - 1.11)
High school	67 (60-74)	0.57 (0.31 - 1.04)	72 (64-81)	0.51 (0.26 - 0.99)*
Less than high school	59 (54-64)	0.52 (0.28 - 0.97)*	70 (63-76)	0.44 (0.21 - 0.92)*
Household Income (%FPL)[b]				
300% or above FPL	89 (86-92)	Ref	83 (79-88)	Ref
200-299% FPL	76 (69-83)	0.51 (0.29 - 0.90)*	79 (72-86)	0.94 (0.47 - 1.89)
100-199% FPL	66 (60-72)	0.47 (0.24 - 0.90)*	76 (69-82)	1.35 (0.62 - 2.96)
0-99% FPL	61 (56-65)	0.48 (0.25 - 0.94)*	71 (64-78)	1.06 (0.39 - 2.88)
Primary Language				
English	83 (80-86)	Ref	84 (80-88)	Ref
Spanish	60 (56-65)	0.68 (0.42 - 1.10)	70 (64-76)	0.71 (0.31 - 1.62)
Other	47 (36-57)	0.29 (0.13 - 0.65)	59 (47-71)	0.74 (0.34 - 1.58)
Country of Birth				
US born	84 (80-87)	Ref	86 (83-90)	Ref
Foreign born	63 (59-66)	0.94 (0.57 - 1.57)	69 (65-74)	0.59 (0.32 - 1.09)
Child Characteristics				
Gender				
Female	78 (75 - 81)	Ref	86 (82-90)†	Ref
Male	66 (62-70)	0.55 (0.41 - 0.74)*	69 (64-74)	0.32 (0.21 - 0.49)*
Age (years)				
13	70 (64-76)	Ref	76 (68-84)	Ref
14	72 (66-77)	1.03 (0.64 - 1.64)	80 (73-86)	1.15 (0.63 - 2.12)
15	74 (68-79)	1.34 (0.84 - 2.12)	74 (66-82)	0.95 (0.49 - 1.86)
16	73 (68-78)	1.17 (0.72 - 1.88)	78 (71-86)	1.25 (0.65 - 2.41)
17	71 (66-77)	1.02 (0.62 - 1.68)	76 (70-82)	1.20 (0.65 - 2.21)
Insurance[c]				
Private	83 (80-86)	Ref	84 (80-88)	Ref
Healthy Families/Healthy Kids	66 (59-73)	1.00 (0.61 - 1.63)	71 (61-80)	0.78 (0.36 - 1.68)
Medi-Cal	59 (53-64)	0.67 (0.42 - 1.08)	73 (67-80)†	0.75 (0.31 - 1.81)
No insurance	60 (59-73)	0.80 (0.44 - 1.45)	61 (61-80)	0.61 (0.20 - 1.91)

Difficulty Accessing Medical Care				
No	74 (72-77)	Ref	79 (76-82)	Ref
Yes	61 (54-68)	0.94 (0.61 - 1.45)	66 (56-76)	0.82 (0.42 - 1.61)
Have Regular Source of Care				
Yes	73 (71-76)	Ref	78 (75-82)	Ref
No	60 (51-69)	1.00 (0.62 - 1.62)	56 (37-74)	0.53 (0.25 - 1.11)

Abbreviations: OR, odds ratio; CI, confidence interval; FPL, federal poverty level

[a] Mutually adjusted for variables in table
[b] Based on U.S. Census Federal Poverty Level thresholds at the time of interview
[c] Healthy Families/Healthy Kids is California's Children's Health Insurance Program. Medi-Cal is the state's Medicaid program.
[†] Confidence intervals between years did not overlap
*p<0.05

Table 2.3 HPV Vaccine Uptake among Girls Aged 13-17y (n=1,779)

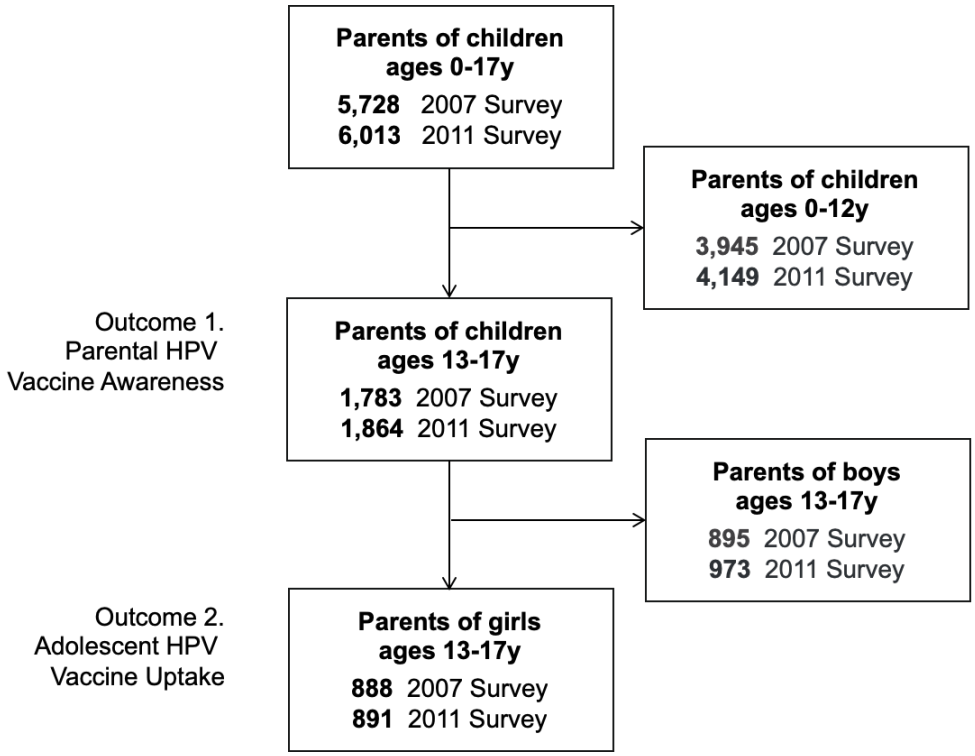
	2007		2011	
	% (95% CI)	Adj. OR (95% CI)[a]	% (95% CI)	Adj. OR (95% CI)[a]
Overall	25 (21-28)	--	48 (42-53)†	--
Parent Characteristics				
Gender				
Female	25 (21-28)	Ref	52 (45-58)†	Ref
Male	21 (4-38)	0.62 (0.22 - 1.72)	35 (24-45)	0.58 (0.32 - 1.05)
Age Group (years)				
50 or over	25 (19-31)	Ref	37 (28-45)	Ref
40-49	23 (18-27)	0.98 (0.62 - 1.56)	46 (39-54)†	1.78 (1.04 - 3.04)*
18-39	27 (20-35)	1.64 (0.92 - 2.93)	58 (47-70)†	3.91 (1.94 - 7.87)*
Race/Ethnicity				
White	31 (24-37)	Ref	53 (43-62)†	Ref
Latino	23 (18-27)	1.35 (0.70 - 2.60)	47 (39-55)†	0.54 (0.26, 1.13)
African American	17 (8-26)	0.48 (0.21 - 1.08)	46 (25-67)	0.36 (0.15, 0.89)*
Asian/Pacific Islander	25 (15-35)	1.51 (0.66 - 3.48)	46 (30-61)	1.04 (0.42, 2.54)
Education				
College or post graduate	36 (29-43)	Ref	50 (41-59)	Ref
Some college or trade school	22 (15-28)	0.52 (0.31 - 0.88)*	55 (42-68)†	1.29 (0.68 - 2.46)
High school	19 (12-27)	0.48 (0.23 - 1.00)	52 (39-65)†	0.85 (0.41 - 1.74)
Less than high school	21 (15-27)	0.70 (0.31 - 1.60)	40 (29-51)†	0.48 (0.19 - 1.20)
Household Income (%FPL)[b]				
300% or above FPL	31 (25-37)	Ref	53 (45-61)†	Ref
200-299% FPL	21 (12-29)	0.74 (0.39 - 1.41)	42 (27-56)	0.46 (0.22, 0.97)*
100-199% FPL	27 (19-35)	1.27 (0.64 - 2.55)	50 (38-62)†	0.91 (0.40, 2.09)
0-99% FPL	18 (13-24)	1.03 (0.46 - 2.32)	43 (32-54)†	0.57 (0.21, 1.57)
Primary Language				
English	29 (24-34)	Ref	51 (44-59)†	Ref
Spanish	19 (13-24)	0.65 (0.29 - 1.45)	47 (37-57)†	1.13 (0.49 - 2.58)
Other languages	17 (7-27)	0.67 (0.23 - 1.95)	35 (19-50)	0.47 (0.18 - 1.24)
Country of Birth				
US born	31 (25-36)	Ref	49 (40-58)†	Ref
Foreign born	20 (16-24)	0.60 (0.32 - 1.15)	47 (39-54)†	1.65 (0.89 - 3.05)
Child Characteristics				
Age (years)				
17	21 (13-30)	Ref	62 (51-74)†	Ref
16	27 (20-33)	1.36 (0.74 - 2.48)	50 (37-63)†	0.57 (0.30 - 1.10)
15	27 (19-35)	1.49 (0.78 - 2.83)	53 (39-66)†	0.74 (0.37 - 1.48)
14	27 (19-35)	1.40 (0.75 - 2.63)	38 (26-50)	0.25 (0.12 - 0.54)*
13	21 (14-28)	1.14 (0.59 - 2.21)	35 (24-46)	0.24 (0.12 - 0.48)*
Insurance[c]				
Private	30 (25-35)	Ref	50 (43-57)†	Ref
Healthy Families/Healthy Kids	21 (12-30)	1.03 (0.47 - 2.24)	43 (29-57)	1.12 (0.49 - 2.58)
Medi-Cal	19 (13-25)	0.75 (0.36 - 1.54)	48 (37-60)†	1.65 (0.67 - 4.08)
No insurance	12 (3-21)	0.66 (0.22 - 1.97)	47 (21-72)†	1.10 (0.36 - 3.38)
Difficulty Accessing Medical Care				
No	27 (23-31)	Ref	49 (43-55)†	Ref
Yes	14 (6-22)	0.62 (0.29 - 1.31)	42 (27-57)†	0.65 (0.32 - 1.33)

Having Regular Source of Care				
Yes	26 (22-30)	Ref	48 (42-53)[†]	Ref
No	10 (2-17)	0.48 (0.16 - 1.45)	51 (24-79)[†]	1.14 (0.36 - 3.55)

Abbreviations: OR, odds ratio; CI, confidence interval; FPL, federal poverty level

[a] Mutually adjusted for variables in table
[b] Based on U.S. Census Federal Poverty Level thresholds at the time of interview
[c] Healthy Families/Healthy Kids is California's Children's Health Insurance Program. Medi-Cal is the state's Medicaid program.
[†]Confidence intervals between years did not overlap
*p<0.05

Figure 2.1 Sample Selection and Inclusion Criteria



Two cycles of data from the Los Angeles County Health Survey, conducted in years 2007 and 2011, were analyzed. Parents of adolescent boys and girls were included in the analysis of parental human papillomavirus (HPV) vaccine awareness, and parents of girls only were included in the analysis of adolescent HPV vaccine uptake.

Appendix 2.1 Los Angeles County Health Survey (LACHS) items

HPV Section Introduction

Human papilloma (PAP-ILL-OH-MAH) virus (VY-RUS), also called HPV, is a common sexually transmitted infection known to cause cervical cancer in women. A vaccine to prevent HPV infection is available for girls and boys starting at age 9 and is called the cervical cancer vaccine, or HPV shot.

Survey Items

The following survey items were selected from the LACHS to construct study measures.

Measure	Survey Items
Primary Outcomes	
Heard of vaccine	Before today, had you ever heard of a vaccine to prevent HPV and cervical cancer?
Received at least 1 dose	Has *(child)* received any HPV shots? How many HPV shots has *(child)* had?
Parent Characteristics	
Gender	I am asked to confirm whether you are male or female?
Age	What is your age?
Race/ethnicity	For classification purposes, we'd like to know what your racial background is. Are you White or Caucasian, Black or African-American, Asian, Pacific Islander, American Indian or an Alaskan native, a member of another race, or a combination of these?
Primary language	In which language would you prefer to be interviewed?
Country of birth	Were you born in California, in some other state in the U.S. or outside the United States?
Education	What is the highest level of school you have completed or the highest degree you have received?
Household income	Is your household's total annual income from all sources before taxes above *(poverty x 2)* or below *(poverty x 2)*?
Child Characteristics	
Gender	Is *(child)* male or female?
Age	What is *(child)*'s age?
Race/ethnicity	For classification purposes, we'd like to know what *(child)*'s racial background is. Is *(he/she)* White or Caucasian, Black or African-American, Asian, Pacific Islander, American Indian or an Alaskan native, a member of another race, or a combination of these?
Insurance	Is *(child)* covered by health insurance or any other kind of health care plan? Is *(child)* currently covered for health insurance through employer, Medi-Cal/Medicaid, Healthy Families, Healthy Kids, military insurance program?
Have regular source of care	When *(child)* is sick or you want advice about *(his/her)* health, is there one particular place or health provider that you take *(him/her)* to MOST often?
Difficulty accessing care	Overall, how easy or difficult is it for *(child)* to get medical care when *(he/she)* needs it? Would you say it is very difficult, somewhat difficult, somewhat easy, or very easy?

Source: Los Angeles County Department of Public Health. Los Angeles County Health Survey; http://www.publichealth.lacounty.gov/ha/hasurveyintro.htm.

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Chapter 3

Impact of Conservative Management Guidelines on Colposcopy Procedures among Low-income Women

3.1 Abstract

Background. To reduce overdetection and potential harmful interventions, consensus guidelines published in 2013 recommended conservative management of abnormal cervical cytology for women ages 21-24 years. We evaluated whether the new guideline contributed to a reduction in colposcopy procedures among young, low-income women.

Methods. We used administrative and claims data from primary care providers in California's Medicaid family planning program. Women ages 21-44 years with at least one Pap test between July 2011 and June 2015 were selected from 216 continuously enrolled provider sites. We calculated rates of colposcopy receipt within 6 months of an index Pap test, controlling for patient and provider characteristics. Using a three-level random intercept model, we estimated the marginal effect of the guideline among women ages 21-24 years, relative to a comparison group of women ages 25-44 years.

Results. Our sample included 480,551 cervical cytology tests from 333,977 women who were predominantly Latina (84%) and Spanish-speaking (66%). The updated management guidelines were associated with a 1.93 percentage point (95% CI 1.62 - 2.25; $p<0.001$) reduction in colposcopies among women ages 21-24 years, relative to the comparison group. The decrease was two-fold greater among women ages 21-24 years compared with those ages 25-44 years (41% vs. 21% relative reduction, respectively), and the strongest effects (3-fold relative decline) were observed in 2014. Colposcopy receipt was associated with speaking primarily English vs.

non-English (OR 1.58, 95% CI 1.51 - 1.65), having a Pap test in the past year vs. not (OR 1.62, 95% CI 1.56 - 1.68), and receiving care from a public vs. private provider (OR 1.23, 95% CI 1.01 - 1.50).

Conclusion. In a large statewide family planning program serving low-income, ethnic minority women, colposcopy procedures among young women significantly declined following issuance of conservative management guidelines, which may protect against risks to future pregnancies.

3.2 Introduction

Early detection of cervical cancer has reduced cervical cancer mortality in the United States,[1] but its benefits must be managed against the risks of overdetection and overtreatment. Cervical cancer incidence is low among young women, with an annual incidence rate of 1.4/100,000 among women ages 21-24 years.[2] Persistent human papillomavirus (HPV) infection causes cervical cancer,[3] and although HPV prevalence is high among young women, infection frequently clears through natural immunity. Low-grade squamous intraepithelial lesions (LSIL), a reflection of active HPV replication, also regresses without treatment—hence the term low grade.[4-6] Colposcopy examination itself, the process of using a magnifying instrument to observe cellular changes in the cervix, is a safe procedure with rare complication of bleeding and infection. Its greatest harm, though, is that it could lead to unnecessary invasive excisional procedures, which have been associated with psychological distress and adverse obstetric outcomes, such as future premature delivery, premature rupture of membranes, and low birth-weight.[7-13] The decision to triage an abnormality to colposcopy therefore requires balancing competing risks: the risk of missing a lesion that may progress to cancer and the risk of unnecessarily treating a lesion that would have otherwise spontaneously resolved.

In response to growing evidence about the natural history of HPV and potential harms of early intervention, the American Society for Colposcopy and Cervical Pathology (ASCCP) convened in 2012 to revise guidelines for management of abnormal cytology.[14] The age-based recommendations published in 2013 reflected not only age differences in cervical cancer risk and net harms of excisional therapy, but also differences in the background rate of true pre-cancers. Prior to 2012, high-risk Atypical Squamous Cells of Undetermined Significance (ASCUS) and LSIL served as the traditional threshold for colposcopy referral due to low sensitivity of cytology to high-grade squamous intraepithelial lesions (HSIL). Among young women, however, LSIL cytology more often reflects true positive low-grade lesions, and even true HSILs are likely to regress. Therefore, revised consensus guidelines recommended

cytological surveillance of minimal abnormalities (ASCUS or LSIL) for women ages 21-24 years, instead of direct referral to colposcopy.

Understanding adoption of these management recommendations is important, yet understudied. Guidelines discouraging overdetection may be particularly challenging to implement in safety net settings serving historically under-screened populations at increased risk of cervical cancer.[15,16] Additionally, ethnic minorities not only have the highest rates of HPV infection and cervical cancer incidence and mortality,[17,18] but also higher rates of preterm delivery than non-Hispanic Whites.[19] Prior research found high adoption of the 2006 management guidelines targeting adolescent girls under age 21 years, which similarly recommended that minimal abnormalities be observed rather than triaged to colposcopy for this group.[20-23] To our knowledge, only a couple of published studies have evaluated impacts of the 2012 guidelines on colposcopies among young women (ages 21-24 years), but they were limited to single institutions, small samples, and were either descriptive or only assessed secular trends.[24,25] Using data from the largest publicly funded family planning program in the nation, this study aims to overcome some sample size limitations, account for confounders, and extend knowledge about cervical cytology management among vulnerable populations.

The purpose of this study is to evaluate the impact of the 2012 cervical cytology management guidelines on colposcopy procedures, a trigger for potential downstream overtreatment, among women ages 21-24 years. We hypothesized that the new guidelines would decrease the proportion of colposcopies among young women with cervical cytology screening tests after compared to before the guideline change. The rationale for this hypothesis is that diffusion of management guidelines may increase provider awareness and thereby encourage them to refer proportionally fewer young women to colposcopy after the guideline change.

3.3 Methods

3.3.1 Study Setting

The setting for this study is the Family Planning Access Care and Treatment (Family PACT) program, California's Medicaid (i.e., Medi-Cal) family planning program. The state uses this innovative approach to providing comprehensive family planning services to eligible low-income (≤200% of federal poverty level) individuals who do not qualify for traditional Medi-Cal. This fee-for-service limited benefits program extends to family planning-related services such as cervical cancer screening and diagnostic tests. The Family PACT network comprises over 2,200 public and private Medi-Cal providers across several specialties and serves over 1.1 million low-income California residents who are predominantly Latino and sexually active—populations at high risk for HPV infection and cervical cancer.[15] Moreover, about half of female clients are nulliparous, and almost all female clients seeking family planning services are of reproductive age—two-thirds of who fall under the age of 30 years.[26] Family PACT therefore represents a relevant setting to study potential overtreatment, given the important clinical consequences among this age group.

3.3.2 Study Design

This study uses a quasi-experimental, difference-in-differences (DID) approach to examine the impact of the most recent cervical cytology conservative management guideline on colposcopy procedures among low-income women. The observation period was July 2011 to June 2015, capturing approximately two years before and after the guideline change was published. Although the ASCCP convened to revise the guidelines in September 2012, we defined the date of guideline issuance as March 21, 2013, corresponding to the date the consensus guidelines were published.[14] Using claims and administrative data from a sample of Family PACT providers, we compared the impact of the guideline on changes in colposcopy procedures among women ages 21-24 years with cervical cytology, relative to a comparison group of

women ages 25-44 years. The University of California Los Angeles and the University of California San Francisco Institutional Review Boards, California's Committee for the Protection of Human Subjects and the Data Research Committee of the California Department of Health Care Services approved this study.

3.3.3 Data Sources

Primary data sources included Family PACT administrative and claims data from the California Department of Health Care Services Office of Family Planning, which administers the Family PACT program. This study is nested in a larger project that evaluated adherence to cervical cancer screening guidelines. For the present study, we linked three Family PACT databases: (1) claims data on cervical cancer screening-related services, which were derived from the Medi-Cal Data Warehouse Family PACT program fee-for-service claims; (2) the program's client enrollment file, which contains individual-level demographic data, and (3) the program's provider enrollment file, which contains data on provider characteristics. "Providers" refer to solo practitioners or clinics and were identified by their National Provider Identifier (NPI) number, a unique 10-digit identification number issued by the Center for Medicare and Medicaid Services (CMS) to individual and organization health care providers. We obtained additional provider site characteristics from two other public data sources: (1) the Every Woman Counts (EWC) program, a state and federally funded program that provides free breast and cervical cancer screening and diagnostic services to low-income women in coordination with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and (2) California's Office of Statewide Health Planning and Development (OSHPD). The final merged analytic file contained data at the client-date of service level; each clinician, procedure, and laboratory claim was attributed to a clinician date of service.

3.3.4 Sample Selection

Figure 3.1 displays sample selection and inclusion criteria. The sampling frame included female Family PACT clients who had at least one clinician visit to any Medi-Cal provider located in one of ten mostly southern California counties, between 2011 and 2015. For the parent study, the sample included providers who served at least 200 women under age 30 years during FY2012-2013 and excluded Planned Parenthood affiliates because their systems track guideline adherence. Among these sites, we selected provider sites that were continuously enrolled between July 2011 and June 2015 (n=216) for the present study. Among the 661,723 female clients served by these 216 sites, we further selected a sample of women aged 21-44 years who had at least one cervical cytology claim between July 2011 and June 2015 and included all Pap tests within the observation period among these women. The final sample included 333,977 women who received 480,551 Pap tests. A woman was assigned to a provider site based on the site of her first visit during the observation period, and age was defined as the woman's age as of her index cervical cytology test date.

3.3.5 Study Cohort

Following national reproductive age definitions,[27] we included women ages 21-44 years, given obstetric risks associated with potential downstream excisional procedures among women who wish to bear future children. The study group (i.e., treatment group) included young women ages 21-24 years, consistent with the age group targeted by the guideline. A comparison group included women ages 25-44 years, a group who should have not been affected by the guideline. This age group likely experienced similar secular trends in clinical practice as women ages 21-24 years, with exception of how providers approached management of abnormal cytology. Comparable to young women, women ages 25-44 years also had guaranteed coverage for colposcopy referrals, were of reproductive age and seeking family planning services, and plausibly experienced similar barriers to follow-up of an abnormal screening test result. Use of

this comparison group therefore allowed us to better identify the independent effect of the guideline, apart from other co-occurring changes that may have impacted the likelihood of colposcopy.

3.3.6 Data Measures

Primary outcome. The primary outcome was colposcopy receipt, defined as having a paid colposcopy claim within 6 months of the index cervical cytology claim (yes/no). We used colposcopies as a more proximal surrogate measure for potential harm, as the procedure could lead to unnecessary and harmful excisional procedures and unnecessary financial and emotional costs. A 6-month follow-up period was used to allow sufficient time for colposcopy appointment scheduling, receipt, and completion.[28] The CPT codes used to define cervical cytology tests and colposcopy procedures are outlined in **Appendix 3.1**.

Main independent variables. The conservative management guideline for women ages 21-24 years was the main independent variable. This measure was constructed as an indicator variable, where 1 indicated the index Pap test occurred after guideline issuance, and 0 indicated the index test occurred before guideline issuance. We defined guideline issuance as the date of publication (March 21, 2013) because this date reflects when providers could have been collectively exposed to the guidelines outlining changes in colposcopy referral indications. **Appendix 3.2** shows specific changes in referral indications for young women.

The second main variable of interest was age, since colposcopy indications vary based on patient age. Consistent with the most recent guideline, we constructed an indicator variable defined as whether woman was age 21-24 years at the time of her index Pap test or not.

Other explanatory variables. Patient-level and provider-level variables hypothesized to be associated with the outcome were also assessed to adjust for any differences between treatment and comparison groups. Patient demographic measures included: (1) *race/ethnicity*, as providers may be more likely to refer higher-risk racial/ethnic groups, and some racial/ethnic

groups have shown to exhibit greater fear towards invasive procedures, modesty, or distrust, which may reduce adherence to follow-up; (2) *primary language*, as, regardless of language concordance, speaking English may help to reduce patient-provider communication barriers and facilitate adherence to a provider's recommendation; and (3) *county of residence*, given counties with greater enabling resources and fewer geographic barriers to care may increase ease of follow-up. To account for clinical history, we also assessed receipt of a *Pap test within the past year* of the index Pap test, since this measure may reflect either: (a) an annual screen (i.e., overscreening), which may be more likely to pick up an abnormality that would have otherwise regressed under 3-year screening or (b) a 1-year repeat Pap test, consistent with guidelines for managing a prior abnormality. In either scenario, these women would be more likely to be referred for a colposcopy than those without a Pap test within the past year. To avoid potential misclassification, we used Pap test history as an explanatory variable instead of a selection criterion for isolating an "initial" Pap test because indications for Pap test or colposcopy cannot be distinguished in our claims data.

Provider characteristic measures included: (1) *ownership* type, as public providers may have greater resources such as Title X funding (federally-funded family planning program) for provider education, clinical decision supports, and patient reminder systems, thereby facilitating provider guideline adherence and patient follow-up at these sites; (2) Family PACT *client volume*, since serving a greater number of Family PACT enrollees may increase awareness about and experience with management guidelines; (3) site *location* (urban vs. rural), with urban location hypothesized to be positively associated with patient adherence, owing to fewer geographic barriers to care; (4) site *county*, as site counties with greater resources for low-income patients may have fewer barriers to follow-up; and (5) *Every Woman Counts* enrollment, which may increase on-site provider education about guidelines and subsequently increase provider adherence.

3.3.7 Statistical Analyses

Descriptive statistics were performed for all measures by age groups. Frequencies and unadjusted proportion of colposcopies [i.e., colposcopies (numerator) among cervical cytology tests (denominator)] were calculated at quarterly periods (i.e., 3-month increments from July 2011 to June 2015). The unit of analysis was patients who received a Pap test. Chi-square tests and univariate logistic regressions were used to explore associations between categorical patient and provider site characteristics and the primary outcome. Multivariable regressions were used to evaluate changes in colposcopy receipt, accounting for clustering and patient and provider site characteristics.

To estimate the effect of the guideline change on colposcopy receipt for young women ages 21-24 years, a difference-in-differences approach was used, with women ages 25-44 years as the comparison group (Equation 1). The first difference represents the change in likelihood of colposcopies between pre- and post-guideline periods, and the second difference represents the difference between the two age groups. We used a three-level random intercept logistic regression model to account for correlation between Pap tests from the same patient (level 2) and correlation between patients from the same provider (level 3). The outcome was modeled as a function of an indicator for younger age group (variable *Age21to24)*, an indicator for whether the observation occurred after the guideline change (variable *PostGuideline*), and an interaction term between younger age group and post-guideline change. The coefficient of the interaction term (β_3) represents the difference-in-differences estimate of the pre-post guideline change in colposcopy receipt among women ages 21-24 years, relative to women ages 25-44 years.

The final multivariable model was constructed considering bivariate associations, moderation effects, multicollinearity, and conceptual significance of measures. Patient characteristic covariates (γ) included age (ages 21-24 years vs. 25-44 years), race/ethnicity (Latina, other vs. White), primary language (English vs. non-English speaking), and Pap test

within the past year (at least one vs. none), and provider site characteristics (Ω) included provider ownership (public vs. private), Every Woman Counts enrollment (yes vs. no), and county (Los Angeles vs. all others). Patient county of residence was excluded from the final model, given similarity of information captured from site county. Provider site location was also excluded since very few sites were located in a rural county, in addition to Family PACT client volume due to minimal variability among sites included in our sample. Odds ratios (ORs) and 95% confidence intervals (CI) were estimated. To assist with interpretation of results, average marginal predicted probabilities were calculated and reported. Statistical significance was assessed at the 0.05 level, and all analyses were conducted using Stata 15.0 (Stata Corp. 2017. College Station, TX: StataCorp LLC).

Regression specification

Difference-in-differences analysis of colposcopy receipt among women ages 21-24y vs. 25-44y

$$Log\,[p/(1-p)] = \beta_0 + \beta_1 Age21to24_i + \beta_2 PostGuideline_t + \beta_3 Age21to24{*}PostGuideline_{it} + \boldsymbol{\gamma} PatientVars_i + \Omega ClinicVars_s$$

Equation (1)

$\boldsymbol{\gamma}$ = vector of patient characteristics (age, race, primary language, prior Pap test)*
Ω = vector of provider site characteristics (ownership, EWC enrollment, county)*

*excluded from final model: patient county of residence, site location, site Family PACT client volume

Sensitivity Analyses. We employed various sensitivity analyses to assess robustness of results. First, we fitted an alternate model (logistic regression with cluster robust standard errors) to assess whether our estimates were sensitive to model specification. Second, we tested the parallel trends assumption underlying the difference-in-differences approach by testing for pre-guideline differences in outcome trajectory for study and comparison groups. Third, to account for potential age differences in follow-up adherence,[29,30] we restricted the comparison group to women ages 25-29 years, whose likelihood of following up on provider

referrals may more closely approximate women ages 21-24 years. Finally, we excluded data after 2014 to address potential confounding effects of the Affordable Care Act (ACA). In post-hoc analyses, we added post-guideline time indicators corresponding to the dates of ASCCP guideline issuance (March 21, 2013), ACA Medicaid expansion (January 1, 2014), and potential trend reversal based on unadjusted trends (October 1, 2014).

3.4 Results

3.4.1 Sample characteristics

Our sample included 480,551 cervical cytology tests from 333,977 women (73,803 women ages 21-24 years and 260,174 women ages 25-44 years at the time of their first Pap test). Overall, women were predominantly Latina (84%) and Spanish-speaking (66%) (**Table 3.1**). Two-thirds (67%) of women received only one Pap test within the study period, and colposcopies were completed on average within 49 days of an index Pap test (data not shown). Over half of women received care from a provider that was private (57%), located in Los Angeles (58%), and not enrolled in Every Woman Counts (59%). Nearly all sites (n=208/216) were located in an urban county (**Table 3.2**). Provider characteristics were comparable across study and comparison groups, but a lower proportion of women ages 21-24 years versus ages 25-44 years were Latina (77% vs. 86%, respectively) and Spanish-speaking (40% vs. 73%, respectively). Within age groups, the distribution of patient and provider characteristics was comparable in pre- and post-guideline periods (**Appendix 3.3**).

3.4.2 Unadjusted trends in colposcopy procedures

Figure 3.2 presents trends in unadjusted proportion of colposcopies among women with a Pap test by age group. Unadjusted proportions at baseline (July-September 2011) were highest for women ages 21-24 years (7.5%), followed by women ages 25-29 years (6.0%) and those ages 30-44 years (3.9%). Between 2011 and 2015, the likelihood of colposcopy significantly declined

among all age groups, beginning in quarter 8 (April-June 2013) among women ages 21-24 years and in quarter 10 (October-December 2013) among women over 24 years, relative to the initial quarterly period (July-September 2011) (ps<0.05; data not shown). Though prevalence of colposcopies was higher among women ages 25-29 years versus 30-44 years, trends paralleled each other throughout the study period. A slight reversal of the declining trend was observed starting in late 2014 (October 2014 to June 2015 period).

3.4.3 Bivariate and multivariable regression analyses for impact of 2012 guideline

Table 3.3 displays predictive margins calculated from the multivariable regression modeling the impact of the guideline, including pre-post changes in the outcome within each age group and the difference-in-differences estimate. After accounting for patient and provider site characteristics and clustering, the guideline was associated with a 1.93 percentage point (95% CI 1.62 - 2.25) decrease in colposcopy procedures among women ages 21-24 years, relative to the reduction among women ages 25-44 years. Among women aged 21-24 years, the predicted probability of a colposcopy declined from 6.70% prior to the guideline to 4.35% after the guideline, a 2.76 percentage point reduction (95% CI 2.44 - 3.07) or 41.1% relative decline. Among women aged 25-44 years, the predicted probability of a colposcopy declined from 3.94% to 3.53%, a 0.82 percentage point reduction (95% CI 0.69 - 0.96) or 20.8% relative decline.

In post-hoc analyses, we observed the strongest effects starting approximately three quarters after guideline issuance, during the January-September 2014 period (2.56 percentage point reduction, 95% CI: 2.16 - 2.97). This result translates to almost a 3-fold relative decline among younger versus older aged women (43.8% versus 15.4% reduction, respectively). Predictive margins for the main and post-hoc analyses are displayed in **Figure 3.3** and **Figure 3.4**, respectively.

Table 3.4 presents unadjusted and adjusted associations between patient and provider site characteristics and the outcome. Bivariate analyses revealed that women who were Latina (vs. White) and received care from provider sites located in Los Angeles County (vs. other counties) were more likely to have a colposcopy procedure, while those who spoke primarily English (vs. non-English), had a prior Pap test (vs. none), and received care from site that were public (vs. private) or enrolled in Every Women Counts (vs. not) had lower likelihood of colposcopy. There were no subgroup differences in pre- versus post-guideline periods, other than age group (**Appendix 3.4**), nor did language appear to moderate the effect of race/ethnicity (**Appendix 3.5**). In adjusted analyses, greater likelihood of colposcopy receipt was associated speaking primarily English vs. non-English (OR 1.58, 95% CI 1.51 - 1.65), having a Pap test in the past year vs. not (OR 1.62, 95% CI 1.56 - 1.68), and receiving care from a public vs. private provider (OR 1.23, 95% CI 1.01 - 1.50).

3.4.4 Sensitivity analyses

Results from sensitivity analyses are reported in the Appendix. The parallel trends test suggested there were no pre-existing trend differences between treatment and comparison groups (**Appendix 3.6**). Additionally, use of an alternate model specification and younger comparison group resulted in highly comparable estimates for the main effect. Restricting observations to the pre-ACA period yielded a slightly lower, but not statistically different, estimate (**Appendix 3.7**).

3.5 Discussion

3.5.1 Main findings

In the largest statewide family planning program, we found that issuance of the 2012 cervical cytology management guidelines were associated with a significant decline in colposcopies among young women. These findings suggest rapid adoption of evidence-based clinical practice

guidelines among diverse private and public safety net providers who were affiliated with California's Medicaid family planning program and standards. Findings have implications for reducing unnecessary morbidity and obstetric complications among minority and low-income women.

3.5.2 Reduction in colposcopy prevalence across all age groups

Our study captured a period of pivotal changes in cervical cancer detection. Baseline colposcopy prevalence fell within a plausible range based on rates of abnormal cytology reported in prior studies[31-33] and patient non-adherence. Not surprisingly, the downward trend in colposcopy prevalence observed among all age groups coincided with the release of the 2012 cervical cancer screening guidelines, which recommended increased screening intervals. Consistent with the screening guideline's goals, our results may reflect an overall reduction in number of abnormal tests, since some abnormalities that would have been identified under routine annual screening were expected to have regressed within the extended 3-year interval. Fewer abnormal tests thus translate to fewer colposcopy referrals. Other studies have observed similar trends.[25,34] One evaluation conducted in a large academic colposcopy referral center serving primarily low-income patients found colposcopy volume declined to nearly one-third of its peak between 2010 and 2015.[34] Similarly, ours declined overall by half.

3.5.3 Guideline impact on young women

Our results suggest the updated management guideline contributed to the steeper decline among women ages 21-24 years, relative to older aged women, starting in mid-2013. This sharper reduction can be explained by the combined impact of not only the increased screening intervals, but also fewer colposcopy referrals following abnormal tests, given the change in colposcopy indications for young women only. Importantly, the highest baseline proportion of colposcopy procedures (~7%) was observed among the youngest women, who represent ages

at lowest risk for HSIL and cervical cancer. Even after accounting for effects of the increased screening intervals, we would have expected higher prevalence of abnormal tests among younger versus older aged women due to greater prevalence of LSIL and ASCUS among women under 25 years. Therefore, the guideline's change in colposcopy indications for young women was likely responsible for driving prevalence in the 21-24 age group even lower than expected with the screening interval change alone. Our estimates translate to approximately 1,400 potentially unnecessary colposcopy procedures averted annually among young women screened in California's family planning program. If providers nationwide exhibited a similar pattern of guideline adoption, the effect of a 2 percentage point reduction in colposcopy procedures could also be substantial, given about 9 million women between the ages of 21 and 24 reside in the U.S. and 3-year cervical cancer screening rates hover around 80%.[16]

3.5.4 Diffusion of evidence-based guidelines

"De-implementation" of practices previously perceived to benefit patients can be challenging, but cytology management guidelines appeared to be quickly adopted. In our study, the strongest effects were observed within less than one year, consistent with prior cytology management guideline changes targeting women under 21 years.[35] Given Family PACT serves a high volume of young adult women seeking family planning services, providers may readily embrace changes that promote optimal reproductive heath. Notably, in 2013, Family PACT issued a clinical practice alert regarding updated cervical screening guidelines, which may have increased provider awareness about management guidelines and speed of adoption. The slight reversal of trends starting in mid-2014, however, illustrates potential limitations of relying solely on passive diffusion of evidence-based guidelines – particularly in settings with high staff turnover, rotating clinical trainees, and limited infrastructure to support systematic training. While this slight reversal could also reflect sensitivity of the data to smaller sample sizes, further

research on how providers choose to adopt and disseminate management guidelines and strategies to sustain implementation in resource-constrained settings is warranted.

3.5.5 Organization-level variation in practice

Our findings extend prior research by revealing potential organizational variation in follow-up of abnormal cytology.[25] Results showed Pap tests among women served by public versus private providers were more likely to result in a (completed) colposcopy, particularly at federally qualified health centers (FQHCs). Public providers may serve higher-risk women requiring referral and also may have greater organizational supports for referral adherence. Nationally, over half of family planning providers refer outside of their practice for abnormal cytology,[36] a risk factor for poor patient compliance.[37] Although private family planning clinics are more likely to have on-site cervical diagnostic services, public providers have shown greater engagement in referral activities to ensure patient follow-up of an abnormal test.[36,38,39] Furthermore, funding at public clinics is often tied to performance reporting, quality improvement initiatives, and care coordination for the underserved, which may increase referral adherence. Prior research showing greater quality and access among FQHCs and Title X-funded clinics compared with private providers have similarly attributed high performance to these incentives.[40,41] Additional research exploring the role of specialty referral coordination in referral adherence may help to explain observed provider-level variation in colposcopy procedures.

3.5.6 Linguistic barriers to follow-up of abnormality

Finally, differences in patient follow-up adherence and preferences may similarly explain greater likelihood of colposcopies among English compared with non-English speakers. Beyond common challenges to understanding medical jargon, non-English speaking women have reported perceiving inadequate communication about the nature of their abnormality, purpose of colposcopy, and steps to navigate follow-up.[42-45] Multi-lingual providers and interpreters, while

effective in reducing communication barriers, may be less accessible in specialty care settings where colposcopy consent occurs. Moreover, our prior work on barriers to abnormal follow-up found Spanish-speakers, in particular, may be hesitant to ask clarifying questions through an intermediary and ultimately prefer information directly from their provider.[42,43] After controlling for language, race/ethnicity did not appear to be meaningfully related to colposcopy receipt. Our sample comprised predominantly English- and Spanish-speaking Latinas, however, which limited granular analyses among our multi-ethnic and multi-lingual sample. Future studies should continue exploring ethnic sub-group differences in referral follow-up.

3.5.7 Limitations

Several study limitations are acknowledged. First, common to many studies using administrative data, our data contained limited measures to help explain our outcome (both provider referral and patient adherence to colposcopy). Chief among these variables is cervical cytology results, which would have helped to improve our identification strategy. While it is possible the effects of HPV vaccination reduced prevalence of cervical abnormalities (and consequently colposcopy referrals) among younger women in our sample,[46] our prior research revealed very low rates of HPV vaccination among uninsured and publicly insured adolescents in the same geographic region.[47] Second, we were unable to capture colposcopies reimbursed outside Family PACT or Medi-Cal providers to whom Family PACT referred. Missing data is expected to be low, however, and likely non-differential between study groups or pre/post-guideline periods. Third, selection may be a concern in our study design if there were systematic differences between treatment and comparison groups or pre/post-guideline periods. Our sensitivity analyses using an alternative comparison group and observation period, in addition to adjustments for patient compositional differences, helped to reduce concern about this competing explanation. Unobserved heterogeneity, however, remains possible. Finally, our sample comprised low-income, mostly Latina, and many undocumented women who received care across fee-for-

service providers serving a large volume of young women. Thus, results may be less generalizable to other ethnic groups, low-volume clinics, or settings where greater compliance with follow-up may be expected, such as integrated networks or commercially insured populations.

3.5.8 Strengths

Despite these limitations, to our knowledge, our study is among the first to evaluate impacts of the 2012 conservative management guidelines on colposcopy procedures among un- or under-insured women. Sample size has been a limitation of prior studies, and our use of a large, longitudinal database permitted examination of a relatively rare outcome over time. Also, our study design and robust results helped to reduce concern about the impact of secular trends during a time of prominent cervical cancer prevention and delivery system reforms. Our sample also uniquely shed light on young, Latina women receiving services from publicly funded family planning providers, a population at increased for both cervical cancer and preterm birth (i.e., women for whom the consequences of under and overdiagnosis could take significant toll).

3.5.9 Clinical and policy implications

Our findings have several clinical implications. The trend towards fewer overall colposcopies reduces training opportunities. Given subjectivity of colposcopy procedures, maintaining sufficient experience is essential to improving technique for accurate diagnoses and favorable patient outcomes.[34] The significant reduction in colposcopies among young women, in particular, has implications for potentially reducing unnecessary morbidity and narrowing disparities in preterm birth among ethnic minority women. Nevertheless, one concern about scaling back intervention is potentially missing significant disease, especially in high-risk populations. Some studies have identified substantial high-grade dysplasia among young, high-risk women with low-grade cytology, and have suggested reconsidering colposcopy rather than cytological

surveillance among similar high-risk (e.g., lower socioeconomic status, minority, uninsured) populations.[48,49] In prior work, we furthermore observed declining 3-year screening among Family PACT clients, suggesting potential unintended consequences of other practice changes, such as reduced pelvic examinations or extended screening intervals.[50] Decision supports for providers serving populations with greater clinical and socioeconomic complexity may be valuable for navigating the risks of not only early intervention, but also failure to intervene.

From an organizational perspective, our study illustrates the contribution of publicly funded family planning programs in maintaining optimal women's health care among low-income, predominantly uninsured populations. Reducing unnecessary colposcopy procedures will translate into measurable cost reductions that could be redirected to other services. Although cytological surveillance would still be associated with costs for cytology testing and office visits, these costs would be arguably lower than for unnecessary cervical procedures and microscopic compared to costs borne by the state for potential downstream obstetric complications and poor birth outcomes. Furthermore, given variation in how and when clinicians access new practice guidelines, reliance on passive diffusion alone may be unsustainable. Therefore, systems changes to dissemination of guidelines and adequate training on implementation in their specific practice setting may be future avenues to explore.

3.5.10 Conclusions

In conclusion, our findings suggest quick adoption of conservative management guidelines among safety net providers affiliated with a statewide family planning program. Future studies capturing nuances of provider referrals, patient adherence to follow-up, and organizational drivers of guideline implementation will help to better characterize variations in care and shape interventions to address them. Continued monitoring of trends over a longer follow-up period is needed to determine whether effects sustain over time.

Table 3.1 Sample Characteristics[a] (n=333,977)

	All n=333,977 n (%)	Age 21-24y[b] n=73,803 n (%)	Age 25-44y[b] n=260,174 n (%)
Patient			
Age at first Pap test			
21-24y	73,803 (22)	73,803 (100)	--
25-29y	81,502 (24)	--	81,502 (31)
30-44y	178,672 (54)	--	178,672 (68)
Race/ethnicity			
Latina	280,280 (84)	56,824 (77)	223,456 (86)
White	22,349 (7)	7,214 (10)	15,135 (6)
African American	14,430 (4)	5,163 (7)	9,267 (4)
Asian/Pacific Islander	11,380 (3)	3,132 (4)	8,248 (3)
Other	5,538 (2)	1,470 (2)	4,068 (2)
Primary language			
Spanish	219,498 (66)	29,834 (40)	189,664 (73)
English	104,246 (31)	42,345 (57)	61,901 (24)
Other	10,233 (3)	1,624 (2)	8,609 (3)
Provider			
Ownership/type			
Private	189,688 (57)	42,913 (58)	146,775 (56)
Federally qualified health center	85,116 (25)	17,144 (23)	67,972 (26)
Other public provider	59,173 (18)	13,746 (19)	45,427 (17)
Family PACT client volume			
Lower (<1,000 clients)	80,717 (24)	17,634 (24)	63,083 (24)
Higher (≥1,000 clients)	253,260 (76)	56,169 (76)	197,091 (76)
Site county			
Los Angeles	193,851 (58)	43,468 (59)	150,383 (58)
Orange	34,258 (10)	6,572 (9)	27,686 (11)
San Bernardino	28,658 (9)	6,834 (9)	21,824 (8)
San Diego	25,089 (8)	5,029 (7)	20,060 (8)
Riverside	14,894 (4)	3,129 (4)	11,765 (5)
Ventura	11,367 (3)	2,495 (3)	8,872 (3)
Kern	10,229 (3)	2,199 (3)	8,030 (3)
Fresno	9,363 (3)	2,261 (3)	7,102 (3)
Santa Barbara	5,435 (2)	1,535 (2)	3,900 (2)
Imperial	833 (<1)	281 (<1)	552 (<1)
Site location			
Urban	326,381 (98)	72,208 (98)	254,173 (98)
Rural	7,596 (2)	1,595 (2)	6,001 (2)
Every Woman Counts enrollment[c]			
Yes	138,174 (41)	28,986 (39)	109,188 (42)
No	195,803 (59)	44,817 (61)	150,986 (58)

[a] Any woman ages 21-44 with at least 1 Pap test between July 1, 2011, and June 30, 2015
[b] Age defined as age as of first Pap test between July 1, 2011, and June 30, 2015
[c] California's Every Woman Counts program provides eligible women with free breast and cervical cancer screening services.

Table 3.2 Provider Site Characteristics (n=216)

Characteristic	n	%
Ownership/type[a]		
Private	126	58.3%
Federally qualified health center	59	27.3%
Other public	31	14.4%
Family PACT client volume		
Lower (<1,000 clients)	97	44.9%
Higher (≥1,000 clients)	119	55.1%
Site location		
Urban	208	96.3%
Rural	8	3.7%
Every Woman Counts enrollment[b]		
Yes	82	38.0%
No	134	62.0%
County		
Los Angeles	126	58.3%
Orange	21	9.7%
San Diego	14	6.5%
San Bernardino	14	6.5%
Riverside	13	6.0%
Fresno	8	3.7%
Kern	9	4.2%
Ventura	4	1.9%
Santa Barbara	6	2.8%
Imperial	1	<1.0%

Abbreviations: Family PACT, Family Planning Access Care and Treatment

[a] Federally qualified health centers included FQHC look-alikes. Other public provider types included county public health department clinics/hospitals, rural health clinics, and free clinics.
[b] California's Every Woman Counts program provides eligible women with free breast and cervical cancer screening services.

Table 3.3 Difference-in-differences Analyses, Percentage Point Change in Mean Colposcopy Rate After Compared to Before Guideline by Age Group

Age Group	**No. of Pap tests**	**Proportion of colposcopies**, *percent*		**Differences**, *percentage points*	
		Pre-guideline	**Post-guideline**	**Pre-/Post-difference**	**Net Change**, relative to age 25-44y
Unadjusted Proportions					
Age 21-24y	93,078	7.57	4.67	-2.90*	**-2.23***
Age 25-44y	387,743	4.45	3.78	-0.67*	
Adjusted Predictions and 95% CIs					
Age 21-24y	93,078	6.70 (6.21, 7.19)	3.94 (3.60, 4.29)	-2.76* (-3.07, -2.44)	**-1.93*** (-2.25, -1.62)
Age 25-44y	387,743	4.35 (4.03, 4.67)	3.53 (3.25, 3.80)	-0.82* (-0.96, -0.69)	

Abbreviations: CI, Confidence Interval

The pre-guideline period was defined as July 1, 2011 through March 20, 2013. The post-guideline period was defined as March 21, 2013 through June 30, 2015. For the adjusted predictions, percentage-point changes were calculated from a random intercept logistic regression model that accounted for the correlation between Pap tests from the same patient and between patients from the same provider. Confidence intervals were calculated using the Delta Method (Taylor series approximation). The outcome was modeled as a function of guideline issuance, age group, a time-by-age group interaction, race/ethnicity, primary language, Pap test within the past year, provider site ownership, Every Woman Counts enrollment, and county. Predictive margins were used to calculate predicted probabilities of the outcome. *p<0.001

Table 3.4 Bivariate and Multivariable Regression Analyses, Likelihood of Colposcopy Receipt, Odds Ratios and 95% CIs

	Bivariate Analyses	Multivariable Analyses[b]
	Unadj. OR (95% CI)	Adj. OR (95% CI)
Total Pap tests, No.	480,551	480,551
Guideline		
Pre-guideline	Ref	Ref
Post-guideline	0.77 (0.75 - 0.79)	0.78 (0.75 - 0.81)
Patient		
Age[a]		
21-24y	1.57 (1.53 - 1.62)	1.70 (1.62 - 1.78)
25-44y	Ref	Ref
Time*age interaction		
Age 21-24*Post-guideline	0.71 (0.67 - 0.76)	0.67 (0.62 - 0.72)
Race/Ethnicity		
White	Ref	Ref
Latina	0.63 (0.60 - 0.67)	0.93 (0.87 - 1.00)
Other	0.83 (0.77 - 0.88)	0.93 (0.86 - 1.00)
Primary language		
Non-English	Ref	Ref
English	1.57 (0.62 - 0.65)	1.58 (1.51 - 1.65)
Pap test within past year		
None	Ref	Ref
≥ 1 Pap test	2.17 (2.00 - 2.36)	1.62 (1.56 - 1.68)
Provider		
Ownership		
Private	Ref	Ref
Public	1.24 (1.21 - 1.28)	1.23 (1.01 - 1.50)
Family PACT client volume		
Lower (<1,000 clients)	Ref	--
Higher (≥1,000 clients)	1.02 (0.99 - 1.05)	--
Location		
Rural	Ref	--
Urban	1.01 (0.92 - 1.10)	--
County		
Non-Los Angeles	Ref	
Los Angeles	0.90 (0.87 - 0.92)	0.85 (0.72 - 1.02)
Every Woman Counts enrollment[c]		
No	Ref	Ref
Yes	1.12 (1.09 - 1.15)	1.05 (0.86 - 1.29)

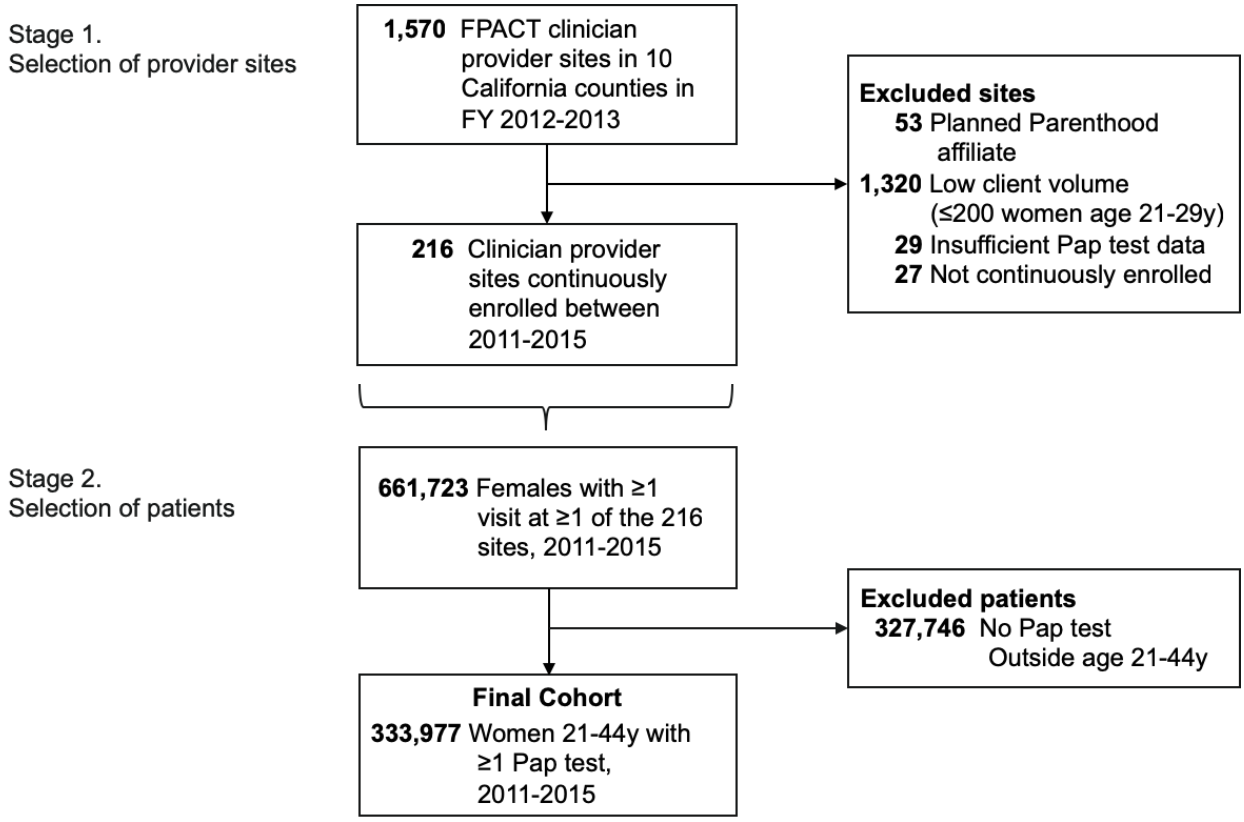
Abbreviations: OR, Odds Ratio; CI, Confidence Interval; Family PACT, Family Planning Access Care and Treatment

[a] Age defined as age on date of index Pap test

[b] The 3-level random intercept model was adjusted for race/ethnicity, primary language, Pap test within the past year, provider site ownership, Every Woman Counts enrollment, and county.

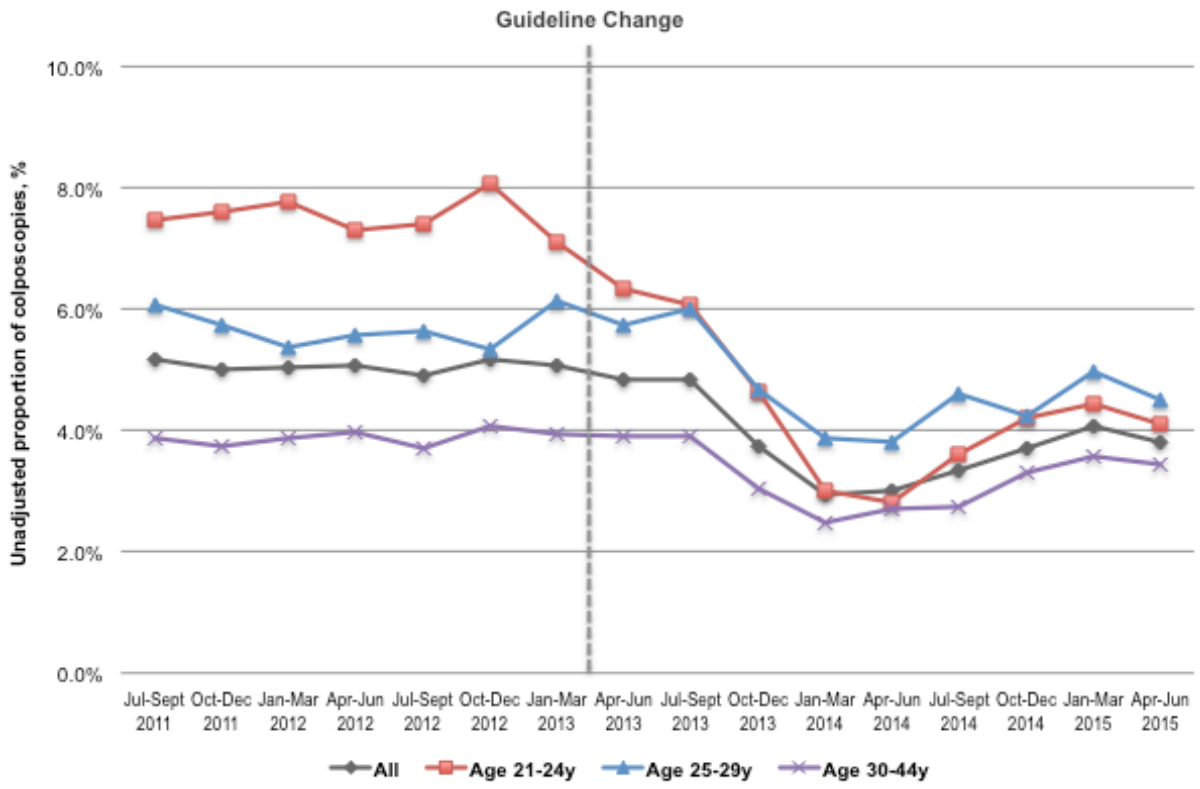
[c] California's Every Woman Counts program provides eligible women with free breast and cervical cancer screening services

Figure 3.1 Sample Selection and Inclusion Criteria



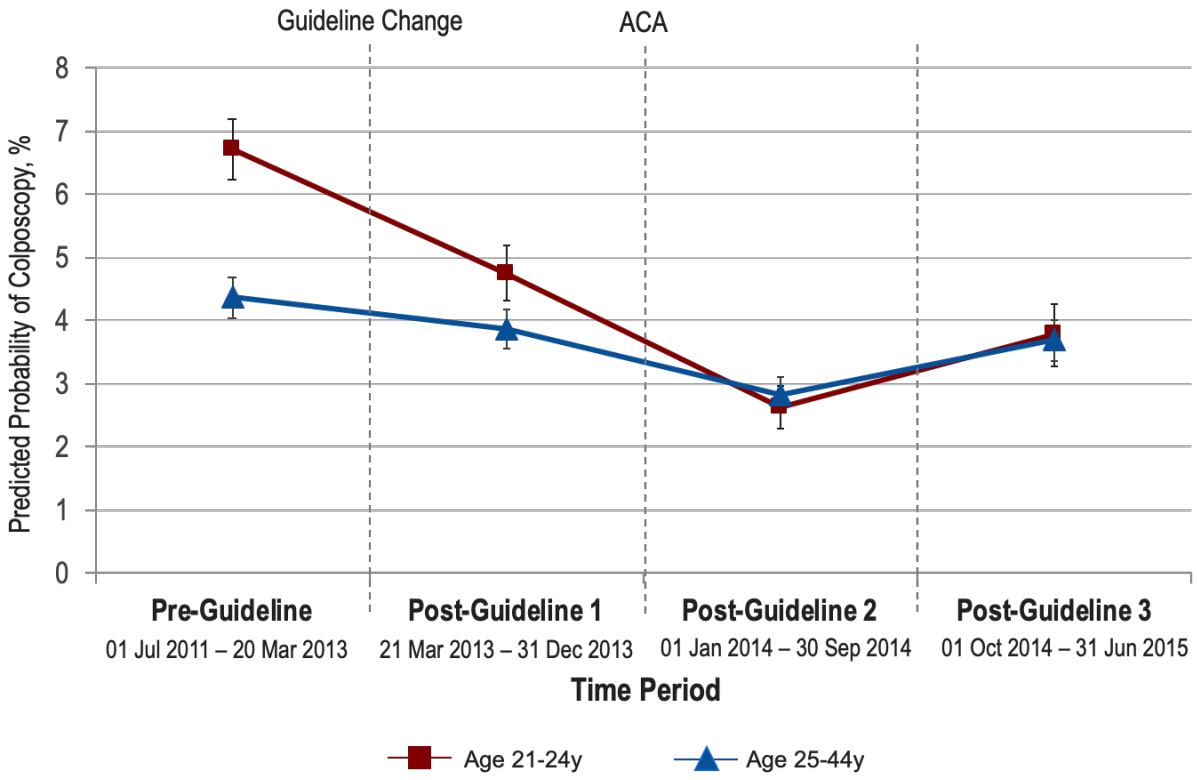
We selected clinician provider sites (n=216) from 10 mostly Southern California counties that were continuously enrolled in the Family Planning Access, Care, and Treatment (FPACT) Program between July 1, 2011 and June 30, 2015. Among these sites, we selected women who received at least one Pap test between ages 21 and 44 years during this period.

Figure 3.2 Unadjusted Proportion of Colposcopy Procedures among Women Ages 21-44y with a Pap Test by Age Group, 2011 to 2015



The full sample included 480,551 cervical cytology tests from 333,977 women (n=73,803 women ages 21-24y, n=65,751 ages 25-29y, and n=170,431 ages 30-44y at time of first Pap test). All quarterly estimates represent mean unadjusted proportions of colposcopies among women with a Pap test. The vertical line represents the publication of the updated cervical cytology management guidelines on March 21, 2013.

Figure 3.3 Post-hoc Analyses: Average Marginal Effect of Guideline on Colposcopy, 2011 to 2015



Predicted probabilities were calculated using a random intercept model that accounted for the correlation between Pap tests from the same patient and between patients from the same provider. The outcome was modeled as a function of time period indicators, age group, a time-by-age group interaction, race/ethnicity, primary language, Pap test within the past year, provider site ownership, Every Woman Counts enrollment, and county. The first vertical line represents the publication of the cervical cytology management guidelines on March 21, 2013. The second vertical line indicates implementation of the Affordable Care Act (ACA) on January 1, 2014, and the third vertical line represents the approximate time point where the trend for both groups appeared to start reversing: October 1, 2014.

Appendix 3.1 Current Procedural Terminology (CPT) Codes

CPT Code	Procedure
Cervical Cytology Test	
88142	Cytopathology, cervical or vaginal, thin layer
88143	Cytopathology, cervical or vaginal, thin layer redo
88147	Cytopathology, cervical or vaginal, automated
88148	Cytopathology, cervical or vaginal, auto rescreen
88164	Cytopathology, cervical or vaginal, the Bethesda System manual
88167	Cytopathology, cervical or vaginal, the Bethesda System select
88174	Cytopathology, cervical or vaginal, auto in fluid
88175	Cytopathology, cervical or vaginal, auto fluid redo
Colposcopy	
57452	Colposcopy of the cervix including upper/adjacent vagina
57454	Colposcopy with biopsy and endocervical curettage
57455	Colposcopy with biopsy of cervix
57456	Colposcopy with endocervical curettage
58100	Endometrial sampling with or without endocervical sampling, without cervical dilation, any method
58110	Endometrial sampling performed in conjunction with colposcopy

For women with a family planning clinician visit, we selected Current Procedural Terminology (CPT) codes ever billable in the Family PACT program for cervical cytology testing and colposcopy for the selected dates of service. If two claims were less than 30 days apart, the second claim was excluded from analyses.

Appendix 3.2 Recommendations for Initial Management of Abnormal Cervical Cytology among Young Women

	Age Group	Cervical Cytology Result			
		ASCUS	**LSIL**	**ASC-H**	**HSIL**
Before 2012 Guideline	≥ 21y	• **HPV Testing*** ; Colposcopy if HPV+ (*Preferred*) • Colposcopy • Repeat cytology @ 6 and 12 months	• **Colposcopy**	• **Colposcopy**	• **Colposcopy** • **Immediate Loop Electrosurgical Excision**
After 2012 Guideline	21-24y	• **Repeat cytology** @ 12 months (*Preferred*) • HPV Testing*; Colposcopy if HPV+ (*Acceptable*)	• **Repeat cytology** @ 12 months	• **Colposcopy**	• **Colposcopy**

Abbreviations: LSIL, Low-grade squamous intraepithelial lesion; ASC-US, Atypical squamous cells of undetermined significance; ASC-H, Atypical squamous cells–cannot exclude HSIL; HSIL, High-grade squamous intraepithelial lesion; HPV, Human papillomavirus

* Refers to testing for high-risk HPV types

This exhibit shows recommendations for initial management of abnormal cytology before and after issuance of the 2012 guidelines. Compared to prior guidelines, the 2012 guidelines recommended more conservative management of initial minimal abnormalities (ASCUS, LSIL) for young women, instead of direct referral to colposcopy.

Note: Recommendations differ for women with a prior abnormal test result. Sources for comprehensive recommendations for management of abnormal cervical cytology are below.

1. Wright Jr TC, Massad LS, Dunton CJ, Spitzer M, Wilkinson EJ, Solomon D. 2006 consensus guidelines for the management of women with abnormal cervical screening tests. Journal of Lower Genital Tract Disease. 2007 Oct 1;11(4):201-22.
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Appendix 3.3 Comparison of Sample Characteristics by Time Period and Age Group[a,b]

	Age 21-24y		Age 25-44y	
	Pre-Guideline	Post-Guideline	Pre-Guideline	Post-Guideline
	n (%)	n (%)	n (%)	n (%)
Total clients, No.	48,328	25,475	184,589	75,585
Patient				
Race/Ethnicity				
Latina	37,178 (77)	19,646 (77)	159,391 (86)	64,065 (85)
White	4,832 (10)	2,382 (9)	10,497 (6)	4,638 (6)
Other	6,318 (13)	3,447 (14)	14,701 (8)	6,882 (10)
Language				
Spanish	20,438 (42)	9,396 (37)	136,503 (74)	53,161 (70)
English	26,855 (56)	15,490 (61)	42,190 (23)	19,711 (26)
Other	1,035 (2)	589 (2)	5,896 (3)	2,713 (4)
Pap test within last year				
None	42,895 (89)	24,104 (95)	165,802 (90)	71,568 (95)
≥ 1 Pap test	5,433 (11)	1,371 (5)	18,787 (10)	4,017 (5)
Provider				
Ownership				
Private	27,056 (56)	15,857 (62)	99,859 (54)	46,916 (62)
Public	21,272 (44)	9,618 (38)	84,730 (46)	28,669 (38)
County				
Los Angeles	28,062 (58)	15,406 (60)	105,200 (57)	45,183 (60)
Non-Los Angeles	20,266 (42)	10,069 (40)	79,389 (43)	30,402 (40)
EWC enrollment[c]				
Yes	19,497 (40)	9,489 (37)	79,040 (43)	30,148 (40)
No	28,831 (60)	15,986 (63)	105,549 (57)	45,437 (60)

Abbreviations: EWC, Every Woman Counts

[a] Age defined as age on date of first Pap test
[b] Pre-guideline was defined as index Pap tests occurring before March 21, 2013, the date of guideline issuance
[c] California's Every Woman Counts program provides eligible women with free breast and cervical cancer screening services

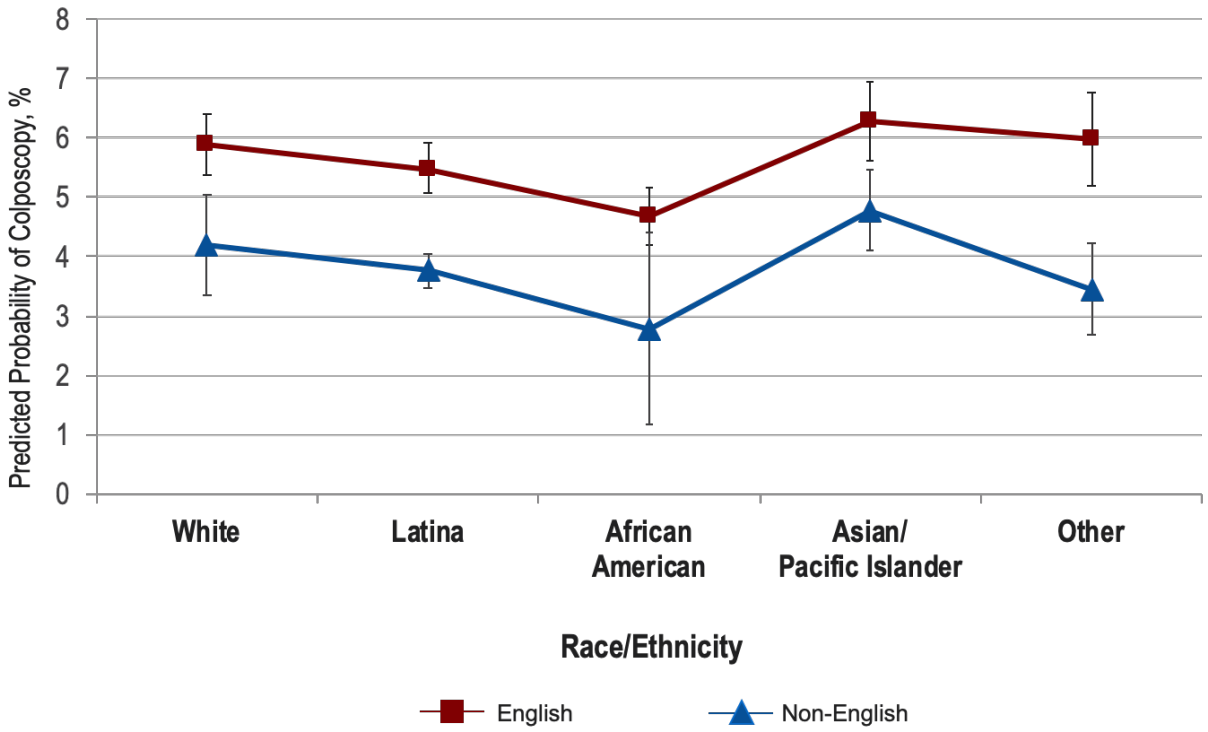
Appendix 3.4 Bivariate Association between Patient and Provider Site Characteristics and Colposcopy Receipt by Time Period, Unadjusted Odds Ratios and 95% CI

	2011 to 2015	Pre-Guideline	Post-Guideline
	Unadj. OR (95% CI)	Unadj. OR (95% CI)	Unadj. OR (95% CI)
Total Pap tests, No.	480,551	281,965	198,586
Time period			
Pre-guideline	Ref	--	--
Post-guideline	0.77 (0.75 - 0.79)	--	--
Patient			
Age[a]			
21-24y	1.57 (1.53 - 1.62)	1.75 (1.69 - 1.82)	1.25 (1.18 - 1.32)
25-44y	Ref	Ref	Ref
Time*age interaction			
Age 21-24*Post-guideline	0.71 (0.67 - 0.76)	--	--
Race/ethnicity			
White	Ref	Ref	Ref
Latina	0.64 (0.61 - 0.67)	0.63 (0.60 - 0.67)	0.67 (0.61 - 0.72)
African American	0.65 (0.60 - 0.70)	0.67 (0.60 - 0.74)	0.61 (0.53 - 0.71)
Asian/Pacific Islander	1.04 (0.96 - 1.12)	1.04 (0.94 - 1.14)	1.04 (0.91 - 1.19)
Other	0.87 (0.78 - 0.97)	0.92 (0.81 - 1.05)	0.80 (0.66 - 0.96)
Primary language			
Non-English	Ref	Ref	Ref
English	1.57 (0.62 - 0.65)	1.68 (1.62 - 1.73)	1.42 (1.36 - 1.49)
Pap test within in past year			
None	Ref	Ref	Ref
≥1 Pap test	2.19 (2.12 - 2.25)	2.17 (2.09 - 2.25)	2.17 (2.07 - 2.29)
Provider			
Ownership/type			
Private	Ref	Ref	Ref
FQHC	1.28 (1.24 - 1.32)	1.32 (1.27 - 1.37)	1.18 (1.12 - 1.25)
Other public provider	1.18 (1.14 - 1.23)	1.19 (1.14 - 1.25)	1.09 (1.03 - 1.17)
Family PACT client volume			
Lower volume (<1,000)	Ref	Ref	Ref
Higher volume (≥1,000)	1.02 (0.99 - 1.05)	1.04 (1.00 - 1.08)	0.98 (0.93 - 1.03)
Location			
Rural	Ref	Ref	Ref
Urban	1.01 (0.92 - 1.10)	0.97 (0.87 - 1.09)	1.08 (0.92 - 1.26)
County			
Los Angeles	Ref	Ref	Ref
Orange	1.34 (1.29 - 1.40)	1.28 (1.21 - 1.34)	1.46 (1.37 - 1.57)
San Diego	1.44 (1.37 - 1.51)	1.31 (1.23 - 1.39)	1.67 (1.54 - 1.82)
San Bernardino	0.75 (0.71 - 0.80)	0.75 (0.70 - 0.81)	0.76 (0.69 - 0.84)
Other	1.01 (0.97 - 1.05)	0.97 (0.92 - 1.02)	1.08 (1.01 - 1.15)
EWC enrollment[c]			
No	Ref	Ref	Ref
Yes	1.12 (1.09 - 1.15)	1.09 (1.05 - 1.13)	1.15 (1.09 - 1.20)

Abbreviations: FQHC, federally qualified health center; PACT, Planning Access Care and Treatment; EWC, Every Woman Counts

[a] Age defined as age on date of index Pap test
[b] Pre-guideline was defined as index Pap tests occurring before March 21, 2013, the date of guideline issuance
[c] California's Every Woman Counts program provides eligible women with free breast and cervical cancer screening services

Appendix 3.5 Exploratory Analyses: Interaction of Race/Ethnicity and Primary Language



Exploratory analyses were conducted to assess the interaction of race/ethnicity and primary language. Predicted probabilities were calculated from a random intercept model that accounted for the correlation between Pap tests from the same patient and between patients from the same provider. The outcome was modeled as a function of age group (age 21-24y vs. age 25-44y), race/ethnicity (Latina, African American, Asian/Pacific Islander, Other vs. White), and primary language (English vs. non-English). Non-English language included Spanish, Korean, Cantonese, Tagalog, Vietnamese, Khmer/Cambodian, Hmong, Armenian, and Other. The figure shows that language does not appear to moderate the impact (i.e., differentially impact the effect) of race/ethnicity on colposcopy.

Appendix 3.6 Tests for Pre-Existing Differences in Trends for Women Ages 21-24y and Women Ages 25-44y

Period	Variable	Adjusted Odds Ratio	95% Confidence Interval	*P* Value
Oct - Dec 2011	Quarter 2*Age21to24	1.06	0.91 - 1.25	0.44
Jan - Mar 2012	Quarter 3*Age21to24	1.08	0.93 - 1.27	0.28
Apr - Jun 2012	Quarter 4*Age21to24	0.99	0.84 - 1.15	0.87
Jul - Sep 2012	Quarter 5*Age21to24	1.04	0.89 - 1.22	0.61
Oct - Dec 2012	Quarter 6*Age21to24	1.10	0.94 - 1.29	0.25
Jan - Mar 2013	Quarter 7*Age21to24	0.91	0.78 - 1.07	0.28
P Value of Joint F Test = 0.31 (hypothesis: all leading interaction coefficients = 0)				

As part of our sensitivity analyses, we tested the parallel trends assumption underlying our difference-in-differences (DID) approach. The DID approach assumes that, in the absence of the guideline change, trends in colposcopy would be similar across the study and comparison groups. It follows that any observed differences in outcome trajectory between study and comparison groups after guideline issuance in March 2013 would be attributed to the guideline change.

To assess pre-existing trends, we first plotted rates of colposcopy receipt (colposcopy procedure within 6 months of index Pap test) by age group (age 21-24 years and 25-44 years). We then formally tested the parallel trends assumption by fitting a logistic regression that interacted our age group indicator variable (*age21to24*) with quarterly time indicator variables (*quarter*), using the first quarter (July-September 2011) as the reference quarter. Each interaction term represented the difference in outcome between age groups, relative to the baseline quarter. We used a 3-level random intercept model and adjusted for the same vector of patient ($\boldsymbol{\gamma}$) and provider (Ω) characteristics as our primary model.

$$\text{Log}\,[p/(1-p)] = \beta_0 + \beta_1 Age21to24_i + \beta_{2\text{-}x} Quarters_{xt} + \beta_{3x} Age21to24{*}Quarter_{xit} + \boldsymbol{\gamma} PatientVars_i + \Omega ProviderVars_s$$

Using an F test, we tested the null hypothesis that all leading interaction terms were jointly equal to 0 (i.e., the coefficients of all pre-guideline interaction terms equal 0). A significant result rejects the null hypothesis and suggests the effect of time modifies the effect of the age group (i.e., diverging trends between age groups). A non-significant effect signifies comparable pre-guideline trends between age groups.

Visual inspection showed that prevalence rates of colposcopy were lower among older aged versus younger women, but trends were parallel prior to guideline publication. The results of the F test confirmed that we could not reject the null hypothesis that all pre-guideline interaction terms were jointly equal to 0 (P=0.31), suggesting pre-guideline colposcopy trends were similar for women ages 21-24 years and women ages 25-44 years.

Appendix 3.7 Sensitivity Analyses: Alternative Definitions and Specifications

	Primary Model[a]	Use Alternate Regression Specification[b]	Redefine Comparison Group to Ages 25-29y[c]	Restrict Analysis to Pre-ACA Period[d]
	(1)	(2)	(3)	(4)
	Adj. Difference-in-Differences[e] (95% CI)	Adj. Difference-in-Difference[e] (95% CI)	Adj. Difference-in-Differences[e] (95% CI)	Adj. Difference-in-Differences[e] (95% CI)
Total Pap Tests, No.	480,551	480,551	212,352	375,130
Colposcopy Receipt	1.93pp* (1.62 - 2.25)	1.94pp* (1.48 - 2.40)	1.92pp* (1.53 - 2.32)	1.47pp* (1.08 - 1.85)

Abbreviations: ACA, Affordable Care Act; pp, percentage point

[a] The primary analysis used a three-level random intercept model that accounted for correlation among observations within individual patients and provider sites. The multivariable logistic regression controlled for race/ethnicity, primary language, Pap test within the past year, provider site ownership, county, and enrollment in Every Woman Counts, a program that provides eligible women in California with free breast and cervical cancer screening services.
[b] Logistic regression with cluster robust standard errors
[c] Age defined as age as of date of index Pap test
[d] Restricted observations to index Pap test claims between July 1, 2011 and December 31, 2015
[e] The adjusted difference-in-differences estimate (measured in percentage points) represents the absolute difference in probability of colposcopy between women ages 21-24 years before versus after the guideline change, relative to a comparison group. Confidence intervals were calculated using the Delta Method (Taylor series approximation).
*p<0.001

3.6 References

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Chapter 4

Provider Perspectives on Communication of Cervical Cancer Screening and Follow-up Recommendations among Low-income Women

4.1 Abstract

Background. Provider recommendations significantly impact patient adherence to cancer screening. Given increasing complexity of cervical cancer screening guidelines and emphasis on patient-centered care, we explored how providers communicate updated recommendations and address patient preferences among vulnerable populations.

Methods. We conducted semi-structured interviews with 24 primary and specialty care clinicians affiliated with a publicly funded family planning program that serves predominantly low-income, Latina, and immigrant populations. We used content analysis to capture emerging themes related to provider communication about cervical cancer screening and follow-up.

Results. Findings revealed that providers perceived patient education influenced patients' acceptance of extended cancer screening intervals. Providers focused explanations on the clinical rationale for guideline changes, emphasizing the progression of HPV infection (for screening) and likelihood of pre-cancerous lesion regression (for management of abnormal cytology). Providers also tailored recommendation content and use of visual education tools to perceptions of patient understanding. Other major themes included the importance of providing emotional reassurance and clarifying uncertainty or ambiguity around tests and results. Providers counseled patients whose preferences deviated from guideline-concordant care.

Some screened at shorter intervals to placate patient emotions, but many were ultimately unwilling to screening earlier than guidelines recommended.

Conclusion. Strategies to guide providers on delivery of clear, short, and informative messages that address both patients' informational and emotional needs warrant further exploration, particularly in safety net settings.

4.2 Introduction

In 2012, the United States Preventative Services Task Force (USPSTF) and other leading professional organizations issued guidelines recommending increased cervical cancer screening intervals.[1-4] The change from screening annually to every three years with cervical cytology testing or to every five years with human papillomavirus (HPV) co-testing for women ages 30 and over increased complexity of guidelines, making them more difficult for providers and patients to accept. Low provider adherence to these recommendations has been attributed, in part, to patient concerns about missing a possible cancer diagnosis and patient demand for a different screening interval.[5-7] Patient accounts reveal that women have been uncomfortable with these changes,[8-10] and research has shown that modifying patient beliefs about the necessity of an annual Pap test is a promising target to increase comfort.[11] Recently, the USPSTF revised these consensus guidelines to include an additional option of primary HPV testing at 5-year intervals,[12] renewing concern about potential provider and patient hesitancy towards guideline acceptance and implementation.

In addition to patient concern, patient confusion and uncertainty about guidelines may impede screening and follow-up. Confusion about the causes of cancer and ambiguity about cancer prevention recommendations have been associated with poor adherence to cancer risk modifying behaviors.[13] Prior studies have shown that many women are unaware that HPV infection causes cervical cancer and that the infection can regress without treatment.[11,14] Additionally, uncertainty about equivocal Pap test results (e.g., ASCUS) and confusion about necessary follow-up procedures can lead to poor adherence to colposcopy referral.[15,16] Thus, research has called for clear messages about cervical cancer screening guidelines, test results, and follow-up processes to ensure patient understanding.

A provider recommendation is a well-established facilitator of patient adherence to cancer screening, yet little is known about how providers can most effectively provide cervical cancer screening recommendations.[17,18] Since the Institute of Medicine's landmark *Crossing the*

Quality Chasm report in 2001, attention has been directed to the value of patient-centeredness in quality care.[19] The National Cancer Institute's (NCI) conceptual framework for Patient-Centered Communication posits six core functions of patient-clinician communication: exchanging information, responding to emotions, managing uncertainty, making decisions, enabling patient self-management, and fostering healing relationships.[20] These actions may strengthen patient knowledge, empowerment, and trust, and ultimately improve patient adherence to provider recommendations. Some evidence supports that shared decision-making increases guideline-concordant cervical cancer screening.[13] The degree to which patient preferences should and realistically can be integrated in cancer screening and follow-up care, however, has drawn mixed perspectives.[21,22]

Given that provider communication is a potentially modifiable factor, we sought to better understand provider perspectives on approaches to screening and management recommendations. The majority of prior studies on patient-provider communication during screening and detection of cervical cancer have focused on patient perspectives,[14,23-26] singular time points such as screening or after diagnosis,[15,16] and private health care settings.[16] Our study extends current literature by representing provider perspectives, probing about both extended screening interval and conservative management guidelines and, importantly, focusing on providers who serve low-income, predominantly uninsured, immigrant, and inadequately screened women—populations at greatest risk for cervical cancer.

Using semi-structured interviews among safety net providers, we explored provider recommendations about cervical cancer screening and management and their responses to patient preferences. We previously observed low rates of guideline-concordant Pap testing and colposcopy among this population,[27] but were unable to assess the contribution of patient-provider discussions. Results will expand understanding of provider approaches to communication and contribute knowledge on potential opportunities and challenges from the provider's perspective.

4.3 Methods

4.3.1 Setting and Sampling

This study was conducted among Medi-Cal provider sites affiliated with a large statewide family planning program. Enrolled provider sites serve predominantly low-income and ethnic minority populations, and a large volume of young women. The sampling frame for this study included provider sites (n=14) in Southern California that participated in a randomized trial to increase adherence to cervical cancer screening guidelines. At these select sites, individual clinicians were eligible to participate in this interview study if they were: (1) a physician or mid-level provider (e.g., physician assistant, nurse practitioner) and (2) involved in cervical cancer screening and the management of abnormal cervical cancer cytology. Given our interest in approaches to both screening and management of abnormal lesions, we purposively sampled participants across both primary and specialty care to maximize variation in perspectives. The University of California Los Angeles and the University of California San Francisco Institutional Review Boards approved this study.

4.3.2 Recruitment

The primary study contact at each of the clinic sites identified eligible providers. Our study team e-mailed eligible participants a recruitment flyer, which briefly informed them about the study and voluntary nature of participation. The provider e-mail also contained a web link to an informed consent to participate in both an interview a brief online survey on demographic characteristics, risk perception, and clinical decision support use. Online consent was obtained for the provider survey and interviews (**Appendix 4.1**), and permission to record the interview was obtained orally. Among the 26 providers from 10 sites who consented to the interview and survey, 24 providers from 10 sites were enrolled in the study.

4.3.3 Interview Guide

Based on a priori areas of interest, we developed a semi-structured interview guide that explored the following domains: decisions around cervical cancer screening and management of abnormal cytology, provider communication, patient preferences, risk perception, provider attitudes, and organizational facilitators of guideline adoption (**Table 4.1**). The guide was piloted and underwent cognitive testing with five providers across different specialties (obstetrics/gynecology, internal medicine, pediatrics) and training (physician, nurse practitioners). Content and structure were revised prior to implementation among eligible study participants, and iterative revisions were made during data collection.

4.3.4 Data Collection and Analysis

Data were collected between April and August 2017. Three trained research assistants conducted one-on-one interviews over the phone, each which lasted approximately 30 minutes. Participants received a $50 gift card following interview completion. All interviews except one were audio-recorded and transcribed verbatim. For the one that was not audio-recorded, detailed notes were taken as the interview was conducted. About 20% of audio files were reviewed to ensure transcription accuracy. Codes were generated and iteratively refined based on initial subset of transcribed interviews, and a final codebook defining major themes and sub-themes was developed. Line-by-line coding of all transcripts was conducted, and content analysis was used to explore themes related to provider communication. Similarities and differences across provider characteristics (physician vs. mid-level provider and family practice vs. obstetrics/gynecology specialty) were also explored. Because minimal differences emerged, overall results were presented, and subgroup differences were highlighted within themes when observed. ATLAS.ti® software (Version 8.2) was used for data management and analysis.

4.4 Results

4.4.1 Sample Characteristics

Sample characteristics (n=24) are reported in **Table 4.2**. The mean age was 48 (sd 14). The majority of providers was born in the U.S (n=19) and spoke English only (n=16). Respondents included medical doctors (n=7), physician assistants (n=7), nurses (n=6), and midwives (n=4); 11 reported specializing in Obstetrics/Gynecology, 13 in Family Practice, and 11 practiced for greater than 10 years.

4.4.2 Themes

Four main overarching themes that characterized provider screening and management recommendations emerged: (1) providing patient education, (2) clarifying uncertainty or ambiguity, (3) providing emotional reassurance, and (4) considering patient preferences. Themes and sub-themes are described below.

Providing patient education

Patient education included explanation of cervical guidelines, and content focused on rationale for guidelines, preventive care, tests and procedures, and use of visual education tools.

Explaining rationale for guideline. In sharing updated cervical cancer guidelines with patients, a minority simply referred to the extended screening intervals: “the guidelines currently say that you should be re-papped in 3 years” (Physician, Family Practice); or the age of screening initiation or discontinuance: “I remind them that when they are 21, it’s time for their first Pap” (Physician, Family Practice). The majority of providers (n=16) described coupling reference to the guidelines with a more in-depth explanation of the *clinical rationale* for the guideline changes, focusing most commonly on the nature of HPV and the ability of pre-cancerous lesions to regress over time:

> "I also them tell that…when they're younger…a lot of people have HPV and the body needs time for it to heal…the body has a way of fighting the virus and you have to give the body a chance to fight the virus." (Nurse Practitioner, Family Practice)

> "…explaining to them that if you have an adequate colposcopy and it shows low grade changes and…over the course of two years, this is gonna resolve…" (Physician, Ob/Gyn)

> "…usually explaining that because of their age and the fact that the virus usually clears itself without any intervention, that we watch and wait and see." (Physician Assistant, Family Practice)

One midwife further described the challenges of explaining the rationale for guidelines in Spanish and under time constraints.

> "All of us dreaded if we had to explain to a person in Spanish, usually, I've always used Spanish, but first of all what HPV was and then trying to explain within the context of a 10-minute follow up visit. You know, 'it's a persistent virus that may not be visible all the time, it can regress, but it's still blah blah.' The whole notion of not having the ability to eradicate something is challenging for people." (Midwife, Ob/Gyn)

In addition to explaining clinical rationales, providers also referenced *scientific research*: "all the studies and statistics behind why the changes happened" (Physician Assistant, Family Practice), and others framed the rationale from a broader *public health perspective* of overscreening in the population, informing patients: "we were overdoing them [Pap tests] before and we were getting false positives" (Nurse Practitioner, Family Practice); "over screening can lead to interventions that are unnecessary" (Midwife, Ob/Gyn).

Couple screening with general preventive care. A sub-theme that emerged among Ob/Gyn mid-level providers only (n=4) was encouraging patients to engage in preventive care during the discussion of cervical cancer screening. Providers expressed using Pap test visits as a gateway to discuss other health behaviors and conditions, for example redirecting patient education to blood pressure management, diet, or breast cancer screening:

> "I tell them you need to be more focused on your breasts and not on your cervix…I tell them you have more of a chance of breast cancer than you do of cervical cancer, unless you get a new partner." (Nurse Practitioner, Ob/Gyn)

They also stressed the importance of counseling patients on other strategies (e.g., lifestyle factors) that decrease transmission of HPV such as condom use and HPV vaccination.

> "…screening itself is not prevention. The screening is vigilance, is watching the progression, and what is really [important] every single time you talk to a patient about the fact that their status has either progressed or not changed or regressed, you want to talk about lifestyle factors." (Midwife, Ob/Gyn)

Explanation of tests and procedures. A few providers described explaining the *purpose of a Pap test or colposcopy*. One provider reported explaining "what cytology is, what the limitations of cytology are" (Physician, Ob/Gyn), referring to the low sensitivity of Pap tests and chance of missing disease. Another explained "the reason that test is important, and what a colposcopy looks at, information we're gathering from a colposcopy" (Physician Assistant, Ob/Gyn), referring to information about changes in the cervix that would help the provider to rule out cancer or not. Respondents discussed different pathways of how *results* would be communicated and rarely mentioned informing patients of specific *care processes* such as how to obtain an appointment or whom to contact. For patients with abnormal Pap test results, many primary care providers (n=11) described briefly explaining colposcopy procedures to patients. Mid-level providers (e.g., physician assistants, nurse practitioners, midwives, n=9) were more likely than physicians (n=2) to indicate that they *deferred in-depth explanations* of the colposcopy procedure, its risks and benefits, and decisions about whether or not to undergo the procedure to the specialist, alluding to these discussions falling outside their expertise or scope of work:

> "…I can explain to them [patients] that, when they get to the specialist, they'll be talking about different procedures but…I don't need to go over those things…" (Physician Assistant, Family Practice)

> "I'm leaving that [discussion of harms of colposcopy] up to whoever I refer to. I don't do that kind of information giving to any patient before I refer them. I mean that would be something whoever was doing the colposcopy would do, not me." (Nurse Practitioner, Family Practice)

Value of educational tools. Several providers (n=15) described visual education tools as another component of patent education. Providers shared clinical algorithms, professional organization mobile application tools, or other educational materials such as pamphlets to provide a visual aid and to build credibility behind their recommendation. One physician assistant described showing clinical algorithms to patients who may be hesitant about lengthening Pap intervals as a strategy to build trust.

> "…a lot of education goes into that and often times I've even pulled up the ASCCP [American Society of Colposcopy and Clinical Pathology] guidelines to show them cuz it helps them to kind of see something, that I'm not making it up. That it's actually something that's studied and recommended and when the patient has that information in front of them, then they're more trusting and understand that the clinical decisions that are being made are educated decisions and not just being made up." (Physician Assistant, Ob/Gyn)

Providers also described *tailoring their use of tools to patients' comprehension*, referencing the vulnerable populations they serve. In response to whether they would share information about guidelines from a mobile application with patients, one provider said: "I really don't because our patients are not very educated…so, they wouldn't know what I was telling them" (Nurse Practitioner, Ob/Gyn). Another provider described inherent challenges to communication through an interpreter: the interpreter must be able to understand the provider well enough to then explain the information to the patient in another language, which is "rare." The provider thus exercised caution in potentially exacerbating any patient confusion with graphics of clinical algorithms:

> "The patient is actually looking at this [guideline algorithm] and it's really foreign…in the majority of patients, it's not something that will help them to understand. And most of the information I give to patients…would be to help them to have a clearer understanding or if they're asking why, so that if I don't think that it will add to a patient's understanding, I don't try to confuse them more." (Physician, Family Practice)

Clarifying uncertainty or ambiguity

Another major theme that emerged among provider interviews (n=18) was communicating uncertainties associated with tests, results, or decisions. Providers discussed

risks of procedures (e.g., cervical damage, pain, cervical incompetence, obstetric complications), lesion progression, and cervical cancer. For example, one provider described telling patients "what their risk of evolving into a worse lesion, for instance if they have ASCUS (Atypical Squamous Cells of Undetermined Significance), evolving into a low-grade or a high-grade lesion" (Physician, Ob/Gyn). Another provider expressed that it can be difficult to explain to patients how recommendations can be open to interpretation. The provider noted that although management guidelines outline age-specific recommendations for colposcopy referral, other factors might guide decision-making, such as women's intention for future pregnancy.

> "When you're consulting with the patient it's like, 'Well, the guidelines kind of like suggest that we should, but then…we don't necessarily have to, that's that reason they're recommending this'…so it can get a little confusing as far as that discussion is concerned." (Physician, Family Practice)

With respect to framing, providers described communicating risks of negative outcomes (e.g., the risk of bleeding, lesion progression, or cancer), often when referring to an attempt to engage a patient in a Pap test or colposcopy. On the other hand, others stressed the importance of framing outcomes positively when screening or intervention is not recommended. For instance, rather than sharing there is a 3% chance of a low-grade lesion progressing to CIN3, one specialist emphasized the high likelihood it would not:

> "…I flip it, 3% chance means 97% chance that it's not going to evolve, then that has a lot of significance to a patient, versus, I have cancer." (Physician, Ob/Gyn)

> "I only tell them it takes, what is it, 6.6 women out of 100,000 that had an abnormal Pap or HPV and goes on to only like, a really small amount… it takes a lot of Paps to find a cancer." (Physician Assistant, Family Practice)

Some providers recognized the *complexity of presenting numeric information*. One midwife reflected on patients with an abnormal screening test and recognized that patients may be scared by information about cervical cancer risk, but conveyed a sense of professional obligation to underscore the consequences of failing to complete a recommended colposcopy procedure.

> "Some people say that they are not having a colposcopy no matter what I say and I say, 'Okay, you be you.' And other people, maybe they're a little bit intimidated by the numbers, but I feel like, in that instance, it's not my wish to intimidate but it would be bad if I did not covey…sort of the risk involved and the decision to fall out of what would be considered a standardized guideline." (Midwife, Ob/Gyn)

Similarly, one provider, when asked whether he would share information about the chance of missing disease or progression to cancer, indicated he would not because it would be "more information than most patients can comprehend—it's not comprehend but need" (Physician, Family Practice).

Providing emotional reassurance

The majority of providers (n=14) described managing patient emotions, mostly related to patients' reluctance to either undergo screening or reduce frequency of screening. One provider described the importance of not only providing a scientific reasoning behind guideline changes (i.e., "rational permission"), but also *emotionally releasing patients* from the perceived obligation to screen annually (i.e., "confidence-based permission").

> "They've just conditioned themselves that this [annual Pap] is what I need to do to stay healthy, and you give them permission, this confidence-based permission and rational permission, to not have to do it every year, they're oftentimes relieved." (Physician, Family Practice)

Providers also dispelled patient concerns that fewer Pap tests equated to lower quality care in safety net settings. One physician who practiced in a federally qualified health center described that offering reassurance facilitated patients' acceptance of the recommendation:

> "…they [patients] think, too, being a part of a community clinic, sometimes it [no Pap test] is… because they don't have insurance or because they don't have money…just offering that reassurance, most commonly, those women will determine later on that they don't want it either." (Physician, Family Practice)

In some cases, providers *placated patient emotions by screening* earlier than guidelines recommend. Providers described, first, attempting to educate patients on the guidelines but ultimately agreeing to annual screening to "put them [the patient] at ease" (Nurse Practitioner,

Family Practice) or "just for the pace of mind of the patient" (Physician Assistant, Family Practice). Another said:

> "there comes a point where you realize that this person is in such an anxious state that it's going to be detrimental to their health for you not to do stuff, [the] procedure still" (Physician, Family Practice)

Finally, one provider described providing assurance but continuing annual screening until their patient became comfortable with reducing screening frequency:

> "…just to help them understand and feel comfortable with the fact that they're not getting screened…to delay their fears, otherwise they spend a year concerned and worried. So, generally try to label it so that they understand that it's totally different diseases and kind of assuring them that, yes, I really am okay" (Physician, Family Practice)

Considering patient preferences

Providers also discussed approaches to responding to patient preferences for or against care. When asked whether they would screen patients earlier than the guidelines would recommend, the majority of providers discussed *engaging patients in a conversation* to ensure they were informed. Providers noted that when patients understood the reason for the guideline, they were amenable to following the provider's recommendation: "Most commonly, patients, once they understand the history, they're okay with changing their screening preferences" (Physician, Family Practice). One provider compared this process of exchanging information as a negotiation: "…you'd try to logically—or negotiate so that you're not just totally doing what they want. You're doing what is indicated" (Physician, Family Practice). A few providers, however, expressed doubt that engaging in a conversation could change their patients' preference. For example, one physician described that some "hypervigilant" patients steadfastly commit to obtaining referrals for certain tests or procedures, even when they are not indicated and, for these patients, no amount of counseling or negotiation will change their mind.

> "I will say, in my experience in the past, that once the decision is made, and there's no logic, there's no algorithm [that I can show the patient] that's going to…make a difference." (Physician, Family Practice)

Although providers commonly engaged patients in discussions, incorporation of patient preferences in decision-making varied. Many providers said patient preferences would *not influence their decision* to recommend or perform a test that was not indicated (n=12). In regards to screening earlier, one provided explained, "I will explain nicely why I'm not doing it and ultimately, I simply won't do it" (Physician Assistant, Family Practice). Providers were more willing to *acquiesce to patient preferences* for non-guideline concordant care in cases where insurance covered more frequent Pap testing or patient requests persisted. Although at times co-occurring with placating patient emotions, the conceptual distinction is that providers described decisions in response to patients' expressed verbal preference, not perceived patient emotions. For instance, when asked about approaching colposcopy referrals for a 24 year-old woman with low-grade cytology, one provider said: "I would try and convince them that it's okay to wait a year, but if they pushed the issue, I would do the colposcopy" (Physician, Ob/Gyn). Providers also honored patient preferences to *defer decision-making to the provider*. Regarding management of abnormal cytology, one provider said:

> "…for the most part most patients, I think, kind of defer to whatever the recommendations are. It's a generally confusing area of medicine. Especially for, I mean it's, you're talking about very scary thing like cancer, but then the virus and explaining all that, so I think they defer to what is recommended to them." (Physician Assistant, Family Practice)

Finally, some providers described a *shared decision-making approach* that involved eliciting patient preferences. When another provider was similarly asked to reflect on management of a low-grade abnormality among young woman, one specialist initially described leaning towards recommending observation, consistent with guidelines. The provider then indicated, however, that she would let the patient weigh in on the decision to observe or treat the lesion, given tradeoffs between multiple potential biopsies involved with surveillance versus a one-time excisional procedure.

> "I'm going to try and delay doing an excisional procedure. I'm going to try and see where that's going to go. But I think I'd be doing pap smears every 6 months on that patient, but I'd also be letting her know that, we're probably going to be doing more biopsies, and the alternative is…we can be very careful in how we do an excision procedure and be done with it, and let her weigh, which way she wants to go based on those factors." (Physician, Ob/Gyn)

Notably, many providers recognized that, despite how they respond to patient preferences in the clinical encounter, the patient ultimately decides whether to follow recommended care or not.

4.5 Discussion

Among a sample of safety net providers affiliated with a statewide family planning program, we explored provider perspectives on communication about the 2012 cervical cancer screening and management guidelines. Providers perceived that patient education influenced patients' acceptance of extended intervals and perceived that women were often relieved to undergo less frequent screening. Providers described multiple dimensions to communication, including not only explaining rationales for recommendations but also providing emotional reassurance and clarifying uncertainty or ambiguity. Although some providers incorporated women's preferences into decisions about colposcopy referral, many expressed they were unwilling to screen earlier than guidelines recommended.

Our study extends prior qualitative research exploring communication about cervical cancer screening and follow-up among medically underserved women. Similar to prior studies that explored patient perspectives, providers in this study highlighted education on HPV,[14] patient uncertainty about the 2012 screening guidelines,[25] communication hand-offs between multiple providers involved in screening and management,[16] and patient-provider communication barriers routed in language discordance.[23,28,29] Prior research that elicited provider perspectives found that providers rarely discussed HPV infection or other risk factors for cervical cancer during post-colposcopy consultations.[15] By contrast, providers in our study described explaining the rationale for guideline changes in the context of HPV infection. One

explanation for this difference is that content of patient education may vary by point of care, and conversations about sexually transmitted infections may more commonly occur among family planning providers who largely serve young women.[14]

Furthermore, tailoring communication was an underlying sub-theme that emerged across domains. Studies among low-income women have shown that communication with healthcare providers can exacerbate patient uncertainty about cervical cancer screening[25] and, moreover, that dissemination of risk information can lower decision satisfaction.[30] In our study, the finding that providers' perceptions of patient comprehension influenced the quantity and type of information they shared (e.g., HPV transmission, risk of progression to CIN3) and modality through which they chose to share it (e.g., verbal communication, visual tools) suggests potential utility for tools that guide providers on how to better assess patient understanding and deliver information that eases understanding without compromising quality.

Importantly, findings regarding the multiple dimensions of provider communication provided empirical support for existing conceptual frameworks. Several themes identified in our study directly aligned with the NCI conceptual framework for Patient-Centered Communication in Cancer Care.[20] Similar to Epstein & Street's framework, our results illustrate the interaction of multiple communication functions, with an emphasis on providing patient education (a form of exchanging information) and responding to patient emotions when explaining changes in cervical cancer screening guidelines. Providers in our sample less frequently discussed other constructs in the framework, such as fostering relationships or enabling patient self-management, possibly because the majority of respondents practiced in federally qualified health centers that may have had dedicated staff for care coordination.

We also observed that providers consistently educated patients who requested annual screening, but their willingness to ultimately screen off-guideline was mixed. Providers' refusal to screen earlier than recommended can be potentially explained by acceptance of cervical screening at longer intervals and uniform signals across professional organizations. Unlike the

USPSTF recommendations for breast and prostate cancer screening, for example, the Grade A cervical screening recommendation does not specifically address incorporating patient preferences. Notably, study participants served a large number of women whose benefits were limited to only one screening modality: cytology at 3-year intervals. Therefore, providers in our sample may have perceived less need for shared decision-making when coverage extended to only one screening modality. Other providers serving patients with greater access to HPV co-testing and primary HPV screening options, however, may be more likely to elicit and incorporate patient preferences, given tradeoffs between longer screening intervals with a test that has high sensitivity versus shorter screening intervals with a test that has lower sensitivity.

Increasing attention has been given to patient-centered care, but the degree to which providers should engage patients in decisions about cervical cancer screening is not well delineated.[31] While there is general consensus that patient engagement in decision-making at the level desired is ideal,[21,22,32] many recognize the reality of primary care time constraints, which requires being selective about the scope of patient education and the type of clinical questions necessitating shared decision-making.[22,32] Our study participants similarly echoed the complex and time-consuming nature of explaining HPV, regression of precancerous lesions, and cancer risk. They also underscored the value of coupling teachable moments about other important preventive behaviors. The finding that solely mid-level providers reported counseling on prevention (e.g., HPV vaccination, condom use) furthermore highlights the crucial role they play in health promotion and disease prevention, especially in safety net clinics.[33]

Our study has important limitations. First, while results are not intended to be generalizable, we recognize that providers who agreed to participate may have been more knowledgeable about and engaged in implementing cervical screening guidelines. Respondents may have also had greater tendency to report communication practices consistent with their perception of quality care. If so, our results would potentially underestimate communication challenges in medically underserved settings. Second, our open-ended questions inductively

elicited provider perspectives on communication with patients, which may not comprehensively reflect other important aspects of communication such as establishing a patient-provider relationship (e.g., trust, discrimination, satisfaction). Finally, our sample size precluded drawing firmer conclusions regarding potential differences by provider characteristics. Given the diverse workforce in community clinics and gap in the literature, exploring this potential variation represents an important direction for future research.

In conclusion, our study substantiates the multifaceted dimensions of provider recommendations for cervical cancer screening and follow-up. Increasing provider awareness and knowledge about guidelines is important, but alone may be insufficient for preventing overscreening and, more importantly, ensuring adequate screening among medically underserved women. Our results suggest the potential value of exploring provider strategies to appraise patient understanding, appropriately tailor education, and distill complex information about screening and follow-up recommendations within a time-constrained visit. This study helps to fill a gap in the literature on provider perspectives, which is essential to implementing interventions that are both acceptable and feasible for providers.

Table 4.1 Semi-structured Interview Guide: Example Questions*

Domain	Question
Decision-making†	What influences your decision-making on how often to screen a patient? What influences your decision-making on when to make a referral to colposcopy? *Vignette*: Suppose you have a 24-year old woman with a low-grade Pap test (LSIL). She did not have an HPV test. She has multiple partners. What influences your decision to recommend colposcopy? What influences your decision-making on treating CIN2? *Vignette*: Suppose you have a woman with a LSIL Pap. She has a colposcopy that is adequate. A cervical biopsy of a lesion shows "HSIL, moderate dysplasia, CIN2" on final histology. What influences your decision to recommend treatment versus surveillance?
Patient preferences† **Communication**†	Would you screen a patient every year if they asked you about that? Please describe. How would that conversation play out?
Risk perception	How do the harms of over-surveillance come into play in your decision about patient management of abnormal cytology? How helpful is it to know the patient's risk of CIN3? Would you want information about the rationale behind these recommendations? Why?
Knowledge, attitudes, acceptability of guidelines	Can you tell me in what ways are the cervical cancer screening and management guidelines helpful to you in your clinical practice? What aspects of the screening and management guidelines do you disagree with? Can you remember a recent situation where the guidelines were not helpful? Is there any scenario you can think of where you would screen someone earlier than the guidelines?
Clinical decision support use **Clinical champions**	Have you ever used the ASCCP app? Why or why not? Is there a particular person who encouraged you to use it? Is there anyone who helps you with it? Any support from your clinic? Please describe. Do you have a sense of how commonly other providers in your clinic use it? What are their thoughts about it?

Abbreviations: LSIL, low-grade squamous intraepithelial lesion; HPV, human papillomavirus; CIN, cervical intraepithelial neoplasia; HSIL, high-grade squamous intraepithelial lesion; ASCCP, American Society of Colposcopy and Clinical Pathology

*These questions were also used to more broadly explore provider decision-making in the parent study.
†Themes related to provider recommendations predominantly emerged from these domains.

Table 4.2 Sample Characteristics (n=24)

Characteristics	n (%)
Age, yrs	
Mean (sd)	48 (14)
29-39	11 (46)
40-70	12 (50)
Not reported	1 (4)
Nativity	
US born	19 (79)
Foreign born	4 (17)
Not reported	1 (4)
Language(s) spoken	
English	16 (67)
English and another language	8 (33)
Educational attainment	
Bachelor's degree	2 (8)
Master's degree	13 (54)
Doctorate degree	9 (38)
Provider type	
Medical doctor	7 (29)
Physician assistant	7 (29)
Nurse practitioner	6 (25)
Midwife	4 (17)
Provider specialty	
Obstetrics & Gynecology	11 (46)
Family Practice	13 (54)
Years in practice	
≤10	13 (54)
10-30	11 (46)
Provider site type	
FQHC or FQHC look alike	22 (92)
Private	2 (8)
Used ASCCP app in last week	
Very often or always	7 (29)
Sometimes	9 (38)
Rarely or never	6 (25)
Not reported	2 (8)

Abbreviations: sd, standard deviation; FQHC, federally qualified health center; ASCCP, American Society of Colposcopy and Clinical Pathology

Appendix 4.1 Recruitment Script and Consent for Online Survey and Phone Interview

Thank you for your participation in this brief online survey and a follow-up 20-minute phone interview. This survey is conducted by the UCLA/UCSF DOTS Study and has been made available to providers of participating clinic sites in Southern California. Your participation is entirely voluntary and the information you provide will be kept strictly anonymous and confidential. There are no right or wrong answers. If you have any questions, you may reach the DOTS Study Project Coordinator at [e-mail address].

This information will not be shared with the clinic where you work and will only be used for research purposes by research staff of the UCLA/UCSF DOTS Study to better understand providers' experiences with the ASCCP mobile application and their decision-making around patient management of abnormal cytology."

By providing consent below you are agreeing to voluntarily participate in this brief online survey and a follow-up 20-minute phone interview with one of our research staff from the DOTS Study.

Are you willing to participate in this online survey and a follow-up 20-minute phone interview?

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Chapter 5

Dissertation Discussion

5.1 Overview

Cervical cancer is a preventable disease and continues to disproportionately impact racial/ethnic minorities and poor women. For decades, the annual Pap test was the gold standard for early detection of cervical cancer. More recently, the landscape of prevention has shifted towards upstream prophylactic HPV vaccination, as well as less frequent screening and fewer follow-up procedures in an effort to balance the benefits of early detection with harms of overdiagnosis and overtreatment. This dissertation investigated these issues among ethnic minority and low-income populations. In distinct studies drawing from different data sources, this dissertation explored adolescent human papillomavirus (HPV) vaccination in Los Angeles County, California, and cervical cancer screening and management in the nation's largest publicly funded family planning program. Together, these studies inform efforts to improve adoption of evidence-based guidelines for primary and secondary prevention of cervical cancer.

5.2 Summary of Studies

Study 1 explored changes in parental HPV vaccine awareness and adolescent HPV vaccination in the first five years following vaccine introduction, and the contribution of individual demographic and access-related factors. Based on population-based survey data from an ethnically and socioeconomically diverse population in LA County, results revealed minimal changes in parental awareness, but significant gains in vaccination among girls who were older, uninsured, and had access-related barriers. By 2011, however, only half of adolescent girls had

been vaccinated against HPV, and, due to differential gains in coverage, gaps emerged by child age and race/ethnicity.

Study 2 evaluated adoption of evidence-based guidelines aimed at balancing the benefits of early detection and potential harms of overtreatment among young women. The study used administrative data from California's family planning program and a difference-in-differences approach that importantly accounted for secular trends during a period of changes in clinical practice and health care reform. Results suggested the 2012 conservative management guideline coincided with on average a 2-fold (peak 3-fold) reduction in potentially unnecessary cervical procedures among young versus a comparison group of older aged women, with less conclusive findings regarding the sustainability of changes over time.

Given the important role providers play in translating evidence-based screening and management guidelines to patient populations, Study 3 sought to understand one potentially modifiable parameter: provider communication. Building upon Study 2, in-depth interviews were conducted among safety net providers affiliated with California's family planning program. Findings revealed providers' role in not only delivering patient education, but also providing emotional support, managing uncertainty around tests and equivocal results, and incorporating patient preferences in discussions.

5.3 Contextualization and Implications of Findings

Taken together, these studies reveal lessons regarding adoption of evidence-based guidelines for cervical cancer prevention, application of guidelines to vulnerable populations, and modifiable targets for intervention.

5.3.1 Adoption of evidence-based guidelines

Evidence-based clinical guidelines are developed to provide optimal care for patients, but are only as effective as their adoption in clinical settings. In Study 1, we observed a long lag in

population-level adoption of HPV vaccine uptake, whereas Study 2 showed relatively rapid adoption of guidelines to prevent overdiagnosis and overtreatment among young women. This difference could be explained, in part, by HPV vaccination involving a “new” prevention strategy, a shift to the pediatric setting, and parents as the medical decision-makers. By contrast, the 2012 management guidelines involved “de-implementation” of a clinical practice, rolled out after a major change in cervical screening, and targeted more proximal clinical consequences for young women. Study 2 further illustrated that passive diffusion alone may initially result in measureable effects, but additional approaches may be needed to ensure sustainability. Therefore, it is critical to consider not only ease of adoption in clinical settings, but also sustainability.

5.3.2 Application of guidelines to vulnerable populations

Second, clinical practice guidelines are rarely one-size-fits-all. In Study 2, we observed trends in colposcopy use consistent with adoption of conservative management guidelines, but a key question remains: are we missing consequential disease? Family PACT is a program of last resort; it is the pipeline for cervical cancer screening for many providers serving individuals, such as unauthorized immigrants, who do not qualify for Medi-Cal expansion (i.e., expansion of access to Medicaid for individuals with incomes up to 138% FPL). While cervical cancer prevention has moved towards less testing and more conservative management of abnormal screens, an underlying assumption supporting these recommendations is that patients will successfully return at the intervals guidelines prescribe, which may not be the case for populations less engaged with the health care system. Furthermore, socially disadvantaged populations remain at risk for inadequate screening. Study 3 showed providers perceived that patients were often reluctant to undergo Pap testing and follow-up procedures, and our earlier work in Family PACT illustrated that about 1 in 3 women have not received even one Pap test in the past three years. Therefore, it is important that public health messaging continues to

communicate the benefits of cervical cancer screening, regardless of preferred screening modality.

5.3.3 Implications for future interventions

Finally, each study in this dissertation highlights sub-populations and factors to target for intervention. Study 1 illustrated gaps in HPV vaccine awareness for parents who were fathers, Asian American, had lower education, and had sons. It also supported interventions targeting increases in vaccination among adolescents who were younger and had African American parents, given African Americans were as aware of the vaccine as White parents, but less likely to have vaccinated daughters. Findings from Study 2 demonstrated significant effects of a national professional guideline among publicly funded family planning providers, but interventions at the organization level warrant further exploration to sustain guideline adoption. Finally, findings from Study 3 suggest the potential benefits of provider-directed interventions that extend beyond solely increasing provider awareness of guidelines. More importantly, providers may benefit from guidance on effective and efficient responses to patients' both informational and emotional needs.

5.4 Limitations of Dissertation

As discussed in individual studies, there are several limitations to this dissertation. Limitations to generalizability, data sources, and measures are revisited below.

5.4.1 Generalizability

Findings from this dissertation may not be generalizable to all ethnically diverse or low-income populations. All three studies were set in Southern California, mostly concentrated in Los Angeles County, and may not reflect other geographically diverse settings. In LA County, the

low-income population disproportionately represents Hispanic individuals, and its health care and social safety net infrastructure may have enabled outcomes examined in this project. This dissertation also does not fully address other important subpopulations at high risk for cervical cancer, including African Americans (who also have greater risk of preterm birth), poor White women, and those who are inadequately screened. Study 2, for example, focuses on only women who received a Pap test and therefore may be missing a key segment of the population for whom we are most concerned: unscreened women.

5.4.2 Data sources and measures

There were also notable limitations to data sources. The first study used population-based survey data, which may have been subject to response bias and reverse causality. Furthermore, measures were limited to personal demographic and access variables. Other provider- and systems-level factors such as provider recommendation may additionally play a prominent role in vaccination. The second study took advantage of longitudinal administrative and claims data. Claims data, however, rely on accuracy of documentation and reflect whether a test or procedure was reimbursed—not whether a provider appropriately referred patients or patients successfully adhered to those referrals. Furthermore, without downstream variables such as cancer diagnosis, we were unable to assess potential unintended consequences of guidelines: namely, missing consequential disease. Despite these limitations, this study showed that administrative data can overcome some of the challenges of prospective data collection involving rare events and can provide a relatively cost-effective method to evaluate adoption of clinical practice guidelines.

5.5 Implications for Future Research

Each of the dissertation studies illustrates opportunities for future research. The first study on primary prevention supports continued surveillance of HPV vaccination uptake at the population-level. Several changes have occurred since 2011: the addition of HPV vaccination as a HEDIS measure for girls and boys, the reduction in number of recommended doses for younger adolescents, and FDA approval of the vaccine for adults up to age 45. This information will help to guide where to focus local resources and targets for intervention. The natural progression of the second and third studies is research focused on drivers of organizational adoption of cervical cancer screening and management guidelines, how safety net providers access guidelines, and how they appraise shared decision making in light of approval of an additional screening modality (i.e., primary HPV testing). Moreover, given fragmentation of cervical cancer care, it is worthwhile to explore provider communication processes across the screening and follow-up continuum. This dissertation supports the value of both quantitative and qualitative methods to address these questions.

5.6 Conclusion

Primary prevention and early detection tools provide opportunities to mitigate racial/ethnic and socioeconomic disparities in cervical cancer. This dissertation captured adherence to recent evidence-based recommendations= around HPV vaccination and cervical cancer screening and management, and highlighted modifiable facilitators of uptake among high-risk populations. As evidence on cervical carcinogenesis and the causal role of HPV infection continues to shape clinical practice recommendations, monitoring uptake of evolving guidelines and understanding strategies to improve adoption among vulnerable populations merits continued attention.