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Effect of a Health Care Professional Communication Training Intervention on Adolescent Human Papillomavirus Vaccination
A Cluster Randomized Clinical Trial

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➕ **Supplemental content**

IMPORTANCE The incidence of human papillomavirus (HPV)–related cancers is more than 35 000 cases in the United States each year. Effective HPV vaccines have been available in the United States for several years but are underused among adolescents, the target population for vaccination. Interventions to increase uptake are needed.

OBJECTIVE To evaluate the effect of a 5-component health care professional HPV vaccine communication intervention on adolescent HPV vaccination.

DESIGN, SETTING, AND PARTICIPANTS A cluster randomized clinical trial using covariate-constrained randomization to assign study arms and an intent-to-treat protocol was conducted in 16 primary care practices in the Denver, Colorado, metropolitan area. Participants included 188 medical professionals and 43 132 adolescents.

INTERVENTIONS The 5 components of the intervention were an HPV fact sheet library to create customized information sheets relevant to each practice's patient population, a tailored parent education website, a set of HPV-related disease images, an HPV vaccine decision aid, and 2½ hours of communication training on using a presumptive vaccine recommendation, followed by motivational interviewing if parents were resistant to vaccination. Each practice participated in a series of 2 intervention development meetings over a 6-month period (August 1, 2014, to January 31, 2015) before the intervention.

MAIN OUTCOMES AND MEASURES Differences between control and intervention changes over time (ie, difference in differences between the baseline and intervention period cohorts of patients) in HPV vaccine series initiation (≥1 dose) and completion (≥3 doses) among patients aged 11 to 17 years seen at the practices between February 1, 2015, and January 31, 2016. Vaccination data were obtained from the practices' records and augmented with state immunization information system data.

RESULTS Sixteen practices and 43 132 patients (50.3% female; median age, 12.6 years [interquartile range, 10.8-14.7 years] at the beginning of the study period) participated in this trial. Adolescents in the intervention practices had significantly higher odds of HPV vaccine series initiation (adjusted odds ratio [aOR], 1.46; 95% CI, 1.31-1.62) and completion (aOR, 1.56; 95% CI, 1.27-1.92) than those in the control practices (a 9.5–absolute percentage point increase in HPV vaccine series initiation and a 4.4–absolute percentage point increase in HPV vaccine series completion in intervention practices). The intervention had a greater effect in pediatric practices compared with family medicine practices and in private practices compared with public ones. Health care professionals reported that communication training and the fact sheets were the most used and useful intervention components.

CONCLUSIONS AND RELEVANCE A health care professional communication intervention significantly improved HPV vaccine series initiation and completion among adolescent patients.

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T he incidence of human papillomavirus (HPV)–related cancers is more than 35 000 cases in the United States each year.[1] Highly effective vaccines against HPV have been available in the United States since 2006 for girls[2,3] and 2009 for boys[4,5] yet are largely underused. As of 2016, only 60.4% of children aged 13 to 17 years had started the HPV vaccination series, and only approximately two-thirds of those starting the series completed it.[6] Attempts to use policy changes to increase uptake, such as mandating HPV vaccination for school entry, have been largely unsuccessful and ineffective.[7] Interventions to improve adolescent HPV vaccine uptake by other means are a national priority.[8]

A key factor influencing adolescent HPV vaccination is whether and how a health care professional recommends it.[9,10] Numerous studies[11-15] demonstrate that medical professionals often fail to communicate effectively about the vaccine with patients and parents. The President's Cancer Panel[8] has indicated that interventions to improve health care professionals' communication about adolescent HPV vaccination are needed.

Our group developed a 5-component health care professional communication intervention based on the precaution-adoption-process model[16] to improve medical professionals' ability to effectively communicate about HPV vaccines with their adolescent patients and their parents. The present study tests our hypothesis that implementation of the intervention increases practices' adolescent HPV vaccine uptake compared with providing usual care.

Methods

Study Design

This was a 2-arm, controlled cluster randomized clinical trial that was performed between February 1, 2015, and January 31, 2016. Because the intervention was at the practice level, cluster randomization was performed at the practice level in a 1:1 ratio. All study activities were approved by the Colorado Multiple Institutional Review Board. The study is registered with clinicaltrials.gov (identifier NCT02456077). Informed consent was waived.

Study Sites

Twenty-four practices in the Denver, Colorado, metropolitan area that were part of a 30-clinic practice-based research network were invited to participate to represent a diverse cross-section of patient and practice demographics. Inclusion criteria were being a pediatrics or family medicine practice with at least 400 active (seen within the last 2 years) adolescent patients (age range, 11-17 years). There were no exclusion criteria. Of these 24, one practice withdrew from the study before randomization owing to new competing time demands (electronic medical record implementation). Seven practices that were part of one safety-net hospital system were dropped before randomization owing to very high baseline adolescent vaccination rates (approximately 90% for series initiation[17]). The final cohort for randomization included 16 practices (4 family medicine and 12 pediatrics) that included 188 medical profes-

Key Points

Question Does implementation of an intervention to improve primary care professionals' human papillomavirus (HPV) vaccine communication lead to increases in adolescent human papillomavirus vaccination?

Finding Among 43 132 patients at 16 practices participating in this cluster randomized clinical trial, a 5-component intervention significantly increased HPV vaccine series initiation, stopped decline of completion, and was effective for both boys and girls. Two specific intervention components, communication training and customized HPV fact sheets, were the most used and useful based on health care professionals' report.

Meaning Disseminating this intervention widely among primary care professionals could substantially increase national adolescent HPV vaccination levels, particularly among boys.

sionals. Each practice participated in a series of 2 intervention development meetings over a 6-month period (August 1, 2014, to January 31, 2015) before officially launching the intervention.

All health care professionals who ordered vaccines for patients (ie, physicians, nurse practitioners, medical assistants, and physician assistants) in these practices could participate. Of these, 5 physicians in a single family medicine practice declined study participation owing to seeing few adolescent patients. This practice was ultimately assigned to the intervention arm, and these medical professionals' data are included in the analyses, which used an intent-to-treat protocol (Supplement 1).

Data Sources

Vaccination data were retrieved from each practice's electronic medical record. The following 2 periods with different but overlapping patient cohorts were compared: baseline (September 1, 2013, to August 30, 2014) and intervention implementation phase (February 1, 2015, to January 31, 2016). The 6-month interval between these 2 time points was for "onboarding" intervention practices in implementation procedures. To ensure completeness, vaccination data were augmented with data from the Colorado Immunization Information System, to which all practices in the study actively reported. Data on all adolescents seen at least once during the study period were included in the analyses. Adolescents who were seen at multiple practices, who were deceased, or who were pregnant at the time of the visit (a contraindication for HPV vaccination) were excluded. Waivers of consent and Health Insurance Portability and Accountability Act of 1996 authorization were obtained to view adolescent vaccination records.

Cluster Randomization

Covariate-constrained randomization[18] was used to assure balance in potential confounding factors across practices, including the following: baseline HPV vaccination rates among individuals aged 11 to 12 years, percentage of pediatric patients reported by health care professionals as eligible for the Vaccines for Children program (a proxy for low-income status and

Medicaid insurance), proportion of medical professionals reporting "strongly" recommending the HPV vaccine for those aged 11 to 12 years, number of adolescent patients,[19] and medical specialty (family medicine and pediatrics).[20,21] Because most practices did not collect patient race and ethnicity data, these were not used as a balance criterion. All possible combinations of eligible practices that would create 2 equal groups (8 intervention and 8 control) were generated using the IML procedure in SAS (version 9.4; SAS Institute Inc). The distribution of the balance criterion was then used to define an acceptable set of study groups that were reasonably balanced in terms of the selected variables.[22] From this, one set was randomly chosen and used to assign study arms. Health care professionals and the study team were not masked to the randomization category, but patients and analysts were.

Health Care Professional Communication Intervention
Intervention practices received a 5-component intervention that was designed based on the precaution-adoption-process model,[16] which distinguishes between various stages of the decision-making continuum (ie, unaware, aware but unengaged, undecided, etc) and was developed to provide tools and training that could be used before, during, or at the end of the clinical encounter. The intervention included the following: (1) a fact sheet library that practices used to create practice-specific fact sheets about HPV infection and vaccination (eFigure 1 in Supplement 2), (2) a parent education website called "iVac" that created individually customized information about HPV vaccination (eFigure 2 in Supplement 2), (3) a series of disease images depicting diseases associated with HPV, (4) a decision aid for HPV vaccination (eFigure 3 in Supplement 2), and (5) communication training to improve health care professionals' vaccine recommendation practices. The communication training consisted of a self-guided, 30-minute webinar, plus 2 in-person, group training sessions that lasted 1 hour each. These sessions focused on opening the HPV vaccine conversation with a "presumptive approach," as defined by Opel et al,[23] followed by the use of motivational interviewing techniques for parents perceived as resistant to vaccination. Intervention practices worked with the study team over a series of 2 meetings lasting 1 hour each to develop and plan for implementation of the intervention within their practice, and each intervention practice chose a study champion to help facilitate the study activities. Medical professional surveys were administered quarterly to collect self-reported use of each tool kit component. Health care professionals in intervention practices received 25 Maintenance of Certification Part IV credits for participation. No other incentives were provided. A detailed description of intervention components, study planning meetings, and implementation procedures is provided in eMethods in Supplement 2.

Control Group
Practices in the control arm continued usual care with regard to communication about HPV vaccines. Health care professionals in the control arm did not receive any incentives for participation.

Sample Size Estimation
Sample size estimates were based on an assumed final sample size of 16 000 adolescents (8000 per arm), and vaccine use centered around 50% (the most conservative estimate). In a mixed-effects analysis with practice as a random effect and an estimated intraclass correlation coefficient of 2%, this sample size would provide 86% power (α = .05) to detect a 10–percentage point (PP) difference in differences in changes in HPV vaccination over time from the baseline to intervention implementation periods between control and intervention groups. Based on practice data, a period of 1 year was allocated to achieve this sample.

Primary and Secondary Study Outcome Measures
The primary outcome was the difference between control and intervention groups in changes over time in the proportion of eligible adolescents initiating (≥1 dose) the HPV vaccine series. Secondary outcomes were uptake of 2 other adolescent vaccines, the meningococcal conjugate vaccine (MenACWY) and the tetanus-diphtheria-acellular pertussis vaccine (Tdap). Completion (≥3 doses) of the HPV vaccine series was also assessed post hoc. The denominator for this analysis was the number of adolescents in the practice who had received the prior 2 doses of vaccine.

Covariates
Patient-level covariates included patient age (11-12 or 13-17 years), sex, race (white, black, or other), ethnicity (Hispanic or non-Hispanic), and insurance at the most recent visit (private, public, other, or none). Medical specialty (pediatrics or family medicine) and practice type (public or private) were hypothesized to be potential effect modifiers and were included in subgroup analyses to examine heterogeneity of treatment effects.

Statistical Analysis
We used an intent-to-treat analysis and generalized linear mixed models,[24,25] as is recommended for cluster randomized trials.[26,27] Clustering of patients within practices was accounted for with a random intercept for each practice. Models are presented as unadjusted and adjusted for covariates significantly associated with the outcome (P < .05) or variables representing factors known from prior research to be associated with HPV vaccination (medical specialty, practice type, age, sex, and insurance).[20,21,28,29] The intraclass correlation coefficient was calculated using an intercept-only model.[30] Patients with unknown sex or with non–private or public insurance were excluded from this analysis. All P values are from 2-sided hypothesis tests. Statistical significance was defined at α = .05. Adjustments for multiplicity were not performed. All analyses used SAS software (version 9.4; SAS Institute Inc). With the exception of the missed opportunities analyses, which were visit-level analyses, all analyses were patient level.

Heterogeneity of Treatment Effects
A series of moderator (effect modification) analyses assessed whether there were differential effects of the intervention by selected practice (medical specialty and practice type) and pa-

Figure. CONSORT Diagram for the Study
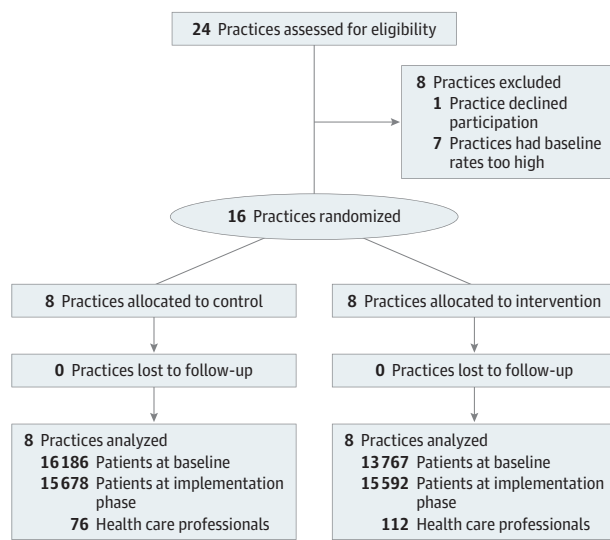
Clinics were randomized by (1) count of patients who were aged 9 to 17 years, (2) percentage of patients who were eligible for the Vaccines for Children program, (3) percentage of health care professionals who strongly recommend human papillomavirus vaccine to girls aged 11 to 12 years, and (4) human papillomavirus vaccine initiation rates among patients aged 11 to 12 years. CONSORT indicates Consolidated Standards of Reporting Trials.

tient (sex, race/ethnicity, and insurance) characteristics by examining the 3-way interaction term of time × study group × moderator and performing stratified analyses. Additional subgroup analyses were performed using (1) patients with a vaccination-eligible visit at age 11 to 12 years, (2) patients with a vaccination-eligible visit at age 13 to 17 years, (3) well-child care visits, and (4) sick visits (see eMethods in Supplement 2 for the definition of well or sick). Also assessed was the proportion of visits where adolescents had a missed opportunity for vaccination, defined as a clinic visit during the study period at which an adolescent was eligible for an HPV vaccine dose but did not receive it.[31,32]

Health Care Professional Use and Perceptions
Descriptive statistics were generated from 7 quarterly health care professional surveys assessing the use of intervention components over time, given to 85 to 107 medical professionals (response rate, 85.5%-100%), depending on the staffing of the clinic at the time. A study describing the use of each tool kit component in detail is in preparation.

Results

Study Participants
All 16 practices in the study were assessed for vaccination outcomes (Figure). As summarized in Table 1, patient and practice variables were mostly evenly distributed between groups except that a higher proportion of patients were reported as having public insurance in the intervention arm. Baseline vaccination rates among individuals aged 11 to 12 years, the vari-

able used in the randomization process, were identical between arms. However, when the trial was completed, it became apparent that HPV vaccination rates among those aged 11 to 17 years differed slightly between arms (37.1% vs 31.6%) (Table 2).

Effect on HPV Vaccination Rates
Both the control and intervention groups significantly increased the proportion of eligible adolescents initiating the vaccine series over time (Table 2 and eFigure 4 in Supplement 2). However, in both unadjusted and adjusted models, these increases were significantly larger in the intervention group compared with control (1.8% increase control vs 11.3% increase intervention; 9.5-absolute PP difference, $P < .001$), with adjusted odds ratios (aORs) of 1.46 for initiation and 1.56 for completion (Table 2). In contrast, series completion significantly decreased in the control practices, while remaining stable in the intervention practices, resulting in intervention practices having significantly higher odds of completing the series than control practices (Table 2 and eFigure 5 in Supplement 2).

Heterogeneity of treatment effects analyses of HPV vaccine series initiation (Table 3) and completion (eTable 1 in Supplement 2) by patient and practice characteristics showed that heterogeneity for HPV vaccination improvement was seen only for series initiation and occurred primarily at pediatric practices (medical specialty interaction term $F_{1,11} = 11.33$, $P = .006$ for initiation and $F_{1,11} = 5.42$, $P = .04$ for completion) and private practices (practice type interaction term $F_{1,13} = 33.63$, $P < .001$ for initiation and $F_{1,13} = 0.76$, $P = .40$ for completion). However, analyses were somewhat limited by the low numbers of adolescents eligible for the vaccine in family medicine practices overall.

Heterogeneity of treatment effects analyses assessed HPV vaccination initiation (Table 4) and completion (eTable 2 in Supplement 2) by adolescent age, sex, and insurance. Increases in series initiation among both age categories were higher in intervention practices than controls. There was no differential treatment effect by sex (sex interaction term $F_{1,13} = 0.01$, $P = .91$ for initiation and $F_{1,13} = 1.58$, $P = .23$ for completion), but a differential treatment effect by patient insurance was seen for series initiation but not for completion (insurance interaction term $F_{1,13} = 17.85$, $P < .001$ for initiation and $F_{1,13} = 2.47$, $P = .14$ for completion). Series initiation increased substantially over time among patients with private insurance (aOR, 1.76; 95% CI, 1.55-1.99) but remained essentially unchanged among those with public insurance (aOR, 0.93; 95% CI, 0.76-1.14). Among the subset of practices with race (n = 6), and ethnicity (n = 2) data available, there were no differences in vaccination by the variables between study arms (eTable 3 and eTable 4 in Supplement 2).

Effect of MenACWY and Tdap Vaccination
Over time, there was a slight increase in MenACWY vaccination (0.4-PP increase to 62.8% for control and 2.1-PP increase to 55.6% for intervention) and a slight decrease in Tdap vaccination (3.4-PP decrease to 60.1% for control and 7.0-PP decrease to 50.1% for intervention). Neither comparison between study arms was significant (eTable 5 in Supplement 2).

Table 1. Characteristics of Participating Practices and Patients in the Trial Assessed for Human Papillomavirus (HPV) Vaccination

Variable	Total	Control	Intervention
Practice Characteristics	(N = 16)	(n = 8)	(n = 8)
Medical specialty, No.			
Pediatrics	12	6	6
Family medicine	4	2	2
Practice type, No.			
Public	6	3	3
Private	10	5	5
FTE of health care professionals in practice, median (IQR)	8.5 (6.0-14.0)	8.0 (4.5-12.0)	9.5 (6.5-16.5)
Preintervention HPV vaccination rates among patients aged 11-12 y, median (IQR), %[a]	31-45 (37)	28-59 (37)	33-40 (37)
Patient Characteristics	(N = 43 132)	(n = 21 892)	(n = 21 240)
Age at beginning of study period, median (IQR), y	12.6 (10.8-14.7)	12.6 (10.8-14.8)	12.5 (10.7-14.6)
Sex, No. (%)			
Female	21 676 (50.3)	10 887 (49.7)	10 789 (50.8)
Male	21 450 (49.7)	11 001 (50.3)	10 449 (49.2)
Missing	6 (<0.1)	4 (<0.1)	2 (<0.1)
Race/Ethnicity, No. (%)			
White	23 681 (54.9)	14 920 (68.2)	8761 (41.2)
Black	1957 (4.5)	836 (3.8)	1121 (5.3)
Other	3398 (7.9)	1407 (6.4)	1991 (9.4)
Missing	14 096 (32.7)	4729 (21.6)	9367 (44.1)
Hispanic	5351 (12.4)	1332 (6.1)	4019 (18.9)
Non-Hispanic	18 553 (43.0)	10 305 (47.1)	8248 (38.8)
Missing	19 228 (44.6)	10 255 (46.8)	8973 (42.2)
Most recent insurance, No. (%)			
Private	27 904 (64.7)	14 886 (68.0)	13 018 (61.3)
Public	13 229 (30.7)	5516 (25.2)	7713 (36.3)
Other	98 (0.2)	30 (0.1)	68 (0.3)
None	1748 (4.1)	1372 (6.3)	376 (1.8)
Missing	153 (0.4)	88 (0.4)	65 (0.3)

Abbreviations: FTE, full-time equivalents; IQR, interquartile range.

[a] Proportion of patients initiating HPV vaccine among patients seen for care and eligible to initiate the HPV vaccine series during preintervention (September 1, 2011, to August 31, 2013) who were aged 11 to 12 years (9-12 years for one of the clinics). Patients with no data in the Colorado Immunization Information System and electronic medical record or patients seen at multiple clinics were excluded.

Table 2. HVP Vaccine Series Initiation and Completion, All Ages and Sexes Combined: Control vs Intervention Difference-in-Differences Comparison of Baseline to Postimplementation Periods[a]

	Control				Intervention				Difference in Differences[b]	
Variable	No. Eligible for HPV Dose	% of Eligible Who Received HPV Dose	OR (95% CI) Unadjusted	OR (95% CI) Adjusted[c]	No. Eligible for HPV Dose	% of Eligible Who Received HPV Dose	OR (95% CI) Unadjusted	OR (95% CI) Adjusted[c]	Unadjusted	Adjusted[c]
Series Initiation										
Baseline	8246	37.1	1.13 (1.05-1.21)	1.11 (1.03-1.20)	7757	31.6	1.61 (1.49-1.73)	1.62 (1.51-1.75)	1.42 (1.28-1.58)	1.46 (1.31-1.62)
Postintervention	7295	38.9			8163	42.9				
Series Completion										
Baseline	2783	73.6	0.66 (0.57-0.76)	0.65 (0.56-0.75)	2206	73.5	1.05 (0.90-1.22)	1.01 (0.87-1.18)	1.59 (1.30-1.95)	1.56 (1.27-1.92)
Postintervention	2747	68.1			2507	72.4				

Abbreviations: HPV, human papillomavirus; OR, odds ratio.

[a] Intraclass correlation coefficients, in order of model presentation, are 0.104 and 0.151.

[b] Ratio of ORs from control vs intervention groups describing the change from baseline to postimplementation time points in the proportion of eligible patients initiating or completing the HPV vaccine series.

[c] Models adjusted for medical specialty (pediatrics or family medicine), practice type (public or private), patient age, sex, and insurance.

Effect on Missed Opportunities for Vaccination

Overall, there was a significant reduction in missed opportunities for vaccination in intervention practices compared with controls (eFigure 6 in Supplement 2). This difference was significant for well-child care checkups (aOR, 0.61; 95% CI, 0.54-0.69) but not for sick visits (aOR, 0.87; 95% CI, 0.68-1.12).

Table 3. HPV Vaccine Series Initiation by Clinical Characteristics: Control/Intervention Difference-in-Differences Comparison of Baseline to Postimplementation Periods[a]

		Control				Intervention				Difference in Differences[b]	
		No. Eligible for HPV Dose	% Of Eligible Who Received HPV Dose	OR (95% CI)		No. Eligible for HPV Dose	% Of Eligible Who Received HPV Dose	OR (95% CI)			
Variable	Study Period			Unadjusted	Adjusted[c]			Unadjusted	Adjusted[c]	Unadjusted	Adjusted[c]
Medical Specialty[c]											
Family medicine	Baseline	290	14.1	1.81 (0.68-2.16)	1.80 (0.68-4.78)	401	24.7	1.04 (0.50-2.16)	1.04 (0.50-2.14)	0.58 (0.17-1.95)	0.58 (0.17-1.94)
	Postintervention	268	22.0			381	24.9				
Pediatrics	Baseline	7956	37.9	1.08 (1.00-1.17)	1.08 (1.00-1.17)	7356	32.0	1.65 (1.53-1.80)	1.66 (1.53-1.80)	1.53 (1.37-1.72)	1.53 (1.37-1.72)
	Postintervention	7027	39.6			7782	43.8				
Practice Type[d]											
Public	Baseline	1337	52.8	1.18 (0.93-1.50)	1.10 (0.85-1.42)	2333	46.5	1.09 (0.93-1.28)	1.10 (0.92-1.31)	0.92 (0.69-1.23)	0.99 (0.73-1.36)
	Postintervention	972	56.2			2482	48.7				
Private	Baseline	6909	34.0	1.12 (1.03-1.22)	1.10 (1.00-1.20)	5424	25.2	1.98 (1.78-2.19)	1.99 (1.80-2.21)	1.77 (1.54-2.02)	1.82 (1.59-2.08)
	Postintervention	6323	36.2			5681	40.3				
Encounter Type											
Routine checkup	Baseline	6079	44.2	1.07 (0.99-1.16)	1.06 (0.98-1.16)	5415	38.3	1.69 (1.55-1.85)	1.72 (1.57-1.87)	1.58 (1.40-1.78)	1.61 (1.43-1.82)
	Postintervention	5557	45.2			6043	51.5				
Sick visit	Baseline	4848	7.0	1.15 (0.96-1.38)	1.13 (0.94-1.36)	4626	7.5	1.34 (1.12-1.60)	1.34 (1.12-1.60)	1.16 (0.90-1.50)	1.18 (0.92-1.53)
	Postintervention	4053	7.3			4098	8.5				

Abbreviations: HPV, human papillomavirus; OR, odds ratio.

[a] Intraclass correlation coefficients, in order of model presentation, are 0.012, 0.063, 0.036, 0.055, 0.109, and 0.154.

[b] Ratio of ORs from control vs intervention groups describing the change from baseline to postimplementation time points in the proportion of eligible patients initiating the HPV vaccine series.

[c] Random intercept mixed models adjusted for patient age, sex, and insurance.

[d] Random intercept mixed models adjusted for medical specialty (pediatrics or family medicine), patient age, sex, and insurance.

Table 4. HPV Vaccine Series Initiation by Patient Factors: Control vs Intervention Difference-in-Differences Comparison of Baseline to Postimplementation Periods[a]

		Control				Intervention				Difference in Differences[b]	
		No. Eligible for HPV Dose	% of Eligible Who Received HPV Dose	OR (95% CI)		No. Eligible for HPV Dose	% of Eligible Who Received HPV Dose	OR (95% CI)			
Variable	Study Period			Unadjusted	Adjusted[c]			Unadjusted	Adjusted[c]	Unadjusted	Adjusted[c]
Age											
11-12 y	Baseline	4440	40.6	1.32 (1.19-1.45)	1.31 (1.19-1.45)	3996	38.1	1.74 (1.57-1.93)	1.74 (1.57-1.93)	1.32 (1.15-1.53)	1.33 (1.15-1.53)
	Postintervention	4151	46.0			4327	51.0				
13-17 y	Baseline	4100	30.6	0.89 (0.80-1.00)	0.90 (0.81-1.01)	3988	23.3	1.55 (1.38-1.73)	1.57 (1.40-1.75)	1.74 (1.48-2.03)	1.74 (1.48-2.04)
	Postintervention	3367	27.6			4012	32.3				
Sex											
Female	Baseline	3691	36.8	1.11 (1.00-1.24)	1.11 (1.00-1.24)	3591	29.9	1.62 (1.45-1.80)	1.62 (1.45-1.81)	1.46 (1.25-1.70)	1.46 (1.25-1.70)
	Postintervention	3457	38.5			3970	40.7				
Male	Baseline	4555	37.3	1.14 (1.04-1.26)	1.14 (1.03-1.26)	4166	33.1	1.62 (1.46-1.79)	1.62 (1.46-1.79)	1.41 (1.23-1.63)	1.42 (1.23-1.63)
	Postintervention	3838	39.3			4193	44.9				
Insurance											
Private	Baseline	6367	34.9	1.08 (1.00-1.18)	1.09 (1.00-1.18)	5286	25.7	1.91 (1.74-2.10)	1.91 (1.74-2.10)	1.76 (1.55-2.00)	1.76 (1.55-1.99)
	Postintervention	5750	36.5			5559	40.0				
Public	Baseline	1879	44.4	1.29 (1.10-1.51)	1.29 (1.11-1.51)	2471	44.4	1.20 (1.06-1.36)	1.21 (1.07-1.37)	0.93 (0.76-1.14)	0.93 (0.76-1.14)
	Postintervention	1545	47.9			2604	49.0				

Abbreviations: HPV, human papillomavirus; OR, odds ratio.

[a] Intraclass correlation coefficients, in order of model presentation, are 0.160, 0.031, 0.091, 0.116, 0.070, and 0.117.

[b] Ratio of ORs from control vs intervention groups describing the change from baseline to postimplementation time points in the proportion of eligible patients initiating the HPV vaccine series.

[c] Random intercept models adjusted for medical specialty (pediatrics or family medicine), practice type (public or private), patient age, sex, and insurance.

Intervention Sustainability

Each intervention component was used by 26.0% to 90.0% of health care professionals over the 12-month study period. Of these, the communication techniques and fact sheets were reported as the most frequently used, with 72.2% to 90.0% and 51.5% to 84.4% of medical professionals reporting using them over the study period, respectively. Surveys done at the end of the intervention period demonstrated that 98.0% of health care professionals were likely to continue to use the fact sheets and that 91.0% of health care professionals were likely to continue to use the communication techniques.

Discussion

Implementation of a health care professional communication intervention to improve adolescent HPV vaccination resulted in a 9.5-PP increase in HPV vaccine series initiation compared with control practices, which was both clinically and statistically significant. The use of the intervention materials, particularly the communication techniques and fact sheets, was sustained over the 12-month intervention implementation period, and medical professionals intended to continue to use these components in the future. The intervention also mitigated decreases over time in HPV vaccine series completion.

To our knowledge, there are 2 other intervention studies that have focused on health care professional communication for improving HPV vaccination. Brewer and colleagues[33] tested the effect of "announcements" (similar to the presumptive communication style) vs "conversations" (similar to the participatory communication style) on HPV vaccination levels in 29 practices. At the 6-month assessment, announcement practices had a 5.4-PP increase in HPV vaccine series initiation and no changes in receipt of Tdap, MenACWY, or HPV vaccine series completion compared with controls. In a smaller study, Perkins et al[34] implemented a multicomponent intervention that included practice coaching every 4 to 6 weeks, HPV education for medical professionals (including "basic motivational interviewing principles," assessment, and feedback on practices' HPV vaccination rates compared with others in their region), and Maintenance of Certification part IV incentives. The HPV vaccination rates were higher in the intervention practice during the active study phase than controls but were sustained only for male participants when assessed 6 months later. Placing our results in this context, it seems that, while a presumptive/announcement approach to the initial HPV vaccine conversation can increase HPV vaccine initiation, there is added benefit to using additional components in our intervention, namely, the motivational interviewing training and customized HPV fact sheets. Inclusion of these items could explain why our intervention had a greater effect than that of the study by Brewer and colleagues,[33] positively affected series completion, and seemed to have a sustained effect over a longer period compared with the study by Perkins et al.[34]

Our intervention appeared less effective in public compared with private practices. This result is opposite of what might be expected given that national data consistently demonstrate increased adolescent HPV vaccine uptake among populations typically served by public clinics.[28,35-38] When examined at the practice level, 2 of the public practices in the intervention arm increased HPV vaccine series initiation levels (by 7.8% and 13.0% over time), whereas the third one decreased by 3.5%. One explanation for this could be that the third practice, which was substantially larger than the other 2, had a large number of trainees, and not all health care professionals were able to fully participate in the intervention training sessions and study meetings, effectively diluting any effect the intervention may have had in this practice.

Improvements in HPV vaccination among intervention practices occurred primarily at well-child care visits. While there was some decrease in missed opportunities for vaccination at sick visits in intervention practices, this decrease was small, and most vaccines were still provided during routine wellness examinations. Anecdotal reports from health care professionals in our study indicate that lack of time and prioritization of other health issues make vaccination at sick visits difficult, a finding that is supported by several other studies.[15,39-41] While there are examples of clinical systems that have successfully implemented routine adolescent HPV vaccination at sick visits,[17] this practice is not widespread. Given that adolescents see medical professionals for sick visits more commonly than for preventive visits,[42,43] finding mechanisms to improve vaccination at sick visits is a clear research priority.

Limitations

This trial had some limitations. First, the most important limitation of our study was that we could not directly examine at an individual patient level the effect of specific intervention components on HPV vaccine uptake. Health care professionals reported quarterly on which intervention components they used during the previous month, rather than after each patient visit. The intervention was developed to be adaptable based on each practice's and medical professional's needs, resulting in variability between and within practices of which intervention components were used and under what circumstances. Based on health care professionals' reports, it appears that the communication training and fact sheets were the most used and useful intervention components. Further research is needed to understand if the other components are needed. Second, an additional limitation is that having an immunization champion and the 2-hour planning meetings with practices, while not part of the intervention per se, could have also had an effect on vaccination rates. This effect was not specifically assessed. Third, we could only assess the vaccination status of the patients who had a clinic visit during the study period. Our intervention was not designed to affect patients who are not seen for care. Fourth, our intervention focused on a single geographic area and may not be generalizable. Fifth, although baseline assessments of HPV vaccination status among those aged 11 to 12 years was identical between arms, baseline vaccination status among those aged 11 to 17 years was slightly lower among intervention practices than control practices, which could have influenced the degree to which the intervention increased vaccination rates. Sixth, the overall in-

fluence of the intervention was modest, and all practices' vaccination levels remained well below the national goal of 80% coverage.

Conclusions

In this cluster randomized clinical trial of a health care professional HPV vaccine communication intervention, there were substantial and sustained increases in HPV vaccine series initiation in intervention practices compared with controls over time. Medical professionals used some tool kit components more than others and planned to continue to use them in the future. Future research will need to examine if similar effects on vaccination rates can be achieved through more generalizable dissemination methods, such as via the internet or through the public health department network.

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