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# A Randomized Intervention of Reminder Letter for Human Papillomavirus Vaccine Series Completion



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## ABSTRACT

**Purpose:** Completion rate for the three-dose series of the human papillomavirus (HPV) vaccine has generally been low. This study evaluated the effectiveness of a reminder letter intervention on HPV vaccine three-dose series completion.

**Methods:** Female members of Kaiser Permanente Southern California Health Plan who received at least one dose, but not more than two doses, of the HPV vaccine by February 13, 2013, and who were between ages 9 and 26 years at the time of first HPV vaccination were included. Eighty percent of these females were randomized to receive the reminder letter, and 20% were randomized to receive standard of care (control). The reminder letters were mailed quarterly to those who had not completed the series. The proportion of series completion at the end of the 12-month evaluation period was compared using chi-square test.

**Results:** A total of 9,760 females were included in the intervention group and 2,445 in the control group. HPV vaccine series completion was 56.4% in the intervention group and 46.6% in the control groups (p < .001). The effect of the intervention appeared to be stronger in girls aged 9–17 years compared with young women aged 18–26 years at the first dose and in blacks compared with whites.

**Conclusions:** Reminder letters scheduled quarterly were effective to enhance HPV vaccine series completion among those who initiated the vaccine. However, a large gap in series completion remained despite the intervention. Future studies should address other barriers to series completion, including those at the providers and the health care system level.

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#### IMPLICATIONS AND CONTRIBUTION

This study shows that a reminder letter intervention scheduled quarterly is effective in improving the adherence to the threedose series of the human papillomavirus vaccine among girls and young women in a managed care setting. However, despite this intervention, a significant gap in series adherence remains to be addressed.

Vaccination with the quadrivalent human papillomavirus (HPV) vaccine (HPV4) presents an opportunity to reduce the burden of conditions caused by HPV types 6, 11, 16, and 18. The Advisory Committee on Immunization Practices (ACIP) recommends routine HPV4 vaccination for girls and boys aged 11–12 years with catch-up vaccination among those up to age of 26 years [1]. Girls and boys as young as 9 years old can also be

vaccinated at a provider's discretion. HPV4 vaccination requires the administration of three doses over a period of 6 months. Specifically, the ACIP recommends the second and third doses be administered 2 and 6 months after the first dose [1]. The vaccine label also suggests the three doses be completed within 12 months.

In the United States, HPV vaccination is generally not required by state law. As a result, the three-dose series may not always be completed by those who initiate the vaccine. In fact, despite steady increases in HPV vaccine initiation over time, the threedose series completion rates among girls and boys have been low, both as a proportion of the overall population and as a

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proportion of those who initiate the vaccine series. The National Immunization Survey-Teen reported that the percentage of adolescent girls age 13-17 years who have received all three doses of the HPV vaccine has increased from 18% in 2008, to 35% in 2011, and to 33% in 2012, comparing with 93% coverage rate for the three-dose hepatitis B vaccine in 2011 [2–4]. Among girls who have received at least one dose of vaccine, completion rates vary but are generally low. In our study at Kaiser Permanente Southern California (KPSC), a large managed care organization, only 43% of those females who initiated the vaccination completed the three-dose series within a 12-month period [5]. Other investigators have found completion rates in females ranging from 28% to 71% [3,6–9]. In fact, recent data indicate that HPV vaccine completion in the United States has actually decreased over time [10]. These data highlight an important and possibly growing gap in HPV vaccine coverage with respect to the series completion.

To realize the full public health benefit of the HPV vaccination program, efforts are critically needed to improve completion of the three-dose series. Several intervention studies have suggested that a reminder system may be effective in increasing HPV vaccine series completion [11–13]. However, interpretation of these results is difficult because of the nonrandomized design in these studies. We thus conducted a randomized study to evaluate the effectiveness of a quarterly reminder letter intervention on the HPV4 three-dose series completion.

#### Methods

#### Study setting and study population

KPSC is a large managed organization serving over 3.5 million members who are broadly representative of the diverse racial/ ethnic and socioeconomic background of the population in Southern California [14]. By nature of the prepaid managed care system, members of KPSC have relatively equal health care coverage. In particular, the HPV4 vaccines are offered to eligible members without additional out-of-pocket cost (variations in office visit copay exist but are small). Furthermore, the second and third doses of HPV vaccine can be administered at a nurse visit without office visit copay.

The eligibility criteria for this study were (1) female members who were between the ages of 9-26 years when receiving the first dose of the HPV4; (2) had at least 1 year of continuous KPSC membership at the beginning of the study, that is, February 13, 2013, to assess HPV vaccination history; (3) received at least one dose of HPV4 between November 13, 2012, and February 12, 2013, and with no more than two doses of HPV4 in entire utilization history; and (4) had a valid address in the membership file. Eligible members who met the following exclusion criteria were excluded from mailing: (1) those with indication for unresolved pregnancy at the time of mailing according to KPSC's electronic medical records (because HPV vaccination is not indicated during pregnancy); (2) those who had not met the minimum HPV vaccine dosing intervals specified by the ACIP, that is, a minimum of 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, and 24 weeks between doses 1 and 3 (this criterion was not applied in the first mailing but was incorporated in the mailing for the second, third, and fourth quarter); and (3) those who terminated KPSC membership during the evaluation period. Eligible females' statuses related to these exclusion criteria were examined at study baseline and

before each wave of subsequent mailing. This is because a subject's status could change during the study period and needed to be updated at each wave of mailing. Study subjects were followed to the end of the study despite that some may turn to be older than age 26 years during the study period. No new subjects were allowed to "age in" after the start of the study.

#### Study intervention

This is a randomized intervention study. Eighty percent of eligible females who met the eligibility criteria were randomly selected to receive the intervention. The intervention under study was a reminder letter, which included a message to remind members of the immunization schedule for the HPV4, the date of their first dose of HPV4, a message to encourage follow-up vaccination visits to complete the series, and the member service telephone number for the member's home medical center (to allow the member to call to schedule a follow-up vaccination visit). These messages were written at the 9th/10th grade reading level. The prescribing information and patient product information for the HPV4 were also enclosed along with the letter. The letter was customized to address each subject by her name and was made to be from the medical office of their primary care physician, as provider recommendation is the most common cited reason for HPV vaccine uptake [15]. Both the English and the Spanish versions of the reminder letter were enclosed in every mailing. A total of four waves of mailings, scheduled quarterly, were sent across the term of this program.

California law (AB499) permits adolescents age  $\geq$ 12 years to obtain medical care for the prevention of sexually transmitted infections (including the HPV vaccine) without parental consent. Thus, to protect study subjects' privacy about HPV vaccination, if the member was 12–26 years old at the first dose of HPV vaccination, the mailing was addressed directly to her. If the member was 9–11 years old at the first dose of HPV vaccination, the mailing was addressed to her parent/guardian. For this age group (9–11 years), parental consent is required for the second and the third dose of HPV vaccina at KPSC.

Three months after the date of mailing, HPV vaccination status of each study subject was examined. Only those in the intervention group who had not received all three doses of HPV4 and did not meet any of the exclusion criteria were sent another reminder letter.

#### Control group

To evaluate the effectiveness of the intervention, 20% of the eligible female members were randomly selected into a control group. The control groups received standard of care. No mailing of study reminder letter was made to females in the control group.

### Statistical analysis

The primary outcome of interest was the proportion of females who completed the three-dose series in the intervention and the control groups. This proportion was calculated as those who have received three doses of HPV4 by the end of the 12month evaluation period divided by the total number of subjects in the intervention or the control groups. This proportion was also calculated stratified by age at the first dose (9–17 and 18–26 years) and by race/ethnicity (white, black, Hispanic, and Download English Version:

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