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Staying on track: A cluster randomized controlled trial of automated reminders aimed at increasing human papillomavirus vaccine completion☆

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ABSTRACT

Objectives: To evaluate whether automated reminders increase on-time completion of the three-dose human papillomavirus (HPV) vaccine series.
Methods: Ten reproductive health centers enrolled 365 women aged 19–26 to receive dose one of the HPV vaccine. Health centers were matched and randomized so that participants received either routine follow-up (control) or automated reminder messages for vaccine doses two and three (intervention). Intervention participants selected their preferred method of reminders – text, e-mail, phone, private Facebook message, or standard mail. We compared vaccine completion rates between groups over a period of 32 weeks.
Results: The reminder system did not increase completion rates, which overall were low at 17.2% in the intervention group and 18.9% in the control group ($p = 0.881$). Exploratory analyses revealed that participants who completed the series on-time were more likely to be older (OR = 1.15, 95% CI 1.01–1.31), report having completed a four-year college degree or more (age-adjusted OR = 2.51, 95% CI 1.29–4.90), and report three or more lifetime sexual partners (age-adjusted OR = 3.45, 95% CI 1.20–9.92).
Conclusions: The study intervention did not increase HPV vaccine series completion. Despite great public health interest in HPV vaccine completion and reminder technologies, completion rates remain low.

1. Introduction

The human papillomavirus (HPV) quadrivalent vaccine (Gardasil; Merck & Co) was approved by the U.S. Food and Drug Administration in 2006 for females aged 9–26 and in 2009 for males aged 9–26 [1]. A bivalent HPV vaccine (Cervarix; GlaxoSmithKline) has also been approved for use in females since 2009 [2]. HPV has been linked to genital warts and cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers [3,4]. In spite of widespread support within the public health community, HPV vaccine initiation and completion rates are persistently low, with disparities in vaccination by age, race, region, and insurance status [5–11].

It is challenging for many patients to return for all three doses of HPV vaccine in accordance with the recommended six-month schedule. In the United States, the national 2012 vaccine series completion rate for girls 13 and younger who had received the first dose was 49.9%, a decrease from the 2011 completion rates of 63.6% for the same age group [12,13]. Vaccine completion is lower among those who present for vaccination after adolescence. In one study of 4,922 women aged 18–26 in a managed care setting, only 47.1% completed the vaccine series [14]. A recent study of eight managed care organizations found that among female initiators 9–26 years old, 42% completed the three dose series within one year [15]. Total rates of completion are even lower in non-managed care settings, with rates ranging from 18.6% for 18–26 year-old initiators at one academic medical center [8] to 35.8% among privately insured women aged 19–26 [16–18].

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Numerous studies have examined barriers to vaccine series completion and conducted interventions aimed at increasing completion rates among adolescent girls [7–10,14–17]; fewer have examined completion among young adult women. Reminder technologies have been proposed as a method of increasing compliance with various health behaviors, including vaccine series completion [19,20]. Previous studies have documented the efficacy of text message and phone call reminders in a variety of clinical settings, including increased attendance rates for healthcare appointments [21–23], for parents of adolescents for compliance with influenza, HPV, and other vaccines, and improved oral contraceptive adherence in women under age 25 [22,24–28]. Provider reminders have also been explored [29,30]. In a commentary on low rates of HPV vaccine uptake and completion in the United States, the National Cancer Institute cited the infrequent use of reminder and recall systems as one of several contributing factors [20].

Given the promising evidence for the efficacy of automated reminders, the primary aim of this study was to evaluate whether an automated reminder system could increase on-time HPV vaccine series completion. The secondary aim was to conduct exploratory analyses to evaluate whether sociodemographic factors predict vaccine series completion.

2. Materials and methods

This study was a prospective, cluster-randomized study conducted at 10 outpatient reproductive health centers – nine Planned Parenthood health centers located in North Carolina, Utah, Arizona, Washington, Colorado, and California, and one hospital family planning clinic located in Illinois. Intervention sites implemented an automated system to remind participants when their next HPV vaccine dose was due. The study protocol and all study instruments were approved by the Allendale Investigational Review Board and the John H. Stroger, Jr. Hospital Institutional Review Board. The work presented in this article has been carried out ethically, in accordance with human subjects protections.

A cluster randomized trial design was used to minimize logistical challenges and to accurately evaluate a site-level intervention [31]. The 10 centers were matched based on monthly overall patient volume, number of HPV vaccine doses administered, and patient demographics (Fig. 1). Online randomization software was used to assign paired units to intervention or control arms using a block randomization technique. Site randomization was conducted prior to participant recruitment and, due to the nature of the intervention, neither participants nor providers were blinded to study arm assignment.

Participant recruitment and enrollment was conducted by trained research staff at each health center. Women aged 19–26 and fluent in English were eligible for screening. Exclusion criteria included previous HPV vaccination, contraindication to HPV vaccine, or lack of access to at least one of the reminder methods (text, phone, e-mail, Facebook message, or mail). Additionally, pregnant women, women who stated that in the next eight months they might want to become pregnant or planned to move from the area, and women who were unwilling to be contacted for follow-up were excluded.

At the enrollment visit, informed consent was obtained and all participants completed a baseline questionnaire. Questions covered demographic characteristics, insurance status, reproductive health history, and knowledge and attitudes regarding HPV. The questionnaire was conducted electronically at intervention sites and on paper at control sites. At this visit, women in both study arms received the first dose of the three-dose quadrivalent HPV vaccine series at no cost. For doses two and three, participants could use insurance, pay for vaccine out-of-pocket, or, with the assistance of health center staff, complete a short application for the financial assistance program maintained by the vaccine manufacturer, which provides same-day approval and reimburses the health center for the vaccine costs for low-income uninsured adults [32].

At the time of the enrollment visit, women in the intervention arm also selected their preferred method for reminders – text message, e-mail, phone call, private Facebook message, or standard mail. The "Staying on Track" software system, designed for this study, recorded subject data and sent the automated reminders. Each intervention participant received four messages (one if she selected standard mail), sent three days apart prior to doses two and three (Fig. 2). The reminder schedule mirrored the recommended dosing schedule. Reminders for dose two were sent six weeks after the initial visit. Timing of reminders for dose three was dependent on when the participant returned for dose two; reminders were sent either 12 weeks after the second dose or 24 weeks after the first dose, whichever was sooner. All messages reminded patients to schedule their next vaccine and provided health center contact information. For example, the text message for participants at Planned Parenthood sites stated: "*Reminder: schedule your next HPV Vaccine if you have not done so. Call 1-800-230-PLAN or go to www.plannedparenthood.org. You will get a total of 4 reminders.*" At nine study sites, patients were able to walk-in to receive same day HPV vaccine, but scheduled appointments were encouraged; at one study site, patients needed to schedule an appointment for vaccination. Each participant had 32 weeks to return for all three doses as part of the study, which allowed for an eight-week "grace period" beyond the recommended 24 week schedule. Women in the control arm received standard care for HPV vaccine follow up from their health center, which was limited to mail reminders at two control sites. None of the control sites provided automated reminders. All participants who failed to return to their initial health center for all three doses by the end of the 32-week study period were contacted via e-mail or phone with five automated survey questions probing reasons for non-completion of the series.

2.1. Statistical methods

Sample size calculation was based on previously published vaccine completion rates, which were estimated at 40% [8,14]. The calculation was adjusted to account for the pair-matched cluster-randomized trial design. Using a coefficient of variation of true proportions between clusters within each group of 0.20, we determined that a total of 10 health centers and 37 participants from each would sufficiently power the study at 90% and account for failure to follow up and for vaccine completion rates that were lower than anticipated [33].

A total of 365 participants ($n = 180$ intervention, $n = 185$ control) were included in analysis at the individual level. The primary outcome measure, proportion of patients completing the vaccine series on time in each group (intervention vs. control), was evaluated using a test for two binomial proportions to account for the cluster design. Categorical variables were compared across groups using one-way, two-way, or multi-level frequency tables and Chi-square tests. Continuous variables were examined for normality and compared across groups using appropriate parametric (t-test, ANOVA) or nonparametric procedures. Multivariable logistic regression was conducted to adjust the treatment effect for baseline differences (race/ethnicity, number of lifetime sex partners, and age) between the two groups. As there was no statistically significant effect of the intervention, the intervention and control arms were pooled together for an exploratory analysis of vaccine completion, and further adjustment for the cluster design was deemed unnecessary. Bivariate logistic regression was used to examine the effects of the baseline covariates on on-time completion of the vaccine series

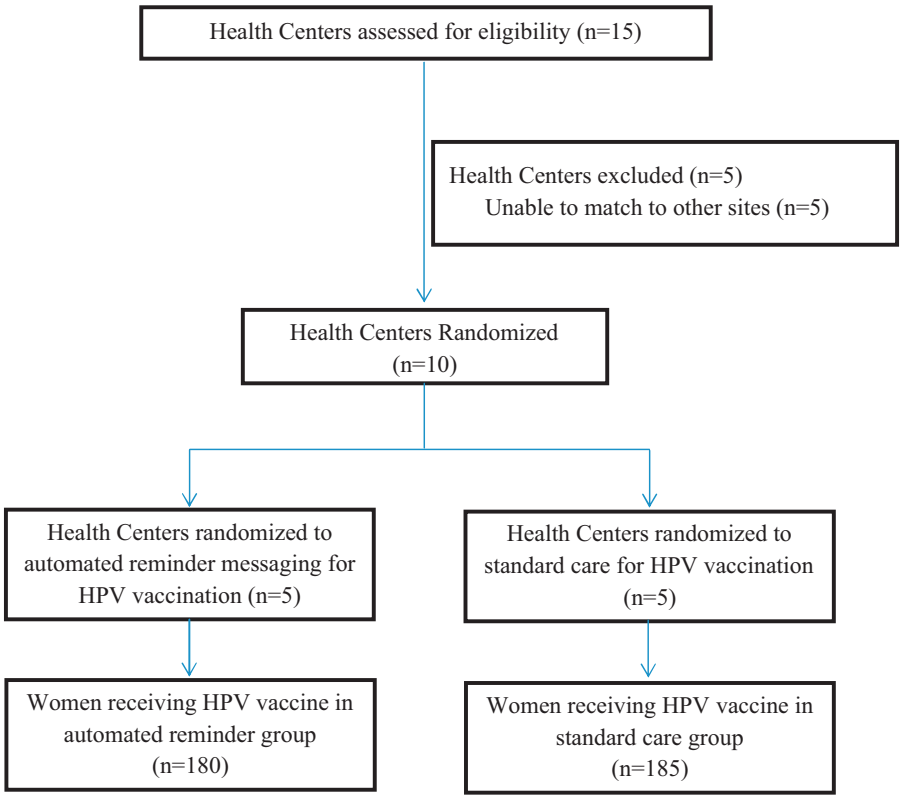

Fig. 1. Study flow diagram.

among all study participants. For significant covariates identified in the bivariate analyses, separate age-adjusted logistic regression models were constructed. Women who completed all three vaccine doses during the 32-week study period at the same health center were considered completers in analysis. All other participants were considered non-completers. Minitab 15® and SPSS 21 were used to complete the statistical analyses.

3. Results

Nine sites enrolled 37 young women aged 19–26 and one site enrolled 32 women, for a total of 365 participants – 180 in the intervention arm and 185 in the control arm. Participants in the intervention and control groups were compared on a variety of sociodemographic variables to assess comparability and were similar except for race/ethnicity, mean age, and number of lifetime sexual partners (Table 1).

On-time completion rates of the HPV vaccine series did not differ significantly between intervention and control groups. 17.2% ($n = 31$) of women in the intervention arm and 18.9% ($n = 35$) of women in the control arm completed the vaccine series within 32 weeks ($p = 0.881$). The same was true for receipt of the second dose – 40.6% ($n = 73$) of women in the intervention group returned for dose two, compared with 40% ($n = 74$) in the control group ($p = 0.915$).

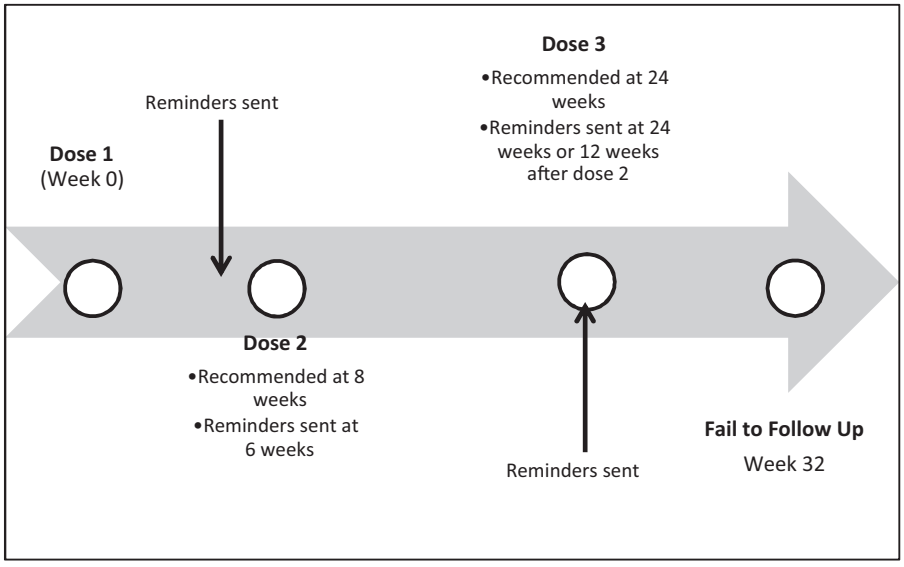

Fig. 2. Vaccine dose and reminder schedule.

Table 1
Characteristics of study participants.

Characteristic	Intervention (n = 180)	Control (n = 185)	Total (n = 365)
Age in years – mean (SD)*	23.2 (2.2)	23.6 (2.2)	23.2 (2.2)
Race/ethnicity – no. (%)**			
White	85 (47.2)	123 (66.5)	208 (57.0)
African-American	40 (22.2)	2 (1.1)	42 (11.5)
Latina/Hispanic/Spanish	30 (16.7)	49 (26.5)	79 (21.6)
Asian/Pacific Islander	13 (7.2)	4 (2.2)	17 (4.7)
Other/unknown	12 (6.7)	7 (3.8)	19 (5.2)
Difficulty coming to health center location – no. (%)			
Not difficult	147 (81.7)	163 (88.1)	310 (84.9)
Somewhat or very difficult	33 (18.3)	22 (11.9)	55 (15.1)
Education –no. (%)			
High school or less	95 (52.8)	90 (48.6)	185 (50.7)
Technical, vocational or 2-year degree	32 (17.8)	44 (23.8)	76 (20.8)
4-year college or more	53 (29.4)	51 (27.6)	104 (28.5)
Health insurance status – no. (%)			
No health insurance	99 (55.0)	108 (58.4)	207 (56.7)
Private insurance	50 (27.8)	50 (27.0)	100 (27.4)
Public insurance	31 (17.2)	27 (14.6)	58 (15.9)
Sexual activity – no. (%)			
Never sex	6 (3.3)	2 (1.1)	8 (2.3)
Ever sex	174 (96.7)	183 (98.9)	357 (97.8)
Number of lifetime sexual partners – no. (%)**			
Less than 3 partners	41 (22.8)	21 (11.4)	62 (17.0)
3 or more partners	139 (77.2)	164 (88.6)	303 (83.0)

* Baseline differences between intervention and control groups that were statistically significant ($p < 0.05$).
** Baseline differences between intervention and control groups that were statistically significant ($p < 0.01$).

Though not statistically significant, the intervention was negatively associated with series completion (OR = 0.82, 95% CI 0.52–1.52). Adjustment for baseline differences between the control and intervention groups slightly attenuated the treatment effect (AOR = 0.97, 95% CI 0.55–1.68) [results not shown].

In an exploratory analysis using the pooled sample, several factors that were found to affect completion rates in previous studies did not in the present study, including race/ethnicity, health insurance status, difficulty coming to the health center location, and knowledge and attitudes about HPV. Three significant predictors of HPV vaccine completion in this study were identified: higher age, having three or more lifetime sexual partners, and having completed a four-year college degree or more (Table 2). Our sample had limited variability in age due to inclusion criteria (19–26 years old); nonetheless participants who were older were significantly more likely to complete the HPV vaccine series (mean age of completers = 23.9 ± 1.9 compared with mean age of non-completers = 23.3 ± 2.2; OR = 1.15, 95% CI 1.01–1.31). There was wide variation in participants' lifetime number of sexual partners, ranging from zero to 70 with a mean of 9.5 (SD = 10.4). When examined as a continuous variable, there was no statistically significant association between the number of lifetime sexual partners and likelihood of vaccine completion. However, as a dichotomous variable, we found that women reporting three or more lifetime sexual partners were significantly more likely to complete the series than women reporting fewer than three partners (OR = 3.73, 95% CI 1.30–10.67). This association remained statistically significant after controlling for age (AOR = 3.45, 95% CI 1.20–9.92). Finally, participants with a four-year college degree or more were more likely to complete the series (OR = 2.85, 95% CI 1.56–5.19) than those with less education. This relationship remained statistically significant after controlling for age (AOR = 2.51, 95% CI 1.29–4.90).

Among intervention participants, 50% chose to receive reminder messages via text message while most other participants opted for phone call or e-mail reminders (24% and 23% respectively). Few participants selected standard mail or private Facebook message (2% and less than 1% respectively) and were excluded when exploring the association between chosen method of communication and vaccine completion. Among the participants who chose text, phone calls, or e-mails, vaccine completion did not vary significantly by method of communication.

Only 16 of the 299 (5.4%) eligible women completed the fail-to-follow-up questionnaire, querying reasons for non-completion.

4. Discussion

This study sought to use patient-friendly technology to address the persistent problem of low HPV vaccine series completion. While evidence in other settings demonstrates that reminder systems can improve completion, on-time vaccine series completion in our study was low and did not differ between intervention and control groups.

Several factors may contribute to these low rates of completion. Health care accessibility (i.e., health center location, hours, transportation) and affordability (i.e., insurance status and cost) have been shown to affect HPV vaccine completion [16,34]. Although within our study there was no significant difference in on-time completion based on insurance status, perception of vaccine cost may have influenced completion. Nearly all participants in both study arms met income eligibility criteria for the manufacturer's financial assistance program, which would have provided vaccination at no cost; however, it is possible that many did not know that the program existed or that they would be eligible. While difficulty of coming to the health center did not affect on-time completion in this study, other logistical barriers shown to affect subsequent dose receipt in adult vaccinations – such as childcare – were not examined [35].

Aspects of study design may have contributed to the low completion rates. Our study assessed vaccine completion within 32 weeks; results from comparable studies show an association between longer time frame and higher completion rates [9,10,17,36]. Indeed, 81.8% of the women who completed the vaccine series during our study did so between week 24 and week 32. This supports the possibility that more women may have completed if given a longer time frame. Additionally, participants needed to return to the same health center for all three doses in order to be considered completers. This aspect of study design may have introduced bias, artificially diminishing the effect of the

Table 2
Odds ratios of the relationship between select baseline characteristics and HPV vaccine completion within 32 weeks among all participants.

Characteristic	Unadjusted models		Age adjusted models	
	OR	95% CI	AOR	95% CI
Age in years	1.15*	1.01–1.31	–	–
Number of lifetime sexual partners				
Less than 3 partners	Ref.	–	Ref.	–
3 or more partners	3.73*	1.30–10.67	3.45*	1.20–9.92
Education				
High school or less	Ref.	–	Ref.	–
Technical, vocational or 2-year degree	1.14	0.53–2.45	1.06	0.48–2.33
4-Year college or more	2.85**	1.56–5.19	2.51**	1.29–4.90

* $p < 0.05$.
** $p < 0.01$.

intervention; the low completion rates must be interpreted with this limitation in mind. Although we sought to exclude women who planned to leave the area in the next eight months, national statistics suggest that as many as 31% of young people aged 18–24 change residences annually [37]. Over one-third of participants (35%) were part-time or full-time students, making it possible that some sought care through their university health services or at another location. Only 16 (5.4%) of non-completers responded to follow up attempts by researchers, limiting our ability to assess whether participants may have completed the vaccine series elsewhere.

Another study limitation that may have contributed to low completion rates is that in order to simulate actual practice, we recruited all-comers, seeking to enroll all eligible women who presented for reproductive health services, rather than specifically recruiting women seeking HPV vaccine. We also provided the first dose at no cost. Therefore, it is possible that women were recruited into the study who were not motivated to complete the series.

The system designed for this study may have affected intervention success as it was not able to send personalized messages, provide participants with appointments, collect information about bounce-backs, or allow women to turn off reminders. Future research should investigate whether a more adaptable and personalized system might be more successful [38].

The strengths of this study include the enrollment of a diverse group of women, representing several U.S. regions, and a range of racial/ethnic groups. Additionally, our study enrolled uninsured, publicly insured, and privately insured women, allowing for cross-group comparisons. Drawing from patients attending Planned Parenthood health centers also enhances broad applicability of study results, as one in five U.S. women visits Planned Parenthood for health services in her lifetime.

Several of our findings warrant future inquiry. In our sample, older women and those with three or more lifetime sexual partners were significantly more likely to complete the vaccine series. These trends have important implications for the public health burden of HPV-related disease and parallel recent findings from the National Health and Nutrition Examination Surveys, 2007–2010 [39]. Interventions should seek to better educate young women, girls, and their parents about the benefits of vaccination before the onset of sexual activity and should address barriers to earlier vaccination.

Globally, voluntary school-based HPV vaccination programs have increased uptake and completion rates and offer the potential for reduction of racial and ethnic disparities in vaccine coverage and HPV-related illness [40–42]. Ultimately, a vaccine with fewer doses and/or greater flexibility in dose timing could prove beneficial; current research shows promise for a revised vaccine schedule [43–47]. Integration of HPV vaccination into postpartum and contraceptive injection visits has demonstrated improved completion rates [10,18] and further research must explore strategies to reduce provider missed opportunities – including vaccine integration into routine practice via standing orders, electronic health record prompts, checking immunization systems, scheduling dose two and three visits after initiation, and automated reminder messages [48,49].

5. Conclusion

Although the HPV vaccine is safe, effective, and broadly supported by the medical and public health communities, both initiation and completion rates are low in the U.S. Modern technology has the potential to improve health outcomes and reduce disparities. This cluster randomized controlled trial at nine Planned Parenthood health centers and one hospital family planning clinic found that automated reminders did not increase on-time completion of the three-dose HPV vaccine series. Future research should continue to explore reminder technologies and should involve patients in determining strategies for improving vaccine completion.

Conflict of interest

This study was funded as an investigator-initiated study protocol by Merck, Sharp, & Dohme Corp. The funder had no role in the design or conduct of study, the collection, analysis, or interpretation of data, nor in the preparation, review, or approval of the manuscript. Dr. Ashlesha Patel has served on advisory boards and speakers bureaus and provided educational programs for Merck, as well as for Bayer HealthCare Pharmaceuticals, Inc. and Teva Pharmaceutical Industries, Ltd. The other authors report no personal, political, commercial, financial, or academic conflicts of interest. All authors have approved the final article.

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