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Missed Opportunities for HPV Vaccination Among Vaccine-Eligible Women with High Grade Cervical Lesions

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ABSTRACT

Background: Incidence of high-grade cervical lesions (HGCL) has declined in the U.S following the introduction of the human papillomavirus (HPV) vaccine in 2006. However, many women continue to be diagnosed with HGCLs, including those eligible to receive the vaccine but did not. We determined self-reported barriers to and correlates of HPV vaccination in vaccine-eligible women diagnosed with cervical intraepithelial neoplasia grades 2, 2/3, 3 and adenocarcinoma in situ (CIN2+).

Methods: Data from a statewide surveillance system in Connecticut for CIN 2+ during 2008–2015 were used for this analysis. Enhanced surveillance data were collected for women residing in New Haven County, including HPV vaccine history and demographic factors, through chart review and patient interviews. Women who reported being unvaccinated were asked why they did not receive the vaccine. We evaluated trends in reasons for not receiving the vaccine using a two-sided Cochran Armitage trend test. Log-binomial analysis was used to assess associations between sociodemographic characteristics and vaccination status.

Results: Between 2008 and 2015, 1625 vaccine-eligible women were diagnosed with CIN2+, with 882 of these women reporting never receiving the HPV vaccine. The proportion of unvaccinated vaccine-eligible women did not significantly change from 2008 to 2015 ($p = 0.18$, range 49.1% to 60.0%). The most commonly reported reason for being unvaccinated was age/too old, followed by previous HPV diagnosis and no provider recommendation. Women who had public or no insurance were significantly more likely than privately insured women to report being unvaccinated ($p = <0.001$, $p = 0.0034$).

Conclusions: Commonly cited barriers to vaccination, such as age/too old and previous HPV diagnosis, are not contraindications for vaccination. Furthermore, frequent reporting of no provider recommendation underscores the important role providers play in the immunization of their patients. These results indicate the need for greater efforts by providers to dispel myths about HPV vaccine eligibility and to promote vaccination for all of their eligible patients.

1. Introduction

Human papillomavirus (HPV) is the most prevalent sexually transmitted infection in the US, with high-risk types 16 and 18 responsible for causing 50% of high-grade cervical lesions (HGCL) and 70% of cervical cancers [1,2]. In June 2006, the U.S Food & Drug Administration (FDA) licensed a highly effective vaccine that prophylactically protects those immunized against HPV infection and subsequent sequelae. The introduction of the vaccine has resulted in declines in incidence of HGCL [3]. However, vaccination coverage has been sub-optimal, and HGCL continue to be diagnosed in women who were age-eligible to receive the HPV vaccine since its introduction. Data from the 2017 National Immunization Survey-Teen and 2016 National Health Interview Survey shows that HPV vaccine coverage for ≥1 dose in 13–17 and 19–26 year olds is approximately 68% and 48%, placing coverage well below the Healthy People 2020 objective of 80% [4–6]. Vaccine coverage for the completion of the 3-dose series in adolescents by age 13 was approximately 43% in 2017 [4]. Lack of provider recommendation and low perceived need for vaccination are known drivers behind this moderate vaccine coverage [7].

Incidence of HGCL may be further reduced by identifying and addressing barriers to vaccination in young adult women. To evaluate barriers to vaccination in this population, and identify potential sociodemographic disparities in vaccine uptake, we assessed

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vaccination status, self-reported reasons for not receiving the vaccine and sociodemographic characteristics among vaccine-eligible women with HGCL in New Haven County, CT from 2008 to 2015. In Connecticut, similar to national estimates, only 71.3% of adolescents have been vaccinated with ≥1 dose of the HPV vaccine, and vaccine eligible women continue to be diagnosed with HGCL [4].

2. Methods

Data for this analysis came from the Connecticut Emerging Infections Program (EIP) HPV-IMPACT Project for which surveillance methods have been previously described [3]. In brief, in 2008 the Centers for Disease Control and Prevention began to monitor the impact of HPV vaccination through population-based surveillance of cervical intraepithelial neoplasia grades 2, 2/3 or 3 and adenocarcinoma in situ (CIN2+) conducted by the Connecticut EIP and four other EIP sites [8]. To facilitate implementation in CT, the state's Department of Public Health added CIN2+ to the list of mandatory reportable diseases statewide, effective January 1, 2008. All 34 pathology laboratories that have served CT residents are in compliance with the reporting requirement. This work has been deemed public health surveillance by university, state, and federal institutional review boards and thus exempt from the need for human subject approval.

Enhanced surveillance activities for women between ages of 18 and 39 years old residing in New Haven County, CT included medical record reviews, patient interviews, and geocoding. Medical records were reviewed through available electronic medical records, or through on-site chart review with the health care provider who performed the cervical biopsy, to obtain patient demographic characteristics and HPV vaccination history. Vaccination history could only be obtained through medical record review as Connecticut only tracks immunizations for children aged 0 to 6.

Interviews with patients were conducted to collect additional or missing demographic and vaccination information not obtained through initial medical record reviews. During the interviews, all women were asked about their awareness of the HPV vaccine, if a health care provider had recommended they receive the HPV vaccine, and HPV vaccine history. Women who reported having received the vaccine were subsequently asked how many doses of the vaccine they received, how old they were when they received these doses, and provider name or practice where the vaccine was administered. Women who reported receiving ≥1 dose of the vaccine had their vaccine history verified by chart review with the reported physician who administered the vaccine. Both in and out of state physicians were contacted to verify vaccine history. If women reported being vaccinated and vaccine history could not be verified by patient-reported physicians, these women were marked as having missing vaccine history. Women who reported not having received the vaccine did not have their vaccine history verified by a provider, and were asked an open-ended question regarding why they did not receive the vaccine.

Finally, all cases were individually geocoded by residential address to the census tract level using the Federal Financial Institutions Examination Council (FFIEC) Geocoding/Mapping System database. Previous analyses of these data have shown census tract-based measures that describe the neighborhoods in which women live reflect important aspects of social context and are important for determinants for health [9]. These geocodes were then matched to American Community Survey data from 2010 for census tract-based measures of race, ethnicity and poverty. Women were then categorized as living in a census tract with high or low proportions of each individual area-based measure of black, Hispanic and below poverty, with high proportion defined as ≥20% and low proportion as <20%.

Data used for this analysis included enhanced surveillance information from New Haven County, CT during the period January 1, 2008 through December 31, 2015. For women with multiple reports, only the first CIN 2+ diagnosis was included in this analysis. Women were classified as either vaccine-eligible or ineligible based upon birth date and the approval date by the FDA for the quadrivalent HPV vaccine. Women were classified as eligible to receive the HPV vaccine (vaccine-eligible) if they were born on or after July 1st, 1980 as these women would have been age 26 years or younger at the time of FDA approval.

Vaccine-eligible women were classified as vaccinated or unvaccinated based on vaccine history data collection measures described above. Women with missing vaccine history were excluded from this analysis. Women were further classified according to timing of vaccination as receipt on/after or prior to the date of their abnormal Pap test result that prompted the cervical biopsy for CIN 2+ diagnosis (trigger Pap). The percent of vaccine-eligible women who were vaccinated or unvaccinated was calculated across 2008–2015 by year of trigger Pap, and assessed for significant changes in prevalence using a two-sided Cochran-Armitage trend test.

Self-reported reasons for not receiving the HPV vaccine were examined over time. Up to two reasons were recorded for each woman interviewed, and were included for this analysis. The most frequently reported reasons were calculated by year of trigger Pap, and evaluated for any significant changes across 2008–2015 using a two-sided Cochran-Armitage trend test. To describe reasons for not receiving the vaccine across age groups, unvaccinated women were divided into two birth cohorts. Birth cohort analyses are important for studies of new vaccines because they capture the experiences of groups of women who are defined by the shared temporal experience of vaccine introduction. The first birth cohort consisted of women born between 1980 and 1986, and the second birth cohort consisted of women born between 1987 and 1996. A two-sided Cochran-Armitage trend test was used to determine any significant differences in reporting of reasons between the two birth cohorts.

The likelihood an unvaccinated women reported receiving a recommendation for the HPV vaccine, as well as having had any previous awareness of the vaccine itself prior to patient interview, was evaluated by birth cohort. A two-sided Cochran-Armitage test was used to detect any significant differences across the two birth cohorts in the frequency of reporting 'yes' to these two questions.

A log-binomial regression model was used to determine associations between sociodemographic characteristics and patient vaccination status among vaccine-eligible women. Patient sociodemographic characteristics included race, ethnicity, health insurance, birth cohort and area-based measures of race, ethnicity and poverty. Race was categorized as white, black/African American, and other. Other races included Asian, Pacific Islander, American Indian/Alaskan Native, or other, and were grouped together due to low frequency. Ethnicity was categorized as Hispanic or non-Hispanic. Insurance status was categorized as private, public (Medicaid or Medicare), or no insurance. The unadjusted associations included each individual characteristic while the adjusted model included all sociodemographic characteristics. SAS 9.4 (SAS Institute, Cary, NC) and R software version 3.4.3 were used for the analysis.

3. Results

A total of 5028 primary CIN 2+ diagnoses were reported to the New Haven County surveillance system during January 1, 2008 through December 31, 2015. Of these, 2985 women were born after June 1980 and deemed vaccine-eligible. There were 1360

women who had missing vaccination history and were excluded from subsequent analyses. Of the remaining women with vaccination history (n = 1625), 882 (54.3%) had not received HPV vaccine, 525 (32.3%) had received the HPV vaccine before the date of their trigger Pap, and 218 (13.4%) received the first dose of the HPV vaccine on or after the date of their trigger Pap.

The women with vaccination history were different in their sociodemographic characteristics than women with missing vaccination history. Women with vaccination history were significantly less likely to be Hispanic, were older at mean age of HGCL diagnosis, and insured mostly by private health insurance as compared to women with missing vaccination history (Table 1). Among women with vaccination history, the mean age for the unvaccinated women was 26.7 (±3.5), and they were predominantly white (63.3%), non-Hispanic (68.3%), and privately insured (58.8%). The vaccinated women had a mean age of 24.4 (±2.9) and were also

Table 1
Sociodemographic characteristics of vaccine-eligible women with CIN 2+ in New Haven County, CT by HPV vaccine history: 2008–2015.

	Vaccination History N = 1625 (n/%)[b]	Missing Vaccination History N = 1360 (n/%)[b]	p-value[a]
Race			
White	1085 (66.7)	900 (66.2)	0.016
Black	279 (17.2)	224 (16.5)	0.225
Other Race	172 (10.6)	286 (21.1)	<0.001
Ethnicity			
Non-Hispanic	1112 (68.4)	964 (70.9)	<0.001
Hispanic	298 (18.3)	394 (29.1)	<0.001
Age			
Mean Age at First Diagnosis	27.7 (±4.9)	26.8 (±3.7)	<0.001
Insurance Status			
Privately Insured	1070 (65.8)	720 (53.0)	<0.001
Publicly Insured	512 (31.5)	560 (41.2)	<0.001
No Health Insurance	39 (2.4)	48 (3.6)	0.014

[a] Chi-Square Test.
[b] Percentages may not add up to 100% due to missing data.

Table 2
Percent of vaccine-eligible women with CIN 2+ in New Haven County, CT by HPV vaccination status: 2008–2015.

Vaccination Status	2008 (n = 255)	2009 (n = 224)	2010 (n = 212)	2011 (n = 241)	2012 (n = 199)	2013 (n = 177)	2014 (n = 178)	2015 (n = 139)	Total (N = 1625)	p-value[a]
Unvaccinated	59.1	56.1	50.7	47.8	52.7	47.8	56.0	52.8	53.0 (n = 882)	0.18
Vaccinated Before Trigger Pap	17.5	24.0	34.7	36.3	34.0	40.1	35.9	34.5	31.4 (n = 525)	<0.001
Vaccinated On or After Trigger Pap	23.3	19.8	14.6	15.9	13.3	12.1	8.2	12.7	15.6 (n = 218)	<0.001

[a] Two-sided Cochran-Armitage trend test.

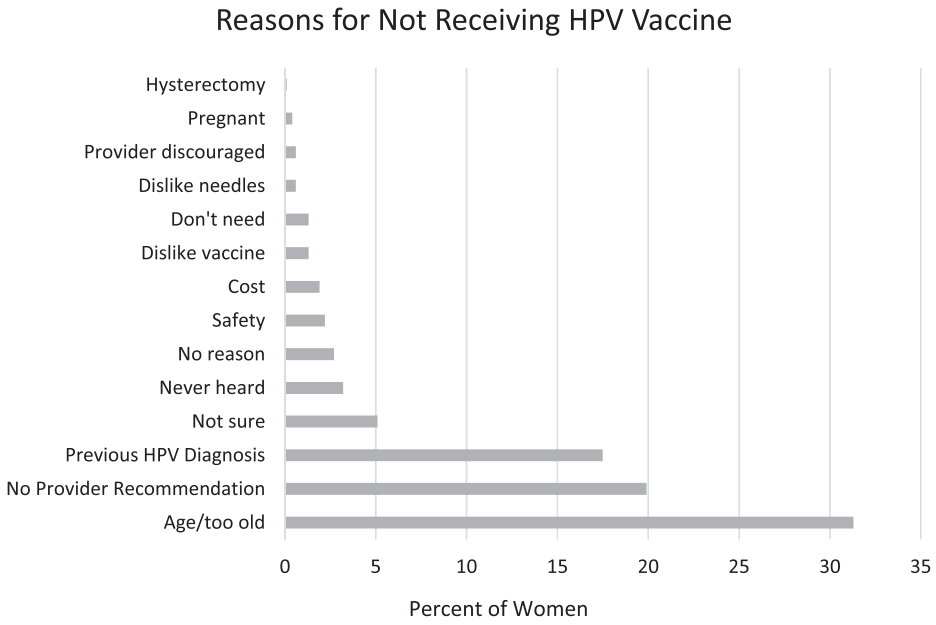

Fig. 1. Reasons for not receiving the HPV vaccine among unvaccinated vaccine-eligible women with CIN2+: New Haven County, CT 2008–2015.

predominantly white (70.9%), non-Hispanic (68.5%) and privately insured (74.3%).

The percent of women who were unvaccinated fluctuated across the study period between 49.1% and 60.0% with no significant trend ($p = 0.18$) (Table 2). However, there was a significant increase in the percent of women vaccinated before the date of their trigger Pap smear ($p < 0.001$), and a significant decline in the women vaccinated on or after the date of their trigger Pap smear ($p < 0.001$).

The three most commonly reported reasons for not receiving the HPV vaccine among unvaccinated women interviewed ($n = 620$) included age/too old to receive vaccine (31.3%), no provider recommendation for receiving vaccine (19.9%), and previous HPV diagnosis (17.5%). Other reasons reported less frequently included not sure (5.1%), never heard of vaccine (3.2%), no reason (2.7%), safety (2.2%), cost (1.9%), dislike vaccine (1.3%), don't need vaccine (1.3%), dislike needles (0.6%), provider discouraged receiving vaccine (0.6%), pregnant (0.4%), and hysterectomy (0.1%) (Fig. 1). The percent of women reporting age/too old significantly increased from 2008 to 2015 ($p = 0.027$), while the percent of women reporting no provider recommendation for receiving vaccine ($p = 0.025$) and previous HPV diagnosis ($p = 0.008$) significantly declined across the study period (Fig. 2). Despite overall increases in reporting of age/too old, there was a significant decline of reporting of this reason between 2014 and 2015 (Fig. 2).

A total of 660 women were placed in the earlier birth cohort (born between 1980 and 1986), and 222 were placed in the later birth cohort (born in or after 1987). The percent of women in the later birth cohort who reported age/too old to receive vaccine ($p < 0.001$) or no provider recommendation for receiving vaccine ($p = 0.018$) was significantly lower than the percent of women in the earlier birth cohort reporting these reasons (Fig. 3). There was no significant difference between the percent of women in the earlier and later birth cohorts who reported previous HPV diagnosis ($p = 0.967$) (Fig. 3).

Unvaccinated women were significantly less likely to report having received a provider recommendation regarding HPV vaccination compared to vaccinated women (59.1% vs 96.3%, $p < 0.001$), as well as less likely to report being aware of the vaccine (90.7% vs 99.3%, $p < 0.001$). The percentage of women who reported having had a provider recommendation to receive the vaccine was significantly higher in the later birth cohort when compared to the earlier birth cohort (66.7% vs 57.4%, $p = 0.052$), but no significant difference between the two birth cohorts in reporting of prior knowledge of the vaccine was observed (90.8% vs 90.8%, $p = 0.998$).

In the unadjusted analyses, women who had public or no health insurance were significantly more likely to be unvaccinated than women who had private health insurance, as were women who were born in the earlier birth cohort compared to women born in the later cohort. Women who lived in a census tract with ≥20% Hispanic residents were significantly more likely to not have received the HPV vaccine than women residing in a census tract with <20% Hispanic residents. In the adjusted model, having public (relative risk 1.23, 95% confidence interval 1.09–1.36) or no health insurance (relative risk 1.37, 95% confidence interval 1.11–1.70) remained significantly associated with being unvaccinated when compared to women with private health insurance. Being born in the earlier birth cohort (relative risk 1.96, 95% confidence interval 1.73–2.23) remained significantly associated with being unvaccinated. Women who lived in census tract with ≥20% black residents were found to be marginally less likely to be unvaccinated when compared to women who lived in a census tract with <20% black residents (relative risk 0.85, 95% confidence interval 0.75–0.97) (Table 3).

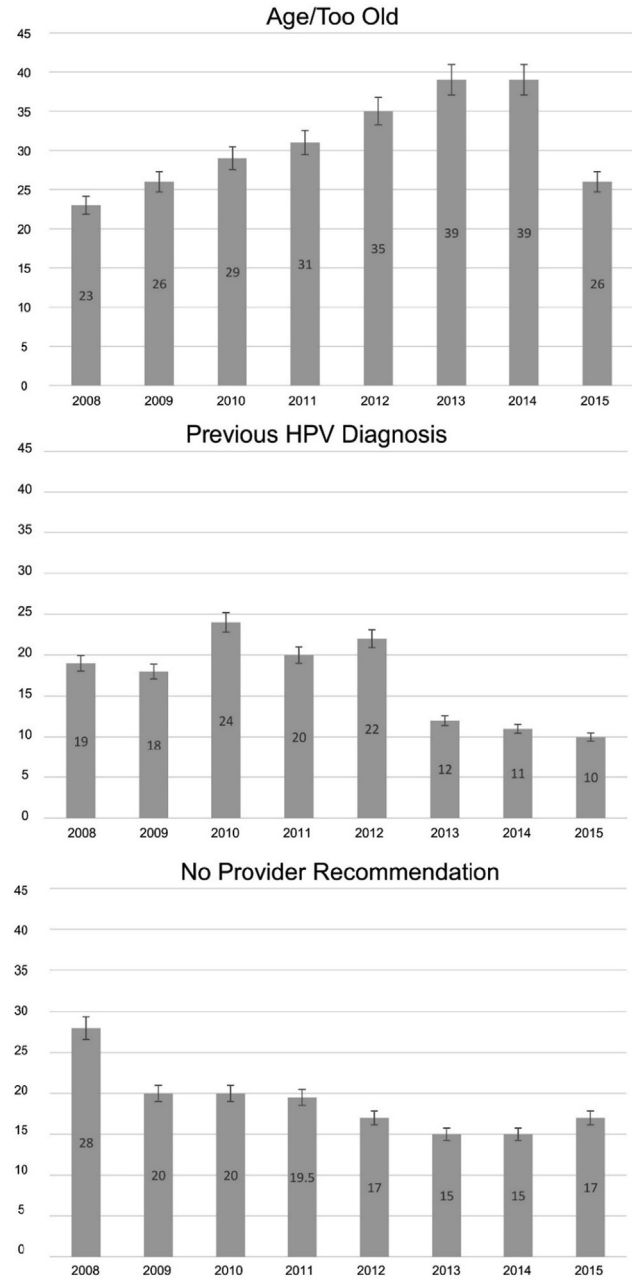

Fig. 2. Trends in reporting of reasons for not receiving HPV vaccine by vaccine eligible women with CIN 2+: New Haven County, CT 2008–2015.

4. Discussion

The prevalence of unvaccinated, vaccine-eligible women diagnosed with CIN 2+ in New Haven County remained at or above ~50% from 2008 to 2015. This reflects ongoing sub-optimal vaccination rates in Connecticut, and highlights the need for efforts to reduce missed opportunities. The increase in the prevalence of women vaccinated prior to trigger pap is reflective of women who were most likely not vaccinated prior to the persistent HPV infection responsible for causing their HGCL, and would only receive protection against future infections due to the solely preventive nature of the vaccine. Increased and targeted efforts are needed to raise sub-optimal HPV vaccine coverage to meet the Health People 2020 objective of 80% coverage among adolescents at the recommended ages of 11–12 years so these individuals will

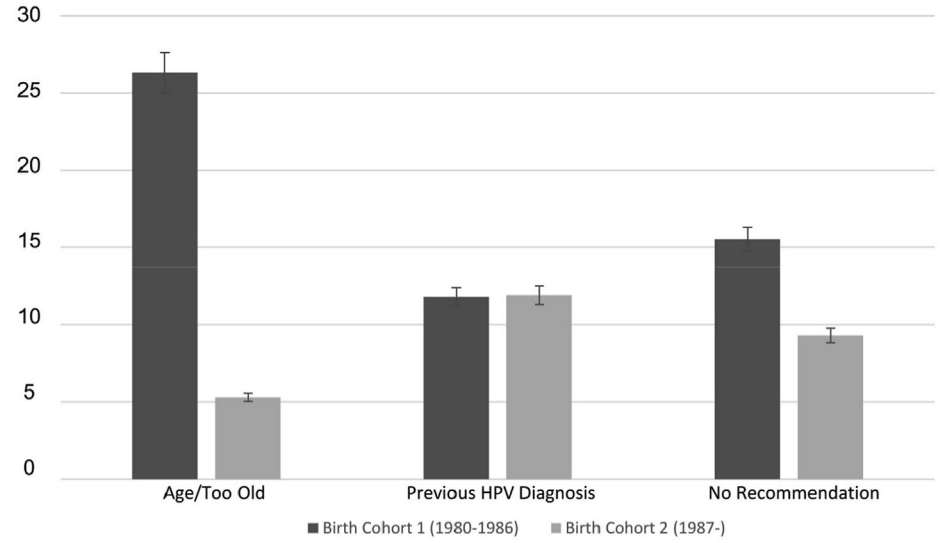

Fig. 3. Reason for not receiving HPV vaccine reported by vaccine eligible women with CIN 2+ By Birth Cohort: New Haven County, CT 2008–2015.

Table 3
Factors associated with being unvaccinated among vaccine-eligible women with CIN 2+ in New Haven County, CT 2008–2015.

Characteristic	N (N = 882)	% Unvaccinated of Eligible CIN 2+ Cases	Unadjusted RR (95% CI)	Adjusted RR (95% CI)	p-value
Race					
White	558	51.43	1.00	–	
Black	155	55.56	1.07 (0.95, 1.21)	–	–
Other	95	55.23	1.06 (0.91, 1.23)		
Ethnicity					
Non-Hispanic	602	54.19	1.00	–	
Hispanic	175	58.72	1.09 (0.98, 1.22)	–	–
Birth Cohort					
1987–1996	222	33.33	1.00	1.00	
1980–1986	660	66.01	1.98 (1.77, 2.23)	1.96 (1.73, 2.23)	<0.001
Health Insurance					
Private	519	48.46	1.00	1.00	
Public	315	61.52	1.28 (1.16, 1.40)	1.23 (1.09, 1.36)	<0.001
Self-Pay	26	66.67	1.38 (1.09, 1.73)	1.37 (1.11, 1.70)	0.0034
Area-based Census Tract SES Measures					
<20% Below Poverty	642	51.89	1.00	–	
≥20% Below Poverty	240	56.25	1.08 (0.98, 1.19)	–	–
<20% Black	636	53.56	1.00	–	
≥20% Black	246	51.66	0.96 (0.87, 1.07)	0.85 (0.75, 0.97)	0.015
<20% Hispanic	540	49.36	1.00	–	
≥20% Hispanic	342	59.90	1.21 (1.11, 1.32)	–	–

be protected against high risk HPV types (16/18) prior to sexual exposure. In the meantime, catchup vaccination among women 18–26 years will remain important for prevention of high-risk HPV infection and subsequent HGCL development.

Prior analyses from this surveillance system reported similar reasons for not receiving the vaccine between 2008 and 2010, including age/too old to receive vaccine, no provider recommendation, and previous HPV diagnosis [10]. Results of this study indicate these barriers have persisted through 2015. While age/too old and no provider recommendation were more likely to be reported by the earlier birth cohort, there was no significant difference between earlier and later birth cohorts in reporting of previous HPV diagnosis, supporting the conclusion that this barrier remains particularly salient and needs to be addressed. With the recent approval of the nonavalent vaccine, which provides coverage against an additional five high risk types of HPV (31, 33, 45, 52 and 58), providers should continue to educate their patients of the potential benefits and protection they may gain from receiving the vaccine as previous HPV diagnosis is not a contraindication for vaccination. Declines in reporting of no provider recommendation signals trends in the right direction, and sustained efforts to continue this pattern will be important given the previously shown salient nature of strong provider recommendation in successful vaccination [11,12].

Strong and significant associations between having public or no health insurance and being unvaccinated may reflect the potential high cost of the HPV vaccine for women in this age group. For children ages 18 and younger, the cost of the vaccine is covered by private insurance and the federal Vaccine for Children program. For those over the age of 18, however, the cost of the vaccine is not likely covered for uninsured individuals. The observation of this association through 2015 is concerning in light of Medicaid expansion in Connecticut as part of the Affordable Care Act, which allows for the coverage of the HPV vaccine for those who are Medicaid-eligible through the age of 26 years [13]. While the coverage of the HPV vaccine through Medicaid expansion should increase vac-

cine coverage in this population, the extent to which this policy change will affect vaccine uptake is still unclear [14]. Interestingly, there was a protective effect for women living in census tracts with ≥20% black individuals for being unvaccinated. This may be explained by consistently higher HPV vaccine initiation among black adolescents as compared to white adolescents [5].

Importantly, the higher likelihood that women in the more recent birth cohort had received a provider recommendation for vaccination and were vaccinated further supports the significant role health care providers have in a woman's decision to be vaccinated. Both birth cohorts were equally likely to be aware of the vaccine, reinforcing the significant impact health care provider recommendations have over other proposed barriers to vaccination. Strong provider recommendations for vaccination of eligible women will be a critical component in efforts to increase HPV vaccine coverage from 68.0% in adolescents and 48% in young adults. This will include dispelling myths about age and/or previous HPV diagnosis as reasons not to be vaccinated.

Some limitations of this analysis should be noted. Selection bias may have occurred due to availability of medical records as well as participation of women who were reachable by telephone and willing to complete an interview. Some data collection measures relied on patient reported data. Women who reported no history of vaccination reported their current health insurance and not the health insurance they held during time of vaccine eligibility. Though birth cohort analyses address different experiences of women with varying time of vaccine-eligibility, women within each cohort still had more limited vaccine-eligibility than others in the same cohort. Findings for this study may not be generalizable beyond New Haven County, CT, or to women without a high-grade cervical lesion diagnosis. The demographics of women included in this study are representative of New Haven County as a whole, with our sample reflecting similar percentages of white, non-Hispanic women compared to New Haven County (68% vs 63%) [15]. Important strengths of this study include robust data collection done through mandated population-based surveillance with high case ascertainment of women diagnosed with HPV-related precancerous lesions, as well as the use of provider medical records for validation of vaccine history.

5. Conclusions

Increased vaccine coverage at the recommended ages of 11–12 years will best protect adolescents against high-risk HPV infection and prevent missed opportunities to vaccinate young adults. At the same time, persistently sub-optimal coverage during adolescence requires that clinicians and patients remain vigilant about immunization in the catch-up range. Providers should strongly recommend the vaccine to all their eligible patients, regardless of previous HPV diagnosis, and educate them on the benefits of vaccination through the age of 26 years for whom the vaccine is currently recommended.

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Declaration of Competing Interest

Dr. Niccolai served as a Scientific Advisor for Merck.

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All authors attest they meet the ICMJE criteria for authorship.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2019.06.061.

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