

**OHSU Knight Cancer Institute**  
**Minimal-Risk Protocol**

**Increasing HPV Immunization Rates: The Rural Adolescent Vaccine  
Enterprise (RAVE)**

**NCT03604393**

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## 1.0 BACKGROUND/ RATIONALE

Dangers Associated with the Human Papilloma Virus & Vaccine Recommendations: HPV-16 and -18 account for about 70% of cancers of the cervix, vagina, and anus and for approximately 30-40% of cancers of the vulva, penis, and oropharynx (4). Other cancers linked to HPV include non-melanoma skin cancer and cancer of the conjunctiva (3). About \$8 billion is spent annually to manage the sequelae of HPV infections, primarily to manage abnormal cervical cytology and cervical neoplasia (1). This exceeds the economic burden of any other sexually transmitted infection except for the human immunodeficiency virus (1).

In 2006, the Food and Drug Administration approved a vaccine to protect against strains of the virus (5), including HPV-16 and -18. Currently, three vaccines (Cervarix, Gardasil, and Gardasil 9) are available (13), and vaccination is recommended starting at age 11 or 12 years for **both males and females**. Unfortunately, the U.S. National Immunization Survey (NIS) has shown that completion of the vaccine series (three shots) often does not occur despite recommendations by several groups (6, 13, 14). Regarding females, national vaccine initiation among 13-17 year olds increased from 53% in 2011 to 60% in 2014. However, vaccine series completion was only 39.7% nationally, with regional variation by state (20.1%-56.9%) (6). Regarding males, modest increases occurred between 2014 to 2015 for initiating the HPV vaccine series (from 41.7% to 49.8%), with completion of the series increasing only from 21.6% to 28.1% (7). In late 2016, the Advisory Committee on Immunization Practices (ACIP) has approved a schedule change for HPV vaccination completion. The ACIP recommends the use of a 2-dose schedule for girls and boys who initiate the vaccination series at ages 9 through 14 years. Three doses remain recommended for persons who initiate the vaccination series at age 15 through 26 years and for immunocompromised persons (15). This policy change will be taken into account in our analyses. HPV vaccination coverage remains lower than meningococcal ACWY (MCV) and tetanus, diphtheria, and acellular pertussis (Tdap) vaccine rates (16). This gap points to the opportunity to reduce missed opportunities for HPV vaccinations.

One of the first studies to use state immunization registry data to assess missed opportunities for HPV vaccines showed a missed opportunity rate of 43.9% between 2008-2012 among females aged 11-26 years. Compared to urban areas, rural areas were more likely to have missed opportunities (OR 1.8) (17). Another study reported that 84% of unvaccinated adolescent females had at least one healthcare visit where non-HPV vaccines were administered and the HPV vaccine was not (18). Other adolescent vaccination rates are relatively high with MCV at 79% and Tdap at 87% (18).

Barriers to HPV Vaccination: Studies on vaccine acceptability indicate most parents react positively to vaccinating their children against HPV, especially when parents believe the vaccine is effective, a physician recommends it, and HPV infection is likely (19-21). Between 6% and 12% of parents fear that vaccination would promote adolescent sexual behavior, a barrier to vaccination (20, 21). Race does not appear to affect acceptability of the HPV vaccine (18). Although cost has been reported as a barrier (22), the cost of the HPV vaccine for uninsured children under 18 years is covered by the federal Vaccines for Children Program (VFC).

Rural areas have unique challenges regarding HPV and are understudied. Access to pediatricians and family physicians is often challenging in rural areas, with preventive care underutilized (23-26). Lower socioeconomic status, health literacy, and religiosity/conservatism are prevalent in rural areas (27). A study of communication disparities (28) found that rural parents are least likely to engage in communication with their children's healthcare clinicians, with lower rates of mutual information exchange, deliberation, and shared decision-making. This study, which used NIS-Teen data from 4,124 parents of daughters aged 13-17 years, showed lower uptake of HPV in rural areas (28).

Studies on medical practice barriers indicate that inadequate reimbursement (68%) and burden of determining insurance coverage (66%) all inhibit primary care practices from stocking the vaccine and providing it to adolescents (29, 30). Practices not providing the vaccine reported more concerns about HPV vaccine provision than practices providing it (n=71 practices: 6.0 vs. 4.5 concerns, p < 0.05) (29). Other barriers include parents deciding to delay rather than refuse vaccination. When this occurs, clinicians are hesitant to discuss the topic, while teens consider themselves passive in the decision-making process (31a).

To overcome these barriers, clinicians either present the HPV vaccine as routine or as optional, while highlighting risks and benefits (31). Additional studies have examined why clinicians do not follow clinical practice guidelines (31b). One systematic review of 76 published studies (31) identified seven common barriers, including lack of awareness, familiarity with details, lack of agreement with guidelines, issues related to self-efficacy (ability to reach goals) (31), outcome expectancy (belief that given behaviors will lead to certain outcomes) (32), ability to overcome practice inertia, and external barriers – such as health insurance coverage (33). Importantly, barriers in one setting are not generalizable to other settings (34). Improving primary care practices’ rates of HPV vaccinations will require a tailored approach.

Several studies have tested interventions to improve preventive services delivery (35-42). One meta-analysis (37) found that organizational change, such as separate clinics or pods within a clinic devoted to prevention, use of a planned care visit for prevention, or designation of non-clinician staff to do specific prevention activities, were most effective intervention strategies, with adjusted odds ratios ranging from 2.5 to 17.6 (37). Financial incentives, patient reminders and education, and clinic feedback were the next most effective intervention strategies, with adjusted odds ratios ranging from 1.1 to 3.4 (37). Additional studies have found that clinician education and office-based systematic patient tracking can increase preventive service delivery by 12-90% (38-40). However, practice members must be involved in choosing what will work in their setting (39, 40). A 2015 systematic review of practice- and community-based interventions identified promising programs to close the gap in HPV vaccination, which had been implemented in diverse populations. Interventions targeted providers with audit and feedback, involved school-based programs, and included social marketing campaigns (11, 36). Figure 1 summarizes the characteristics of recent studies that have addressed HPV vaccination interventions and highlights those features we will include in our intervention study.

Figure 1. Characteristics of Practice- and Community-Based HPV Vaccination Interventions

	BUNDY	CASSIDY	CATES (2011)	CATES (2014)	DALEY	FIKS	GILKEY	KHARDANDA	MATHESON	MOSS	STUBBS	SUH	SZILAGYI (2011)	SZILAGYI (2013)	ORPRN PROPOSAL
<b>EVALUATED APPROACH</b>															
Reminder/recall		x				x		x	x			x	x	x	x
Providers	x	x	x	x		x	x			x					x
Schools					x						x				
Social marketing			x	x											x
<b>MULTIPLE STRATEGIES</b>	x	x	x	x		x	x						x	x	x
<b>INCLUDED OTHER VACCINES</b>	x				x		x			x		x	x	x	x
<b>PROVIDER STRATEGIES</b>															
Electronic decision support	x					x									x
Audit & feedback	x					x	x			x					x
Education/training		x	x	x		x	x			x					x
<b>DESIGN: Randomized</b>	x				x	x	x					x	x	x	x
Quasi-experimental	x	x	x	x				x	x	x	x				
<b>SEX*: Female</b>	x	x	x		x	x	x	x	x	x	x	x	x	x	x
Male				x					x						x
<b>AGES*: ≤ 13 years</b>		x	x	x	x		x								x
<b>SETTINGS: Rural</b>			x												x
Urban	x	x			x	x	x	x	x	x	x	x	x	x	

(a) Multiple strategies within or across approaches (overarching design); not necessarily evaluated separately.  
\* either restricted to specified group or reported findings separately for each group

## 2.0 OBJECTIVES

The overarching goal of this study is to engage rural primary care clinics and community organizations to test interventions designed to increase HPV vaccinations in both male and female patients aged 11-17 years. Using a step-wedge randomized controlled trial, we will design and test the effectiveness of multicomponent primary care practice-based interventions on the completion of the HPV vaccine series and will explore implementation timing in high and low functioning practices to determine how specific characteristics affect the delivery of the full series. Additionally, we will design and test the impact of a community organization-based intervention intended to educate the public about HPV and cancer risk and risk reduction via vaccination.

### 3.0 STUDY DESIGN/METHODOLOGY

**Aim I: Primary Care and Community-based Organizations:** Conduct a baseline assessment of how primary care practices, public health programs, and community-based organizations are initially addressing initiation and completion of the HPV vaccine series.

We have already determined HPV vaccination rates in 53 rural primary care practices (available from the Oregon Immunization Program – OIP), which has helped us identify “hot spots” for intervention research. We will conduct a baseline assessment in 20 of these practices using direct observation of workflows and validated measures of team-based care effectiveness and practice-level knowledge of HPV and current HPV vaccine recommendations. This will assist us in developing tailored intervention approaches for busy rural primary care practices and enable us to assess which practice characteristics affect delivery of the full HPV series. We will also conduct an in-depth assessment of activities undertaken in rural Oregon communities to inform the public about cancer risks and HPV vaccines.

**Aim II: Primary Care:** Implement and test, using a stepped-wedge cluster randomized trial design, the effectiveness of a multi-component primary care practice-based intervention on initiation of and completion of the HPV vaccine series as well as reduction in rates of missed opportunities to vaccinate.

The intervention will be conducted in 40 primary care practices we plan to enroll and will involve: 1) practice facilitation to engage clinics in a practice-wide planning process to redesign patient care and communication strategies to optimize HPV vaccine completion; 2) workflow mapping adapted to practice context to support HPV vaccine delivery; 3) a practice improvement model designed to firmly establish reminder and recall systems and standing orders; and 4) education for patients and parents that underscores HPV vaccination is safe, effective, and an important approach for reducing cancer risk. We will additionally explore uptake of the intervention in terms of implementation timing and component features in high- and low-functioning practices to determine which practice characteristics affect delivery of the full HPV series.

**Aim III: Community Organizations:** To explore the extent to which an evidence-based social marketing campaign, implemented in partnership with participating practices, will increase HPV vaccine demand.

In this Aim, primary care practices will select a community-level organization to partner with, such as a regional Accountable Care Organization (ACO) Community Advisory Council (CAC), patient and family advisory group, or local public health program based on existing relationships. Together, the clinic and community group will attempt to implement an evidence-based community-level intervention (11,12) designed to improve knowledge among adolescents and their parents on HPV, cancer risk, and risk reduction via vaccination, as well as the safety and effectiveness of the vaccine series. The plan specifically explores the extent to which this partnership brings “vaccine ready” adolescent and parents to primary care clinics and increases the demand for HPV vaccination.

**Aim IV: National Dissemination:** To explore the impact of sharing promising clinical and community intervention features in a toolkit with practices, state public health programs, and Accountable Care Organizations (ACOs).

We will create a practice and community HPV improvement toolkit for use by practices, ACOs, and state public health agencies. The toolkit will be electronically disseminated, with the assistance of our partners in the ACOs and at OIP, and we will assess its spread.

### 4.0 STUDY POPULATION

Rural adolescents aged 11-17 years, along with their parents, will be included in this study. In addition, rural family physicians and pediatricians and members of their clinical practices will be active participants and will uniquely partner with community-based organizations to undertake comprehensive communication, education, and social messaging approaches to address inequities in a much understudied population, rural America. Members of community-based organizations who partner with practice members to implement a social media campaign will also be participating.

The numbers below reflect the anticipated recruitment of 11-17 year old subjects in rural Oregon, according to 2015 U.S. Census Bureau Data from Oregon on gender, race, and

**Table 1. Total Planned Enrollment:** ethnicity status.

<b>TARGETED/PLANNED ENROLLMENT: Number of Subjects</b>			
<b>Ethnic Category</b>	<b>Sex/Gender</b>		
	<b>Females</b>	<b>Males</b>	<b>Total</b>
Hispanic or Latino	1,384	1,355	2,739
Not Hispanic or Latino	9,511	9,324	18,835
<b>Ethnic Category: Total of All Subjects *</b>	10,895	10,679	21,574
<b>Racial Categories</b>			
American Indian/Alaska Native	196	192	388
Asian	479	470	949
Native Hawaiian or Other Pacific Islander	44	43	87
Black or African American	228	224	452
White	9,948	9,750	19,698
<b>Racial Categories: Total of All Subjects *</b>	10,895	10,679	21,574

\* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

## 5.0 INCLUSION/EXCLUSION CRITERIA

We will enroll ORPRN primary care clinics located in rural communities that see adequate numbers of patients in the age range we are studying (age 11-17 years). To date, 62 clinics have committed to participating in the study. We decided to exclude urban practices in order to study the intervention specifically in under-resourced rural settings. Based on our sample size estimates, we need 20 practices for Aim I and 40 practices for Aim II of the study. By over-enrolling to 45 practices for Aim II, we accounted for an attrition rate of 11%. *We are confident, based our extensive experience recruiting and retaining practices in research studies, we will easily retain the 40 practices needed to test study hypotheses for Aim II.*

## 6.0 VULNERABLE POPULATIONS

No subject will be excluded from the study on the basis of racial or ethnic origin. Both male and female clinicians (including pregnant clinicians) and practice members will be included in the study. Additionally, male and female patients (including pregnant patients) and parents of patients (including pregnant parents) at enrolled practices will be included in analyses. This protocol does involve male and female children ages 11 to 17 years. We will not include neonates, decisionally impaired adults, and prisoners in this study. We will not collect information that would identify a woman as pregnant. The study poses minimal risk to pregnant women.

## 7.0 SETTING

Aim I: We will engage 20 rural primary care clinics throughout Oregon – and, their affiliated public health programs and community organizations – to understand workflows and clinical structures present in high/low/medium HPV vaccine-performing clinics.

- Eligibility. Primary care clinics in rural Oregon that report data to the state ALERT IIS program
  - Inclusion criteria:
    - Located in a rural area of Oregon (defined using RUCA codes)
    - Family Medicine or Pediatric Practice
    - Provide primary care services (school based clinics, public health clinics that do not deliver primary care, pharmacies, etc. are not be eligible).
    - Non-tribal
    - Participating in VFC

Aims II and III: We will engage at least 40 rural primary care clinics throughout Oregon – and, their affiliated public health programs and community organizations – to test interventions designed to increase HPV vaccinations in male and females aged 11-17 years, with an emphasis on 11-12 year olds.

## 8.0 STUDY PROCEDURES AND SCHEDULE OF EVENTS

The proposed study subjects are family physicians and pediatricians, other healthcare providers (nurse practitioners and physician assistants), office staff located and patients in 40-60 practices from ORPRN (practices that participate in Aim I can participate in Aim II). Additional participants will include members of community-based organizations who will partner with participating practices to implement a social media campaign to educate the public about the HPV vaccine. More specifically, patient participants will include: 1) male and female patients between the ages of 11 and 17 years (and their parents for 11-12 year olds) who are either receiving routine healthcare at enrolled ORPRN clinics or reside within the catchment areas of these clinics.

Aim I:

- Pre-Site Visit Phone Interview (45 min – 1 hour). The purpose of these calls is to coordinate the Formal Site Visit and to gain buy-in for the visit. This will include confirming locations for observation (front desk, patient encounters, back office, population outreach, lab) and gathering names of individuals for interviews. As time allows, we will also gather initial information on organizational structure, key stakeholders involved in the immunization process, and the practice's basic approach for immunizations.
- Practice Intake Survey (5 min). This brief intake survey will be completed by the clinic point of contact and provide descriptive data regarding practice characteristics (ownership, QI team) and patient panel information (total visits, demographic profile).
- Formal Site Visit (1-2 days) with supplemental informal key-informant interviews. The observation visits will last 1.5 days and be conducted by two members of the study team.
  - The observation will be used to document clinical workflows, organizational culture, and other factors that may influence HPV vaccination rates. We are interested in vaccine delivery and missed opportunities.
  - Informal interviews will be conducted with clinical staff members to supplement and clarify onsite observations. These interviews will occur “on the fly” when there are breaks in clinical care.
- Community Partner Survey (10 min). We will administer surveys (either through SurveyMonkey or on paper) to approximately six people – from various sectors (healthcare services, public

health, education, policy, etc.) in the communities where Aim I practices are located – to gather knowledge and perceptions of the HPV vaccine and to understand how we could/should market the HPV vaccine in the community.

Qualitative data from Aim I will be transferred into Atlas.ti for data management and analysis:

- Field notes from pre-site visit phone interview reviewed/finalized.
- Jottings from observation visits typed into field notes within 24 hours.
- Interviews audio transcribed.

Quantitative data (brief practice intake survey, pre-observation visit call) will be transferred from Survey Monkey (or paper form) into Excel for descriptive analysis. Quantitative data from OIP (ALERT IIS) sent to OHSU via secure file transfer (SFT) and added into Excel for descriptive analysis.

Aims II and III: Members in each practice (n=40) will be asked to complete a Practice Survey (PS) at baseline and again annually (for variables that might change). The PS ascertains information about practice and practice’s patient demographics, practice change, payer mix, revenue and payments, HPV vaccine priority, internal structure and strategies for improving HPV vaccine rates, external reporting, registries, and clinical guideline availability. A Staff Member Survey (SMS) will also be administered at baseline and annually (for variables that might change). It ascertains information on staff member demographics, adaptive reserve, patient needs, clinician and staff satisfaction and burnout, staff motivation, staff turnover, practice leadership, practice cohesion and rewards, and practice readiness to change. A Quality Improvement Change Assessment (QICA) will be administered every six months. It ascertains information on the foundational change concepts for building quality improvement (QI) capacity in primary care: Organized, Evidence-Based Care; Quality Improvement Strategy; Continuous & Team-Based Healing Relationships; and Care Coordination. Intervention Site Visits will be conducted monthly, which will involve workflow mapping; patient data collection: eligible patient population, patient demographics, and other characteristics of the patient population; quarterly immunization rates; quarterly community education data collection: existing education programs, efforts, and partnerships; PDSA cycle worksheets; and field notes. We will also conduct Patient/Parent Surveys every six months, which will ascertain children’s and parents’ knowledge about cancer risk reduction and the HPV vaccine series, where and how information about HPV and cancer risk reduction via vaccination was sought, and patient and parental demographic information. Lastly, we will conduct Pre- and Post-Community Partner surveys and Group Interviews that will assess perspectives on community acceptability of HPV vaccination.

**Table 2. Measures and Methods According to Solberg Model Constructs**

Aim I: Data Collection Methods & Timing	Measures	Solberg Model Constructs
Pre-Site Visit Phone Interviews – once at Baseline	<ol style="list-style-type: none"> <li>1. Staffing structure</li> <li>2. Presence of QI team</li> <li>3. EHR</li> </ol>	Priority
Formal Site Visit – once at Baseline	Baseline workflows; baseline patient data collection: eligible patient population, patient demographics, and other characteristics of the patient population; baseline immunization rates; baseline community education data: existing education programs and efforts, existing partnerships	Content
Practice Intake Survey (PS) – once at Baseline	<ol style="list-style-type: none"> <li>1. Ownership</li> <li>2. Presence of a designated QI team</li> <li>3. Relationship with community groups with regard to public health (and description, quantity)</li> <li>4. Percentage of minor patients</li> <li>5. Total patient visits in past week</li> <li>6. Patient demographics (Race &amp; Ethnicity)</li> </ol>	Priority



ALERT IIS – once at Baseline	1. Vaccine initiation rates for children ages 11-12 2. Vaccine completion rates for children ages 13-17 3. Insurance status	Priority
Community Partner Survey – once at baseline	Knowledge and perceptions of HPV vaccinations; relationship between HPV and cancer; perceived utility of a social marketing campaign on HPV vaccination, community health, and cancer rates	Priority Content
<b>Aim II: Data Collection Methods &amp; Timing</b>	<b>Measures</b>	<b>Solberg Model Constructs</b>
Practice Survey (PS) – annually	Practice & practice’s patient demographics, practice change, payer mix, revenue & payments, HPV vaccine priority	Priority
	Internal structure & strategies for improving HPV vaccine rates, external reporting, registries & clinical guideline availability	Capability
Staff Member Survey (SMS) – annually	Staff member demographics, adaptive reserve, patient needs, clinician and staff satisfaction and burnout, staff motivation, staff turnover, practice leadership, practice cohesion and rewards	Priority
	Practice readiness to change	Capability
ALERT IIS – every six months (or more, TBD)	1. Vaccine initiation rates for children ages 11-12 2. Vaccine completion rates for children ages 13-17 3. Insurance status	Priority
Quality Improvement Change Questionnaire (QICA) – every six months	Engaged Leadership	Priority
	Organized, Evidence-Based Care; Quality Improvement Strategy; Continuous & Team-Based Healing Relationships; Care Coordination	Capability
Site Visits – monthly	Workflows; patient data collection: eligible patient population, patient demographics, and other characteristics of the patient population; quarterly immunization rates; quarterly community education data: existing education programs and efforts; existing partnerships	Content
Intervention Data Entries – monthly	PDSA cycle worksheets, workflow mapping, field notes	Content
<b>Aim III: Data Collection Methods &amp; Timing</b>	<b>Measures</b>	<b>Solberg Model Constructs</b>
Pre- and Post-Community Partner Group Interviews	Acceptability of HPV vaccination	Priority
Patient/Parent Surveys – every 6 months	Child and parents’ knowledge about cancer risk reduction and the HPV vaccine series; where and how information about HPV and cancer risk reduction via vaccination was sought; demographic information	Content

*As Aim II and III project materials are developed (e.g., surveys, QICA document, site visit materials), they will be submitted to the IRB.*

## 9.0 DATA AND SPECIMENS

### a) Handling of Data and Specimens

#### ALERT Immunization Information System (IIS) Abstraction

We will extract clinic-level data through ALERT IIS – via our collaboration with OIP – to investigate how the intervention we are testing affects patient outcomes (increases in HPV vaccine series completion) and practice outcomes (reductions in missed opportunities to vaccinate). These data will be used to determine how clinic rates of delivering HPV vaccination series changed throughout the study. We will identify established male and female patients in each practice who are between the ages of 11-17 years. Information on number of visits and dates of services for each patient in the practice during the study years outlined in our application will be captured.

### b) Sharing of Results with Subjects

Practices will receive their HPV vaccination rate data via ALERT IIS.

### **c) Data and Specimen Banking**

Not Applicable.

## **10.0 RISKS TO SUBJECTS**

Risks associated with this project are expected to be minimal; loss of confidentiality is the greatest potential risk. The surveys and assessments, mentioned above, pose minimal risk to practice members because the instruments contain minimal personal information. It is possible that someone in the practice could use information about a respondent's role (e.g., Office Manager) to identify that person and his or her responses. For this reason, our study team collects these data personally, and the data we collect is kept completely confidential and only used by the study team. If data is reported to practices, we report these data in aggregate so that it is not possible to link an individual to his or her responses. The risk of loss of confidentiality for patients/parents is higher because the survey for these individuals contains more sensitive information about HPV knowledge and attitudes regarding vaccination.

All data entered or sent to the study offices will be handled in a highly confidential manner consistent with the high standards established at OHSU and ORPRN. All employees at OHSU and ORPRN are required to sign a confidentiality statement and abide by standards of confidentiality and data security outlined in a manual developed for this purpose. A unique encrypted identifier will replace names on all study instruments and documents, including field notes and interview transcripts, and in a master database that will hold all study data. Data presented in all presentations and publications will not be associated with the name of any participating person or practice. All computer systems at OHSU and ORPRN are protected from possible external access using network security systems. Only study researchers and staff will have access to the data.

We will use industry standard Secure Sockets Layer (SSL) technology with server and client certificates to insure the confidentiality of data use and any data transfer.

## **11.0 POTENTIAL BENEFITS TO SUBJECTS**

### Potential Benefits of the Proposed Research to the Subjects and Others

The study may contribute long-term benefits of new scientific knowledge about providing HPV vaccinations to male and female patients aged 11-17 years. The participants will not directly benefit from their participation. The benefits of improving cancer risk reduction and vaccine delivery processes far outweigh the remote possibility of a breach in confidentiality.

### Importance of Knowledge to be Gained

The information gained from this study may provide critical information on how to reduce the burden of cancer in morbidity and mortality. The findings from this research may be useful to other areas of vaccine research. Additionally, this study will help us understand how to improve QI within rural primary care practices, and it will help determine the relationship between community-based organizations and primary care practices.

## 12.0 TIMELINE & MILESTONES

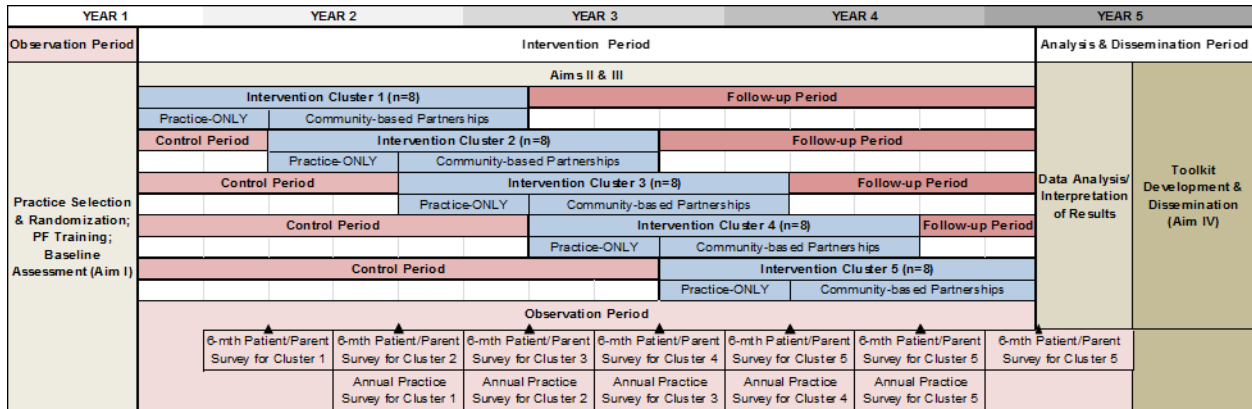


Figure 2. Overall Project Timeline

Figure 3. Aim 1 Timeline (below)

### RAVE Aim 1 Timeline

	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April
Planning	X	X	X								
Tool refinement		X	X								
Clinic ranking			X								
Recruitment				X	X	X	X	X	X	X	
Obs. visits completed (20)*				1	3	3	2	2	2	4	3
Analysis					X	X	X	X	X	X	X
Aim 2 Instrument refinement							X	X	X	X	X
Dissemination								X	X	X	X

\* We will monitor for saturation, which may occur after 12-15 visits.

## 13.0 BIO-STATISTICAL CONSIDERATIONS

Our proposed stepped-wedge cluster randomized trial (78) will evaluate the impact of the proposed intervention on HPV outcomes in 40 primary care practices (Aim II). We will specifically test two hypotheses: 2a) More patients will have initiated and completed the HPV vaccine series in intervention practices compared to control practices, and 2b) Practices receiving the intervention will have lower rates of missed opportunities to vaccinate compared to control practices. The primary outcome variables will include receipt rate of the initial (age 11-12 years) and full series of HPV vaccines and a reduction in the rates of missed opportunities to vaccinate among males and females aged 11-17 years. We will conduct block randomization of practices in five waves every six months. Outcomes will be measured every three months in all clusters at every period, so that each cluster provides data points in both the control and intervention conditions. Practices in each wave will be stratified based on designation of pediatric or family medicine clinic to balance pediatric/family medicine clinics at each wave. Outcome data collection will be collected from ALERT IIS beginning in quarter four of the study and up to 17, for 14 longitudinal data collection points per practice. Dr. Marino, who has no contact with the study practices, will perform the randomization for all practices prior to the start of the first intervention wave. Randomized assignment will not be revealed to practices until their cluster begins the study.

The primary goal of Aim II is to establish whether the intervention is effective and the degree to which it is accomplishing its goals. Our outcome evaluation includes a rigorous research design so we may attribute positive findings to the intervention and not to existing threats to internal validity. To compare the effect of the intervention with usual care on HPV outcome measures in the context of a stepped-wedge design, we will utilize Generalized Linear Mixed Models (GLMMs) (79). In particular, to assess the intervention effect, we will use a Poisson model with random effects for practice. The general model is as follows:

$$(1) \log(Y_{it}|b_i) = \beta_0 + \beta_1 t + \beta_2 I_{it} + \beta_3 I_{it}(t - s_i) + \beta_4 Z_i + b_i + \log(E_{it})$$

where  $Y_{it}$  is the number of patients in practice  $i$  who had HPV completion during period  $t$  for  $t \in (0, 1, \dots, 13)$ . Data is collected every three months (i.e., quarterly), and  $t = 0$  is the baseline quarter. Additionally,  $I_{it}$  is an indicator variable where  $I_{it} = 1$  if practice  $i$  has been assigned to the intervention at period  $t$ , and  $I_{it} = 0$  otherwise. Term  $s_i$  is the period when the intervention begins for practice  $i$ . The practice-level term to denote a family medicine or pediatric practice is denoted by  $Z_i$  where  $Z_i = 1$  if practice  $i$  is a family medicine practice and  $Z_i = 0$  if pediatric practice.  $E_{it}$  is the number of patients in the practice  $i$  who were eligible to be counted during period  $t$  and the  $\log(E_{it})$  term is considered the 'offset' in the Poisson regression model. The term  $b_i$  denotes a random effect term for practice  $i$  with mean 0 and variance  $\sigma_b^2$ . The estimation via model (1) takes into account the general time trend, and allows for the intervention effect to grow over time following intervention implementation. Model (1) estimates the intervention effect with the within site difference between HPV completion rates pre- and post-intervention, averaging across practices and accounting for possible secular trends which might confound with the timing of the intervention implementation. In model (1),  $\beta_0$  is the (log of) average pre-intervention HPV completion rate for pediatric practices (i.e.,  $Z_i = 0$ ) with the random effect set to 0.  $\beta_1$  is the effect of the general time trend of the HPV completion rate without the intervention.  $\beta_2$  represents the intervention effect that appears in the first time period of the intervention.  $\beta_3$  represents the added intervention effect that accrues over time following intervention implementation. Model (1) will also apply for outcome of HPV initiation, completion, and rates of missed opportunities to vaccinate by replacing  $Y_{it}$  and  $E_{it}$  with the appropriate numerator and denominator. Hypothesis tests will be two-sided, with type I error set to 0.05. Because statistical tests are specified a priori and our proposed outcome measures are highly related, we will follow recommendations to report p-values rather than adjust for multiple comparisons (80, 81). Goodness of fit statistics and model fitting diagnostics will be used to assess for influential points and over-dispersion and to evaluate alternative model specifications.

**Power Calculations:** We assess the power to detect effects that are clinically meaningful and realistic. For this calculation, we assess the power to detect at least 80% power of a 2-sided significance test with  $\alpha = 0.05$ . We are interested in comparing the rate of HPV completion in the sixth quarter after intervention with HPV completion rate at baseline. Given the following conditions: 1) Pre-specified total sample size of 40 practices; 2) Design (stepped-wedge with five cohorts of eight practices starting six months apart); 3) Two-sided significance level of 0.05; 4) Starting practice-level HPV completion of 24% as described above; 5) Intra-cluster correlation (ICC) of patients within practices of 0.08 (82, 83), we will have at least 80% power to detect a minimum of 19.4% difference in the absolute change (increasing from 24.0% to 43.4%). If we are successful at retaining all 45 practices that will be recruited, we will have at least 80% power to detect a 18.1% difference in absolute change. These estimates assume a conservative ICC of 0.08. As most studies show an  $ICC < 0.001$  (84), the proposed study will have sufficient power to detect differences of health policy importance. Estimates of parameters for these power

calculations were obtained from model (1) and the most recent, up-to-date OIP dataset. These power calculations estimate the minimum numbers needed to detect minimum changes.

Analysis Considerations: If we find significant practice differences between cohorts, we will utilize propensity score weighting methods to reduce the observed bias, help minimize external threats to the validity of results, and adjust for imbalances (85, 86). Additionally, model (1) can accommodate missing data resulting from practice attrition. We will explore model missingness by including relevant variables in the analysis as covariates (87, 88). If non-trivial levels of missing data are observed, we will use methods such as multiple imputation to include these practices in analyses (87). We will conduct a sensitivity analysis comparing parameter values for models using completers only, all practices without multiple imputation, and all practices with multiple imputation, to understand any biases introduced by differential attrition or missing not at random (88). Our project has control, intervention, and follow-up periods in all seasons, which will allow us to detect and account for the potential effect of seasonality on the receipt of indicated adolescent vaccines.

## **14.0 RECRUITMENT METHODS**

Participating clinicians and practice staff members will be verbally asked if they agree to participate in the study after receiving a study information sheet at the start of baseline data collection (Aim I) [Note: The clinic team will receive a fact sheet – via in-person meetings with ORPRN staff and/or e-mail communication – that describes the study and all study activities prior to being asked to participate.]. Participation will be voluntary and will consist of agreeing to allow researchers to observe practice operations and interview practice clinicians and staff. For Aim II, clinicians and practice staff members will also be asked to complete study surveys at designated intervals. Patients selected to receive surveys will also receive information about the study, explaining how the data they provide on their surveys will be used. An information sheet about the study will be included with the survey mailings. Community partners will be identified by the participating practice members and project team members; these individuals will also receive a fact sheet about the study and an information sheet to help them decide whether or not to participate in the study.

### Women and Minorities

No subject will be excluded from the study on the basis of racial or ethnic origin. Both male and female clinicians and practice members will be included in the study. Additionally, male and female patients and parents of patients at enrolled practices will be included in analyses. Clinicians and practice members will be asked to provide confirm interest at the start of the study. Parents will receive information about the study, explaining how the data they provide on their surveys will be used. We will not collect information that would identify a woman as pregnant. The study poses minimal risk to pregnant women.

## **15.0 INFORMED CONSENT**

### Children

This protocol does involve male and female children ages 11 to 17 years. In Aim III, we will be sending children (and their parents) that get seen in the clinics we will work with in Aim II surveys to complete that describe the children's (and their parents') knowledge, attitudes, beliefs, and behaviors relating to the HPV vaccine. In addition to the surveys, children and their parents will receive information about the study – via information sheets – explaining how the data they provide on their surveys will be used. These information sheets will be used in lieu of signed consent forms in order to

not collect patient names or other PHI. However, the sheets will contain check boxes for individuals to indicate their consent to participate in the study. If the study team receives an information sheet with a dissenting (“No, I would not like to participate in the study.”) remark, we will not review that patient’s survey data (if completed). A letter from the child’s physician will also accompany the survey and information sheet. This letter will describe why the clinic is participating in the study, what the survey results will be used for, and contact information for the study’s project manager so the child/parent can call and ask this individual questions relating to the study and their participation and/or the survey. If need be, we will create information sheets, surveys, and letters in Spanish, Russian, French, etc. to accommodate non-English speaking subjects.

We are waiving documentation of consent due to the 1) desire for the study team to not obtain PHI-related data from the children and/or their parents; we want to collect anonymous data, and 2) the large number of children and parents we hope to engage in this part of the study, making it not feasible for us to obtain consent in-person or over the phone with each child and their parent.

Once Aim III materials are finalized, we will submit them to the IRB.

## **16.0 CHANGES TO PROTOCOL**

Any modification of this protocol must be documented in the form of a protocol revision or amendment signed by the principal investigator and approved by the Knight Cancer Institute and the IRB before the revision or amendment may be implemented. The only circumstance in which the amendment may be initiated without regulatory approval is for a change necessary to eliminate an apparent and immediate hazard to the patient. In that event, the investigator must notify the IRB in writing within 5 working days after the implementation.

## **17.0 PRIVACY, CONFIDENTIALITY, AND DATA SECURITY**

The data we collect will not contain any personal identifiers. All data will be stored on secure servers as well as secure, password-protected computers in locked offices. We will use information sheets in lieu of signed consent forms for the interviews and surveys; participants and data/responses cannot be connected. The data will be maintained indefinitely..

## **18.0 OHSU IRB REPORTING OF UNANTICIPATED PROBLEMS AND ADVERSE EVENTS**

Not Applicable.

## **19.0 OHSU KNIGHT CANCER INSTITUTE DATA AND SAFETY MONITORING PLAN**

Not Applicable.

## **20.0 INCLUSION OF WOMEN, MINORITIES AND CHILDREN**

No subject will be excluded from the study on the basis of racial or ethnic origin. Both male and female clinicians and practice members will be included in the study. Additionally, male and female patients and parents of patients at enrolled practices will be included in analyses. Clinicians and practice members will be asked to confirm participation at the start of the study (via an information sheet).

Parents will receive information about the study, explaining how the data they provide on surveys will be used.

## **21.0 INCLUSION OF CHILDREN**

This protocol does involve male and female children ages 11 to 17 years. We will attain children’s assent regarding completion of surveys by having them check a box on page 3 of the information sheet indicating whether they want to participate in the study or not. Children will receive information about the study via the information sheet, explaining how the data they provide on their surveys will be used.

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