

ORIGINAL ARTICLE

"1-2-3 Pap" Intervention Improves HPV Vaccine Series Completion Among Appalachian Women

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Completion of the Human Papillomavirus (HPV) vaccine series is a national priority. This study not only identified correlates of intent to complete the vaccine series and actual series completion, but also tested the efficacy of a DVD intervention to promote series completion. Women's beliefs that all 3 doses reduced cancer risk predicted intent and completion. Intention predicted completion, as did the belief that having a friend accompany the woman would promote completion. Beyond these effects, women assigned to the intervention were 2.44 times more likely than women in the usual care group to complete the series. Thus, in controlled analyses, a theory-grounded DVD intervention successfully promoted HPV series completion in a community setting. This method of intervention has high translational potential.

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Vaccination against the Human Papillomavirus (HPV), the most common sexually transmitted infection, is a primary prevention strategy to protect women against cervical cancer (CDC, 2012). Annually, cervical cancer affects approximately 12,000 women in the United States and results in death for another 4,200 women (ACS, 2012). Women residing in rural and other medically underserved communities are disproportionately burdened by cervical cancer incidence and mortality (Freeman & Wingrove, 2005). Despite the fact that these women stand to benefit most from HPV vaccination, evidence suggests that HPV vaccination diffusion in the United States has been inequitable, HPV vaccination goals are not being met, and adherence to the full 3-dose regimen is suboptimal (Dorell, Stokley, Yankey, & Markowitz, 2011; Williams et al., 2012). Importantly, clinical evidence supporting vaccine efficacy to

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prevent HPV infection, precancerous cervical lesions, and cervical cancer is based on completion of the entire 3-dose series (Markowitz *et al.*, 2007).

Young women 18–26 years old should be considered a priority population for HPV vaccination, considering their vaccination rates lag behind that of adolescent females. Whereas the national vaccination rate for adolescent females aged 13–17 is 48.7% (Dorell *et al.*, 2012), vaccination rates for young women are estimated at 21% (Williams *et al.*, 2012); regional variation in uptake ranges from 9 to 49% (Dempsey, Cohn, Dalton, & Ruffin, 2011). The few regional studies reporting three-dose completion rates indicate that rates range from as low as 2% to high as 47%, with disparities observed among African Americans, rural women, those covered by public insurance, and females living in educationally disadvantaged neighborhoods (Chao, Velicer, Slezak, & Jacobsen, 2009; Crosby, Casey, Vanderpool, Collins, & Moore, 2011; Dempsey *et al.*, 2011). For women completing all three doses, many fail to complete the series within the 6-month clinical protocol (Dempsey *et al.*, 2011).

Lack of vaccination in young women represents a missed opportunity, given that this age group is burdened by the highest prevalence rate of HPV infection among all age groups (Dunne, Unger, & Sternberg, *et al.*, 2007). Many of these young women were not afforded opportunities to receive the vaccine as adolescents and were not targeted by pharmaceutical companies' marketing campaigns (Jain *et al.*, 2009). Finally, these women do not qualify for the Vaccines for Children program and are often under- or uninsured, making them responsible for substantial out-of-pocket healthcare costs (Dempsey *et al.*, 2011; Jain *et al.*, 2009).

To date, much of the HPV vaccination-related research has solely focused on identifying predictors of vaccine acceptability, intent to vaccinate, and/or vaccine initiation without examining adherence to the full dosing schedule (Allen *et al.*, 2010; Brewer *et al.*, 2011; Bynum, Brandt, Sharpe, Williams, & Kerr, 2011; Chao, Velicer, Slezak, & Jacobsen, 2010; Katz *et al.*, 2010; Lechuga, Swain, & Weinhardt, 2011; Reiter, Brewer, Gottlieb, McRee, & Smith, 2009; Teitelman *et al.*, 2011; Vanderpool, Casey, & Crosby, 2011). Past research has examined different theories of health behavior as explanatory for variation in HPV vaccine acceptance. For example, Allen *et al.* (2009) used the transtheoretical model (Prochaska, Redding, & Evers, 2008) to assess the stage of adoption of the HPV vaccine, the theory of reasoned action (Ajzen & Fishbein, 1980), and social cognitive theory (Bandura, 2004) to explain barriers to vaccine uptake. Constructs from the health belief model (Rosenstock, 1974) have also been reported extensively in the HPV vaccination literature (Allen *et al.*, 2009; Bennett, Buchanan, & Adams, 2012; Brewer & Fazekas, 2007; Gerend & Shepherd, 2012; Katz *et al.*, 2010; Krawczyk *et al.*, 2012a, 2012b; Teitelman *et al.*, 2011).

In particular, the theory of planned behavior (TPB; Ajzen & Fishbein, 1980) has successfully predicted HPV vaccination intentions and vaccine uptake (Bennett *et al.*, 2012; Gerend & Shepherd, 2012). This theory suggests that constructs such as attitude toward the behavior, subjective norms, perceived behavioral control, and intention to perform the behavior are the primary mechanisms for behavior change, including adherence (Ajzen & Fishbein, 1980; Bennett *et al.*, 2012). Specifically, the subjective

norms construct has received a great deal of attention in the HPV vaccine-related literature as a predictor of intention to vaccinate, as well as vaccine uptake (Allen *et al.*, 2010; Bennett *et al.*, 2012; Gerend & Shepherd, 2012; Juraskova *et al.*, 2011; Kahn, Rosenthal, Hamann, & Bernstein, 2003; Krawczyk *et al.*, 2012b; Teitelman *et al.*, 2011).

Beyond understanding the theoretical underpinnings of a health behavior, there is value in developing interventions based on previous assessments of the target population. Consider the women who reside in the mountainous region of Appalachian Kentucky in the United States. These women shoulder a disproportionate burden of cervical cancer while also experiencing poor socioeconomic conditions, lower Pap testing rates, geographic isolation, and limited access to healthcare (ARC, 2008; Hopenhayn, King, Christian, Huang, & Christian, 2008; Huang *et al.*, 2002; Wingo *et al.*, 2008). From 2005 to 2009, the 5-year cervical cancer incidence rate in this region was notably higher than the rest of the country (9.85 per 100,000 vs. 8.0, respectively; KCR, 2012; NCI, 2012). Cervical cancer mortality rates are 45% higher in Appalachian Kentucky (KCR, 2012; NCI, 2012). Approximately one in five women in eastern Kentucky has not had a Pap test in the past three years (KDPH, 2008). The majority of counties in Appalachian Kentucky are designated as healthcare professional shortage areas (HRSA, 2012), and all but three counties are considered distressed or at-risk by the Appalachian Regional Commission on the basis of federal unemployment, income, and poverty indicators (ARC, 2012).

There is substantial need to address cervical cancer prevention in this rural, medically underserved population. In response, we conducted multiple quantitative and qualitative studies related to HPV vaccination behaviors. Our first effort involved recruiting young women in Appalachian Kentucky into a women's health study (Crosby *et al.*, 2011; Mills, Vanderpool, & Crosby, 2011; Vanderpool *et al.*, 2011; Vanderpool, Crosby, Casey, & Bates, 2010). The HPV vaccine was offered at no cost. Young women 18–26 years of age were provided with vouchers for the full series and were encouraged to initiate the series in the clinic upon enrollment. Of 246 women recruited from rural health clinics, only 45% initiated dose one. Furthermore, only 14% of those who received dose one returned for dose two, and only 5% received dose three (Crosby *et al.*, 2011). Through this work, we learned that access and free vaccination were not sufficient to help women overcome barriers to series completion. Our qualitative research suggested that young rural women report barriers to vaccination, including normative social influences (especially maternal and peer), insufficient knowledge, negative (even stigmatized) or ambivalent attitudes toward vaccination, questions concerning vaccine safety and efficacy, and barriers such as cost and anticipated vaccine pain (Cohen *et al.*, *in press*; Head & Cohen, 2012; Mills, Head, & Vanderpool, *in press*).

Because of the cervical cancer burden and low rates of HPV vaccination in Appalachian Kentucky, as well as the fact that there have been few health communication studies that have assessed variables predicting completion of all three HPV vaccine doses among young women (Allen *et al.*, 2010; Chao, Slezak, Coleman, & Jacobsen, 2009; Dempsey *et al.*, 2011; Katz *et al.*, 2010) or intervened on full series

completion, we designed a randomized controlled trial to test a theory-grounded intervention targeted to the unique needs of this rural population of young women. Accordingly, the purpose of this study was twofold. First, the study used the TPB to identify correlates of positive intent to complete the 3-dose series and actual series completion among a sample of women, ages 18–26, residing in Appalachian Kentucky. We hypothesized that women intending to complete the series, as well as actually completing all three doses, would be more likely to (a) have supportive HPV vaccination attitudes, (b) have norms supporting vaccine completion, and (c) report perceived behavioral control beliefs favoring series completion. We also hypothesized that positive intention to complete the 3-dose series would predict adherence to the full vaccine regimen. Second, and more importantly, the study tested the efficacy of a field-based DVD communication intervention designed to promote series completion. We hypothesized that women randomized to the DVD-arm would be significantly more likely than those receiving standard-of-care to complete the vaccine series, even after controlling for baseline level of intent to complete the series as well as controlling for other predictor variables corresponding with the TPB.

Method

Participants and processes

In order to deliver an intervention immediately following the first dose of a vaccine and conduct a randomized trial of vaccine completion, it is necessary to begin with a population being newly vaccinated with dose one. From 2010 to 2011, we launched a social marketing campaign informed by Rogers' (1995) diffusion of innovations designed to promote uptake of the first HPV vaccine dose (Cohen *et al.*, in press). The social marketing campaign targeted young women from an eight-county catchment area of Appalachian Kentucky in the United States by promoting the availability of free HPV vaccines for 18- to 26-year-old women. Research nurses provided free vaccination (dose one) at local health departments, medical clinics, community colleges, outdoor festivals, Wal-Mart stores, businesses, and women's homes. To be eligible to receive dose one, women had to be 18–26 years old, not be pregnant, not previously vaccinated against HPV, and not have had prior vaccine reactions that prevented HPV vaccination. All vaccinated women received a standard-of-care pamphlet about the risks and benefits of the vaccine published by the Centers for Disease Control and Prevention.

Following uptake of dose one, women were asked to participate in a research study (see Figure 1 for study design). All women agreed to participate. Three primary reasons explain this success: The women received dose one of the vaccine for free; the research nurses were from the women's community; and women received a free t-shirt as part of the social marketing campaign. In essence, the research nurses' small overture to participate in a research study was viewed favorably by our study participants. After providing written informed consent, women were asked to complete a baseline survey using audio-computer-assisted self-interviewing

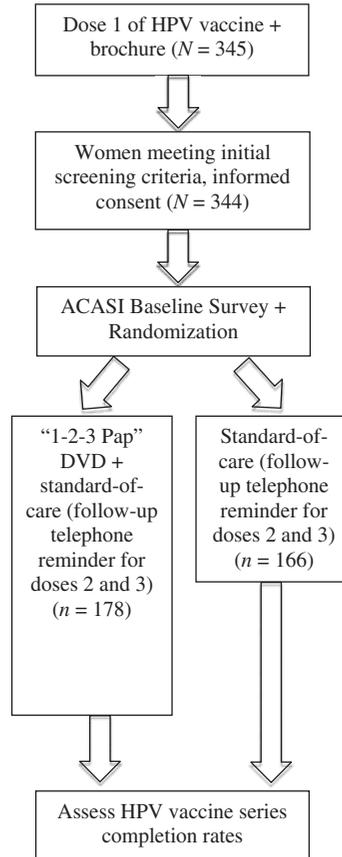


Figure 1 "1-2-3 Pap" communication intervention study design.

(ACASI) administered on a laptop computer. Intervention or comparison group allocations were assigned at the end of the ACASI using a random number sequence. Investigators and research nurses in the field were blinded to the allocation sequence. All research activities were approved by the University of Kentucky Institutional Review Board, including compensating women with a \$25 gift card upon baseline survey completion.

Intervention

Women randomized to the intervention arm watched a 13-minute educational DVD, entitled "1-2-3 Pap," from a laptop computer, using stereo headphones. Design and development of the DVD was guided by the information, motivation, behavioral skills model (IMB; Fisher & Fisher, 2002), which has been widely used in HIV prevention projects (Fisher & Fisher, 2002), and more recently, improving adherence to health recommendations (Ferrer, Morrow, Fisher, & Fisher, 2010). The IMB was developed as a well-validated, comprehensive framework for integrating commonly

	Themes	Logo
Opening	"1-2-3 Pap" is a special project designed to reduce cervical cancer disparities among young adult women from eastern Kentucky	
1	HPV is a common disease	
2	The HPV vaccine is effective	
3	Granddaughter/grandmother narrative about cervical cancer	
4	The benefits of vaccination and Pap testing overwhelm the short-term consequences of each	
5	Vaccine and Pap test schedule	
6	Overcoming stigma associated with HPV vaccination	
7	Remember to schedule your Pap test	
8	A Pap test is private and routinely conducted by medical professionals	
9	Overcoming obstacles to HPV vaccination (i.e., personal influences)	
10	Scheduling efficacy	
Closing	RCPC information and cues to action	

Figure 2 1-2-3 Pap themes and logo.

used health behavior constructs into a single model for message design. The IMB specifies a three-phase process for intervention development, including eliciting the information, motivation, and skills factors important to the target behavior. Accordingly, DVD content was based on formative research with young women from Appalachian Kentucky regarding their HPV vaccination and Pap testing behavior (Cohen *et al.*, in press). The resultant intervention design included specific health information relevant to the target health behavior and specific to the population; personal motivation and normative cues; and skills training to increase efficacy (Fisher, Fisher, & Harman, 2003). Specifically, the content of the DVD included risks of HPV and HPV-related harm, encouraged women to consider the benefits of vaccination and Pap tests, informed patients about the necessity to complete the vaccine series, motivated series completion, enhanced self-efficacy for series completion, and helped women overcome personal obstacles to series completion. The DVD was organized into 10 broad message segments (see Figure 2 for thematic overview) and included a roughly 1-minute opening and closing with cues to action delivered by a local Appalachian, young female TV news reporter. The DVD footage also featured young women (proscriptive models), a nurse practitioner, and a physician, all of whom were from the target community. The young women and healthcare providers discussed eastern Kentucky cervical cancer statistics, HPV infection and its relation to cervical cancer, HPV vaccination, and Pap testing. It used a mixture of video footage, narrative and informational content sequences, still shots, and written captions. Recording and editing occurred at a local studio.

Study measures

The baseline survey was informed by previous research (Brewer & Fazekas, 2007; Crosby *et al.*, 2011; Crosby, Schoenberg, Hopenhayn, Moore, & Melhan, 2007) and

included specific questions addressing TPB constructs. Wording of survey items and their response options are listed in Table 1. These measures were initially used to identify TPB correlates of positive intent to complete the 3-dose vaccine series, as well as actual series completion. These measures were also controlled for during analysis assessing the intervention effect on series completion. Women's vaccination dates and series completion were tracked by medical record review for up to nine months past the initial vaccine dose. This article includes all records that were complete according to study protocol by June 30, 2012; additional medical record review and checking for data completion and accuracy will continue.

Data analysis

For the first purpose of the study, continuous TPB correlates of young women's intent to complete the vaccine series were evaluated by using independent groups *t* tests at the bivariate level. Next, dichotomous TPB correlates of intent, as well as two control variables (whether women reported ever having had penile-vaginal sex and whether they had ever been told they had an abnormal Pap test) were evaluated using chi-square tests at the bivariate level. Subsequently, a hierarchical logistic regression model was constructed using two blocks. The first block contained the two control variables if determined significant at $p \leq .10$. The second block used a forward stepwise entry procedure to test all TPB continuous and dichotomous correlates significant at a screening level of $p \leq .10$ at the bivariate level for their independent association with intent. At the multivariate level, significance was established by 95% confidence intervals and their respective *p* values.

For the second purpose of the study, the same bivariate procedures used in the cross-sectional study of intent were applied to vaccine series completion. Subsequently, a hierarchical logistic regression model was constructed using three blocks. The first block contained the two control variables if determined significant at $p \leq .10$, in addition to containing intent as a predictor variable. The second block used a forward stepwise entry procedure as before and contained TPB continuous and dichotomous variables significant at a screening level of $p \leq .10$ in the bivariate analysis. The third block contained only the independent variable (intervention vs. usual care). Multivariate significance was established by 95% confidence intervals and their respective *p* values. All analyses were conducted using SPSS version 19.0.

Results

From 2010 to 2011, 345 women received dose one of the HPV vaccine through the social marketing campaign. Subsequent to receiving the vaccine, 100% of the women agreed to participate in the randomized controlled trial; one woman agreed to participate, but did not have time to participate in the survey/passively refused to complete the survey. The final sample for analysis was 344 women. The mean age was 22 years ($SD = 2.4$); the sample was primarily non-Hispanic White (94%), reflecting 2010 Census data for this region (Center, 2012). Ninety percent of the women had

Table 1 Study Measures

Construct	Survey Question	Response Options ^a
Attitudes	Do you feel that HPV vaccinations will help some women prevent pain, possibly even death by preventing cervical cancer?	6-point agreement scale; DK, Refusal, N/A
	I feel that if I get all three shots of the HPV vaccine that I will decrease my chances of getting cervical cancer.	5-point agreement scale; DK, Refusal, N/A
	Do you feel that HPV vaccinations will reduce the number of cases of cervical cancer?	6-point agreement scale; DK, Refusal, N/A
Subjective norms	Have any of your friends been vaccinated against HPV?	Yes, No, DK, Refusal, N/A
	Do you have friends who have failed to take doses 2 and 3?	Yes, No, DK, Refusal, N/A
	I would be much more likely to get dose 2 and dose 3 of the vaccine if my father encouraged me to do so.	5-point agreement scale; DK, Refusal, N/A
	I would be much more likely to get dose 2 and dose 3 of the vaccine if my mother encouraged me to do so.	5-point agreement scale; DK, Refusal, N/A
	I would be much more likely to get dose 2 and dose 3 of the vaccine if a friend went with me.	5-point agreement scale; DK, Refusal, N/A
Perceived behavioral control	Would childcare prevent you from getting dose 2 and 3?	Yes, No, DK, Refusal, N/A
	Would your work schedule prevent you from getting doses 2 and 3?	Yes, No, DK, Refusal, N/A
	Would transportation prevent you from getting doses 2 and 3?	Yes, No, DK, Refusal, N/A
	I would be much more likely to get dose 2 and dose 3 of the vaccine if a health care provider called to remind me.	5-point agreement scale; DK, Refusal, N/A
Intention	I would not get dose 2 and dose 3 of the vaccine if I had to make a special appointment.	5-point agreement scale; DK, Refusal, N/A
	Do you intend to get all three HPV vaccine shots?	Yes, No, DK, Refusal, N/A

DK = don't know; N/A = not applicable.

^aDon't know, refusal, and not applicable responses were recorded as missing.

lived in southeastern Kentucky for over five years. Only one-quarter (25.6%) were employed full-time; however, almost half (48.0%) reported some college as their highest level of education. Thirty percent of the women were married and 39.0% reported having children at home. The sample was sexually experienced, with 93.9% reporting they had ever had penile-vaginal sex; half the sample (49.3%) reported current birth control use. Almost half of the women (46.0%) reported ever having an abnormal Pap test, 21.8% had been told by a medical provider that they have a sexually transmitted disease, and 15.7% had been told they have HPV.¹

Positive intent to complete the vaccine series was indicated by 64.3% of the women ($n = 220$). Just over one-third (37.8%) of the sample completed the three-dose series. Randomization produced roughly equivalent sized groups, with 178 (51.7%) randomized to the intervention condition and 166 (48.3%) randomized to the standard-of-care condition. Of note, randomization did not yield equivalence regarding intent. Positive intent was indicated by 58.2% of those randomized to the intervention condition and 70.9% in the control condition ($p = .014$). Nearly half of the women (43.3%) randomized to the DVD intervention completed the 3-dose series, whereas 31.9% of women assigned to the comparison group completed the series, for a percent relative difference of 35.7% ($p = .03$).

Bivariate findings

Table 2 displays the bivariate findings from the cross-sectional study of positive intent; there were no differences by group assignment for any of the continuous-level or dichotomous correlates (data not shown). As hypothesized, the majority of assessed TPB correlates were significantly associated with intent ($p \leq .10$), each in the anticipated direction. For example, women with positive intent to complete the vaccine series were more likely to agree that getting all three doses of the HPV vaccine would decrease their chance of getting cervical cancer (i.e., supportive vaccine attitudes). Likewise, women with positive intent were less likely to report childcare, transportation, and work as barriers to series completion. However, inconsistent with our supportive norms hypothesis, women with positive intent were less likely to agree with statements that their mother and father encouraged vaccination. The control variables, history of an abnormal Pap ($p = .001$) and having had previous sexual intercourse ($p = .001$), were both significantly associated with positive intent to complete the vaccine series (data not shown).

Table 3 displays the bivariate findings for actual vaccine series completion. As shown, five of eight TPB predictors assessed at the continuous level were significantly associated with series completion ($p \leq .10$). For example, women who completed the vaccine series were more likely to agree that the HPV vaccine will reduce the number of cervical cancer case (i.e., supportive vaccine attitudes). Two dichotomous variables, transportation and work schedule, achieved significance as would be expected; in other words, those who did not complete the vaccine series were more likely to report that these barriers would prevent their return for subsequent doses. Inconsistent with our subjective norms hypothesis, however, neither father encouragement to complete

Table 2 Correlates of Positive Intent to Complete the 3-Dose HPV Vaccine Series (N = 344)

Continuous-Level Correlates ^a	Mean Among those With Negative Intent	Mean Among Those With Positive Intent	t	p Value
3 doses decreases my cervical cancer risk ^b	2.33	0.99	9.50	.0001
Vaccine prevents cervical cancer pain and death ^c	2.05	1.78	2.29	.02
HPV vaccine will reduce number of cervical cancer cases ^c	2.11	1.26	7.77	.0001
Provider phone call reminder helpful ^b	2.12	1.28	5.62	.0001
Would not return if special appointment ^b	2.72	2.87	1.24	.22
Would return if friend came with me ^b	2.84	2.36	3.56	.0001
Father encourages vaccine completion ^b	1.27	1.77	2.59	.01
Mother encourages vaccine completion ^b	1.06	1.40	3.82	.0001
Dichotomous Correlates ^d	% Negative Intent	% Positive Intent	p Value	
Childcare would prevent return				
Yes	68.2 ⁺	31.8		.001
No	33.4	66.6		
Transportation issues would prevent return				
Yes	54.5 ⁺	45.5 ⁻		.0001
No	29.7	70.3		
Work schedule would not prevent return				
Yes	62.5 ⁺	37.5 ⁻		.0001
No	24.2 ⁻	75.8 ⁺		
Friends have been vaccinated				
Yes	38.9	61.1		.50
No	42.8	57.2		
Friends failed to complete full vaccine series				
Yes	36.1	63.9		1.00
No	36.1	63.9		

^aLower scores represent greater agreement with the statement.

^b5-point agreement scale.

^c6-point agreement scale.

^d+ represents significantly higher frequencies based on standardized residual (≥ 2 or ≤ -2); - represents significantly lower frequencies based on standardized residual (≥ 2 or ≤ -2).

Table 3 Correlates of Vaccine Series Completion ($N = 344$)

Continuous-Level Correlates ^a	Mean for Series Non-completers	Mean for Series Completers	<i>t</i>	<i>p</i> Value
3 doses decrease my cervical cancer risk ^a	1.72	0.95	5.85	.0001
Vaccine prevents cervical cancer pain and death ^c	1.90	1.84	.54	.59
HPV vaccine will reduce number of cervical cancer cases ^c	1.74	1.27	4.82	.001
Provider phone call reminder helpful ^b	1.74	1.33	2.83	.005
Would not return if special appointment ^b	2.79	2.88	.76	.44
Would return if friend came with me ^b	2.72	2.22	3.70	.001
Father encourages vaccine completion ^b	1.57	1.65	.54	.59
Mother encourages vaccine completion ^b	1.19	1.42	1.75	.08
Dichotomous Correlates ^d	% Series Incomplete	% Series Complete	<i>p</i> Value	
Childcare would prevent return				
Yes	60.9	39.1	.870	
No	62.6	37.4		
Transportation issues would prevent return				
Yes	78.5	21.5 ⁻	.001	
No	57.0	43.0		
Work schedule would prevent return				
Yes	78.1 ⁺	21.9 ⁻	.001	
No	55.7	44.3		
Friends have been vaccinated				
Yes	66.4	33.6	.78	
No	68.0	32.0		
Friends failed to complete full vaccine series				
Yes	69.4	30.6	.39	
No	62.1	37.9		

^aLower scores represent greater agreement with the statement.

^b5 point agreement scale.

^c6 point agreement scale.

^d+ Represents significantly higher frequencies based on standardized residual (≥ 2 or ≤ -2);

– represents significantly lower frequencies based on standardized residual (≥ 2 or ≤ -2).

the vaccine series nor peer vaccination behaviors were significantly correlated with series completion. Of the two control variables, history of an abnormal Pap was significantly correlated with series completion ($p = .03$), while history of previous sexual intercourse was not ($p = .664$; data not shown).

Table 4 Multivariate Findings for Positive Intent to Complete the Vaccine Series (*N* = 308).

Correlate	AOR ^a	95% CI	<i>p</i> Value
Sexually experienced	6.62	1.61–34.48	.026
Ever had abnormal Pap test result	3.05	1.53–6.06	.002
3 doses decreases my cervical cancer risk	1.42	1.09–1.87	.011
HPV vaccine will reduce number of cervical cancer cases	1.75	1.23–2.50	.002
Would return with provider phone call	1.40	1.09–1.81	.009
Father encourages vaccine completion	0.72	0.54–0.95	.019
Work schedule would not prevent return	3.97	2.07–7.60	.001
Childcare would not prevent return	5.94	1.54–22.89	.010

AOR = adjusted odds ratio; CI = confidence interval.

^aOdds ratio adjusted for all other variables in the model.

Multivariate findings

Table 4 displays the results of the two-block model regressing intent on the assessed correlates. The model fit the data well, $\chi^2(8) = 135.32, p = .001$. As shown, of the two control variables that were forced into block one, both the experience of ever having an abnormal Pap test result ($p = .002$) and having had previous sexual intercourse ($p = .026$) were significantly associated with intent. Six of the correlates retained multivariate significance in block two, and each was associated with intent in the anticipated direction, with the exception of father encouragement, which was consistent with the bivariate findings.

Table 5 displays the results of the three-block model regressing series completion on the predictor variables assessed at baseline. The model fit the data well, $\chi^2(5) = 52.97, p = .001$. As hypothesized, positive intent was a strong predictor of series completion, with those indicating positive intent being about 2.1 times more likely to complete the series ($p = .016$). The one control variable, ever having an abnormal Pap test result, failed to achieve multivariate significance despite being forced into block one. Only two of the variables entered in block two achieved multivariate significance. Women indicating a belief that all three doses would reduce their risk of cervical cancer were 1.5 times more likely to complete the series than those not having this attitude ($p = .001$). Also, women indicating that they would be more likely to complete the series if a friend went with them were about 1.5 times more likely to complete the series than those not indicating this facilitating factor ($p = .011$). Most importantly, women randomized to the intervention were 2.44 times more likely to complete the vaccine series than those assigned to the standard-of-care condition ($p = .001$).

Discussion

To our knowledge, this is the first communication intervention trial to promote completion of the 3-dose HPV vaccine series in a community setting. Previous intervention studies have focused exclusively on college students' HPV vaccine

Table 5 Multivariate Findings for Completion of Vaccine Series ($N = 336$).

Predictor Variable	AOR ^a	95% CI	<i>p</i> Value
Ever had abnormal Pap test result	1.20	0.73–1.99	.466
Intend to complete the series	2.07	1.15–3.76	.016
Would return if friend came with me	1.29	1.06–1.56	.011
3 doses decreases my cervical cancer risk	1.49	1.18–1.87	.001
Randomized to intervention condition	2.44	1.47–4.05	.001

AOR = adjusted odds ratio; CI = confidence interval.

^aOdds ratio adjusted for all other variables in the model.

knowledge, intentions, and initiation using different educational approaches (Hopfer, 2012; Krawczyk et al., 2012a; Leonard, Kola, & Walsh, 2011). Alternatively, our DVD-based intervention to improve vaccine adherence was conducted in a real-world setting, using nurse providers working in a challenging sociocultural environment.

As posited by the TPB, intention was a strong predictor of completing the 3-dose vaccine regimen among this sample of Appalachian Kentucky women. Previous research suggests that intention is the strongest correlate of HPV vaccination uptake among young women (Gerend & Shepherd, 2012; Juraskova et al., 2011). Although, intention is a meaningful predictor of health behavior, it often falls short in fully explaining behavioral outcomes (Armitage & Conner, 2001; Webb & Sheeran, 2006). Beyond intention to vaccinate, our data demonstrate that a field-based DVD intervention can have an equally strong effect on future behavior. In essence, the effect of the DVD was robust given that the model was constructed to preferentially allow a large number of other variables to explain the variance in series completion. Although this study is the first to examine the outcome of adherence, this effect size is consistent with the findings of Hopfer's (2012) "combined" peer-expert video intervention in improving vaccine acceptance.

Impressively, 31.9% of the comparison group achieved series completion while only receiving standard-of-care procedures, including an informational HPV vaccine brochure and reminder telephone calls for doses 2 and 3. This vaccine series completion rate is lower than Chao, Velicer, et al.'s (2009) research in southern California (47.1%); however, women in that study were followed over a 2-year period and were part of a managed care insurance plan with a large network of primary care providers. The rate in our study is substantially higher than Dempsey et al.'s (2011) research in Michigan (10%) among 19- to 26-year-old women and the previous Crosby et al. (2011) study (clinic-recruited sample 4.5%), which was conducted with a similar population of medically underserved women in Appalachian Kentucky. Our findings may serve as an example for practitioners in medically underserved communities. Specifically, working with manufacturer reimbursement programs to provide vaccines at low or no cost and following standard-of-care procedures that include follow-up phone call reminders and community-based vaccination clinics can optimize HPV vaccination adherence rates.

The bivariate data predicting intention to vaccinate were intriguing. These data partially supported two TPB-related hypotheses examining intent to complete the series outcome: positive attitudes toward HPV vaccination and access to care barriers (as viewed through the lens of perceived behavioral control). One unique finding was the inverse relationship between parental encouragement and intention to vaccinate. One possible explanation is that because these women had already received dose one, their reported belief that a parent did not encourage vaccination actually strengthened their existing intention to complete the full dosing regimen (a possible reactance effect; Brehm & Brehm, 1981).

Additionally, in the multivariate model, women reporting the experience of an abnormal Pap test were three times as likely to report positive intent to complete the vaccine series, suggesting these women may experience increased perceived susceptibility to cervical cancer and desire to take proactive steps to prevent the disease. Clinicians should consider an abnormal Pap test as an opportunity to educate young women about the benefits of the HPV vaccine (Kepka, Berkowitz, Yabroff, Roland, & Saraiya, 2012). Believing that three doses of the vaccine reduces personal cervical cancer risk and reduces incidence of cervical cancer was also predictive of positive intent to complete the vaccine series in the final model. Similarly, lack of scheduling barriers predicted positive intent. These data suggest the benefits of including vaccine efficacy data related to the prevention of precancerous cervical lesions and cervical cancer, as well as strategies for overcoming common barriers to vaccination in persuasive messages.

Bivariate data were mixed in offering support of our hypotheses relative to predicting series completion. Although having a friend accompany the woman for subsequent doses and favorable perceptions of vaccine efficacy significantly predicted completion, perceptions of paternal encouragement and peer vaccination behaviors were not significant. As expected, barriers of transportation and work schedule were significantly associated with series completion; however, the barrier of childcare was not.

The final multivariate model did not support parental influence or peer behaviors as significant predictors of series completion. Several studies have suggested that normative social influence (particularly maternal influence and health care providers) predicts vaccination series initiation (Kester, Zimet, Fortenberry, Kahn, & Shew, 2012; Krieger, Kam, Katz, & Roberto, 2011; Krieger, Katz, Kam, & Roberto, 2012). However, our study population had already initiated the vaccine series; therefore, parental influence may not be as relevant. Related, parental influences may fade or become less salient for young women making health decisions as adults (Teitelman *et al.*, 2011). Prescriptive norms may be more meaningful for adolescent audiences given that parental permission is legally required for vaccination.

These findings suggest that the TPB offers more limited explanatory power for predicting behavioral adoption over time and that studying series completion as distinct from initial vaccine uptake and intention to receive three doses of the vaccine is an important area for scholarly consideration (Dempsey *et al.*, 2011). Our findings show that potential barriers to and facilitators of series completion

are quite different. There is no "one size fits all" approach to encouraging HPV vaccination uptake and series completion. Rather, communication interventions should differentiate persuasive strategies appropriate to improving uptake and improving series completion in target populations sharing similar sociocultural beliefs and barriers to vaccination.

Limitations

There are noted limitations to our research. We recognize the cross-sectional nature of the baseline survey does not allow for measuring temporal changes in health-related attitudes and beliefs, the influence of subjective norms, perceived behavioral control, and behavioral intentions. An alternative approach would examine differences in key TPB variables between the usual care and intervention groups at doses 2 and 3, in addition to baseline/dose 1. Moreover, there may be other theoretical constructs, structural barriers, and cultural practices that are unaccounted for in our analysis and participants may have experienced difficulties in recalling past sexual health experiences. Because ours was a community-based study, we did not include a probability sample of patients. However, random assignment of participants to each condition was designed to ensure the translatability of the intervention effects to similar populations.

Despite these limitations, our study focused on improving health equity and reducing cervical cancer disparities among a high-risk population of young women residing in the Appalachian Mountains of eastern Kentucky. Women in this medically underserved region are disparately burdened by cervical cancer compared to other Kentucky women and the general female population residing in the United States. These findings of significant improvements in series completion after the DVD-based intervention are robust, as they were achieved in comparison to an idealized standard-of-care protocol. One limitation to external validity is that the vaccine was provided at no cost; however, in medically underserved communities similar to Appalachian Kentucky, providers can be reimbursed for vaccine costs through manufacturers' vaccine assistance programs, and the vaccine can remain free to women.

Areas for future research

Clearly, the DVD production process should be repeated with other populations to create effective, appropriate, and translatable communication strategies. Notably, our theory-based DVD was guided by information gathered from formative research conducted in the target community (Cohen & Head, *in press*; Head & Cohen, 2012). Similar processes of formative research used for this study could garner insights into the appropriate substitution of local data, expert, and peer narratives. Future research may also consider appropriate ways to target messages to other groups. If our video were shown to adolescent girls, messages related to Pap testing, which may not be appropriate for females under age 18, could be excluded from the video. Alternatively, key message components could be maintained and video footage reshot for use with males because they are now eligible for the HPV vaccine (Dunne *et al.*, 2011).

In an era of more "personalized" medicine, educational interventions at the point of clinical services may become routine. Future research may also consider how brief clinical assessments of individual patient's barriers to vaccination (and adherence) may be used to create tailored digital educational messages to enhance vaccination schedule adherence. Given the Affordable Care Act's incentives for improving digitization of medical records, future research also may consider how digital educational materials can be integrated into the electronic medical record and patient education system. The digital video format ensures the fidelity of the message, supports potential integration into existing clinic resources, and is compatible with delivery in community settings (e.g., delivered via iPad, portable DVD, kiosk, laptop, or desktop computer), provided equipment security and patient privacy concerns are addressed.

Finally, future research may consider how training nurse practitioners and community health workers may be used to improve the delivery of vaccinations in medically underserved communities. For example, training staff to assist with pharmaceutical companies' reimbursement paperwork could serve as a cost-effective measure to obtaining free or low-cost vaccine supplies for the provider, as well as eliminate patient costs.

Conclusions

A theory-grounded DVD education intervention was successful in improving HPV vaccination completion rates. Our approach has the potential to be adapted and replicated with other populations of women, including other rural communities and African American and Hispanic populations; these populations also are recognized for cervical cancer disparities and share many similarities with our target population, such as low socioeconomic status, limited access to care, and poor living environments (Freeman & Wingrove, 2005). As advocated by Glasgow, Marcus, Bull, and Wilson (2004), ultimately, the long-term goal of this evidence-based intervention is widespread dissemination; in fact, dissemination has been a priority since conceptualization of the study. For decades, there has been a documented chasm between research and public health practice (Green, Ottoson, García, & Hiatt, 2009; IOM, 2001). An intervention such as ours can be modified to other populations, can be delivered in a variety of nonclinical settings, and requires few time, staff, and organizational resources to implement. Indeed, it could become routine clinical practice to show the video to women immediately after receiving dose one of the HPV vaccine.

Findings also suggest the potential for translating this approach to other vaccination contexts in which adherence to a multiple dosage regimen is necessary (e.g., Hepatitis B; H1N1 for children). Theory-based communication interventions designed to overcome barriers to dissemination from the beginning (Glasgow *et al.*, 2004) and promote successful translation from research to practice (Schoenwald & Hoagwood, 2001) help to make an immediate impact on population-level cancer incidence, morbidity, and mortality.

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Note

- 1 The HPV vaccine is not therapeutic for existing HPV infection or cervical abnormalities; however, women with a history of HPV infection and/or an abnormal Pap are still eligible for HPV vaccination to help prevent against infection with HPV virus types not already acquired (Markowitz et al., 2007).

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