

The Impact of a Group Health Cooperative HPV Vaccination Promotion Program  
on Initiation of the HPV Vaccine

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Abstract

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**Purpose:** The purpose of this study is to examine the impact of a Group Health Cooperative outreach and reminder program on initiation of the HPV vaccine among 10-12 year olds receiving care at seven Group Health clinics in Western Washington.

**Study Design:** The outreach and reminder initiative was a randomized control trial. Eligible children were randomized to receive an outreach letter and reminder calls about the HPV vaccine (intervention) or usual care (control). Randomization was at the child-level and stratified by clinic and gender, but outreach and reminder efforts were addressed and targeted to parents.

**Methods:** This study conducted a preliminary analysis of the impact of the outreach and reminder program on initiation of the HPV vaccine for the overall study population and stratified by age. Chi-square tests were used to assess associations between group assignment (intervention

or control) and receipt of HPV dose 1. Kaplan-Meier survival curves with log-rank tests were used to compare HPV vaccine initiation over time between the intervention and control groups.

**Results:** A total of 1,805 children were included in the study; 1,354 were randomized to the intervention and 451 to control. Our analysis included 1,770 children after excluding 35 children who disenrolled after randomization, but before the intervention began. Overall, the intervention was not significantly associated with initiation of the HPV vaccine; 398 (30.1%) intervention children received HPV dose 1 compared to 121 (27.1%) control children (Chi-square test,  $p=0.23$ ). There was also no association between the intervention and initiation of the HPV vaccine when the children were stratified by age (Chi-square test, 10 yrs,  $p=0.78$ ; 11 yrs,  $p=0.31$ ; 12 yrs,  $p=0.38$ ). The Kaplan-Meier analyses showed that the difference in the vaccine initiation rates between the groups was not significant, overall (Log-rank test,  $p=0.08$ ), nor when the children were stratified by age (Log-rank test, 10 yrs,  $p=0.71$ ; 11 yrs,  $p=0.10$ ; 12 yrs,  $p=0.31$ ). Yet, a secondary analysis looking at vaccine initiation from the start of the reminder calls to the end of the analysis period showed a 6.2% difference in vaccine initiation rates between the intervention and control groups for 11 year olds (Chi-square test,  $p=0.07$ , Log-rank test,  $p=0.06$ ).

**Conclusions:** Group Health's outreach and reminder program was not significantly associated with an increase in initiation of the HPV vaccine. However, while not significant, our data suggests that reminder calls may increase the initiation of the HPV vaccine among 11 year old children eligible for the vaccine in an insured population.

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And a final shout out to the eMPH 2013 cohort! What a special group of people. I couldn't have imagined going on this journey with anyone else. I cherish the friendships and connections that I made with this group and I know that I will know they will be in my life for many years to come.

## **DEDICATION**

This work is dedicated to my mother, Stephanie Gundersen, my champion.

## INTRODUCTION

The Human Papillomavirus (HPV) is the most common sexually transmitted infection in the United States (1). The Centers for Disease Control and Prevention (CDC) estimates that approximately 80 million people in the U.S., or one in four, are currently infected with HPV and there are approximately 14 million incident infections each year (2). The majority of HPV infections are cleared by a person's immune system within two years; however, persistent infections with high risk HPV subtypes (HPV 16 and 18) can lead to cancer (3). HPV infection is most commonly associated with cervical cancers, but it can cause other anogenital and oropharyngeal cancers as well as other diseases like genital warts (4). Approximately 17,600 women and 9,300 men are diagnosed with HPV-associated cancers each year (1). It has been estimated that it costs the U.S. health care system \$8.0 billion to prevent and treat HPV-related infections every year, infections that are preventable with the HPV vaccine (5).

The US Food and Drug Administration (FDA) has approved three HPV vaccines: Cervarix<sup>®</sup>, Gardasil<sup>®</sup>, and Gardasil<sup>®</sup> 9 (Appendix B). Cervarix<sup>®</sup> is only licensed for use in females, whereas both Gardasil<sup>®</sup> and Gardasil<sup>®</sup> 9 are approved for use in females and males. All three vaccines protect against the two most prevalent and virulent HPV strains: HPV 16 and 18, which cause approximately 70% of cervical cancers (3, 6). Gardasil<sup>®</sup> and Gardasil<sup>®</sup> 9 include protection against HPV 6 and 11, which cause 90% of genital warts (6, 7). Gardasil<sup>®</sup> 9, which offers protection against five additional HPV strains, has the potential to prevent up to 90% of cervical cancers (6, 8).

The HPV vaccine is a 3-dose series administered over six months. The CDC Advisory Committee on Immunization Practices (ACIP) recommends the vaccine for females and males

aged 11-12 years; nonetheless, the vaccine can be initiated as early as age nine. “Catch-up” vaccination is recommended for females up to age 26 and males up to age 21 as well as for men who have sex with men and immunocompromised men up to age 26. Dose 1 should be administered when adolescents reach the ACIP recommended age or as soon as possible thereafter. Dose 2 should be administered 1-2 months after dose 1 and dose 3 should be administered 4 months after dose 2 and 6 months after dose 1 (3). Children 11-12 years old have a greater immune response to the vaccine than older age groups, but more importantly, the vaccine is most effective when administered prior to the initiation of sexual activity and HPV exposure, and sexual debut is often earlier than many health care providers and parents realize (3, 9, 10).

The vaccine is safe and works well. The vaccines are over 90% effective against the strains included in the vaccines (8, 11, 12), and in the 10 years since its initial recommendation, there has been a 64% decrease in the prevalence of HPV-related disease in girls aged 14-19 years and a 34% decrease in women aged 20-24 years (13). Yet despite these promising results, the rate of HPV vaccination remains low. Nationally, as of 2014, 60% of girls 13-17 years old had received the first dose of the vaccine and only 39.7% of girls had completed the vaccine series. For boys 13-17 years old, 41.7% had received at least one dose of the vaccine and only 21.6% had completed the series (14). These rates are considerably lower than the 80% completion target set by the Health People 2020 initiative (15). The rates in Washington State are slightly better than the national average: 65.8% of girls have initiated the vaccine and 43.8% have completed the series and 53.8% of boys have initiated the vaccine and 24.6% have completed the series (14). Factors influencing the initiation of a vaccine series are different than those driving its completion (16). The HPV vaccine was not approved for use in males until 2009, and the

ACIP did not make a vaccination recommendation for males until 2011 (17). However, this does not fully explain why vaccine rates for boys continue to lag behind those for girls.

A 2014 report from the President's Cancer Panel on the HPV vaccine identified three main factors contributing to slow uptake of the vaccine: missed clinical opportunities, parent/guardian hesitancy to vaccinate, and access to vaccine services. In fact, the CDC has identified missed clinical opportunities as the primary reason HPV vaccine rates remain low (17). Health care providers play a key role and parents/guardians are more likely to vaccinate when they receive a recommendation from their provider (18). Practice-based reminder-recall programs have also been shown to increase immunization rates for children and adults (19).

In 2015, Group Health Cooperative, an integrated healthcare delivery system in the Pacific Northwest began a pilot outreach and reminder program to improve HPV vaccine initiation (dose 1) and completion (3 doses) rates among health plan members eligible for the vaccine. This analysis looks specifically at the impact of the pilot initiative on the receipt of HPV vaccine dose 1. A larger study is looking at the impact of the program on completion of the series and will examine the impact of the reminder program on completion of dose 2 and 3.

## **METHODS**

### **Setting and study population**

Seven Group Health clinics were selected to participate in the larger study based on the volume of adolescent patient populations. Four of the clinics are located north of Seattle, two are south of Seattle, and one is located in downtown Seattle. All clinics received two newly designed HPV vaccine educational resources for parents: a tri-fold brochure and a window cling for writing the target dates for HPV dose 2 and 3 for parents to take home (Appendix C). Clinics

were asked to place the brochures in a visible place at the clinic and offer the window cling to parents of children who received HPV dose 1.

Children aged 10-12 years assigned to one of the seven clinics and who had not received the HPV vaccine were eligible to participate in the outreach and reminder initiative. Children were randomized with a 3:1 allocation to the intervention or control group. Randomization was at the person-level and stratified both by clinic and gender. The study did not account for families with two or more eligible children. Three-quarters of the study population were randomized to the intervention group in order to provide sufficient power to evaluate the impact of phone and text message reminders on HPV dose 2 and 3.

This analysis was reviewed and approved by the Group Health Research Institute Institutional Review Board (IRB). The IRB approved the study's request for a waiver of consent and HIPAA authorization to collect data to conduct this analysis.

### **Usual Care**

At Group Health, routine childhood and adult vaccines are covered by a standing order in the electronic health record (EHR). This means that providers (physicians, physician assistants, nurse practitioners) and other clinical staff (registered nurses, licensed practical nurses, medical assistants) can encourage families to have their children vaccinated if they are the appropriate age and fit the clinical criteria for a particular vaccination. Group Health clinics have designated injection rooms staffed by nurses who administer shots and vaccines. Families can also bring an eligible child to a clinic injection room without any staff involvement, and the injection room nurse will vaccinate the child as long as they fit the appropriate clinical criteria.

EHR clinical alerts for the HPV vaccine begin on a child's 11<sup>th</sup> birthday. As long as the clinical alert stays active, providers are alerted any time they access a child's record for any reason (acute, urgent, or well child care). Providers and clinical staff may opportunistically offer the vaccine to 10 year olds if they are seen in the clinic close to their 11<sup>th</sup> birthday. They will also vaccinate 9-10 year olds if parents inquire and consent to vaccination.

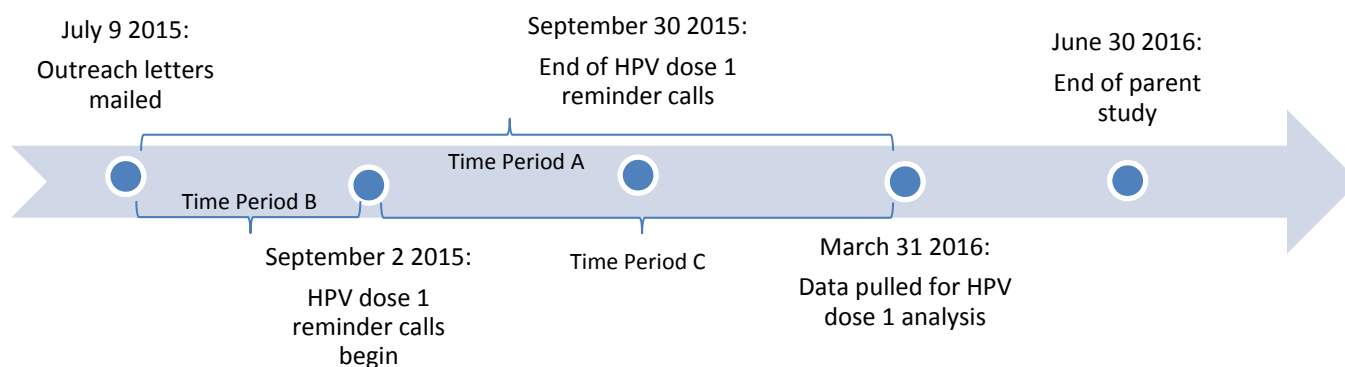
### **Intervention**

Outreach letters were mailed to the intervention group on July 9, 2015. The letters told parents that their child was eligible for the HPV vaccine and provided educational information about HPV disease, the HPV vaccine, and where parents could obtain the vaccine for their child (Appendix C). The letters were signed by a Group Health pediatrician and nurse from the Immunization Team and included an informational brochure about the vaccine that was designed for this study (20).

Intervention families received up to two reminder calls about dose 1 via an interactive voice response (IVR) system during the first two weeks of September 2015 (Appendix D). IVR is an automated telephone response system that interacts with callers and collects data via voice response and touch-tone keypad selection. The reminder call protocol and telephone scripts were developed by Group Health and Eliza, Inc. The reminder calls told parents that the call was a follow-up to the outreach letter they received and a reminder to take their child to get the first dose of the HPV vaccine. Parents were asked if they planned to take their child to get the vaccine in the next week or so. Those who responded in the affirmative were reminded that they could get the vaccine at any Group Health clinic without an appointment and were referred to Group Health's website to find the nearest clinic. Those who indicated that they were not planning to

get their child vaccinated soon were asked four questions about common barriers to HPV vaccination in order to try to better understand why they were not ready to take their child to get the vaccine. Parents were also encouraged to talk with their doctors about any questions or concerns they had about the HPV vaccine. If the target parent could not be reached, the IVR system could leave a message for the parent via voicemail or with the individual who received the call. The message told parents that Group Health was calling about their child's immunizations and asked the parents to call back. Parents could place inbound calls to the IVR system to receive the reminder message. As part of the IVR protocol, parents were also given the option to receive future HPV vaccine reminders via text message.

The intervention was designed based on the findings of a needs assessment Group Health conducted in fall 2014, which showed a gap in resources for providers to talk about the vaccine with parents and patients. Group Health also felt there was a need for vaccine reminders to address logistic barriers to vaccine initiation and series completion. Additionally, the intervention was informed by the President's Cancer Panel report on accelerating HPV vaccine uptake. The report identified developing more effective ways to communicate about HPV-related disease and the HPV vaccine as a high-priority research area. The report cited the need for more research to determine which strategies and messages work best for a variety of populations and to inform the development of tools providers can use to talk with adolescents and parents about HPV and the vaccine. The advisory panel also recommended that future research examine factors associated with the initiation and completion of the vaccine series to advise the development of better interventions (17).



**Figure 1.** Study timeline

## Analysis

For the purpose of this analysis, we defined the study period as starting on July 9, 2015, when the outreach letters were mailed to the intervention group, and ending on March 31, 2016, allowing for sufficient time for children to receive dose 1.

A priori least-detectable-difference calculations were performed to estimate sufficient sample size to achieve adequate power in the parent study. The sample size was determined by the number of eligible children identified at the seven participating clinics. All eligible children were randomized. All methods assumed a single child from each family. The analysis did not account for families with two or more eligible children.

Characteristics of the study children were described overall and by group assignment. Chi-square tests were used to compared gender, age, ethnicity, race, Group Health clinic, number of child well visits in the year prior to randomization, and receipt of the TDap, meningococcal, and flu vaccines between the intervention and control groups.

The primary outcome of interest was initiation of the HPV vaccine, defined as documented receipt of HPV dose 1 appearing in the EHR by March 31, 2016. All analyses related to vaccine initiation were conducted for the overall study population and stratified by age. Age stratification enabled the examination of the intervention's impact on vaccine initiation in each age group. Chi-square tests were used to evaluate the impact of the intervention by comparing proportions of children receiving HPV dose 1 in the intervention and control groups. The analysis also looked at percent difference of children receiving dose 1 in the intervention group compared to the controls and the corresponding 95% confidence intervals.

Kaplan-Meier survival curves and log-rank tests were used to compare HPV vaccine initiation over time between the intervention and control groups. Individual children who disenrolled before or didn't receive dose 1 by the end of the follow-up period were censored. We also conducted secondary analyses looking at initiation of the HPV vaccine in the intervention versus control groups during the time period between the letter mail date and the start of the reminder calls (time period B) and the time period from the reminder call start date to the end of the HPV dose 1 analysis (time period C) (Figure 1).

A two-sided 0.05 significance level was used to determine the statistical significance for all comparisons. Data were analyzed using SPSS (IBM version 22) statistical analysis software.

## **RESULTS**

Approximately, 2,729 children were enrolled at the Group Health clinics participating in the outreach and reminder initiative and 1,805 (66.1%) eligible children were identified that had not received HPV dose 1. Among these children, 1,354 were randomized to the intervention group and 451 to the control group. Of the 1,354 children randomized to the intervention group,

outreach letters were mailed to 1,323 families; 31 children had disenrolled before the outreach letters were sent. Four control group children disenrolled during the same time period. Our analysis included 1,770 children; 1,323 in the intervention group and 447 in the control group.

HPV dose 1 reminder calls were made to 1,207 intervention families. Dose 1 reminder calls were not made to 116 families whose child, per Group Health's vaccine data, had received HPV dose 1 before the reminder calls began (Figure 2). In fact, 186 intervention children had received HPV dose 1 before the reminder calls began (Table 3). This discordance is due to a lag in the upload of vaccination data into Group Health data systems.

During the dose 1 analysis period, 119 (6.7%) children disenrolled from Group Health; 83 (6.3%) in the intervention group and 36 (8.1%) in the control group. These children were censored in the Kaplan-Meier analysis at the time they disenrolled.

There were no significant demographical differences between the intervention and control groups (Chi-square test,  $p > 0.05$ ; Table 1). Girls and boys were equally represented in the study population. Almost half of the children were 10 years old, 31.9% were 11 years old, and 19.8% were 12 years old. The majority of the children were not Hispanic/Latino (87.7%) and White (64.9%); 16.2% were Asian, and 6.3% were African American. About half of these children had a wellness visit in the year prior to randomization and had used MyGroupHealth (Group Health's patient website, [www.ghc.org](http://www.ghc.org)) since 2014. Approximately 30% of the children received the TDap and meningococcal vaccines during the study period. The intervention and control groups were similar with regard to gender, age, race, ethnicity, Group Health clinic assignment, number of wellness visits in the year prior to randomization, MyGroupHealth use, and receipt of the TDap, meningococcal, and flu vaccines during the study period.

Vaccine initiation rates were higher in the intervention group compared to controls (Table 2), but the differences were not significant; 398 (30.1%) intervention children received HPV dose 1 compared to 121 (27.1%) control children (Chi-square test,  $p=0.23$ ; Table 2). There was no association between the intervention and receipt of HPV dose 1 when the children were stratified by age (Chi-square test, 10 yrs,  $p=0.78$ ; 11 yrs,  $p=0.31$ ; 12 yrs,  $p=0.38$ ; Table 2). The largest difference in vaccine initiation, 4.9%, was seen among the 11 year olds (Table 2). The Kaplan-Meier analyses showed that the difference in the vaccine initiation rates between the groups was not significant, overall (Log-rank test,  $p=0.08$ ; Figure 3) and when the children were stratified by age (Log-rank test, 10 yrs,  $p=0.71$ ; 11 yrs,  $p=0.10$ ; 12 yrs,  $p=0.31$ ; Figure 4).

There were no differences in vaccine initiation for the intervention and control groups, overall and stratified by age, during the time period between when the outreach letters were mailed on July 9, 2015 and when the dose 1 reminder calls began on September 2, 2015 (Chi-square test and Log-rank test,  $p>0.05$ ; Table 3 and Figure 4).

During the time between when the reminder calls began and the end of the dose 1 analysis, the intervention was not significantly associated with HPV vaccine initiation, overall and when the children were stratified by age (Chi-square test,  $p > 0.05$ ; Table 4). The Kaplan Meier analyses show a similar result (Log-rank test,  $p > 0.05$ ; Figure 4). Still, during this time period there was a 6.2% difference in vaccine initiation rates between the intervention and control groups for the 11 year olds (Chi-square test,  $p=0.07$  and Log-rank test,  $p=0.06$ ; Table 4 and Figure 4).

## **DISCUSSION**

This analysis examined the impact of an outreach and reminder program on initiation of the HPV vaccine. We found that the intervention was not significantly associated with HPV vaccine initiation; 30.1% of the intervention children received HPV dose 1 compared to 27.1% of the control children. There was also no association between the intervention and receipt of HPV dose 1 when the children were stratified by age. Vaccine initiation rates were higher in the intervention group compared to controls, but the differences were not significant. The largest difference in vaccine initiation, 4.9%, was seen among the 11 year olds. The results of the Kaplan Meier survival analyses were also not significant, overall or when stratified by age. The outreach letter alone may not be a sufficient intervention “dose” to impact vaccine initiation rates, but the 6.2% greater initiation rate in the 11 year olds following the reminder calls may indicate the presence of some impact that should be explored further.

Increasing HPV vaccine coverage is a national priority with a focus on strategies to increase receipt and completion of the vaccine series. A systematic review of patient reminder and recall systems for immunizations found that they are effective at increasing adult and child immunization rates (19). However, the review only included one study of adolescent immunization reminders that looked at the impact of an autodial reminder system in a low-income, urban population and had negative results (19, 21).

Although our findings were not significant, we did see a modest increase in vaccination rates in the intervention group, consistent with other studies of reminder/recall programs for adolescent immunization. None of the studies focused solely on vaccination initiation. They looked at HPV vaccine uptake and series completion or exclusively at vaccine series completion. In general, telephone reminders had more impact than mailed reminders and text messages

appeared to influence immunization behavior when parents and adolescents opted-in to receive them (22-27). A reminder/recall initiative at Kaiser Permanente Southern California, which has a similar health plan and care delivery model to Group Health, randomized its 9-26 year old female members to receive a quarterly outreach letter about the HPV vaccine or usual care. Letters sent to 9-11 year old members were addressed to parents; letters sent to members 12 years and older were addressed to the member. HPV vaccine series completion increased in the intervention group by approximately 10% (28).

We may have initiated the program too early for 10 year olds more than 6 months away from their 11<sup>th</sup> birthday. Parents of children in this age group may not have considered them eligible for the vaccine. The 12 year olds, on the upper end of the ACIP recommendations, may have already chosen to delay the vaccine for some reason and may be inherently different from the 10 and 11 year olds. This age group may need different strategies or messaging to motivate them to initiate the vaccine.

Interestingly, rates for other adolescent vaccines, the tetanus, diphtheria, pertussis (TDap) booster and meningococcal conjugate (MenACWY) vaccine, which are also recommended for 11-12 year olds, are much higher than those for HPV and in line with national targets. Nationally, the TDap vaccination rate is 87.6% and the MenACWY rate is 79.3%. In Washington State, the TDap vaccination rate is 88.5% and the MenACWY rate is 82.1% (14). The TDap vaccine is required for school in Washington State; the MenACWY and HPV vaccines are not. The school requirement does not completely explain the higher vaccination rates. Even though MenACWY is not required for school, its vaccination rate is still high, on par with TDap. Some parents and caregivers are reluctant to vaccinate their children for HPV. They question the need to vaccinate when children are not sexually active and worry that vaccination

may encourage sexual activity, although several studies have shown this not to be the case (9). There are no contraindications to receiving the three vaccines, TDap, MenACWY, and HPV, together. Our data show an association between receipt of the TDap and MenACWY vaccines and the HPV vaccine (data not shown). Providers and clinical staff could capitalize on clinical and vaccine opportunities to encourage receipt of all three adolescent vaccines at the same time, as a panel (29), establishing a social norm around getting all three vaccines together.

Cost and access can also be barriers to HPV vaccine receipt. All vaccines for children less than 19 years old are paid for by the Washington State Childhood Vaccine Program, but getting the vaccine can be a significant logistical problem. Getting to a doctor's office or clinic to receive the three doses of the HPV vaccine on schedule, or even at all, is challenging for busy families with competing priorities. A reduced dosing schedule and the ability to receive the vaccine at alternate venues, such as pharmacy-based clinics or school-based clinics, could help increase vaccine series initiation and completion rates. A two-dose version of the vaccine has been approved and is in use in other countries, but not the U.S. Studies of the effectiveness of the two-dose vaccine are ongoing and promising (30). In King County, Washington, school-based health centers can provide immunizations to students with parental consent.

Additional research on modes and messaging for reminder and recall programs targeted at adolescent populations and their parents is needed to inform best practices for increasing HPV vaccination rates. Qualitative research is also needed to better understand the barriers to vaccine initiation at the parent, provider, and system level.

## **Limitations**

This study has limitations. The study population is an insured, urban population, so the findings may not be generalizable to other settings. Also, all seven Group Health clinics participating in the outreach and reminder program received the new HPV brochure and window clings. Control families could have been exposed to the new HPV materials at their clinics and clinic staff could have altered their usual care practices given their exposure to the intervention. We do not have a way to measure the impact or role the materials may have played on HPV vaccine initiation in either the intervention or control groups. However, since there was no observed difference in vaccine initiation rates after the outreach letters were sent, it's unlikely that the clinic materials or practices had an impact on vaccine initiation.

## **CONCLUSIONS**

Overall, Group Health's outreach and reminder program was not significantly associated with an increase in initiation of the HPV vaccine. However, while not significant, our data suggests that reminder calls may increase the initiation of the HPV vaccine among 11 year old children eligible for the vaccine.

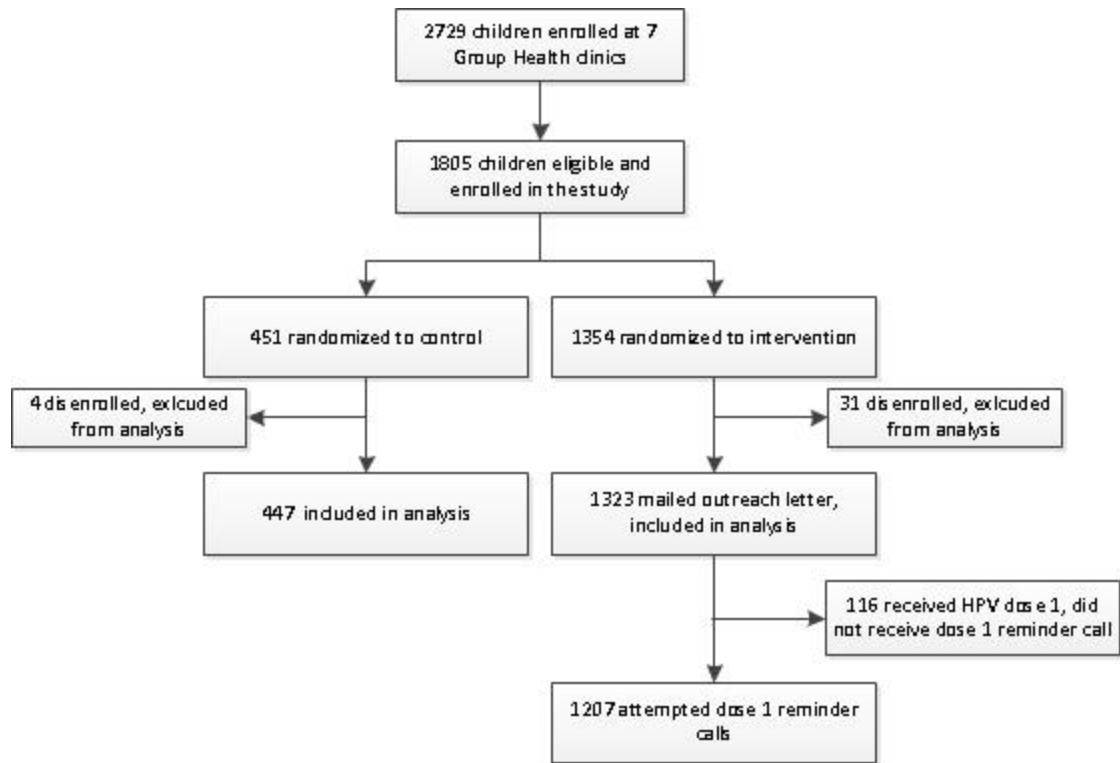
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**Figure 2.** Consort diagram

**Table 1.** Characteristics of the study population

	<b>All Participants n = 1770</b>	<b>Intervention Group n = 1323 (74.7)</b>	<b>Control Group n = 447 (25.3)</b>	<b>P-Value</b>
<b>Female</b>	858 (48.5)	642 (48.5)	216 (48.3)	0.94
<b>Age at Randomization</b>				0.66
10 year olds	855 (48.3)	645 (48.8)	210 (47.0)	
11 year olds	564 (31.9)	422 (31.9)	142 (31.8)	
12 year olds	351 (19.8)	256 (19.3)	95 (21.3)	
<b>Ethnicity</b>				0.53
Hispanic/Latino	106 (6.0)	79 (6.0)	27 (6.0)	
Not Hispanic/Latino	1553 (87.7)	1166 (88.1)	387 (86.6)	
Unknown/not reported	111 (6.3)	78 (5.9)	33 (7.4)	
<b>Race</b>				0.55
American Indian/Alaskan Native	30 (1.7)	23 (1.7)	7 (1.6)	
Asian	287 (16.2)	215 (16.3)	72 (16.1)	
Native Hawaiian or Pacific Islander	32 (1.8)	24 (1.8)	8 (1.8)	
Black or African American	111 (6.3)	83 (6.3)	28 (6.3)	
White	1149 (64.9)	868 (65.6)	281 (62.9)	
Unknown/not reported	161 (9.1)	110 (8.3)	51 (11.4)	
<b>Clinics</b>				1.00
Clinic 1	288 (16.3)	214 (16.2)	74 (16.6)	
Clinic 2	309 (17.5)	232 (17.5)	77 (17.2)	
Clinic 3	191 (10.8)	142 (10.7)	49 (11.0)	
Clinic 4	315 (17.8)	236 (17.8)	79 (17.7)	
Clinic 5	189 (10.7)	142 (10.7)	47 (10.5)	
Clinic 6	273 (15.4)	204 (15.4)	69 (15.4)	
Clinic 7	205 (11.6)	153 (11.6)	52 (11.6)	
<b>No. wellness visits in the year prior to randomization</b>				0.57
0 visits	904 (51.1)	673 (50.9)	231 (51.7)	
1 visit	832 (47.0)	627 (47.4)	205 (45.9)	
2 visits	34 (1.9)	23 (1.7)	11 (2.5)	
<b>MyGroupHealth use since 2014</b>	840 (47.5)	634 (47.9)	206 (46.1)	0.50
<b>Received TDap during the study period</b>	559 (31.6)	424 (32.0)	135 (30.2)	0.47
<b>Received meningococcal during the study</b>	558 (31.5)	420 (31.7)	138 (30.9)	0.73
<b>Received flu during the study period</b>	669 (37.8)	506 (38.2)	163 (36.5)	0.50

**Table 2.** Receipt of HPV vaccine dose 1 during the study period, July 9, 2015-March 31, 2016 (Time period A)

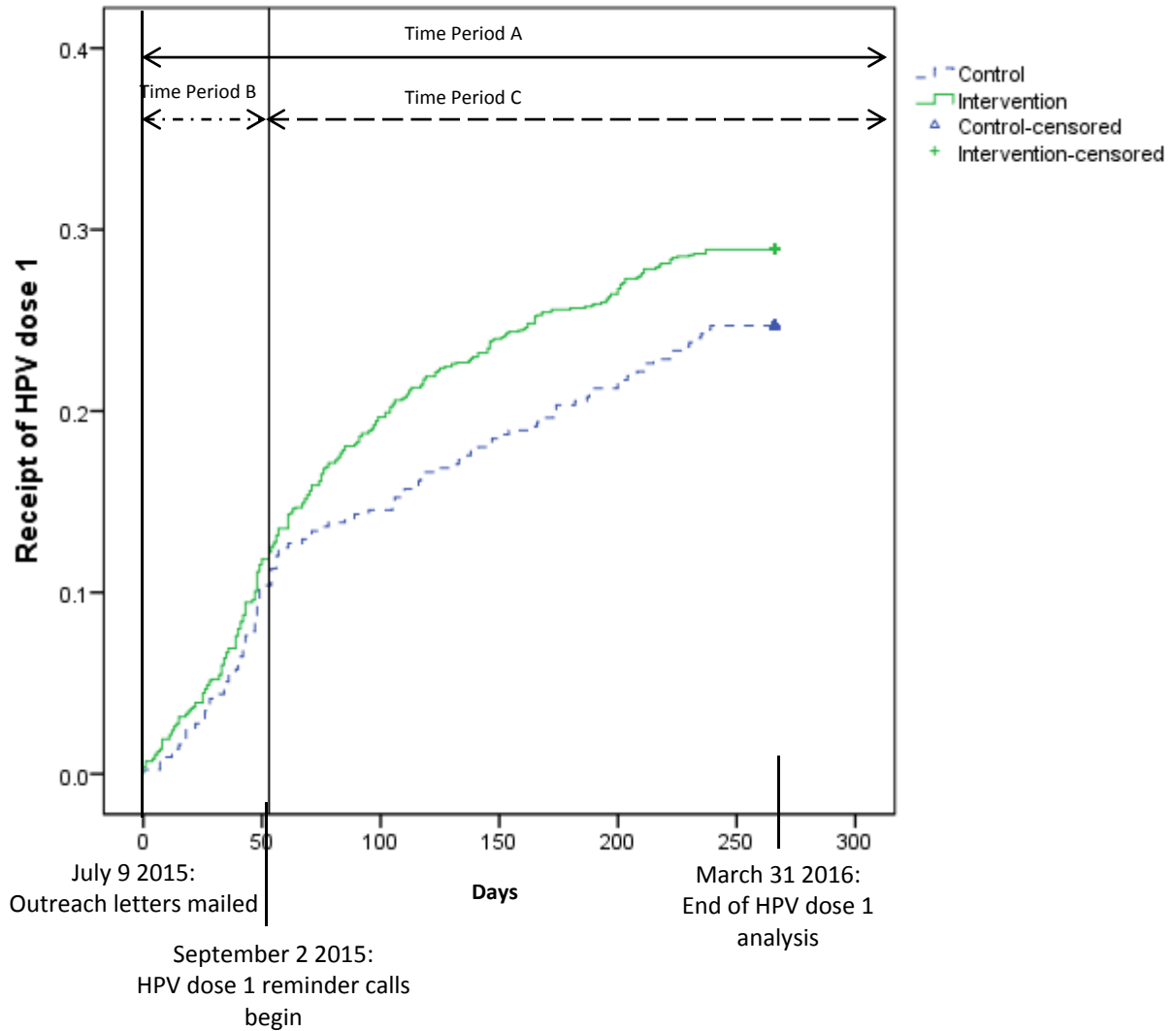
	<b>Intervention Group N(%)</b>	<b>Control Group N(%)</b>	<b>Difference in vaccine rates (%) (95% CI)</b>	<b>P-Value</b>
<b>All Children</b>	398 (30.1)	121 (27.1)	3.0 (-1.8, 7.8)	0.23
<b>Age at Randomization</b>				
10 years	169 (26.2)	53 (25.2)	1.0 (-5.8, 7.7)	0.78
11 years	175 (41.5)	52 (36.6)	4.9 (-4.4, 14.1)	0.31
12 years	54 (21.1)	16 (16.8)	4.3 (-4.8, 13.3)	0.38

**Table 3.** Receipt of HPV vaccine dose 1 between July 9, 2015, when the outreach letter was mailed, and September 2, 2015, when the reminder calls started (Time period B)

	<b>Intervention Group N(%)</b>	<b>Control Group N(%)</b>	<b>Difference in vaccine rates (%) (95% CI)</b>	<b>P-Value</b>
<b>All Children</b>	186 (14.1)	62 (13.9)	0.2 (-3.5, 3.9)	0.92
<b>Age at Randomization</b>				
10 years	54 (8.4)	15 (7.1)	1.3 (-2.9, 5.3)	0.57
11 years	107 (25.4)	38 (26.8)	-1.4 (-9.8, 7.0)	0.74
12 years	25 (9.8)	9 (9.5)	0.3 (-6.6, 7.2)	0.94

**Table 4.** Receipt of HPV vaccine dose 1 between September 2, 2015, when the reminder calls started, and March 31, 2016, the end of the HPV dose 1 analysis (Time period C)

	<b>Intervention Group N(%)</b>	<b>Control Group N(%)</b>	<b>Difference in vaccine rates (%) (95% CI)</b>	<b>P-Value</b>
<b>All Children</b>	212 (16.0)	59 (13.2)	2.8 (-0.9, 6.5)	0.15
<b>Age at Randomization</b>				
10 years	115 (17.8)	38 (18.1)	-0.3 (-6.3, 5.7)	0.93
11 years	68 (16.1)	14 (9.9)	6.2 (0.2, 12.3)	0.07
12 years	29 (11.3)	7 (7.4)	3.9 (-2.6, 10.5)	0.28

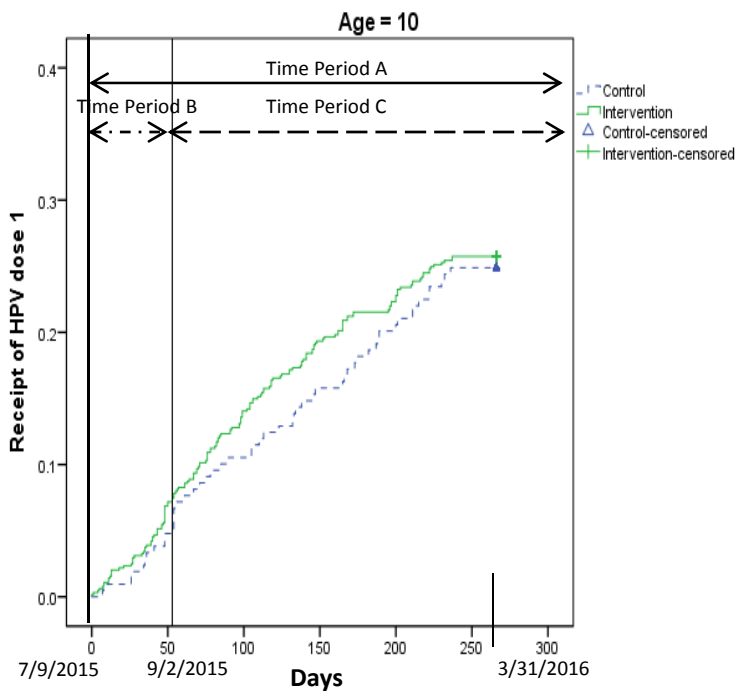


**Figure 3.** Kaplan-Meier analyses of time from July 9, 2015 to receipt of first HPV vaccine dose for all children. The x-axis represents time in days from July 9, 2015 to receipt of first HPV vaccine dose. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is March 31, 2016.

**Time period A:** July 9, 2015 to March 31, 2016. Outreach letter mail date to the end of the HPV dose 1 analysis. P-value = 0.08.

**Time period B:** July 9, 2015 to September 2, 2015. Outreach letter mail date to the start of the reminder calls. P-value = 0.43.

**Time period C:** September 2, 2015 to March 31, 2016. Start of the reminder calls to the end of the HPV dose 1 analysis. P-value = 0.09.

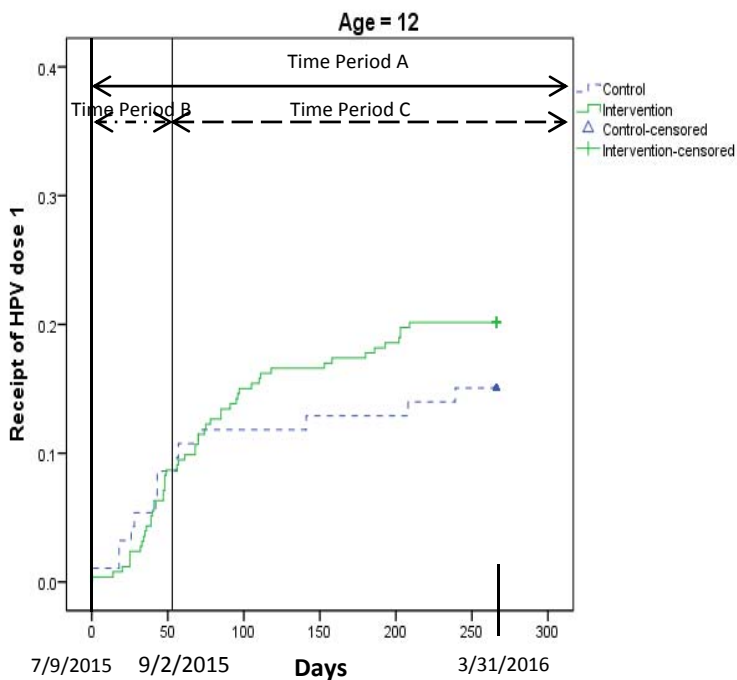
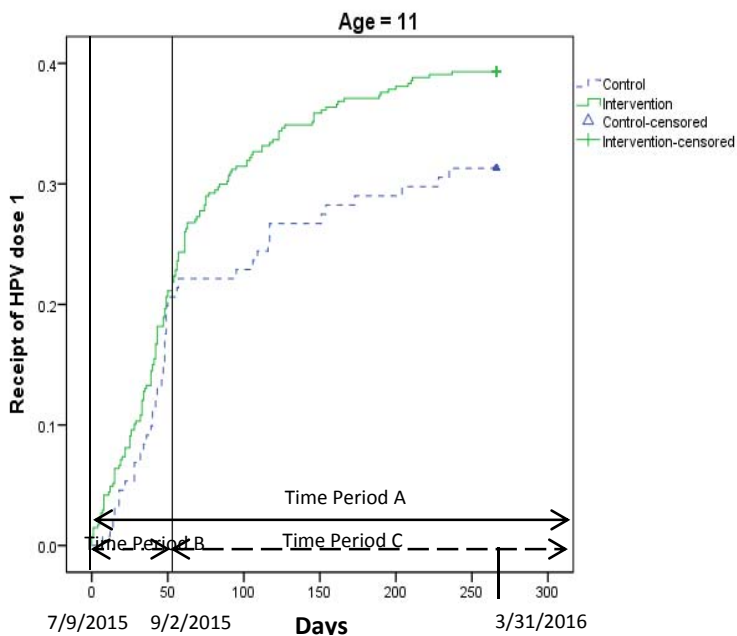


**Figure 4.** Kaplan-Meier analyses of time to receipt of first HPV vaccine dose, stratified and by age. The x-axis represents time in days. The y-axis represents the cumulative proportion of children who initiated the vaccine series.

**Time period A:** July 9, 2015 to March 31, 2016. Outreach letter mail date to the end of the HPV dose 1 analysis.  
 10 yrs, p-value= 0.71  
 11 yrs, p-value= 0.10  
 12 yrs, p-value= 0.31

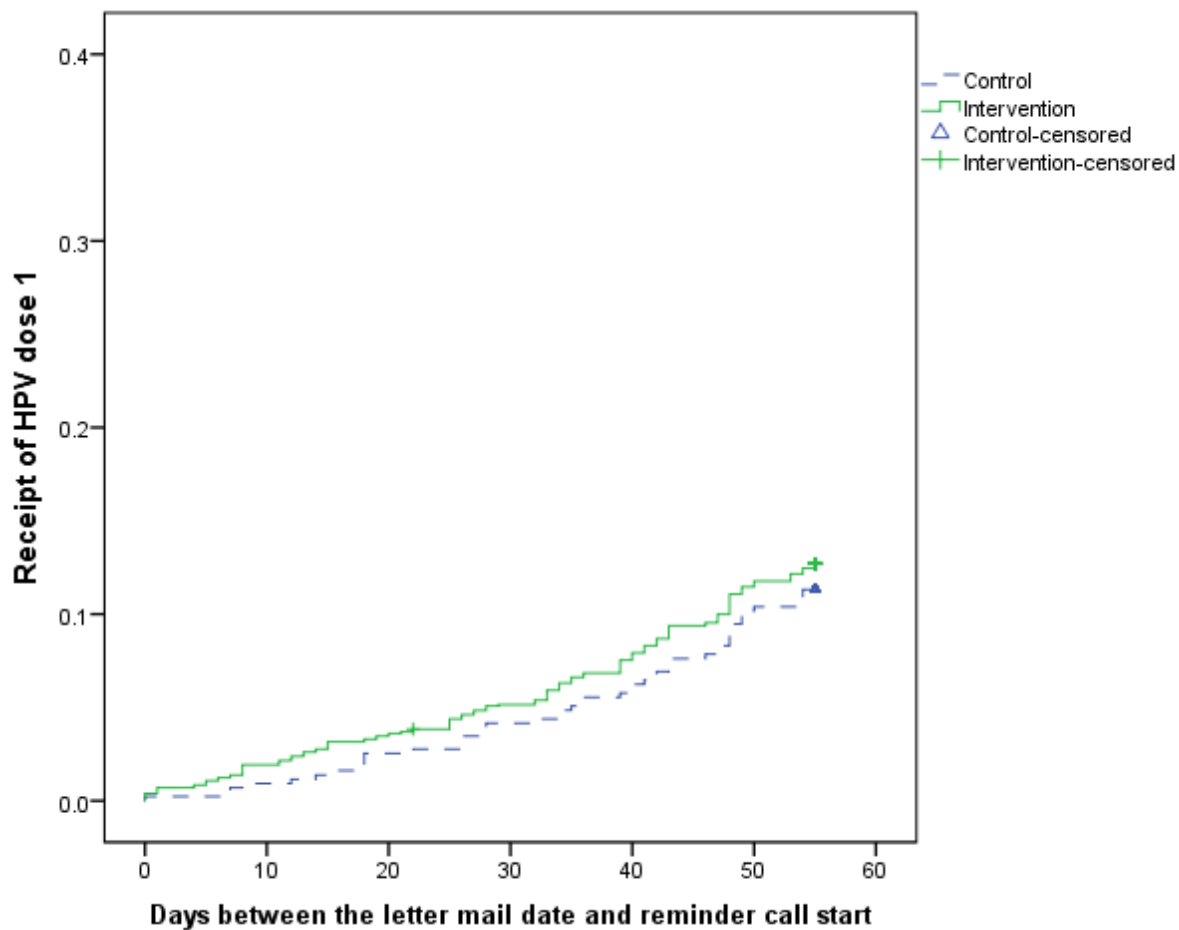
**Time period B:** July 9, 2015 to September 2, 2015. Outreach letter mail date to the start of the reminder calls.  
 10 yrs, p-value= 0.54  
 11 yrs, p-value= 0.56  
 12 yrs, p-value= 1.00

**Time period C:** September 2, 2015 to March 31, 2016. Start of the reminder calls to the end of the HPV dose 1 analysis.  
 10 yrs, p-value= 0.92  
 11 yrs, p-value= 0.06  
 12 yrs, p-value= 0.17

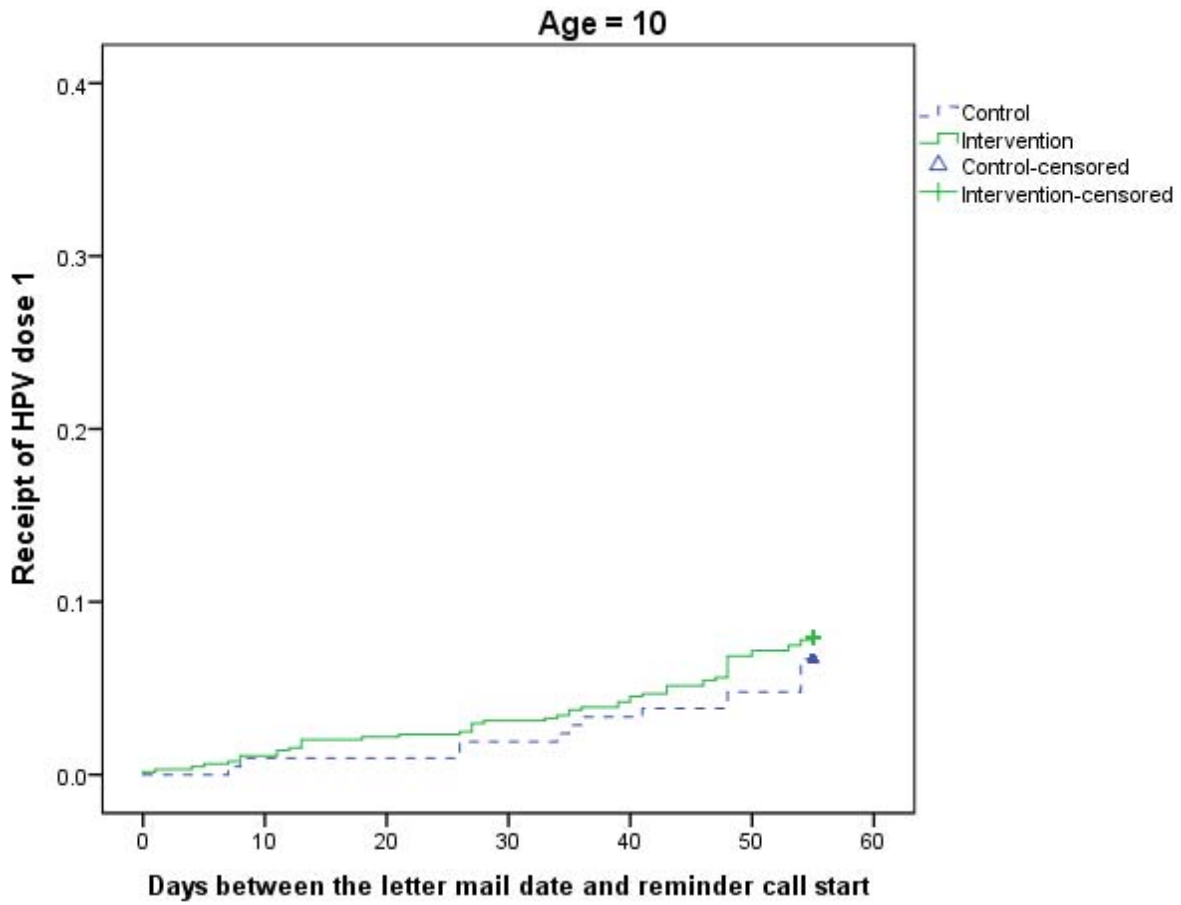


## Appendix A

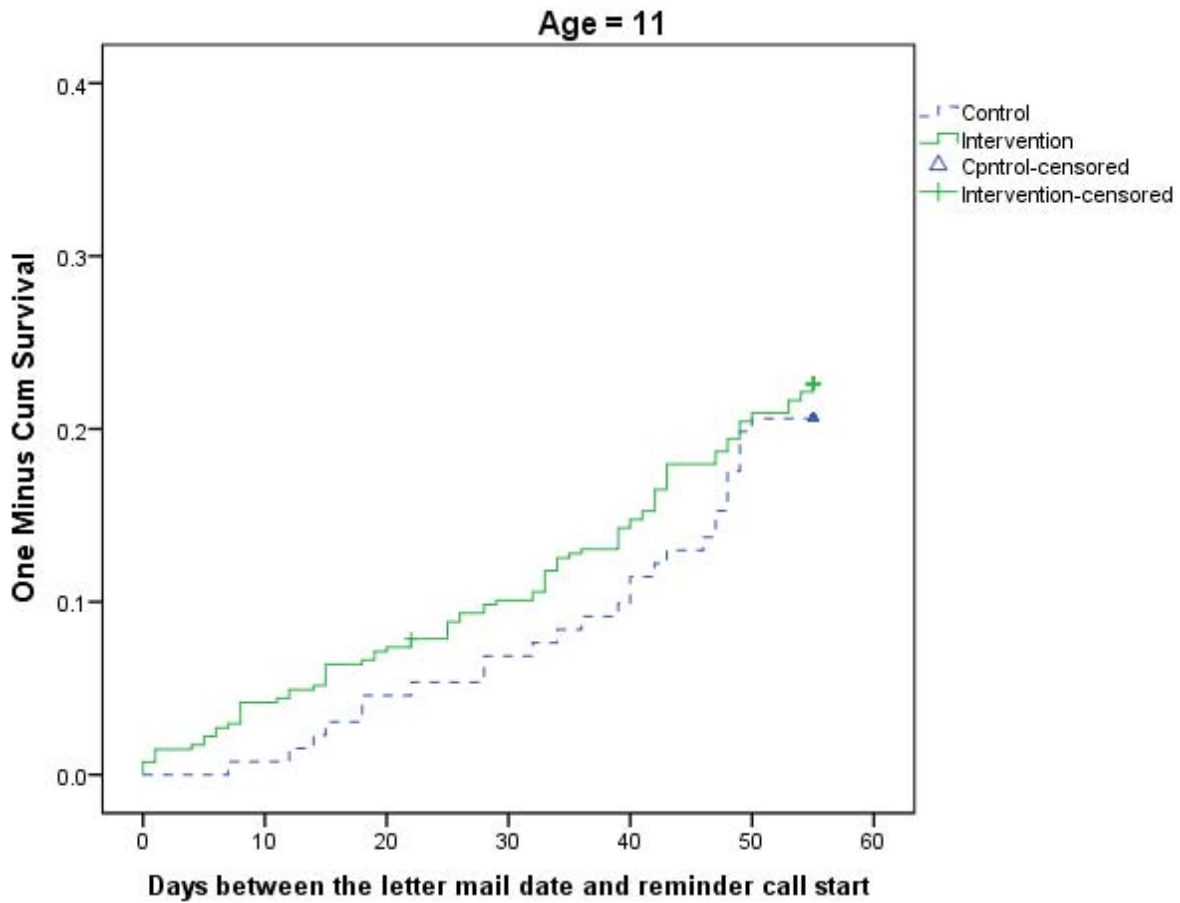
### Additional Kaplan Meier Analyses



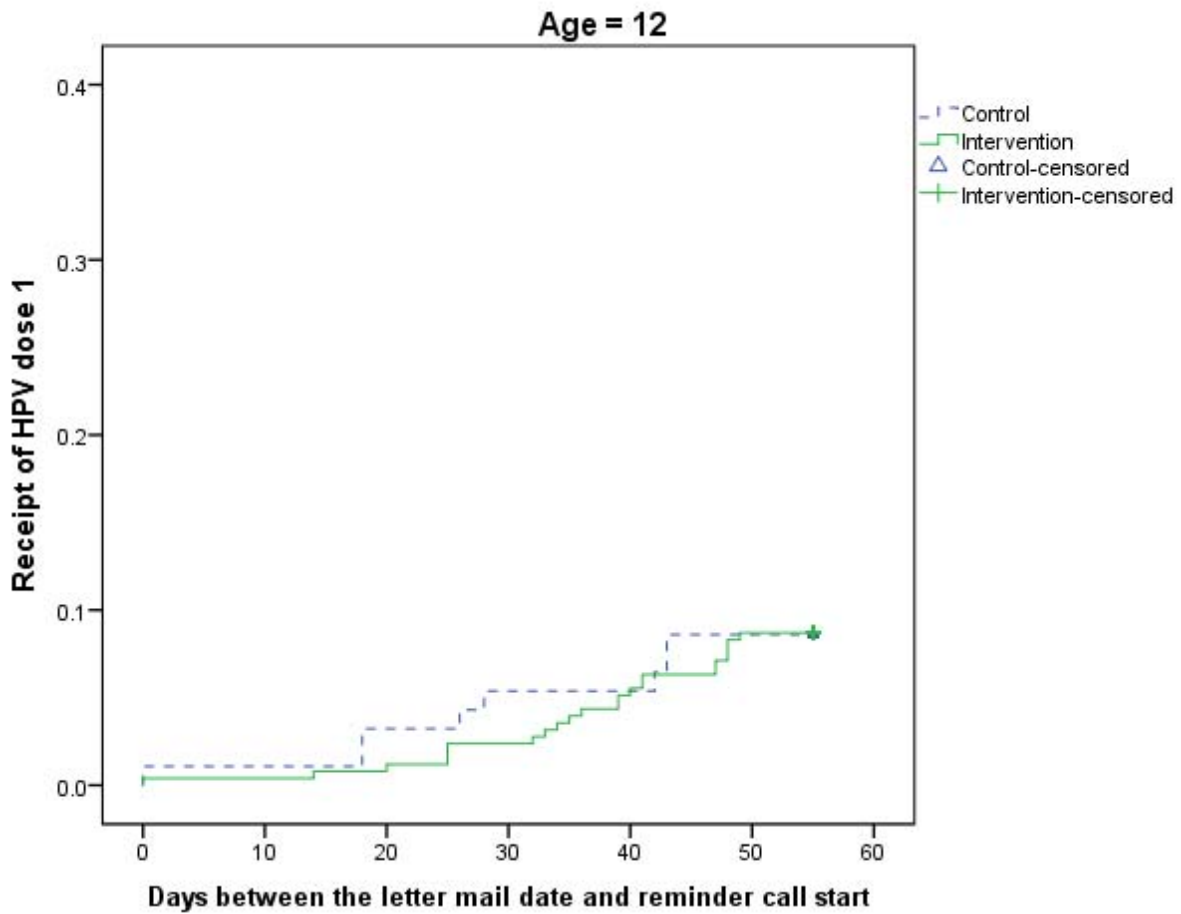
Kaplan-Meier analyses for time period B. The x-axis represents time in days from the mailing of the outreach letter to the start of the dose 1 reminder calls. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is September 2, 2015. P-value = 0.43.



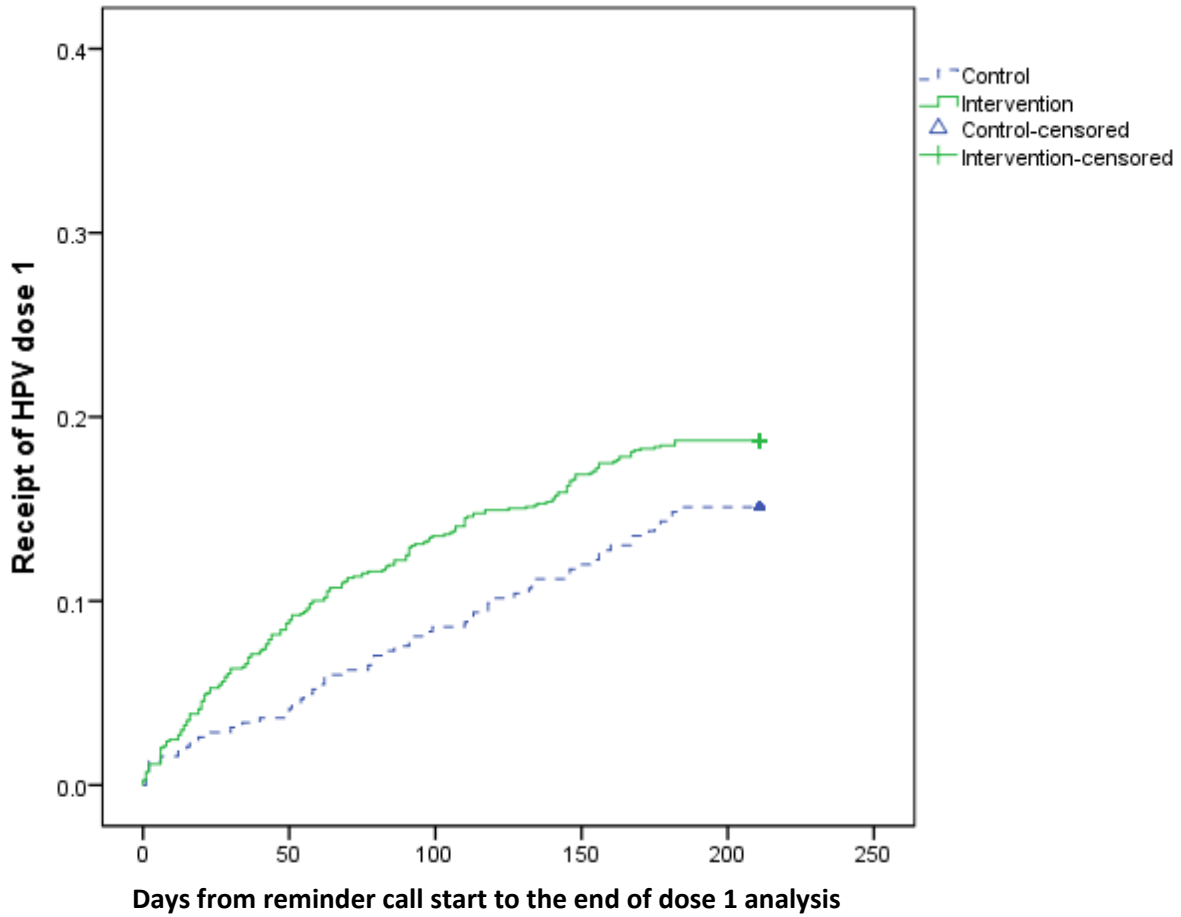
Kaplan-Meier analyses for time period B for 10 year olds. The x-axis represents time in days from the mailing of the outreach letter to the start of the dose 1 reminder calls. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is September 2, 2015.  
P-value = 0.54.



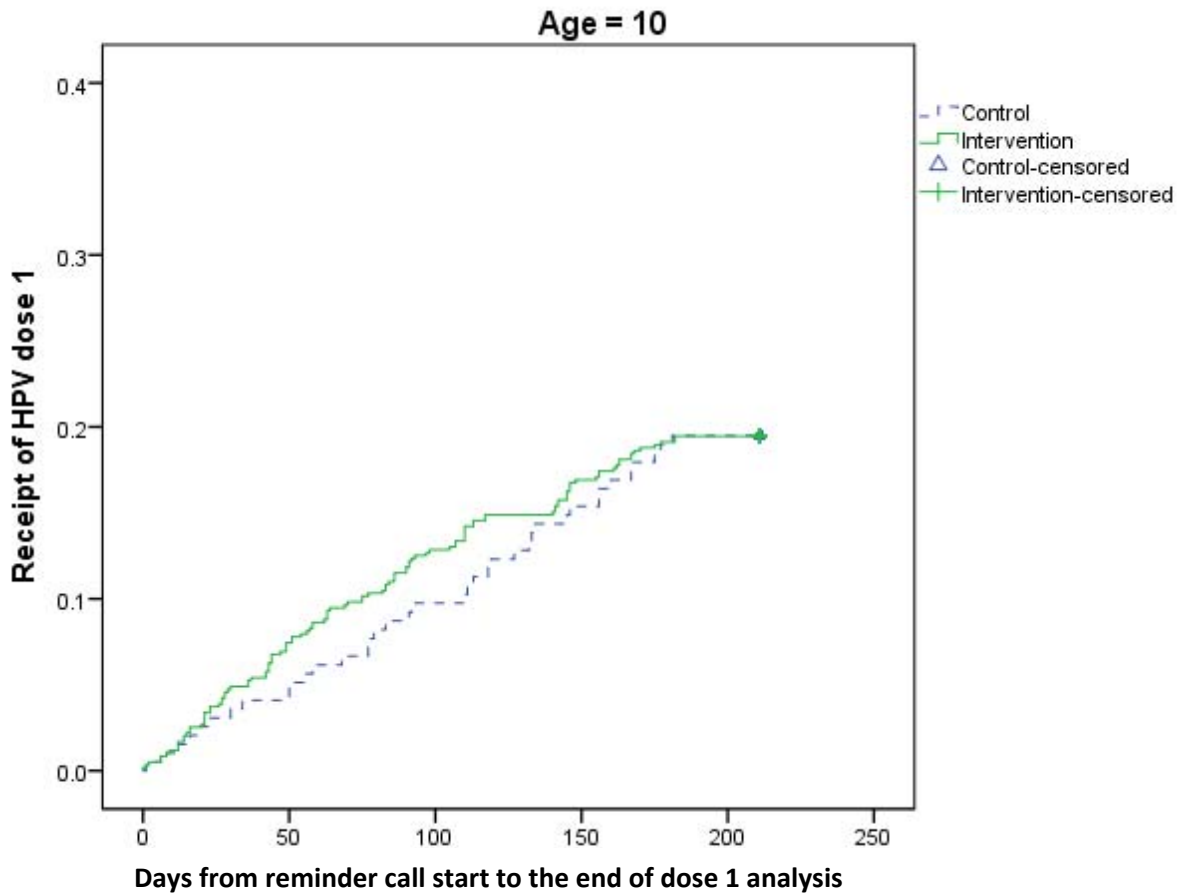
Kaplan-Meier analyses for time period B for 11 year olds. The x-axis represents time in days from the mailing of the outreach letter to the start of the dose 1 reminder calls. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is September 2, 2015.  
P-value = 0.56.



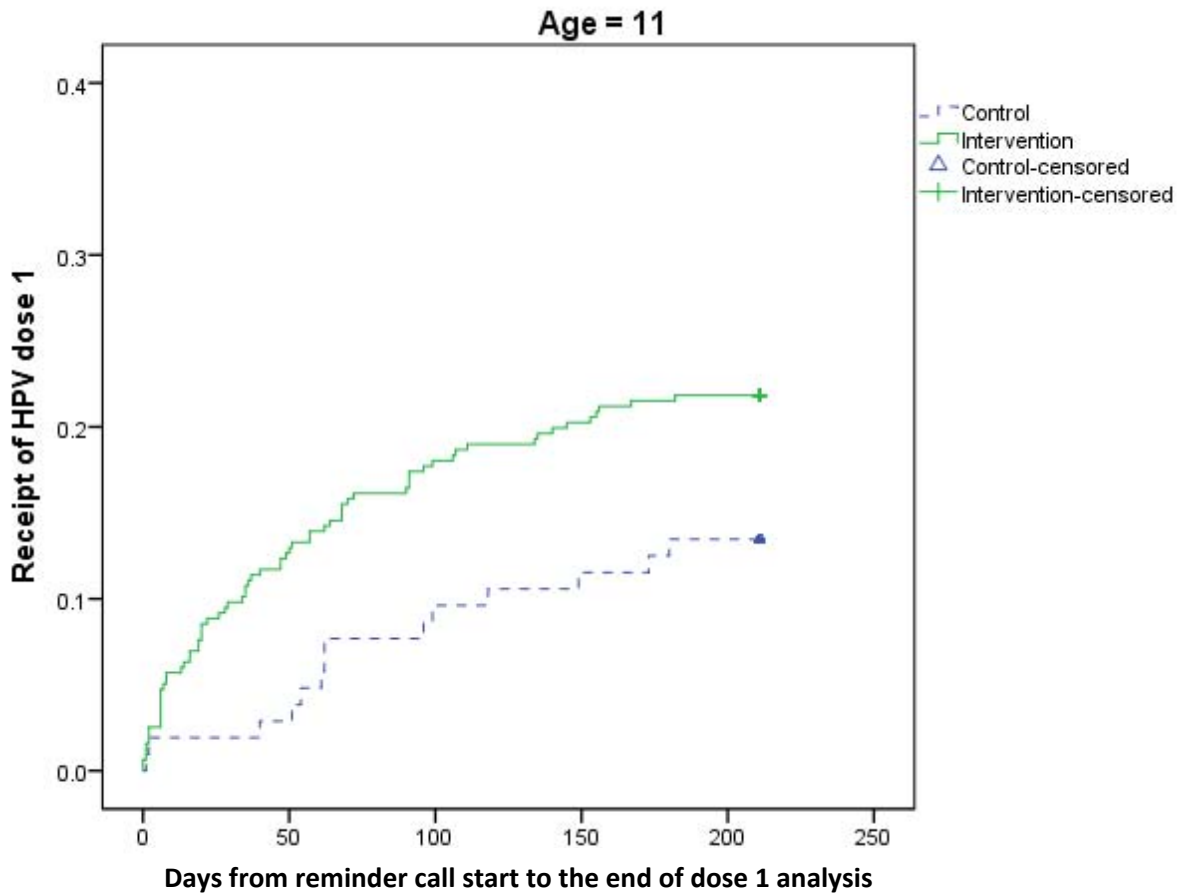
Kaplan-Meier analyses for time period B for 12 year olds. The x-axis represents time in days from the mailing of the outreach letter to the start of the dose 1 reminder calls. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is September 2, 2015.  
P-value = 1.00.



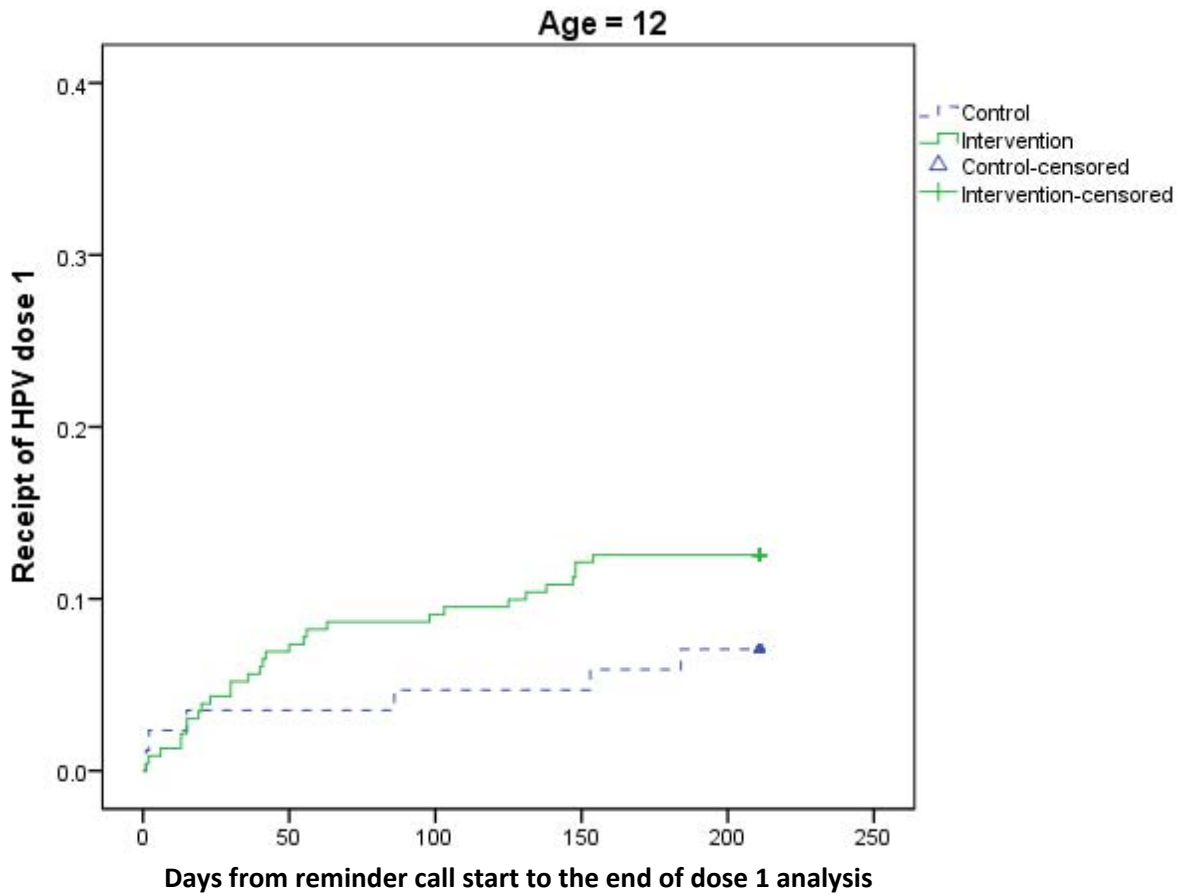
Kaplan-Meier analyses for time period C. The x-axis represents time in days from the start of the dose 1 reminder calls to the end of the HPV dose 1 analysis. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is March 31, 2016. P-value = 0.09.



Kaplan-Meier analyses for time period C for 10 year olds. The x-axis represents time in days from the start of the dose 1 reminder calls to the end of the HPV dose 1 analysis. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is March 31, 2016.  
P-value = 0.92.



Kaplan-Meier analyses for time period C for 11 year olds. The x-axis represents time in days from the start of the dose 1 reminder calls to the end of the HPV dose 1 analysis. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is March 31, 2016.  
P-value = 0.06.



Kaplan-Meier analyses for time period C for 12 year olds. The x-axis represents time in days from the start of the dose 1 reminder calls to the end of the HPV dose 1 analysis. The y-axis represents the cumulative proportion of children who initiated the vaccine series. End date is March 31, 2016.  
P-value = 0.17.

## APPENDIX B

### HPV Vaccines Licensed for Use in the United States

	<b>Bivalent (2vHPV)*</b>	<b>Quadrivalent (4vHPV)</b>	<b>9-valent (9vHPV)</b>
Brand name	Cervarix <sup>®</sup>	Gardasil <sup>®</sup>	Gardasil <sup>®</sup> 9
Manufacturer	GlaxoSmithKline	Merck	Merck
Protection against HPV strains	16,18	6,11,16,18	6,11,16,18,31,33,45,52,58
FDA approval	10/2009 - Females	06/2006 - Females 10/2009 - Males	12/2014 - Females & Males

# **APPENDIX C**

## **Outreach and Reminder Program Materials**

Dear Parent or Guardian,

*You are receiving this letter because your child is eligible for the human papillomavirus (HPV) vaccine.*

Group Health is committed to your family's health. We seek to provide the best information, expert advice, and support possible to help your family make health care decisions. One of those decisions will soon be whether to have your child vaccinated for HPV.

The HPV vaccine is recommended for boys and girls 11-12 years old. Most people are exposed to HPV at some point in their lives and HPV infection can cause several cancers in men and women as well as genital warts. Fortunately, most HPV-related cancers and warts can be prevented by the HPV vaccine. The vaccine is given in three doses over six months and is available at Group Health clinics, other in-network clinics, and Group Health CareClinics at Bartell Drugs.

As co-chairs of the Group Health Immunization Team, we strongly recommend you vaccinate your child against HPV. The vaccine will be offered at your child's 11 year-old well visit, along with the meningococcal and TDap vaccines. It is also available any time your child visits a health care provider, or when you drop-in at a Group Health clinic.

We know families have busy schedules so, in partnership with Group Health Research Institute, we are also trying a new HPV vaccine reminder program in several clinics. When your child receives the first HPV vaccine shot, you may be selected to participate. Parents in the program receive text messages or phone calls when their child is due for HPV vaccine doses 2 and 3.

If you are selected to participate, you will receive a phone call notification asking if you prefer text messages or phone calls. You may also elect to opt-out of the program.

For more information, please see the enclosed brochure and visit <https://www.grouphealthresearch.org/live-healthy/top-topics/vaccines/>.

Regards,



John Dunn, MD  
Co-Chair, Immunization Team



Kristine Moore, MN, RN  
Co-Chair, Immunization Team

## What you need to know

- The HPV vaccine protects your child from cancer and genital warts.
- For full protection, both girls and boys need to get vaccinated at 11-12 years old—well before they become sexually active.
- Make sure your child gets all three doses of the vaccine.

**Dose 1** – At age 11, or as soon as possible after.

**Dose 2** – Two months after dose 1.

**Dose 3** – Four months after dose 2.



### The HPV vaccine is:

#### Safe.

Years of testing and monitoring show there are no serious safety concerns with the vaccine.

#### Effective.

The vaccine provides almost 100 percent protection against the most dangerous types of HPV.

#### Long-lasting.

The latest research shows the vaccine is effective for at least 10 years.

- For more information about the HPV vaccine, please talk to your health care provider and visit: [grouphealthresearch.org](http://grouphealthresearch.org) and click on Live Healthy to reach the HPV vaccine page.

## HPV Vaccine Cancer prevention for girls and boys



## What is HPV?

Human papillomavirus (HPV) is a common virus that is spread through sexual contact. There are approximately 40 types of HPV.

Most people will be infected with at least one type of HPV at some point in their lives. About 79 million Americans are infected with HPV at any given time.

Many people will never know they have been infected. But some types of HPV can lead to genital warts or several forms of cancer, including:

- Cervical cancer in women
- Penile cancer in men
- Anal and throat cancer in both women and men



## What is the HPV vaccine?

The HPV vaccine protects against the types of HPV that cause most cases of cervical cancer and genital warts. The vaccine also helps protect against anal, throat, and penile cancer.

**Who should get the HPV vaccine and when?** All boys and girls should get the HPV vaccine when they are 11-12 years old. Catch-up vaccinations can be given to boys 13-21 years old and girls 13-26 years old.

**Why does my child need the HPV vaccine at age 11-12?** The vaccine will not prevent cancer or genital warts in someone who is already infected with HPV. It must be given before exposure to the virus. That's why it is so important to vaccinate your child well before he or she becomes sexually active.

**27,000**  
people get cancer caused by HPV each year in the United States



That's **1 person** every **20 minutes**

## How can I get my child vaccinated?

Your child can get all three doses of the HPV vaccine at your Group Health clinic **without an appointment** and at **no cost**. Just drop in at a time that is convenient for your family.





- If your clinic has an Injection Room, check-in there for the vaccine.
- If your clinic does not have an Injection Room, check-in as you normally would for an appointment.
- Come back at another convenient time when your child is due for the second and third doses.




**Dose 2** – Two months after dose 1.

**Dose 3** – Four months after dose 2.

Your child can also get vaccinated at any CareClinic located at Bartell Drugs. CareClinic visits require a co-pay, but you can walk-in without an appointment. For more information, visit <http://care-clinic.org/>.



**HPV vaccine**  
**3 shots for cancer prevention**

-  **Dose 1:** *first dose given*
-  **Dose 2:** *write in due date*  
(2 months after dose 1)
-  **Dose 3:** *write in due date*  
(4 months after dose 2)

**Group Health HPV Vaccine Reminder Window Cling**

# **APPENDIX D**

## **HPV Dose 1 Reminder Call Script**



**ELIZA CORPORATION  
75 SYLVAN ST  
DANVERS, MA 01923**

**Group Health  
HPV First Dose  
TBD**

[Note]

## POPULATION NOTE

- Commercial population
- Parents/guardians of adolescent children who haven't yet received the first dose of the HPV vaccine.



### Outbound Call

Hello, this is <Greeting>, calling for the parent or guardian of <child's first name> <last name>. [Target -] *Yes or no, is this <his/her> parent or guardian?*

[Target:Yes -] *Great!* This call may be recorded for quality assurance. [Go To]

Introduction |

[Target:No -] [Go To] **Unavailable** |

### Inbound Call

Hello! Thank you for calling <Group Health> to receive some important health information. This call may be recorded for quality assurance.

[Go To] **Inbound Call Verification** |

### Introduction

[Note] Website = [www.ghc.org](http://www.ghc.org) |

We sent you a letter a few weeks ago about the HPV vaccine your child is due for. This is the shot that helps protect your child against several types of cancer. We're calling as a follow-up to remind you to take your child to get the vaccine.

**Intent HPV -** Please say yes or no, do you plan on taking your child to get their HPV shot soon, say within the next week or so?

**Intent HPV:Yes -** Fantastic! You can drop-in at any Group Health clinic to get your child the shot – no appointment is necessary. If you need help finding a Group Health clinic near you, please visit us online at <Website> and click on the Provider & Facility Directory link. **[Go To SMS – Option]**

**Intent HPV:No -** Okay. **Already Had -** Is that because you already took your child to get the HPV shot?

**Already Had:Yes -** Fantastic! **[Go To SMS – Option]**

**Already Had:No -** All right. **[Go To Barriers]**

## **Barriers**

We'd like to better understand why you might not be ready to take your child to get their HPV shot.

**Barrier Uncertain -** Do you have some questions or concerns about the HPV shot?

**Barrier Uncertain:Yes -** Okay. Please discuss your questions or concerns with your child's doctor. They are there to help you make your decision for your child's health. **[Go To Barrier\_Young]**

**Barrier Uncertain:No -** Okay. **[Go To Barrier\_Young]**

**Barrier Young -** Do you think your child is too young to get the HPV shot?

**Barrier Young:Yes -** All right. "it's" or "Group Health" recommend that all boys and girls get the HPV vaccine when they are 11 to 12 years old to make sure they're protected before they are exposed to the virus. **[Go To Barrier\_Time]**

**Barrier Young:No -** All right. **[Go To Barrier\_Time]**

**Barrier Time -** Are you having trouble finding time to take your child to get their shot?

**Barrier Time:Yes -** Okay. We know life can be busy. You can drop-in at any Group Health clinic – no appointment is necessary. **[Go To Barrier\_Cost]**

**Barrier Time:No -** Okay. **[Go To Barrier\_Cost]**

**Barrier Cost -** Are you worried about the cost of the vaccine?

**Barrier\_Cost:Yes -** All right. These HPV shots are actually free as part of your child's benefits. **[Go\_To Barrier Wrap Up]**

**Barrier\_Cost:No -** All right. **[Go\_To Barrier Wrap Up]**

## **Barrier Wrap Up**

**If Said no to all barriers -** Whatever your reasons are for not being ready to take your child to get their HPV shot, we hope you'll give your doctor a call to discuss it. They are there to help you make the best decisions for your child's health.

**If Otherwise -** We hope you'll consider taking your child to get their HPV shot soon.

**[Go\_To SMS – Option]**

## **SMS – Option**

For future HPV vaccine reminders like these, we can send you a text message reminder instead of calling you.

**Send\_Future\_SMS -** Would you prefer to receive a text message reminder?

**Send\_Future\_SMS:Yes -** Great. **[Go\_To Gather\_SMS]**

**Send\_Future\_SMS:No -** All right. **[Go\_To Satisfaction Question]**

**Gather\_SMS -** Then we need to make sure we have your cell phone number. So using your keypad, please enter your cell phone number, including area code, now. **[Record]**

**Gather\_SMS:Response -** Thank you. Please know that message and data rates may apply and SMS text messages are typically not encrypted. Also, Group Health will not request personal health information via these text messages. **[Go\_To Satisfaction Question]**

## **Satisfaction Question**

**Helpful -** Finally, so that we can continue to improve our ability to serve you, please tell me yes or no, did you find this call helpful?

**Helpful:Yes -** Great! **[Go\_To Wrap Up]**

**Helpful:No -** All right. We'll continue to work on the resources and support we provide. **Go To Wrap Up**

### **Wrap Up**

Thank you for your time. If you don't want to receive any further reminders about this, call **<Group Health Toll Free Number>**. Have a good **<day/evening>**. Goodbye. **END CALL**

### **Unavailable**

### **Answering Machine 1**

Hello, this is **<Greeting>** calling for the parent or guardian of **<child's first name>** **<last name>**. We're calling to follow-up with you about your child's immunizations. Please call us back 24/7, toll-free at 1 **<Eliza Inbound Number>**. *Again, the number is 1 **<Eliza Inbound Number>**. Thank you and have a good **<day/evening>**. Goodbye.* **END CALL**

### **Answering Machine 2**

Hello, this is **<Greeting>** calling again for the parent or guardian of **<child's first name>** **<last name>**. We wanted to remind you that there is an important shot your child needs at their age. We sent you a letter about it a few weeks ago. You can take your child to any Group Health clinic to get it taken care of. For more information, *please call us back 24/7, toll-free at 1 **<Eliza Inbound Number>**. Again, the number is 1 **<Eliza Inbound Number>**. Thank you and have a good **<day/evening>**. Goodbye.*

### **Human Message 1**

**HM1 -** *Would you be willing to take a message for me?*

**HM1:Yes -** Okay. We're calling to follow-up with them about their child's immunizations. Please ask them to call us back 24/7, toll-free at 1 **<Eliza Inbound Number>**.

**Repeat HM1 -** Would you like me to repeat that number?

**Repeat\_HM1:Yes -** Again, please ask them to call us back 24/7, toll-free at 1 <**Eliza Inbound Number**>. *Thank you for passing this message along and have a good <day/evening>. Goodbye.* **END CALL**

**Repeat\_HM1:No -** *Thank you for passing this message along and have a good <day/evening>. Goodbye.* **END CALL**

**HM1:No -** *Okay, thank you anyway and have a good <day/evening>. Goodbye.* **END CALL**

## Human Message 2

**HM2 -** *Would you be willing to take a message for me?*

**HM2:Yes -** Okay. We need to talk to them about an important vaccine for their child. Please ask them to call us back 24/7, toll-free at 1 <**Eliza Inbound Number**>.

**Repeat\_HM2 -** Would you like me to repeat that number?

**Repeat\_HM2:Yes -** Again, please ask them to call us back 24/7, toll-free at 1 <**Eliza Inbound Number**>. *Thank you for passing this message along and have a good <day/evening>. Goodbye.* **END CALL**

**Repeat\_HM2:No -** *Thank you for passing this message along and have a good <day/evening>. Goodbye.* **END CALL**

**HM2:No -** *Okay, thank you anyway and have a good <day/evening>. Goodbye.* **END CALL**

## Inbound Call Verification

### If One Record Found AND Caller ID Available -

**If Initial IB Verification -** *Before we get started,*

**Is\_This\_PD -** *Please tell me yes or no, is this the parent or guardian of <child's first name> <last name>?*

**Is\_This\_PD:Yes -** Great! **Go\_To** Introduction **||**  
**Is\_This\_PD:No -** **Go\_To** Caller ID Unavailable **||**

### If Multiple Records Found AND Caller ID Available -

**Child Name 1 PD -** It looks like there may be more than one child in our records associated with this phone number. Just to be sure, please tell me yes or no, are you calling about <child's first name #1> <last name #1>?

**Child Name 1 PD:Yes -** **[Go To]** Is\_This\_PD\_2 **|**  
**Child Name 1 PD:No -** **[Go To]** Child\_Name\_2\_PD **|**

**Child Name 2 PD -** Okay – sorry about that. Are you calling about <child's first name #2> <last name #2>?

**Child Name 2 PD:Yes -** **[Go To]** Is\_This\_PD\_2 **|**  
**Child Name 2 PD:No -** **[Go To]** Child\_Name\_3\_PD **|**

**Child Name 3 PD -** All right. We also have <child's first name #3> <last name #3>? Please tell me yes or no, are you calling about <child's first name #3>?

**Child Name 3 PD:Yes -** **[Go To]** Is\_This\_PD\_2 **|**  
**Child Name 3 PD:No -** **[Go To]** Child\_Name\_4\_PD **|**

**Child Name 4 PD -** Okay. What about <child's first name #4> <last name #4>?

**Child Name 4 PD:Yes -** **[Go To]** Is\_This\_PD\_2 **|**  
**Child Name 4 PD:No -** **[Go To]** Child\_Name\_5\_PD **|**

**Child Name 5 PD -** All right. Well, are you calling about <child's first name #5> <last name #5>?

**Child Name 5 PD:Yes -** **[Go To]** Is\_This\_PD\_2 **|**  
**Child Name 5 PD:No -** **[Go To]** If Not Confirmed End Call **|**

**Is This PD 2 -** And are you their parent or guardian?

**Is This PD 2:Yes -** *Terrific!* **[Go To]** Introduction **|**  
**Is This PD 2:No -** **[Go To]** If Not Confirmed End Call **|**

**If Caller ID Unavailable -** Okay. We will need to verify your phone number so we can look up your information. **PhoneSpeech PD -** Using the keypad on your telephone, please enter the telephone number including area code where we left our message for you, now. **PhoneSpeech PD:Response -** Thank you. Please hold while we retrieve your information.

**If Phone Confirmed -**

**If One Record Found -** **[Go To]** IsThis\_PD **|**  
**If Multiple Records Found -** **[Go To]** Child\_Name\_1\_PD **|**

**If Phone NOT Confirmed -** **PhoneDTMF\_PD -** *I'm sorry, but I'm not finding a match for that number. Let's try again using the keypad on your telephone. Please enter the telephone number, including area code, where we left our message for you, now.*

**PhoneDTMF\_PD:Response -** *Thank you. Please hold while we retrieve your information.*

**If Phone Confirmed -**

**If One Record Found -** **[Go To]** **IsThis\_PD** **||**

**If Multiple Records Found -** **[Go To]** **Child\_Name\_1\_PD** **||**

**If Phone Not Confirmed -** **[Go To]** **Not Confirmed End Call** **||**

**If Not Confirmed End Call -** *We're sorry – we weren't able to find a match for you. We do have some specific information to share, but in order to protect your privacy, we need to make sure we're speaking with the right person. So please try calling us back from the number where we left our original message. Thank you for your time and have a good <day/evening>. Goodbye.*

**END CALL**