Impact of the Affordable Care Act on Early Stage Cervical Cancer Diagnoses in Pennsylvania: An Interrupted Time Series Analysis

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Abstract

Significant advances in cervical cancer screening have led to improved survival rates and reduced cancer burden in the United States but disparities remain. Race, socioeconomic and insurance status and region strongly influence cervical cancer outcomes. The Affordable Care Act (ACA) included multiple provisions that aimed to expand access to coverage and cancer screening and care. The purpose of this study was to investigate the impact of ACA, following Medicaid expansion, on early stage cervical cancer diagnoses for women in Pennsylvania, with a focus on minority women and rurally located women. The study utilized data from the Pennsylvania Cancer Registry, a statewide data system responsible for collecting information on all new cancer cases diagnosed in Pennsylvania, to identify cervical cancer cases in Pennsylvania from 2010 through 2016. The effect of Medicaid expansion in Pennsylvania through implementation of the ACA was assessed on cancer stage at diagnosis using a retrospective natural experiment design and interrupted time series analysis. Multiple logistic regression models utilizing the interrupted time series analysis framework were estimated to assess the relationships between the implementation of the ACA, patient characteristics and the likelihood of an early stage cervical cancer diagnosis. A total of 2,052 cervical cancer cases in women aged 26 to 64 years were included in analysis over the study period between 2010 and 2016. Average age of the sample was 46 years (SD = 10.24). Most women were white (79.74%) and non-Hispanic (90.99%) and were privately insured (52.13%). The study did not find a significant effect of ACA implementation on early stage cervical cancer diagnoses across Pennsylvania, both when examining the full sample and when stratifying to examine effects for specific subpopulations, but results do highlight interesting trends in patterns of cervical cancer diagnosis between 2010 and 2016 motivating further research.

Keywords: cervical cancer, Affordable Care Act, Pennsylvania, insurance coverage and cancer prevention

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1.0 Background and Significance

The American Cancer Society estimates that almost 15,000 new cases of invasive cervical cancer will be diagnosed in the United States in 2021 and that over 4,000 of those women may die from the disease. Cervical cancer was previously the leading cause of cancer death for American women. However, with significant advances in screening, including the widespread use of the Papanicolaou (Pap) test and the HPV test, mortality rates have significantly declined over the last 40 years (American Cancer Society, 2021). Despite these improvements, disparities in cervical cancer incidence and mortality remain. Race, socioeconomic status, and region strongly influence cervical cancer outcomes. For example, the five-year survival rate for Black women is 58% compared to 71% for white women (American Cancer Society, 2021). Cervical cancer incidence and mortality rates are also higher in rural and nonmetropolitan areas than in metropolitan areas (Yu, Sabatino, & White, 2019).

The Appalachian region, in particular, experiences higher incidence and mortality due to cervical cancer when compared with other regions of the United States (Yao, 2016). This 420-county region extends from New York down through to northern Mississippi. Around 42% of the Appalachian region is considered rural, compared with only 20% of the U.S. population (Appalachian Regional Commission, 2020). In addition, systemic factors such as a lack of comprehensive healthcare facilities and providers, contribute to the observed disparities in cervical cancer seen in the region. These systemic challenges are often exacerbated by socioeconomic factors such as high rates of poverty and low levels of health literacy and education which often result in poorer observed health behaviors and infrequent contact with health care providers (Paskett et al., 2020).

Pennsylvania presents a useful case through which to examine differences in access to cervical cancer screening care and outcomes given the geographically diverse population and number of counties designated as part of the Appalachian region. It is also important to acknowledge the diverse experiences of individuals who reside in the Appalachian region of the United States. The region encompasses a broad range of populations and communities and public health challenges cannot be generalized across the whole of the region. This paper aims to shed light on the relationships between health care access and women's health outcomes in one state of the region to inform future research directions and public health solutions.

1.1 Literature Review

Review of previous literature demonstrates that women who are uninsured are less likely to utilize cancer screening services and are more likely to present with a later stage cancer at diagnosis and to have poorer survival outcomes (Chen et al., 2012; Sabik et al., 2015; Churilla et al., 2016). Early stage diagnosis of cervical cancer is associated with improved survival rates, less aggressive treatments and overall improved quality of life (American Cancer Society, 2021). Rural women, in particular, are more likely to fall under the category of uninsured (Cheeseman Day, 2019). The first section of this review will discuss early policy reform in the 1990s and early 2000s which established the foundations for preventative women's health care while the second section highlights modern reforms in the context of the Affordable Care Act (ACA).

1.1.1 Early Reform in Cervical Cancer Care

In 1990, Congress enacted the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) as an amendment to the Public Health Service to improve access to screening. Despite advances in screening in both breast and cervical cancer beginning in the mid 20th century, low income and minority women were less likely to be screened for both types of cancers four decades later (Hardy et al., 1996). Among US women aged 18 years and older, 75% had received Pap testing within the preceding 3 years to screen for cervical cancer. However, poor and uninsured women were much less likely to have received a Pap test (Lee et al., 2014). Congress established the program to address these significant disparities. The program provides grants to states to fund breast and cervical cancer screening, support services, case-management services (added by amendments enacted in 1998), and other services and activities aimed at developing greater capacity to serve at-risk populations. Since its 1991 implementation, the NBCCEDP has provided service for nearly 10 million breast and cervical cancer screening exams to almost four million women, with diagnoses of more than 52,000 breast cancers, 2,800 invasive cervical cancers, and nearly 137,000 premalignant cervical lesions (Rosenbaum, 2012). Despite the program's significant accomplishments in expanding access to screenings to women across the nation, the program lacked provisions to finance the treatment and follow up of abnormal screening results. Lack of follow up care and treatment left uninsured women especially vulnerable with few resources to rely on after receiving abnormal results. Moreover, due to the underwriting policies of the individual markets, independently purchasing a private policy would have been impossible for an uninsured woman with abnormal test results. In 2000, Congress enacted the Breast and Cervical Cancer Prevention and Treatment Act (BCCPTA) to address the gaps in coverage for treatment.

The BCCPTA established a state Medicaid eligibility option to cover uninsured women, regardless of income or assets, whose screenings through NBCCEDP revealed abnormal results. All states have adopted the expansion option, although variations exist in program design, eligibility and administration (Rosenbaum, 2012). Women were only able to enroll in the program after abnormal results had been found, often leading to delays in treatment. Lantz et al. (2009) uses a longitudinal time series design using data from 1995 through 2005 to evaluate the impact that the Medicaid expansions enacted through the BCCPTA may have had on time to diagnosis and time to treatment for women with abnormal breast and cervical cancer screening results. The authors found that the Act did have some positive impacts including a 12.8% decrease in the average number of days to definitive cervical diagnosis for white women. However, results also showed that the average time between diagnosis of cervical dysplasia or cancer and the initiation of treatment for Black and Hispanic women significantly increased after implementation of the policy. The authors discuss that these results may be explained by racial/ethnic disparities that exist in regard to access to gynecologists and other clinicians who treat cervical conditions and accept Medicaid patients. It is important to consider modern reforms to cervical cancer care policy to understand the ways modern reform intended to address these shortcomings of early programs and to highlight areas that may still need further adjustment and improvement.

1.1.2 Modern Reform in Cervical Cancer Care: the Affordable Care Act

The Affordable Care Act (ACA) included multiple provisions that aimed to expand access to coverage and cancer screening and care. Literature at the intersection of health care reform through the ACA and the cervical cancer care continuum has focused on three main provisions of the ACA: the dependent coverage mandate, Medicaid expansion and the elimination of cost sharing for preventative services for privately insured individuals.

Early data following implementation of the ACA from the National Cancer Database[1] found that women younger than 26-years-old had substantial increases in early stage cervical cancer diagnoses as a result of the dependent coverage mandate (Robbins et al., 2015). When examining changes in cervical cancer screening rates utilizing national self-report data from the Behavioral Risk Factor Surveillance System (BRFSS)[2] and Medical Expenditure Panel Survey (MEPS)[3], evidence remains mixed for young women (Garrdio et al, 2020; Han et al., 2015; Bhandari & Li, 2019). The mixed results in screening utilization may reflect the changes in cervical screening guidelines that occurred concurrently with the national implementation of the ACA. Additionally, the development and uptake of the HPV vaccine, approved for use in the United States in 2006, may impact cervical screening behavior as well (Garrido, 2020).

When examining Medicaid expansion, significant expansion effects have been identified when considering both cervical cancer screening in low income women (Hendryx, 2018, Sabik et al., 2018) and stage at diagnosis (Albright, 2021). Bhandara & Li (2019) also studied outcomes in the context of the elimination of cost sharing for preventative services but did not find an increase in guideline-concordant utilization among privately insured individuals using MEPS data. A supporting study utilizing claims data from Massachusetts found no significant effects on

[1] The National Cancer Database is an oncology outcomes database for accredited cancer programs in the United States and Puerto Rico, a joint program of the Commission on Cancer of the American College of Surgeons and the American Cancer Society
[2] The Behavioral Risk Factor Surveillance System (BRFSS) is a national telephone based health survey that collects data on health-related risk behaviors, chronic health conditions and use of preventative services
[3] The Medical Expenditure Panel Survey (MEPS) is a set of surveys of families and individuals, their medical providers and employers nationally

utilization for cervical cancer screening with elimination of cost sharing for preventative services (Steenland et al., 2019).

Much of the literature has utilized national data from BRFSS or the Surveillance, Epidemiology and End Results (SEER) program[4]. Although these sources provide large, nationally representative populations to examine, they lack the granularity that state cancer registries possess to examine more specific area level factors and regional changes. Even at the state level, trends observed in one state may not extrapolate to another.[5] It is important to understand regional trends within states to develop targeted and effective cervical cancer prevention and mitigation strategies. Moreover, the BRFSS contains self-report data regarding cervical screening practices but does not include objective information on cancer stage and treatment. Additional literature has also shown that these large population-based databases have underrepresented rural populations (Zahnd et al., 2019). Based upon 2009–2013 American Community Survey data and the USDA's Rural-Urban Continuum Codes (RUCC), only 10.6% of the geography covered in SEER is rural, while 14.8% of the U.S. population (more than 46 million people) is rural (Blake et al., 2017). Because the research question aims to investigate the impact of the ACA on cervical cancer diagnoses, particularly for women living in rural areas of Pennsylvania, the Pennsylvania Cancer Registry data is well situated to explore these relationships. To the best of the author's knowledge, the current study will be the first to examine changes in cervical cancer diagnoses in Pennsylvania under the context of the Affordable Care Act utilizing Pennsylvania Cancer Registry data. The goal of this paper is to investigate the impact of the Affordable Care Act, following Medicaid

[4] The Surveillance, Epidemiology and End Results Program (SEER) collects incidence, prevalence and survival data on cancer in the United States

[5] For instance, literature has found significant increases in early stage breast cancer diagnoses in Pennsylvania after implementation of the ACA (Spada, 2020) while Ohio, a state similar in population and size to Pennsylvania, did not exhibit the same trend in breast cancer diagnoses after implementation (Kirkpatrick, 2020)

expansion, on cervical cancer diagnoses for women in Pennsylvania, with a focus on minority women and rurally located women.

2.0 Methods

2.1 Data and Population

This paper utilized data from the Pennsylvania Cancer Registry, a statewide data system responsible for collecting information on all new cancer cases diagnosed in Pennsylvania, to identify cervical cancer cases in Pennsylvania from 2010 through 2016. The United States Preventive Services Task Force recommends cervical cancer screening every three years for women aged 21 to 29 years and for women aged 30 to 65 years who screen with cytology (by Pap smear) alone. The recommendation of screening every 5 years is for women aged 30 to 65 years who are screened through cotesting (Pap + hrHPV testing) or through hrHPV testing alone. The USPSTF does not recommend screening for women younger than 21 years, older than 65 years, or for any woman who has had a total hysterectomy. The American Cancer Society has suggested that screening can be delayed until age 25 years. Because screening guidelines are continuing to shift away from screening younger populations and the assumption that the ACA may impact stage at diagnosis through increased access to screening, the sample was limited to female residents of Pennsylvania aged 26-64 years of age. Restricting the sample to women aged 26 years and older also limits biases associated with the implementation of the dependent coverage mandate in order to isolate the impact of insurance expansions taking place later than 2014 in Pennsylvania. Cervical cancer cases diagnosed at death were excluded. The included PSite codes used to identify cervical cancer cases are identified in Appendix A.

2.2 Measures

The primary outcome measure was defined as the likelihood that a new case of cervical cancer diagnosed (in the county quarter-year) would be categorized as early stage. The National Cancer Institute's SEER summary stage variable is coded within the registry to indicate summary stage at the initial diagnosis or treatment of the reportable tumor. Summary stage categorizes how far a cancer has spread from its point of origin. The variable uses all information available in the medical record; it is a combination of the most precise clinical and pathological documentation of the extent of disease. Diagnoses that were in situ, local, or regional by direct extension only were considered early-stage; those that were regional with lymph nodes involved, regional not otherwise specified, and distant were considered late-stage (Soni et al., 2018, Lin et al., 2020).

Race and ethnicity were coded according to the SEER Program Coding and Staging Manual; codes correspond to racial and ethnic categories used by the U.S. Census Bureau. For location of residence subgroups, patients were divided into urban, defined as patients whose census tract of residence was assigned a rural–urban commuting area (RUCA) code of 1–3, and nonurban, defined as cases with a RUCA code of 4–10 (Cromardie, 2019, Spada et al., 2020). Age at diagnosis as recorded in the registry was included in complete years.

2.3 Statistical analysis

The effect of Medicaid expansion in Pennsylvania through implementation of the Affordable Care Act was assessed on cancer stage at diagnosis using a retrospective natural experiment design and interrupted time series analysis. An interrupted time-series analysis is useful for assessing the effects of population-level interventions (i.e. pre- and post-intervention) and provides a long term analytical framework that can detect immediate and more delayed changes in the outcome of interest (Kontopantelis, 2015). Interrupted time series analysis incorporates time and utilizes multiple consecutive pre and post intervention observations in a single population. Because the observations are undertaken for the same population, between group differences do not present an issue and the temporal structure allows for the control of underlying trends and measured time-varying confounders (Bernal et al., 2019).

In this interrupted time series analysis, the pre-intervention time period is defined as January 1st, 2010 through December 31st, 2013. The post intervention period is defined as January 1st, 2015 through December 31st, 2016. Because health insurance marketplaces under the ACA were introduced in 2014, the pre-intervention period will exclude any 2014 observations to limit biases associated with the beginning of the implementation of the ACA. Therefore, the resulting 16 consecutive quarterly time points prior to intervention and eight consecutive quarter periods post intervention were examined.[6]

Under a single group analysis, the following baseline specification is estimated:

$$[1]\ logit(\Pr(Y_t = 1)) \ = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t T_t + \beta_4 X_i$$

where Y_t is the outcome of interest for early stage diagnoses of cervical cancer measured at each quarter year time point, t. The outcome of interest was a binary variable to assess the likelihood that a new diagnosis of cervical cancer at the county-quarter level would be categorized as an early

[6] Quarters for each year defined as January 1st -March 31st, April 1st –June 30th, July 1st – September 30th and October 1st – December 31st

stage diagnosis.[7] T_t is the time since the start of the study in quarter years. X_t is an indicator variable representing the implementation of Medicaid expansion in Pennsylvania through the Affordable Care Act and X_tT_t is an interaction term noting the interaction between quarter-year and the indicator variable representative of the policy intervention. In the baseline model β_0 represents the intercept or base level of the likelihood of an early stage cervical cancer diagnoses in the county quarter. β_1 is the slope or trajectory of early stage cervical cancer diagnoses until the introduction of the intervention. β_2 represents the change in the level of the outcome that occurs in the period immediately following the introduction of the intervention compared with the counterfactual.[8] β_3 represents the difference between preintervention and post intervention slopes of the outcome. Thus, significant p-values in β_2 indicate an immediate treatment effect and significant values in β_3 indicate a treatment effect over time (Linden and Adams, 2011). β_4 is represents a vector of coefficients for a matrix of covariates of additional individual level characteristics (including age at diagnosis, race and rural/urban residence). Multiple logistic regression models utilizing the interrupted time series analysis framework were constructed to assess the relationships between the implementation of the ACA, patient characteristics and the likelihood of an early stage cervical cancer diagnosis. A logistic regression was selected to model relationships of interest because the primary outcome examined is measured as the likelihood that a new case of cervical cancer at the county-quarter year level is categorized as early stage, which should follow a binomial distribution. Standard errors were clustered at the county level. The model does not specify an error term because logistic regression models the predicted mean rather than modelling each value of the outcome with a predicted mean plus an error term consistent with other types of generalized linear

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[7] Y_t =1 if early stage, Y_t = 0 if late stage
[8] The preintervention trend projected into the treatment period serves as the counterfactual in the case of a single group model such as this one

models (Chang, 2021). Odds ratios with 95% confidence intervals are presented for each logistic regression. Statistical significance was assessed at a significance level of .05.

The assumptions necessary for causal inference in the single-group interrupted time series analysis are plausible when the preintervention trend prior to the expansion of Medicaid as a part of the ACA is flat or consistent followed by a significant change in the outcome variable immediately following expansion that is sustained over time. Assumptions for use of logistic regression models with an interrupted time series framework were assessed and conclusions are reported in the results section of the paper.

Stratified models were estimated to assess the impact of Medicaid expansion on early stage cervical cancer diagnoses for subpopulations of women in Pennsylvania. The first set of stratified models examined the likelihood that a new case of cervical cancer at the county-quarter year level would be categorized as early for non-white women in the sample versus minority women. The second set of stratified models examined the likelihood that a new case of cervical cancer at the county-quarter year level would be categorized as early for women who live in non-urban areas (large towns or rural areas) compared to urban areas of the state. All models controlled for age at diagnosis. All data management and analysis was completed in Stata (16.1, StataCorp LLC, College Station, Texas).

3.0 Results

Sample characteristics by pre and post ACA interruption time periods are shown in Table 1 below. Sixty-six of Pennsylvania's 67 counties were included in analysis. Unstaged cases were excluded from the analysis population providing a sample of 2,052 total diagnosed cases of cervical cancer during the study period. Within this study population, the average age was 46 years (SD = 10.24). Most women were white (79.74%) and non-Hispanic (90.99%) and were privately insured (52.13%). Interestingly, the percentage of women with Medicaid as their primary source of coverage at diagnosis significantly decreased in the post Medicaid expansion period from 28.89% prior to the implementation of the ACA to 23.99% in the post intervention period ($z=4.59$, $p<.001$). The number of uninsured women did decrease in the post intervention period, although this difference was not statistically significant ($z=1.42$, $p=.16$). Sixty five percent of cases of cervical cancer were categorized as early stage in both the pre and post ACA periods. Overall, there were small imbalances in demographic characteristics between the pre and post ACA periods.

Table 1. Summary statistics for cervical cancer cases: overall and by time period

Note: privately insured indicates cases coded with managed care, HMO and PPO plans; American Indian includes all indigenous populations of the Western hemisphere; Other Asian includes Asian, NOS, and Oriental, NOS

	All women	Pre-ACA (2010-2013)	Post ACA (2015-2016)
Total cases	2,108 (100.0)	1,412	696
Early Stage (in situ, local, regional by direct extension)	1,379 (65.42)	923 (65.37)	457 (65.66)
Late stage (regional with lymph nodes involved, regional NOS and distant)	677 (32.12)	460 (32.58)	217 (31.17)
Unstaged	52 (2.47)	29 (2.05)	22 (3.16)
Age, years, mean (SD)	46.46 (10.24)	46.57 (10.16)	46.24 (10.41)
Insurance status, n (%)			
Uninsured (+self pay)	47 (2.23)	36 (2.55)	11 (1.58)
Privately insured	1,100 (52.18)	726 (51.42)	374 (53.74)
Insurance, NOS	186 (8.82)	121 (8.57)	65 (9.34)
Medicaid	575 (27.28)	408 (28.89)	167 (23.99)
Medicare	142 (6.74)	84 (5.95)	58 (8.34)
TRICARE	8 (.38)	4 (.28)	4 (.57)
Veteran Affairs	7 (.33)	5 (.35)	2 (.29)
Indian Public Health Service	1 (.05)	1 (.07)	--
Insurance status unknown	42 (1.99)	27 (1.91)	15 (2.16)
Race and ethnicity			
White	1,681 (79.74)	1,105 (78.26)	576 (82.76)
Black	316 (14.99)	226 (16.01)	90 (12.93)
Asian Indian	6 (.42)	6 (.42)	--
American Indian	4 (.19)	3 (.21)	1 (.14)
Chinese	7 (.33)	6 (.42)	1 (.14)
Filipino	6 (.28)	2 (.14)	4 (.57)
Korean	10 (.47)	6 (.42)	4 (.57)
Thai	1 (.05)	--	1 (.14)
Pacific Islander	1 (.05)	--	1 (.14)
Vietnamese	13 (.62)	8 (.57)	5 (.72)
Other Asian	14 (.66)	12 (.85)	2 (.29)
Other	19 (.90)	17 (1.20)	2 (.29)
Unknown	30 (1.42)	21 (1.49)	9 (1.29)
Hispanic ethnicity	1,918 (90.99)	1,286 (91.08)	632 (90.80)
Non-Hispanic	125 (5.93)	81 (5.73)	44 (6.33)
Hispanic	65 (3.08)	45 (3.19)	20 (2.87)
Unknown			
Location of residence			
Urban	1,852 (87.86)	1,229 (87.04)	623 (89.51)
Large Town	177 (8.40)	125 (8.85)	52 (7.47)
Rural	79 (3.75)	58 (4.11)	21 (3.02)

In the full baseline model, the dependent variable measured the likelihood that a new case of cervical cancer in the county-quarter year would be categorized as early stage. The full model controlled for age, race and location of residence. Table 2 displays results from logistic regression models predicting the odds of early stage cancer diagnosis at the county-quarter year over time period 2010-2016. The table includes results from the full baseline specification and the stratified models examining effects for subpopulations of women in Pennsylvania.

Table 2. Results from logistic regression models predicting the odds of early stage cervical cancer diagnosis

Note: * indicates significant and marginally significant results at the .05 level

Model statistic Odds ratio (CI)	Full sample (n=2,052)	White race (n=1,650)	Nonwhite race (n=406)	Urban (n=1,806)	Large town (n=174)	Rural (n=74)
Quarterly trend pre-ACA ($ß_1$)	1.02 (0.99, 1.04)	1.02 (0.99, 1.05)	1.03 (0.98, 1.07)	1.02 (0.99, 1.05)	0.99 (0.91, 1.07)	1.04 (0.91, 1.19)
Level change immediately following ACA implementation ($ß_2$)	0.27 (0.06, 1.19)	*0.22 (0.05, 1.02)	1.10 (0.01, 205.51)	0.35 (0.07, 1.73)	0.22 (0.00, 49.91)	0.00 (<.001, 3.46)
Change in the quarterly trend between pre and post ACA periods ($ß_3$)	1.06 (0.98, 1.14)	1.06 (0.98, 1.16)	1.00 (0.80, 1.26)	1.04 (0.96, 1.13)	1.09 (0.86, 1.39)	1.57 (0.88, 2.83)

In the full model, there was not a significant treatment effect of ACA implementation ($ß_3$) on the likelihood of early stage cervical cancer diagnosis found over time (OR=1.06, CI: 0.98, 1.14, z=1.52, p=.128). There also was not any significant change in the likelihood of early stage diagnosis in the quarterly period immediately following the implementation ($ß_2$) of the ACA (OR=0.27, CI: 0.06, 1.17, z=-1.75, p=.08). Although not significant, the negative $ß_2$ coefficient suggests the model's estimate of a sizeable drop in likelihood of early stage cervical cancer diagnoses in the period following policy implementation ($ß_2$= -1.31 as compared to $ß_0$ =2.55), a counterintuitive result in the context of a hypothesis arguing that early stage diagnoses were likely to increase after the implementation of the ACA in 2015. $ß_0$ represents the baseline odds of early stage cervical cancer diagnosis in this population estimated by the model at 10.24 (CI: 5.95, 17.61, z=8.41, P<.001). In the full baseline model, age at diagnosis (z=-6.48, p<.001) and race (z=-2.51, p<.001) were both significant covariates. For each additional year in age, a woman's odds of being diagnosed with early stage cervical cancer (as compared to a late stage diagnosis) decreased by 4%. In this sample, being white reduced the chance of early stage diagnosis (as compared to a late stage diagnosis) by 18%. The sample was predominantly white so this finding could result from noise due to the smaller minority populations. When plotting the results of the full model (Figure 1), although the trends are not statistically significant, it can be observed that the likelihood of an early stage diagnosis has a gradual upward sloping trend in the pre intervention period and an upward sloping trend in the post intervention period. Despite the smaller intercept at the policy intervention, the upward sloping trend in the post intervention period is consistent with the hypothesis that the likelihood of early stage diagnosis increases throughout the post intervention period and implies that further research using a larger post intervention time period may find a significant upward sloping trend.

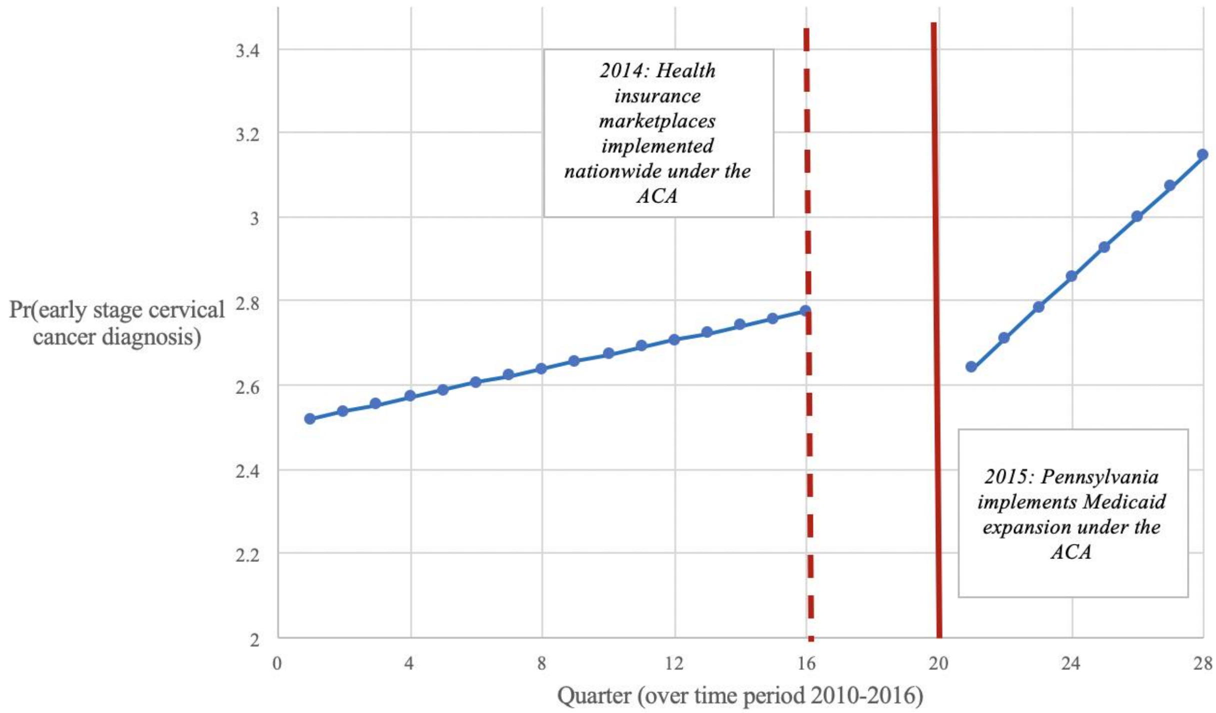


Figure 1. Probability of early stage cervical cancer diagnosis plotted from the baseline model, 2010-2016

Note: Model not significant at the .05 level

Similar trends were seen in the stratified models used to estimate impacts for various subpopulations of women in Pennsylvania. Because the sample contained small numbers of each category of non white race,[9] categories were combined together to represent minority women. When considering non white women in Pennsylvania, there was not a significant treatment effect of ACA implementation over time (OR=1.00, CI: 0.80, 1.26, p=.975) nor was there an immediate treatment effect following implementation (OR=1.10, CI: 0.01, 205.51, p=.970). When considering only White women, there was not a significant treatment effect of the ACA over time (OR=1.06, CI: 0.98, 1.16, p=.135), but there was a marginally significant immediate treatment

[9] Black women comprised 14.99% of the total sample while all other categories comprised less than 1% of the total sample

effect (OR= 0.22, CI: 0.05, 1.02, p=.054). There were no significant treatment effects of the ACA over time when considering women living in urban areas (OR: 1.04, CI: 0.96, 1.13, p=.324), women living in large towns (OR: 1.09, CI: 0.86, 1.39, p=.466) and women living in rural areas (OR: 1.57, CI: 0.88, 2.83, p=.129). In addition, there were no significant immediate treatment effects following implementation when considering women living in urban areas (OR: 0.35, CI: 0.07, 1.73, p=.200), women living in large towns (OR: 0.22, CI: 0.00, 49.51, p=.586) and women living in rural areas (OR: <.001, CI: <.001, 3.46, p=.081). Age and race remained significant covariates in all stratified models except for the model including only women living in a large town in which neither age nor race were significant.

Finally, post estimation diagnostics were conducted to determine fit of the model and check assumptions of the logistic regression used to model relationships between early stage cervical cancer diagnosis, implementation of the ACA and patient characteristics over the study period. Multiple logistic regression requires that observations are independent, that the outcome of interest is a binary variable and that predictors are linearly related to logit of the outcome. The sample did not consist of repeated measures or matched data so independence is satisfied. The independent variables are linearly related to the logit of the binary outcome for early stage cervical cancer diagnoses as depicted in partial residual plots (plots contained in Appendix B). In addition to the odds ratios of predictors in the model, the pseudo r-squared statistic provides a measure of effect size for the model. In the full baseline model, the pseudo r-squared is calculated at .0275. Generally, a pseudo r-squared of at least .20 indicates that the assessed model provides an improvement over the null model (Scott, 2020). In this case, the small pseudo r-squared implies that the specified model may not be an ideal fit for the variables included. Variance inflation factor

(VIF) was assessed for each independent variable; VIFs remained low indicating that multicollinearity is not an issue within the model.[10]

Additional model specifications were tested to explore the counterintuitive trends that were indicated in the full baseline specification and stratified models. Given that the ACA impacted access to care for women in Pennsylvania through Medicaid expansion, a model limited to only cases reported with Medicaid as the primary payer at diagnosis was tested. Results were consistent with the full baseline model and stratified models: none of the results were estimated as significant and the coefficient for $ß_2$ remained negative, indicating a drop in likelihood in early stage cervical cancer diagnoses with the implementation of the ACA. A model excluding all patient characteristic covariates (age, race and location of residence) was explored as well. Interestingly, results remained consistent in this model as well, with very minimal shifts in each of the coefficient estimates (and no significant impact of the policy intervention) suggesting that the trends that are observed are not largely explained by patient characteristics. The full baseline model was also tested using a linear regression because of the issues associated with interpreting odds ratios in logistic regression models that contain interaction terms (Karaca-Mandic et al., 2011). Results were consistent in the linear regression as well.

[10] Multicollinearity is the occurrence of high intercorrelations among two or more independent variables in a multiple regression model

4.0 Discussion

The current study examined the impact of Medicaid expansion, implemented through the ACA, on early stage diagnoses of cervical cancer for women in Pennsylvania, particularly among minority women and those in rural areas of the state. It was hypothesized that with increased access to cervical cancer screenings and healthcare through Medicaid expansion as a part of the ACA, the likelihood of cervical cancer diagnosis at an early stage would increase for women in Pennsylvania. Early stage diagnosis of cervical cancer is associated with increased survival rates and overall improved prognosis and quality of life. It was also argued that the implementation of the ACA may have larger impacts on cervical cancer outcomes for women living in rural areas of the state and minority women of the state, who are less likely to be insured and to be up to date with cervical cancer screenings (MacLaughlin et al., 2019). The current study is the first to examine changes in cervical cancer diagnoses in Pennsylvania in the context of the Affordable Care Act utilizing Pennsylvania Cancer Registry data. However, this study did not find a significant effect of ACA implementation on early stage cervical cancer diagnoses across Pennsylvania, both when examining the full model and when stratifying to examine effects for specific subpopulations, but does highlight interesting trends in patterns of diagnosis between 2010 and 2016 and motivates further research into each of these trends.

When considering all cases of cervical cancer diagnosed during the study period, there was not a significant treatment effect of ACA implementation on the likelihood of early stage cervical cancer diagnosis found over time. There also was not any significant change in the likelihood of early stage diagnosis in the quarterly period immediately following the implementation of the ACA. These results were consistent when considering subpopulations of women, including non white women and women who reside in non-urban areas. Age and race were estimated as significant covariates in the majority of models. Although not statistically significant, the full model estimated a sharp drop in the likelihood of early stage diagnoses at policy implementation followed by an upward sloping trend in the post intervention period. These results are contrary to the hypothesis and are inconsistent with some previous literature.

Previous literature has found significant reductions in the rate of uninsurance at diagnosis for women with cervical cancer nationally (Zhao, 2020; Albright, 2021). The current study did not find a significant decrease in the number of cases diagnosed without coverage, although the numbers of cases diagnosed without insurance were very small (n=47) potentially contributing to the lack of significance observed. Additionally, the number of cases diagnosed with Medicaid as the primary source of coverage significantly decreased over the study period, the opposite result of what was expected with the expansion of Medicaid in 2015. Nationally, enrollment in Medicaid increased quickly after expansions as a part of the ACA (Berchick et al., 2019). There were also smaller increases in enrollment in non expansion states, likely due to the "welcome mat effect," in which enrollment increases among individuals who were previously eligible for coverage but not enrolled. The majority of literature has not has described significant decreases in Medicaid enrollment immediately following the ACA in expansion states such as Pennsylvania (Kaiser Family Foundation, 2019), as was found in the current study. Beginning in 2017, diverse groups of states, including Wyoming, Missouri and New Hampshire, saw decreases in Medicaid enrollment (MACPAC, 2019) due to a number of factors.[11] The proportion of cases diagnosed with Medicaid as primary coverage was moderate in the sample (almost one third of the sample)

[11] Kaiser Family Foundation (2019) reports that changing economies, renewal process barriers, and a reduction of funds in outreach and enrollment assistance may all play a role in the decreases in enrollment observed across a number of states.

likely ruling out noisy data as an explanation for this finding. The result motivates questions regarding the effectiveness of the policy implementation in Pennsylvania, for example, were women who were eligible to enroll in Medicaid able to enroll in 2015? Was there sufficient promotion of the policy change in the first year of implementation? Did patients have the necessary tools to complete paperwork and apply for enrollment (for example, was the enrollment process internet based and also accessible to any Pennsylvania residents who may not have consistent internet access)? Reducing barriers to enrollment in Medicaid may be critical to finding a significant increase in proportion of patients using Medicaid as their primary coverage source if there is one. Moreover, the BCCPTA allows for private insurance coverage at higher income levels contingent on a cancer diagnosis so there may have been more women in the 133-200% FPL range who utilized private coverage rather than Medicaid post ACA. Additionally, insurance "churning," or coverage disruption or loss, could also explain a significant decrease in enrollment even during an expansion period. Difficulties navigating state renewal and redetermination procedures as well as income fluctuations or changing family circumstances can result in loss of coverage. Human service organizations play a role in this context in helping to get women who may be eligible for Medicaid enrolled in post expansion periods.

Previous studies examining screening utilization also found significant expansion effects for cervical cancer screening, although much of the literature has focused on a national scale and utilized self-reported survey data (Hendryx et al., 2018; Sabik et al., 2018). Significant expansion effects on screening utilization would presumably result in greater early detection of cervical cancer thus resulting in greater proportions of early stage cervical cancer diagnoses. Significant increases in the proportion of early stage cervical cancer diagnoses for women younger than 26 years were found as an effect of the implementation of the dependent coverage mandate under the

ACA. However, early stage diagnosis trends remained flat for women in the older age group studied (Robbins, 2015), similar to the trends observed in the current study despite the statistical insignificance. Albright et al. (2021) did find a significant increase in the proportion of early stage diagnoses with the implementation of Medicaid expansions, although the analysis was conducted at the national level (comparing expansion states to non-expansion states) and aggregated gynecological cancers together[12] so specific expansion effects for cervical cancer alone are unclear. Despite previous evidence that has linked rural residence to differences in cancer screening and diagnosis (Paskett et al., 2020), area of residence was not a significant factor in explanation of early stage cervical cancer diagnosis in the current study, although the results may be biased by the lack of cases in non-urban residential categories.

The current analysis is potentially limited by unobserved confounders, such as national trends in cervical cancer screening and diagnosis. With guidelines shifting towards less frequent screening and the increase in the uptake of the HPV vaccine, women may be less likely to be up to date with screenings. As of 2019, just over two thirds of women were up to date with cervical cancer screenings; this rate can be even lower for certain subpopulations of women (for example, those living below the poverty line and those with an education level equivalent to less than a high school education) (National Cancer Institute, 2021). Parekh et al. (2017) found a significant decrease in guideline-based cervical cancer screening after the change in screening guidelines in 2009 when examining Pennsylvania Medicaid claims data. Additionally, the American Cancer Society adjusted their guidelines for cervical cancer screening in 2012. Although the U.S. Preventive Services Taskforce guidelines are considered the standard for clinical

[12] Invasive cancers of the uterus, ovary, fallopian tube, cervix, vagina and vulva were aggregated together (Albright et al., 2021)

recommendations, the shift in recommendations by the American Cancer Society in 2012, in the middle of the study period, may have influenced results as well. Infrequent screening of cervical cancer increases the likelihood that a case may go undetected for an extended period thus increasing the likelihood of diagnosis at a more advanced stage. Potential reasons for infrequent screening include a lack of knowledge about guidelines for screening by healthcare providers, which may be especially prevalent with continually shifting guidelines and differing guidelines between advisory bodies, limited access to healthcare systems and patient expectations. For example, women who have received the HPV vaccine may believe that they are exempt from regular screening but it is important that women who are vaccinated continue to be screened, especially because the vaccine may not protect against all types of cervical cancer (CDC, 2016). When considering these trends, it is possible that the cases included in the present study are already more likely to be diagnosed at a more advanced stage. Some studies have examined the impact of shifting guidelines on utilization of screenings and outcomes that tend to be coupled with cervical cancer screening, such as STD testing (Naimer, 2017), but few have specifically investigated the impact of recently shifted guidelines directly on early stage diagnoses. Inclusion of national immunization and screening rates, from sources such as the National Immunization Surveys or the BRFSS, may be helpful additions to models estimating early stage cervical cancer diagnoses.

The current analysis included covariates for age, race and urban and non-urban residence but did not include other patient level or area and system level characteristics. Income level, health literacy and health system factors, such as provider concentration and location, have been shown to influence cervical cancer outcomes (Moss et al., 2017). Given that the current model estimates were not shown to be an improvement over the null hypothesis and remained consistent when removing patient characteristics from the model in exploratory analysis, consideration of these systemic and sociodemographic variables will be crucial for future analyses. For example, the Appalachian region in particular experiences severe provider shortages. There are 12 percent fewer primary care physicians per 100,000 residents and 28 percent fewer specialty physicians per 100,000 residents in the Appalachian region as compared to the nation overall (Paskett, 2020). The severe lack of providers in the region presents further barriers to access even for insured women. The current study's results may also suggest that health promotion factors may be particularly important to reducing barriers to cervical cancer prevention in addition to policy interventions such as the ACA aimed at reducing financial and coverage barriers. A recent systematic review by Kriubarajan (2021) highlights facilitators and barriers to cervical cancer. Facilitators included strong self-efficacy in health, a positive and consistent relationship with a healthcare provider and health literacy regarding cancer prevention and cervical cancer risk factors. Barriers included poorer health literacy, transportation challenges and negative experiences or perceptions of gynecological care[13] among others. Multilevel public health and health promotion interventions will be needed to address cervical cancer health literacy and to incentivize guideline concordant screening, particularly for marginalized populations of women.

The large sample size representative of all counties across the state of Pennsylvania remains a strength of the present study. Additionally, restricting the sample to women aged 26 to 64 years limits any biases associated with the implementation of the dependent coverage mandate within the ACA. Use of the Pennsylvania state cancer registry allows for exploration of regional trends and provides a more representative presentation of rural communities in the state as compared to larger national and state-based surveys. The objective nature of the state cancer

[13] History of childhood abuse and sexual trauma increased the risk for cervical cancer through a number of pathways including lack of screening, risky sexual behavior and higher levels of smoking and perceived stress (Hindin, 2019)

registry ensures that data is reliable and meets quality standards[14] as compared to subjective self-report surveys. Despite these advantages, significant causal relationships could not be inferred from this analysis. Although the Pennsylvania Cancer Registry data utilized in this analysis has been helpful in exploring regional trends and variations, generalizability is limited because the data comes from only one state. Additionally, minority patients in this study were predominantly Black whereas the broader nation's racial and ethnic population is much more diverse. The study may be limited by the sole inclusion of a binary outcome to represent likelihood of early stage diagnosis of cervical cancer as compared to rates of incidence or counts of cases placed in the context of population size. Future studies may look to incorporate these various measures of the outcome to capture a more comprehensive perspective on cervical cancer diagnosis in Pennsylvania. The current study only has two years of post-intervention data, after the implementation of Medicaid expansion in Pennsylvania in 2015, and so may underestimate the impact of expansion and access on cervical cancer diagnoses and outcomes for women in Pennsylvania. Further research in broader populations with expanded post intervention data and more comprehensive models incorporating community level covariates will be needed to provide support for true null findings. In conclusion, while the current study did not provide significant evidence of the ACA's impact on early stage diagnoses for Pennsylvania women aged 26 to 64 years, it does motivate further research to understand the trends observed and additional factors that may contribute to cervical cancer prevention for women in Pennsylvania.

[14] Reporting to the PCR is mandated by the Pennsylvania Cancer Control, Prevention, and Research Act of 1980 and the Pennsylvania Department of Health's regulations concerning Reporting of Communicable and Noncommunicable Diseases. Cancer data are reported by hospitals, clinics, laboratories, radiation facilities, cancer centers, surgical centers, doctor's offices, death certificates and through data exchange when Pennsylvania residents are diagnosed or treated in other states

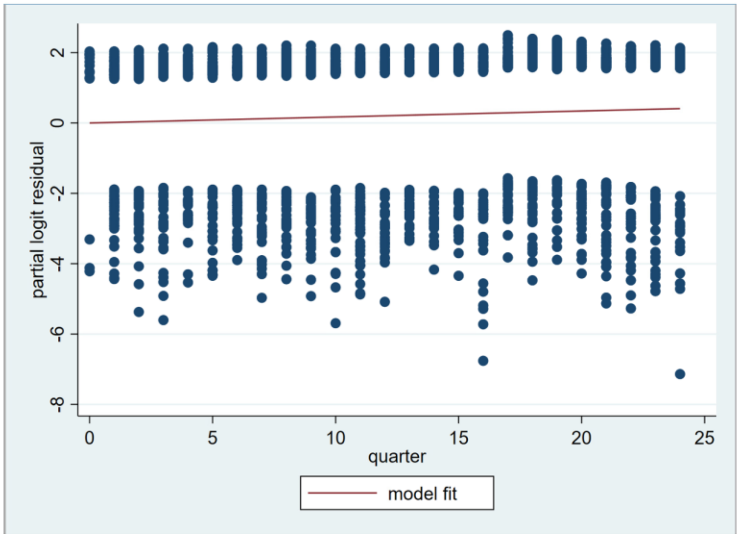
5.0 Public Health Impact

Cervical cancer is unique in that the vast majority of cases can be prevented through screening and vaccination. Detection of cervical cancer at early stages is a key public health priority in the United States and has the potential to reduce mortality and disease burden. While the present study did not find significant changes in early stage diagnoses of cervical cancer with the implementation of the Affordable Care Act in Pennsylvania, it does suggest the crucial roles that health promotion and education play in addressing cervical cancer and reducing health disparities in cancer control.

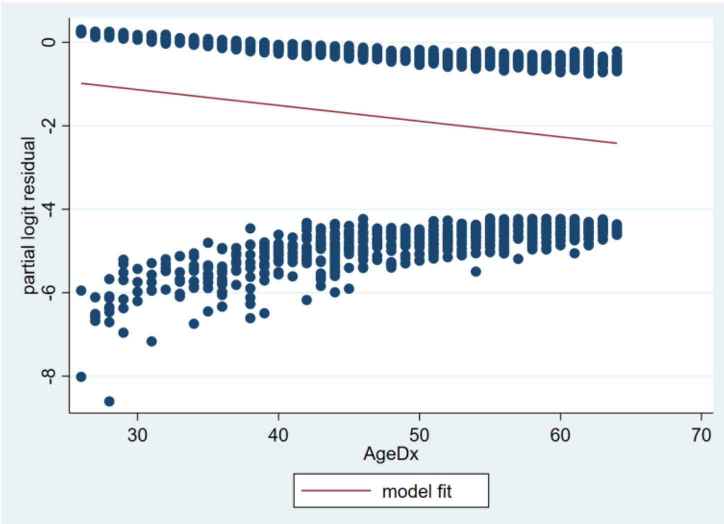
Appendix A PSite Codes

The cases included in analysis were restricted to cervix uteri PSite codes: ICD-0-2 Site = C530-C539; excluding histology codes 9050-9055, 9140, 9590-9992

Appendix B Partial Residual Plots



Appendix Figure 1. Partial residual plot depicting the relationship between the logit and quarter year



Appendix Figure 2. Partial residual plot depicting relationship between the logit and age at diagnosis

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