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RESEARCH ARTICLE

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HPV vaccine initiation at 9 or 10 years of age and better series completion by age 13 among privately and publicly insured children in the US

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ABSTRACT

The US Advisory Committee on Immunization Practice recommends routine human papillomavirus (HPV) vaccination at 11–12 years of age, but states that vaccination may be initiated as early as 9 years. Our primary goal was to assess whether initiating HPV vaccination at 9–10 years of age, compared to 11–12, was associated with a higher rate of series completion by 13 years of age, and to identify factors associated with series completion by age 13. The study used vaccine claims and other data from the IBM MarketScan Commercial Claims and Encounters (privately insured) and IBM MarketScan Multi-State Medicaid (publicly insured) databases. Participants were 9–12 years of age and initiated HPV vaccination between January 2006 and December 2018 (publicly insured) or February 2019 (privately insured). Among 100,117 privately insured individuals, those initiating the HPV vaccination series at 9–10 years of age had a significantly higher series completion rate by 13 years of age than did those initiating at 11–12 years of age (76.2% versus 48.1%; $p < .001$). The same pattern was observed for 115,863 publicly insured individuals (70.4% versus 40.0%; $p < .001$). Provider and health care plan type, female sex, race/ethnicity, and wellness checks or non-HPV vaccinations during the baseline period were significantly associated with series completion by 13 years of age. Proactive initiation of HPV vaccination at 9–10 years of age was associated with higher rates of series completion by 13 years of age. These findings can inform provider education and other interventions to encourage timely HPV vaccination series completion.

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Introduction

Persistent infection with certain strains of the human papillomavirus (HPV) can cause cancer and other cytological abnormalities.[1] Oncogenic strains of HPV are causative factors for ~4.5% of all cancers, including almost all cases of cervical cancer and an estimated 88% of anal, 78% of vaginal, 50% of penile, 31% of oropharyngeal, and 25% of vulval cancers.[2] A nonavalent HPV vaccine (9vHPV) is currently used in the US.[3] In clinical trials, 9vHPV was safe and highly effective against the target strains of HPV, and provided long-lasting protection against HPV infection and related cytological abnormalities, genital warts, pre-cancerous lesions, and risk of cervical surgery related to vaccine-targeted HPV strains.[4–6]

The individual and population-level protective effects of HPV vaccines are greatest in countries with high (≥50%) vaccine coverage and multi-cohort vaccination.[7] However, the rate of HPV vaccine initiation is still relatively low in the US, as is the rate of series completion among those receiving a first dose.[8–20] Reported barriers to HPV vaccination include parental concerns about vaccine safety, low perceived risk of HPV infection (especially for males), and lack of a recommendation from health care providers.[21–23] Physicians report discomfort around discussing sexually transmitted infections with teens and their parents as well as a lack of feeling of urgency to discuss HPV vaccine initiation in the recommended age group, which may inhibit them from making recommendations about timely HPV vaccination.[21,24,25] In addition, the COVID-19 pandemic has curtailed the delivery of health services, including HPV vaccination and other immunization programs, and affected the rates and patterns of vaccine hesitancy.[26–31]

The US Department of Health and Human Services has set a target of 80% HPV vaccination series completion for adolescents 13–15 years of age by 2030 (from a 2018 baseline of 48%), as reflected in its Healthy People 2030 goals.[32] However, there is growing consensus in the scientific community that earlier series completion—i.e., by 13 years of age – is preferable, for several reasons. For example, the immune response to and clinical benefits of HPV vaccination are greater in cohorts vaccinated at younger ages.[7–33–37] Earlier HPV vaccine series completion would also aid in efforts to prevent HPV infections and related diseases by ensuring protection well before sexual debut in a higher percentage of the population.[38] Indeed, the National Committee on Quality Assurance now lists HPV vaccination series completion by the 13th birthday as one of its Healthcare Effectiveness Data and Information Set performance measures.[39]

The US Advisory Committee on Immunization Practices (ACIP) states that HPV vaccination can begin at 9 years of age, but currently recommends that routine HPV series initiation occur at 11–12 years of age.[40] In 2019, the American Academy of Pediatrics (AAP) began to recommend initiation of HPV vaccination at 9 years of age.[41] Around one-fifth of

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respondents to a 2021 provider survey indicated that they are already following the updated AAP guidelines and routinely recommend vaccination at 9–10 years of age.[42] In a previously published analysis, vaccination initiation at 9–10 years of age and series completion by 13 years of age were both associated with female gender, race or ethnicity, and government insurance.[43]

The primary goal of this study was to test the hypothesis that earlier HPV vaccine initiation is associated with an increased rate of series completion by 13 years of age. We therefore sought to compare the rates of HPV vaccination series completion by 13 years of age in proactive initiators (individuals receiving their first dose of HPV vaccine at 9–10 years of age) versus routine initiators (individuals first vaccinated at 11–12 years of age). We also sought to identify demographic and clinical factors associated with proactive versus routine initiation of HPV vaccination series, and with completion of the series by 13 years of age.

Methods

Study design

This was an observational, retrospective cohort analysis. Data used in the study came from databases that are certified as de-identified, and all study procedures were compliant with the US Health Insurance Portability and Accountability Act. The study, therefore, did not require Institutional Review Board approval or specific informed consent.

Study sample

The study sample included individuals residing in the US, 9–12 years of age at the date of HPV vaccine initiation, and enrolled in the IBM MarketScan Commercial Claims and Encounters Database (privately insured) or the IBM MarketScan Multi-State Medicaid Database (publicly insured). The study databases include information on inpatient and outpatient medical services use, prescription drug claims, and health care expenditures. The privately insured database has around 60 million unique enrollees in 12 health plans, including employees of >100 large employers from across the US and their spouses and dependents. The publicly insured database covers 25 million annual lives from 28 US states' Medicaid-managed care programs. The data from each database were analyzed separately.

Study timeline

The study period for the privately insured database ran from 1 December 2014 to 1 March 2020, with the index period (cohort selection window) being between 1 January 2016 and 1 February 2019 (Figure 1a). For the publicly insured database, the study period was from 1 December 2014 to 31 December 2019, with an index period of 1 January 2016 to 1 December 2018 (Figure 1b). The study and index periods were chosen to use the latest available data while limiting any effect of the COVID-19 pandemic on the analysis. Continuous enrollment was required for ≥13 months (baseline period) prior to the date of the first dose of HPV vaccine (index date), to ensure that the index date reflected the first dose in the series. For the primary analysis, ≥13 months of enrollment during the follow-up period was also required, which is 1 month longer than the 6–12-month gap between doses specified on the vaccine label. The follow-up period ended during the year of the participant's 13th birthday or at the end of enrollment, whichever occurred first.

Eligible participants were male or female individuals 9–12 years of age when they received a first dose of 9vHPV during the index period, as identified by use of Current Procedural Terminology (CPT-4) code 90651 or by the following National Drug Codes (NDCs): 00006411901, 00006411902, 00006411903, 00006412102, 54569667100, 50090244300, 00006412101. Exclusion criteria were as follows: a claim for any HPV vaccine in the baseline period or an International Statistical Classification of Diseases (ICD-9 or ICD-10) code indicating

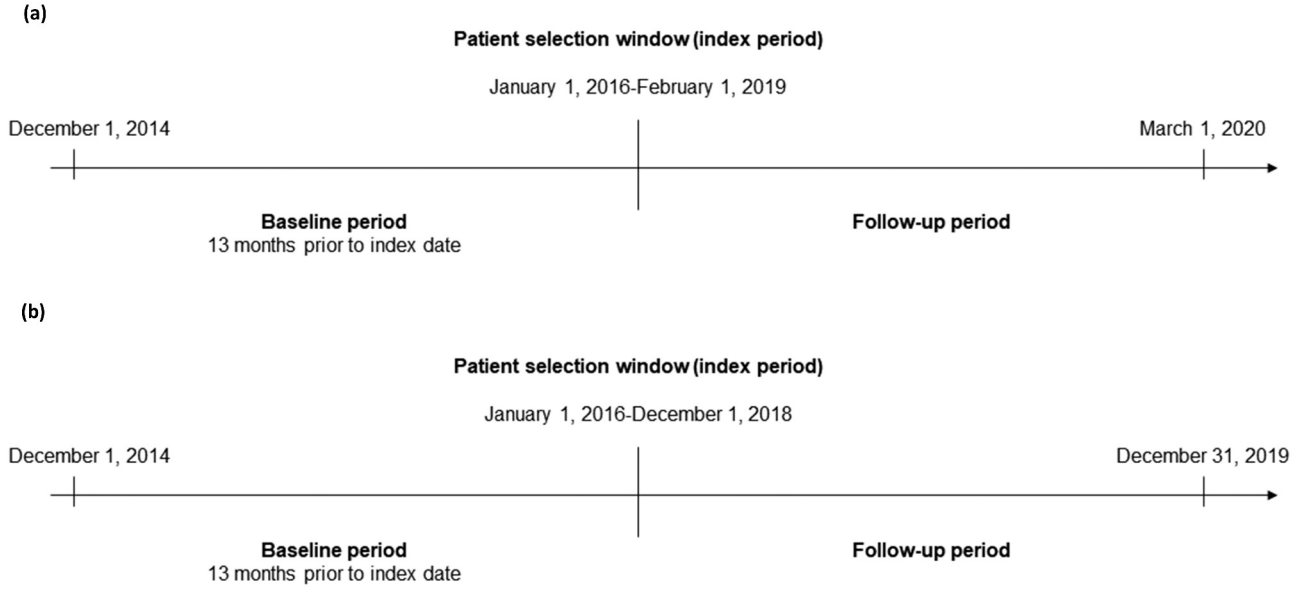

Figure 1. Summary of study design for (a) privately insured enrollees and (b) publicly insured enrollees database. Note: The index date was defined as the date of receipt of first dose of HPV vaccine within the index period.

pregnancy or delivery (codes 640.x–669.x, V22.x, V23.x, V27.x, V28.x, V72.42×, Z34.x, O60–O77, O80–O82, O00–O09).

Study measures

The key outcome measure was completion of an HPV vaccination series by 13 years of age. The recommended schedules for 9vHPV are summarized in Supplementary Table S1. Completion of a vaccination series was defined as receipt of a full 2- or 3-dose series, as applicable, with the minimum gaps between doses defined in the relevant schedule, by an individual receiving a first HPV vaccine and indicated to receive a full series of HPV vaccine. Any subsequent doses of HPV vaccine after completion of the schedule were disregarded. Individuals with evidence of an immunocompromising condition, as defined using the codes listed in Supplementary Table S2, required evidence of receipt of 3 doses; 2 doses were required for all other enrollees.

The following were recorded as categorical variables, using labels from the study databases: participant's binary sex on index date (male, female); race/ethnicity (publicly insured database only: White, Black, Hispanic, Other); provider type administering first vaccination dose (family medicine, pediatrician, physician [unspecified or rare specialty], internal medicine, nurse practitioner, other); metropolitan statistical area on index date (urban, rural); geographical region on index date (Northeast, South, Midwest, West, unknown); plan type on index date (health maintenance organization [HMO], preferred provider organization [PPO]/exclusive provider organization [EPO], point of service [POS] with capitation, comprehensive high-deductible health plan [HDHP]/consumer deductible health plan [CDHP], other); vaccine financing policy (Vaccines for Children [VFC] program only, VFC and underinsured select, universal, universal select, unknown). The vaccine financing policy variable was coded based on the residential state information of privately insured enrollees and information on the policy in each state, derived from the latest available data from the VFC Management Survey.[44] Information on the state of residence was not available for enrollees in the Medicaid database. Proactive initiation of HPV vaccine was defined as receipt of a first HPV vaccine at 9 or 10 years of age, and routine initiation as receipt of a first HPV vaccine at 11 or 12 years of age.

Receipt of other vaccines commonly administered to individuals 9–12 years of age (seasonal influenza; tetanus, diphtheria, and pertussis [Tdap]; meningococcal conjugate) during the baseline period was coded as a binary variable, with a value of 1 indicating receipt of any of these vaccines. Wellness visits during the baseline period were also captured as a binary value (a value of 1 indicates that the participant had a wellness visit). The following codes were classified as wellness visits: ICD-9 V20.0–20.2, V21.0, V21.2, V70.0, V70.3; ICD-10 Z00.0–00.5, Z76.1–76.2; CPT 99382-99385, 99392-99395, S0302.

Statistical analysis

For each database, the percentage of all eligible individuals 9–12 years of age who initiated an HPV vaccination series was calculated, as were the percentages of these initiators who were 9–10 versus 11–12 years of age on their index date. The percentage of each initiator group who completed the vaccination series by 13 years of age was also calculated. Descriptive statistics (mean, standard deviation [SD]) were used to compare continuous variables between groups initiating HPV vaccination at different ages; frequencies and percentages were calculated for categorical variables. Factors potentially associated with completion of an HPV vaccination series by 13 years of age were modeled in a multivariable logistic regression model. Adjusted odds ratios (ORs) and their 95% confidence intervals (CIs) were computed for all variables. All programming was conducted using SAS statistical software, version 9.4 or later (SAS Institute Inc., Cary, NC, USA).

Results

HPV vaccination series initiation

There were 100,117 enrollees 9–12 years of age who initiated an HPV vaccination series in the privately insured database, and 115,863 in the publicly insured database (Supplementary Figure S1). In both databases, almost all of these individuals (privately insured database, 98.03%; publicly insured database, 93.45%) initiated the series at 11–12 years of age (routine initiators) rather than at 9–10 years of age (proactive initiators; Supplementary Table 3).

Demographic and clinical characteristics were compared between proactive and routine initiators (Table 1). Among privately insured enrollees, routine initiators were more likely to have PPO or CDHP/HDHP health care plans than proactive initiators at index date (48.1% versus 44.9% and 28.3% versus 23.9%, respectively, $p < .001$); in the publicly insured population, proactive initiators were more likely than routine initiators to be enrolled in an HMO health care plan (78.0% versus 66.6%, $p < .001$; Table 1) at index date. Routine initiators from both databases were more likely to have received their first dose of HPV vaccination from a pediatrician than were proactive initiators (privately insured, 74.1% versus 67.4%, $p < .001$; publicly insured, 36.8% versus 26.4%, $p < .001$). Privately insured proactive initiators were more likely than routine initiators to have an immunocompromised condition during the baseline period (0.8% versus 0.3%, $p = .001$). In both databases, proactive initiators were more likely than routine initiators to have had a wellness check visit during the baseline period (privately insured, 54.2% versus 50.9%, $p = .004$; publicly insured, 47.9% versus 43.4%, $p < .001$). Proactive initiators in the publicly insured database, but not the privately insured database, were also more likely than routine initiators to have received a non-HPV vaccine during the baseline period (37.9% versus 31.6%, $p < .001$). Proactive initiation was not associated with gender in either database, and was not associated with urbanicity in the privately insured database. Among publicly insured individuals, routine initiators were more likely to be non-Hispanic White (42.5% vs 34.2%) as compared to proactive initiators, who were more likely to be non-Hispanic Black (37.1% vs 35.5%) or Hispanic (16.5% vs 12.4%).

HPV vaccination series completion

Among privately insured HPV vaccination series initiators, a higher proportion of proactive initiators completed the

Table 1. Baseline characteristics of study samples[A].

	Privately insured database (*N* = 100,117)			Publicly insured database (*N* = 115,863)		
	Proactive initiators (*N* = 1,976)	Routine initiators (*N* = 98,141)	*p*-value	Proactive initiators (*N* = 7,586)	Routine initiators (*N* = 108,277)	*p*-value
Gender			.332			.185
Female	1,037 (52.5)	50,422 (51.4)		3,763 (49.6)	54,563 (50.4)	
Male	939 (47.5)	47,719 (48.6)		3,823 (50.4)	53,714 (49.6)	
Race/ethnicity						<.001
Non-Hispanic White	–	–		2,596 (34.2)	45,972 (42.5)	
Non-Hispanic Black	–	–		2,812 (37.1)	38,458 (35.5)	
Hispanic	–	–		1,251 (16.5)	13,404 (12.4)	
Other[B]	–	–		927 (12.2)	10, 443 (9.6)	
Plan type			<.001			<.001
PPO	888 (44.9)	47,253 (48.1)		–	–	
CDHP or HDHP	472 (23.9)	27,743 (28.3)		–	–	
HMO	398 (20.1)	13,858 (14.1)		5,915 (78.0)	72,150 (66.6)	
Other[C]	218 (11.0)	9,287 (9.5)		16 (0.2)	212 (0.2)	
Comprehensive	–	–		1,665 (21.8)	35,915 (33.2)	
Urbanicity			.615			
Rural	155 (7.8)	8,005 (8.2)		–	–	
Urban	1,821 (92.2)	90,136 (91.8)		–	–	
Geographic region			<.001			
Northeast	288 (14.6)	12,315 (12.5)		–	–	
North Central	626 (31.7)	24,334 (24.8)		–	–	
South	652 (33.0)	40,398 (41.2)		–	–	
West	403 (20.4)	20,586 (21.0)		–	–	
Unknown	7 (0.3)	508 (0.5)		–	–	
Vaccine financing policy			<.001			
VFC only	727 (36.8)	34,495 (35.1)		–	–	
VFC and underinsured	530 (26.8)	27,716 (28.2)		–	–	
VFC and underinsured select	48 (2.4)	4,592 (4.7)		–	–	
Universal	179 (9.1)	2,751 (2.8)		–	–	
Universal select	74 (3.7)	6,454 (6.6)		–	–	
Other	418 (21.2)	22,133 (22.6)		–	–	
Provider type[D]			<.001			<.001
Family medicine	260 (13.2)	9,812 (10.0)		107 (1.4)	4,644 (4.3)	
Pediatrician	1,331 (67.4)	72,686 (74.1)		2,006 (26.4)	39,803 (36.8)	
Physician (unspecified or rare specialty)	126 (6.4)	5,909 (6.0)		1,066 (14.1)	21,355 (19.7)	
Internal medicine	22 (1.1)	1,690 (1.7)		19 (0.3)	469 (0.4)	
Nurse practitioner	45 (2.3)	2,498 (2.6)		210 (2.8)	10,253 (9.5)	
Other	192 (9.7)	5,546 (5.7)		4,178 (55.1)	31,753 (29.3)	
Immunocompromised status			.001			.083
Yes	15 (0.8)	326 (0.3)		32 (0.4)	332 (0.3)	
No	1,961 (99.2)	97,815 (99.7)		7,554 (99.6)	107945 (99.7)	
Wellness check visits			.004			<.001
Yes	1,070 (54.2)	49,954 (50.9)		3,630 (47.9)	46,972 (43.4)	
No	906 (45.8)	48,187 (49.1)		3,956 (52.2)	61,305 (56.6)	
Prior vaccinations			.621			<.001
Yes	948 (48.0)	46,534 (47.4)		2,873 (37.9)	34,251 (31.6)	
No	1,028 (52.0)	51,607 (52.6)		4,713 (62.1)	74,026 (68.4)	
Index year			.001			<.001
2016	496 (25.1)	27,935 (28.5)		2,521 (33.2)	33,435 (30.9)	
2017	615 (31.1)	31744 (32.3)		2,723 (35.9)	38,552 (35.6)	
2018	852 (43.1)	37,676 (38.4)		2,342 (30.9)	36,290 (33.5)	
2019	13 (0.7)	786 (0.8)		–	–	

CDHP, consumer directed health plan; HDHP, high-deductible health plan; HMO, health maintenance organization; PPO, preferred provider organization; VFC, Vaccines for Children. Proactive initiators were 9–10 years of age and routine initiators were 11–12 years of age at their index date.

[A]Values presented as *n* (%). The statistical significance of differences between cohorts was assessed using the chi-square test.

[B]Individuals with no recorded data for race/ethnicity were included in the "Other" category.

[C]Privately insured database: individuals with comprehensive, EPO, POS, POS with capitation, or any other health care plan were classified in the "Others" category. Publicly insured database: individuals with PPO or any other health care plan were classified in the "Others" category.

[D]The category Physician (unspecified or rare medical specialty) in both databases includes Physician, Surgery, Neonatal-Perinatal Medicine, Obstetrics & Gynecology, Medical doctor, where Physician includes Multi-Specialty Physician Group and Physician Assistant and Surgery includes Surgeon (NEC), Colon & Rectal Surgery, Neurological Surgery, Orthopedic Surgery, Abdominal Surgery, Cardiovascular Surgery, Dermatologic Surgery, General Vascular Surgery, Head and Neck Surgery, Pediatric Surgery, Transplant Surgery, Traumatic Surgery, Cardiothoracic Surgery and Thoracic Surgery. Individuals with pharmacist or missing data for provider type were included in the "Other" category.

vaccination series by 13 years of age compared to routine initiators (76.2% versus 48.1%; $p < .001$, Figure 2), corresponding to an OR of 3.51 (95% CI 3.15, 3.90; Table 2). Female individuals were more likely to complete their vaccination series by age 13 than males (OR 1.13 [95% CI 1.10, 1.16]). Receipt of a non-HPV vaccine (OR 1.39 [95% CI 1.35, 1.43]) or having a wellness check visit (OR 1.33 [95% CI 1.30, 1.37]) during the baseline period were also associated with an increased likelihood of HPV vaccination series completion by age 13.

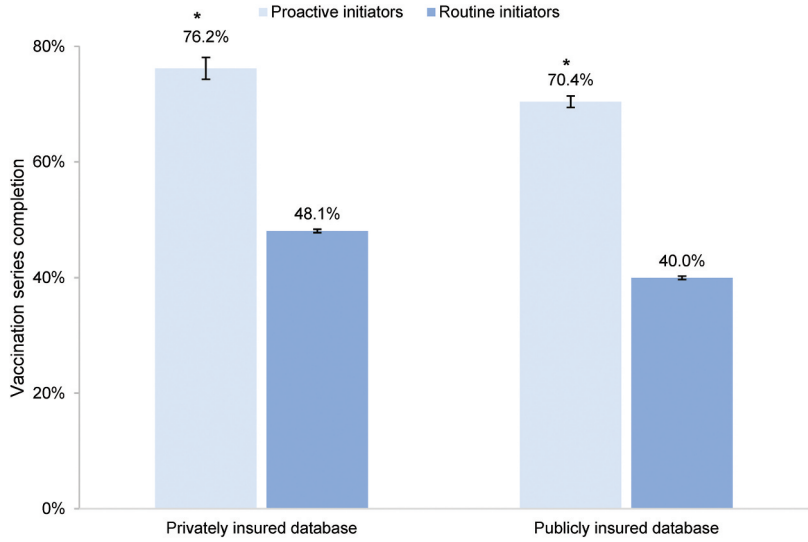

Figure 2. Percent HPV vaccination series completion by 13 years of age among proactive and routine initiators enrolled in the privately insured and publicly insured databases. Note: The base-case results are denoted by the blue bars. The error bars show the 95% confidence intervals. Asterisk indicates a statistically significant difference between proactive and routine initiators in the base-case analysis ($p < 0.001$).

Table 2. Demographic and clinical characteristics associated with HPV vaccination series completion by 13 years of age in a logistic regression analysis[A].

Characteristic	Value	Privately insured database	Publicly insured database
Age at initiation (years; Referent: 11–12)	9–10	3.51 (3.15, 3.90)	3.50 (3.32, 3.68)
Sex (Referent: Male)	Female	1.13 (1.10, 1.16)	1.07 (1.05, 1.10)
Provider type (Referent: Pediatrician)[B]	Family medicine	1.08 (1.04, 1.13)	0.92 (0.86, 0.98)
	Physician (unspecified or rare specialty)	1.12 (1.06, 1.18)	1.08 (1.04, 1.12)
	Internal medicine	1.04 (0.94, 1.15)	0.85 (0.70, 1.02)
	Nurse practitioner	0.96 (0.89, 1.04)	1.03 (0.98, 1.08)
	Other	0.94 (0.89, 1.00)	1.05 (1.02, 1.09)
Race/ethnicity (Referent: Non-Hispanic White)	Non-Hispanic Black	–	0.80 (0.78, 0.82)
	Hispanic	–	1.11 (1.07, 1.16)
	Other	–	1.04 (0.997, 1.09)
Region (Referent: South)	Northeast	1.05 (1.00, 1.09)	–
	Northcentral	1.09 (1.05, 1.13)	–
	West	1.15 (1.11, 1.19)	–
	Unknown	0.59 (0.49, 0.71)	–
Urbanicity (Referent: Urban)	Rural	1.06 (1.02, 1.12)	–
Plan type (Referent: HMO)	PPO	0.81 (0.78, 0.85)	–
	CDHP or HDHP	0.82 (0.78, 0.85)	–
	Comprehensive	–	0.97 (0.94, 1.01)
	Others	0.91 (0.87, 0.96)	1.20 (0.91, 1.57)
Vaccine financing policy (Referent: VFC only)	VFC and underinsured	1.00 (0.96, 1.03)	–
	VFC and underinsured select	0.87 (0.81, 0.93)	–
	Universal	0.90 (0.83, 0.97)	–
	Universal select	0.73 (0.69, 0.77)	–
	Other	1.08 (1.04, 1.12)	–
Immunocompromised status (Referent: No)	Yes	0.09 (0.07, 0.14)	0.09 (0.06, 0.14)
Prior vaccinations (Referent: No)	Yes	1.39 (1.35, 1.43)	1.45 (1.41, 1.49)
Wellness check visits (Referent: No)	Yes	1.33 (1.30, 1.37)	1.38 (1.34, 1.41)
Index year (Referent: 2016)	2017	0.82 (0.79, 0.85)	0.86 (0.84, 0.89)
	2018	0.73 (0.70, 0.75)	0.84 (0.82, 0.87)
	2019	0.68 (0.59, 0.79)	–

[A]Analysis performed via logistic regression. Results presented as odds ratio (95% confidence interval).
[B]The category Physician (unspecified or rare medical specialty) in both databases includes Physician, Surgery, Neonatal-Perinatal Medicine, Obstetrics & Gynecology, Medical doctor, where Physician includes Multi-Specialty Physician Group and Physician Assistant and Surgery includes Surgeon (NEC), Colon & Rectal Surgery, Neurological Surgery, Orthopedic Surgery, Abdominal Surgery, Cardiovascular Surgery, Dermatologic Surgery, General Vascular Surgery, Head and Neck Surgery, Pediatric Surgery, Transplant Surgery, Traumatic Surgery, Cardiothoracic Surgery and Thoracic Surgery. Individuals with pharmacist or missing data for provider type were included in the "Other" category.

Among publicly insured individuals, a higher proportion of proactive initiators completed the vaccination series by 13 years of age compared to routine initiators (70.4% versus 40.0%, $p < .001$, Figure 2), corresponding to an OR of 3.50 (95% CI 3.32, 3.68; Table 2). Female individuals were more likely than males to complete their vaccination series by age 13 (OR 1.07 [95% CI 1.05, 1.10]). Receipt of prior non-HPV vaccinations (OR 1.45 [95% CI 1.41,1.49]) and wellness visits during the baseline period (OR 1.38 [95% CI 1.34, 1.41]) were associated with an increased likelihood of series completion by 13 years of age. Non-Hispanic Blacks were less likely than Non-Hispanic Whites to complete an HPV vaccination series by 13

years of age (OR 0.80 [95% CI 0.78, 0.82]), while Hispanic individuals were more likely than White individuals to complete the series by 13 years of age (OR 1.11 [95% CI 1.07, 1.16]).

Sensitivity analyses

Three sensitivity analyses with extended follow-up periods (≥25 and ≥37 months) or an additional 30-day grace period for series completion were also carried out to assess the extent of the impact of misclassification due to lack of enrollment. Similar to the primary analysis, all sensitivity analysis results consistently indicated that proactive initiation was associated with higher likelihood of series completion by 13 years of age (Supplementary Table S4, Supplementary Table S5, Supplementary Table S6). We also conducted a post-hoc sensitivity analysis to compare series completion rates for both groups within 3–4 years, i.e., by 13 years of age for proactive initiators and by 15 years of age for routine initiators (Supplementary Table S7, Supplementary Table S8, Supplementary Table S9). Consistent with our primary analysis results, among publicly insured individuals, proactive initiators had statistically significantly higher completion rates compared to routine initiators (82.98% versus 78.64%, $p < .001$). However, there was no significant difference in completion rates between proactive and routine initiators among the privately insured population (88.89% versus 88.01%, $p = .633$).

Discussion

In this study, we compared the rates of HPV vaccination series completion by 13 years of age between individuals who received their first HPV vaccine at 9–10 years of age (proactive initiators) and those who initiated the vaccination series at 11–12 years of age (routine initiators). We found that proactive initiation was associated with higher rates of series completion by 13 years of age. This trend persisted in all sensitivity analyses.

There is mounting evidence that HPV vaccine series completion by 13 rather than 15 years of age is beneficial, for reasons including superior immune response and protection before sexual debut in a higher proportion of adolescents.[7–33–38] In a 2011 analysis of National Immunization Survey – Teen data conducted by the US Centers for Disease Control and Prevention, proactive initiation of HPV vaccination was suggested as a means to increase HPV vaccine uptake and on-time series completion by allowing more time and consequently more opportunities for completion.[8] Our findings are consistent with this suggestion and with the results of a previous study in which 97.5% of proactive initiators completed the series by 13.5 years of age, compared to 78.0% of routine initiators.[43] To determine whether factors other than longer follow-up time may account for the higher on-time completion rates associated with proactive initiation, we conducted a post-hoc sensitivity analysis with a 3–4-year follow-up period for all enrollees to compare completion rates between proactive and routine initiators. In the Medicaid population, consistent with our main analysis, proactive initiators had higher completion rates compared to routine initiators. Our finding that wellness checks and receipt of non-HPV vaccinations were associated with proactive series initiation and with series completion suggests that differences between the groups in overall health-seeking behavior may contribute to the higher overall completion rate among proactive initiators. Conversely, in the commercial population, the completion rates were not significantly different between proactive and routine initiators. Further research is needed to understand the reasons for these findings.

Others have also reported benefits of proactive HPV vaccination series initiation. Widdice *et al.* reported that proactive initiators were more likely than routine initiators to complete the 3-dose series within the schedule's recommended 7 month window (12.9% versus 10.7%).[12] Similar patterns were observed when the series completion window was expanded to 12 months after initiation.[12] Another study reported higher rates of HPV vaccine series completion within 12 months for proactive versus routine initiators (32.8% versus 32.2%, respectively).[16] Many of these previous studies used data relating to the use of bivalent and quadrivalent HPV vaccines whose use has subsequently been discontinued in the US. Similar trends in our findings for 9vHPV provide evidence that the benefits of proactive HPV vaccination series initiation are not dependent on the type of vaccine used.

In response to this growing body of evidence for the benefits of proactive initiation, the AAP and American Cancer Society (ACS) now endorse initiation of the HPV vaccination series at 9–10 years of age—i.e., at the younger end of the full range recommended by the ACIP.[40,41,45] The AAP states that there are several advantages and no known disadvantages of proactive HPV vaccination series initiation, and the ACS has concluded that proactive initiation is expected to prevent more HPV-related cancers.[41,45] The AAP guidelines also assert that proactive initiation offers health care providers more flexibility and prevents delays in HPV vaccination caused by scheduling conflicts with a cluster of other vaccinations routinely administered at 11–12 years of age, specifically the Tdap and meningococcal conjugate vaccines.[41] In their first statement on the use of a quadrivalent HPV vaccine, the ACIP cited a theoretical *advantage* of administering the Tdap, meningococcal, and HPV vaccines together at a single visit to ensure that adolescents receive all 3 vaccines on schedule.[46] Since then, however, uptake of Tdap and meningococcal vaccines in the US has exceeded that of even the first dose of HPV, indicating that concomitant administration of the HPV vaccine with other vaccines was not a successful strategy to increase uptake.[43,47] Indeed, the AAP states that "if a vaccine is delayed at the 11- or 12-year visit, it almost always is the HPV vaccine."[41]

The AAP and ACS guidelines also reference the advantages of decoupling HPV vaccination from discussion of sexual behavior.[41,45] A qualitative survey of US health care providers has reported that offering the HPV vaccine well before puberty may serve to reduce parental vaccine hesitancy related to the perceived association between HPV vaccination and the initiation of sexual activity.[48] The study also reported that despite physicians' initial skepticism about recommending HPV vaccination before 11 years of age, parental and child acceptance of proactive vaccination initiation was high.[48] The survey respondents felt that discussing the vaccine's higher efficacy when initiated at younger ages, as well as the decreased number of vaccines required per visit when starting

the series sooner, encouraged parental acceptance of proactive initiation of the series.

While our data support the hypothesis that earlier initiation of HPV vaccination correlates with earlier series completion, the overall rates of proactive initiation in the current study populations were extremely low, in line with previous US studies.[17,19,20] Several studies of physician attitudes to proactive initiation of HPV vaccination have concluded that additional provider education may be needed to encourage timely uptake of HPV vaccines among the target age group.[21,24,25,42,48] A recent survey indicated that willingness to recommend proactive HPV vaccination series initiation may be lower among pediatricians than among family medicine practitioners, and also among providers with ≥20 years of practice experience compared to those with ≤9 years of experience.[42] It has also been reported that adolescents from racial/ethnic minorities are less likely than White adolescents to complete an HPV vaccination series and to receive an HPV vaccination recommendation from a physician; encouraging universal provider recommendations may thus also help to mitigate some of the systemic barriers to HPV vaccination faced by racial and ethnic minorities.[49] Examples of interventions that successfully encouraged physicians to recommend proactive HPV vaccination series initiation have been reported.[26–50–52] The interventions included provider education; changing the age of the electronic medical record immunization alert to prompt providers about patients turning 9 years of age, rather than 11; formation of a quality improvement team; and staff financial incentives.[26,50,52] Similar initiatives at the provider network, state, and national levels – as well as additional or stronger recommendations from ACIP and other relevant organizations – may be necessary to encourage more US providers to recommend proactive HPV vaccination series initiation; more research is needed to determine the optimal format and targeting of such initiatives. Our finding that proactive initiation correlated with attendance at wellness check visits, which the AAP recommends annually during the target age range,[53] suggests that these visits may offer an appropriate venue for promotion of proactive HPV vaccination.

Limitations of the current study are noted. Any HPV vaccination events that were not submitted for insurance reimbursement were not captured; it is not known how common these events would be among the study population, although they would be expected to be rare in a population with a requirement for ≥26 months of continuous enrollment. In addition, an analysis of the 2018 National Immunization Survey-Teen data found that 99.1% of adolescents aged 13–17 years received HPV vaccination in a medical setting.[54] While it is not known how many HPV vaccination events from the present analysis were not submitted for an insurance claim, the results from the 2018 study indicate that the majority of HPV vaccination events occur in a setting that would allow for an insurance claim to be submitted and that the magnitude of vaccination offered outside the medical setting would have minimal impact on the outcome and conclusion of the present study. The generalizability of the sample to the overall US population is unknown, given potential differences in population demographics and health care plan coverage. For example, all enrollees in the commercial database are covered by health insurance plans offered by large employers, and the study population may thus differ from individuals covered by plans obtained through smaller employers and other sources, as well as from uninsured individuals. This database has been previously reported to have a slight skew toward older age compared to the general US population, and to have an overrepresentation of individuals from the South, but to otherwise closely represent the overall US population.[55] Further, the Medicaid database comprises data reported anonymously by multiple states, which may introduce unquantifiable biases due to regional variation in demographic and clinical variables. However, the size and multi-state nature of the study databases provide confidence that the study's findings are generalizable to the overall US population. Certain variables – including race/ethnicity, geographical region, and urbanicity – were only available for 1 of the 2 study databases. Other variables of interest that may affect HPV vaccination series initiation or completion rates, such as parental income, education level, and vaccine hesitancy, were not available for either study sample. Any enrollees who completed the vaccination series outside our study period were not captured. Our study and its interpretation are also limited by the accuracy of the data in the study databases, which may be subject to coding errors or missing values.[56]

Our study data were obtained prior to the COVID-19 pandemic, during which the overall uptake of HPV and other vaccines decreased.[26–31] In addition, the politicization of the vaccines developed to protect against infection with the SARS-CoV-2 virus may have affected the demographic patterns of hesitancy related to other vaccines; for example, early data indicate that hesitancy related to the seasonal influenza vaccine has increased in the US since the start of the pandemic, with political affiliation and choice of news media as important predictors.[30,57,58] Although the full impacts of the COVID-19 pandemic on the rates and patterns of HPV vaccination are not yet known, a study conducted at 2 medical practices in the Boston area between March 2016 and October 2020 concluded that efforts to encourage proactive HPV series initiation had mitigated the impact of COVID-19 on overall vaccination coverage by allowing more time for missed doses to be made up before the 13th birthday.[26] Larger-scale analyses will be required to determine whether this observation is generalizable to the overall US population, and whether proactive initiation can also help to reduce the impact of other interruptions to HPV vaccination series administration.

In conclusion, our study provides additional evidence that proactive initiation of the HPV vaccination series, at 9–10 years of age, increases the likelihood that all required doses will be administered before the age of 13. Our analysis also identifies factors associated with series completion by 13 years of age that offer avenues for further research and targeted interventions focused on increasing the rate of proactive initiation.

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