

Official Title	PREVENT: Practice-based Approaches to Promote HPV Vaccination in the Safety Net - BootCamp Translation
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SPECIFIC AIMS

Human papillomavirus (HPV) infection causes of over 36,000 new cancer cases of cervical, ano-genital, and oropharyngeal cancers in the United States each year.¹ While multi-valent vaccinations to prevent HPV infections have been available since 2006, **uptake of the HPV vaccine is well below national Healthy People 2030 targets** (80% of adolescents at ages 13-15 years up-to-date with HPV vaccination).² Adolescent vaccination rates are especially **low in rural areas** (more than 11% lower than in urban areas).³

Compared to urban residents, rural residents have a higher incidence of HPV-related cancers and face unique barriers to HPV vaccination, including limited access to providers, fewer vaccine reminders, longer travel time to clinics, and less favorable societal norms about HPV vaccination.⁴⁻⁸ Moreover, rural adolescents are less likely than their urban counterparts to receive a provider recommendation for the HPV vaccine.⁹ Rural healthcare teams are often limited by a lack of systematic methods to identify and track eligible patients and/or their parents for outreach.^{9, 10} While much is known about clinic-based approaches to improve HPV vaccination among urban residents, less is known about their effectiveness among rural residents, including rural Hispanic populations, the fastest growing sub-population in rural settings. Hispanic persons have a higher incidence of HPV-related cancers than non-Hispanic white persons.¹¹ As a result, ensuring that Hispanics persons are up to date on HPV vaccination is a public health priority. The proposed study is designed to address these barriers by adapting and testing approaches to effectively communicate the importance of vaccination to improve HPV vaccination rates for rural populations, and the sub-populations within (e.g., Hispanic persons).

The most promising approaches to increase HPV vaccine uptake include the use of patient reminder systems and strong provider recommendations (e.g., presumptive messages and bundling HPV vaccination with other recommended vaccines).¹² While these communication strategies often occur during clinic visits, they have not been incorporated into low-cost reminders for rural patients, such as automated phone calls and text messages. Research is critically needed to leverage public health messages to promote broad-scale vaccination and lessen HPV vaccination disparities. Our study includes a randomized controlled trial of adapted HPV vaccination reminders to address the needs of diverse rural populations. We will create clinic systems to prompt vaccination for eligible children/adolescents and deliver messages to parents/caregivers, whose mode and content is specifically tailored for rural and rural Hispanic populations.

Our study, Practice-based Approaches to Promote HPV Vaccination in the Safety Net (PREVENT), incorporates formative patient- and clinic-informed research to design and evaluate an automated data-driven reminder intervention using low-cost approaches (automated phone calls and text messages). We will compare **usual care** to **Automated Patient Reminders (Auto)**, and to a higher-intensity intervention arm using automated messages plus linguistically and culturally tailored interventions to deliver live reminders, **Automated Plus Live Patient Reminders (Auto-Plus)**. PREVENT's design and evaluation will involve tailoring message mode and content for parents/caregivers of rural and ethnically diverse rural patients.

Our Specific Aims are listed below: :

Aim 1: Design format and content of an intervention to promote adolescent HPV vaccine coverage that will consider the unique information needs of diverse rural parents/caregivers. Bootcamp

Translation methods will provide the framework to effectively target HPV vaccination messages for rural and rural Hispanic Mountain West parents/caregivers of HPV vaccine eligible children/adolescents.

Aim 2: Test a set of automated reminders (defined during Aim 1) on timely receipt of next needed HPV vaccine dose and on series completion. Hypotheses: Auto and Auto-Plus interventions will be more effective than usual care and Auto-Plus will be more effective than Auto at increasing HPV vaccination.

Aim 3: Assess implementation outcomes and identify multi-level barriers and facilitators to implementation and effectiveness. Implementation outcomes (e.g., acceptability, fidelity, adoption, acceptance, maintenance) are defined using Proctor and RE-AIM frameworks.

This study will **serve as one of the first** to develop and test the effectiveness of strategies to promote HPV vaccination among diverse rural parents and caregivers of children ages 11-17 years in the Mountain West. Our strong multi-disciplinary research team demonstrates successful partnerships with primary care practices in rural populations. Once implemented into practice, our intervention could significantly reduce disparities in the burden of HPV-associated cancers among rural populations in the United States.

RESEARCH STRATEGY

A. SIGNIFICANCE

A.1. Improving HPV vaccine uptake could prevent tens of thousands of cancer cases each year. HPV is a sexually transmitted infection that causes cervical, anal, penile, vaginal, vulvar, and oropharyngeal cancers, and genital warts. While HPV vaccination can prevent most HPV-related cancers, more than 21,000 women and 15,000 men are diagnosed with HPV-associated cancers each year in the United States (**US**).¹³ In addition, more than 200,000 women are diagnosed with HPV-related pre-cancer of the cervix, more than 500,000 persons are diagnosed with genital warts, and thousands are diagnosed with recurrent respiratory papillomatosis (**RRP**).¹⁴ This is troubling given that HPV vaccination rates remain substantially lower than national Healthy People 2030 targets (80% of adolescents at ages 13-15 years up-to-date with HPV vaccination).¹⁵ Indeed, only about 55% of adolescents have met this target more than 14 years after the vaccine was recommended for girls and 9 years after the recommendation for boys.¹⁶ *Improving uptake of the HPV vaccine is a public health imperative.*

A.2. Higher HPV vaccine uptake in rural communities could improve health outcomes for this unique population. US nonmetropolitan residents have higher cervical cancer incidence, late-stage diagnoses, and HPV-related cancer death rates than metropolitan residents.⁴ Data from the 2020 National Immunization Survey-Teen survey show startlingly low HPV vaccine initiation and series completion rates for adolescents in rural regions at up to 11.2 percentage points lower than for urban regions. In 2019, similar disparities are shown for HPV vaccination by rurality in the US (**Figure 1**).¹⁶ Using vaccine registry data, in Utah, teens living in rural areas were 1.8 times more likely than urban residents to have a missed opportunity for HPV vaccination. This occurs when another immunization is received without concomitant delivery of the HPV vaccine.¹⁷ In Montana, 54% of more than 71,000 vaccination visits were missed opportunities. Furthermore, rural adolescents had more than a 1.1 adjusted relative risk for a missed opportunity for the HPV vaccine compared to urban residents.¹⁸ *Developing and deploying effective strategies for improving rural HPV vaccine coverage is critical.*

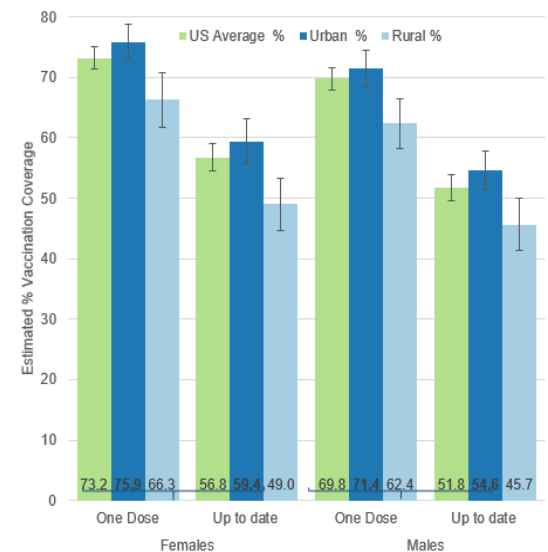


Figure 1. NIS-Teen HPV vaccination coverage among teens by urbanicity of geographic residence, 2019. Includes 95% confidence intervals.

Hispanics represent the fastest growing rural subgroup in the US.¹⁹ Nevertheless, data on HPV vaccination practices among rural Hispanics are scarce. National Immunization Survey-Teen (2018) data show that while Hispanics ages 13–17 years have higher overall HPV vaccination rates than non-Hispanic whites (76% vs. 64%), **the Hispanic urban-rural disparity is particularly stark: a 17–21 percentage-point difference exists in Hispanic urban-rural rates of HPV vaccine initiation (73% vs. 56%) and series completion (61% vs. 40%).**²⁰ In a survey carried out by Dr. Kepka in 2020-21 of young adults in the Western United States (N=2,937), rural Hispanic young adults ages 18-26 were less likely to have received any dose of the HPV vaccine compared to urban Hispanics (50.5% vs. 59.0%, respectively). Moreover, significantly fewer Hispanic rural young adults (55.0%) expressed vaccine confidence compared with their Hispanic urban counterparts (71.0%). *Hispanics face a disproportionate burden of HPV-related cancers*, including a 1.4-fold increased cervical cancer incidence and a 1.5-fold increased penile cancer incidence, compared to non-Hispanic whites.¹¹ Furthermore, compared to urban Hispanics, rural Hispanics often have lower incomes, fewer resources, lower levels of education, and face additional challenges related to access to healthcare in rural settings.²¹⁻²³ Thus, *closing the disparity in HPV vaccination rates will require efforts to engage parents/caregivers (**P/C**) of rural adolescents, including rural Hispanic subpopulations.*

A.3. Rural barriers to HPV vaccination are multi-factorial. A robust body of literature explicates barriers to receiving preventive health services, including vaccination for HPV,⁵⁻⁸ underscoring distinct challenges faced by rural residents.²⁴⁻²⁶ At the patient level, individuals and P/C often lack awareness of the importance of vaccination, experience fear or fatalism, or are dissuaded by prevailing anti-vaccination norms.^{7, 12, 27-29} Rural residents may experience limited health care (**H/C**) access. For example, studies show that rural adolescents

are less likely than urban counterparts to attend a well-child visit and to receive a provider recommendation for HPV vaccination.^{9, 30-33} In addition, providers and clinics are often limited by a lack of systematic methods for identifying patients eligible for vaccination; inadequate reimbursement and time for counseling about vaccination; and follow-up systems that do not track intervals for repeated doses.¹⁰

Rural clinics also face shortages of medical providers, especially pediatricians, well-versed in delivering vaccines.^{8, 34, 35}

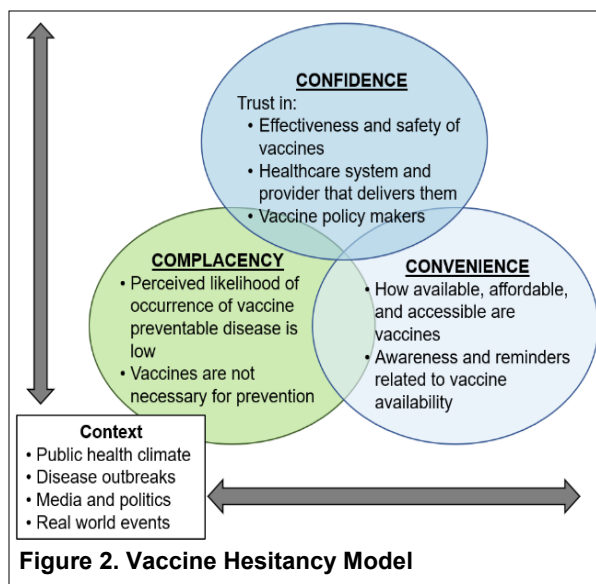
Rural communities have been further challenged by the coronavirus disease pandemic (**COVID-19**) from early 2020-present. Rural communities have lost more lives than urban communities from 2020-2021.³⁶ Rural communities have also had higher rates of COVID-19 vaccine hesitancy compared to urban communities in the US.^{37, 38} In the Mountain West, our team found that rural young adults, compared to urban young adults, were less likely to say that they would receive the COVID-19 vaccine and were more likely to state that they do not trust vaccines in general.³⁹

Specifically, COVID-19 has placed unprecedented strain on the entire US healthcare (**HC**) system.⁴⁰ In the US, the vast majority of non-essential medical care (e.g., well-child visits) did not occur during the peak of the COVID-19 pandemic.^{41, 42} Early in the pandemic, up to 40% of appointments for children's immunizations, and up to 80% of appointments for teen's HPV vaccinations, have been missed.⁴³ As well-child visits have been resuming, adolescents have been the least likely to catch-up on immunizations, compared to younger children and infants.⁴⁴ Furthermore, publicly-insured adolescents have experienced significantly greater declines in immunizations since March 2020 than privately insured adolescents.^{45, 46} Although doses delivered during June-September 2020 increased, this increase was insufficient to achieve adequate catch-up coverage.⁴⁷ HPV vaccination has declined as a major priority for healthcare teams during the complications of the pandemic.⁴⁸ It is expected that it will take from 2-10 years to recover from the losses in adolescent and childhood immunizations related to disruptions in care from the COVID-19 pandemic.⁴⁹ In a recent survey of rural healthcare team members in Utah, Dr. Kepka and her team found that throughout the pandemic, rural clinics faced many healthcare system level challenges that took priority over getting adolescents back on track with adolescent immunizations.

A.4. Now is the time to improve HPV vaccinations in rural settings to accomplish our Healthy People 2030 goal of 80% of adolescents ages 13-15 years up to date on HPV vaccination. Assisting primary care providers with tailored and effective P/C reminder systems for child and adolescent (**C/A**) vaccinations may facilitate timely P/C access to primary care services following COVID-19 related interruptions in non-essential medical care services. Our study will specifically design and evaluate an intervention to address the needs of diverse rural populations whose members are predominantly Hispanic (primarily of Mexican origin) and non-Hispanic white.

A.5. Strategies are needed to reduce HPV vaccine hesitancy in rural communities. Our proposed intervention will reduce vaccine hesitancy. Vaccine hesitancy is influenced by aspects of P/C confidence, complacency, and perceived convenience (**Figure 2**). HPV vaccination confidence relates to a P/C's trust in their HC team's recommendation,^{50, 51} complacency reflects prioritization and perceived importance of vaccination,⁵²⁻⁵⁴ and convenience describes the ease of receiving the vaccine.^{55, 56} These factors are influenced by contextual components such as a global pandemic. For this project, the COVID-19 pandemic may raise awareness about the importance of vaccination, enhance P/Cs' trust in provider recommendations,^{57, 58} and activate P/C to engage in preventive practices (e.g., vaccination for HPV). Other epidemics have been associated with improved vaccination rates and attitudes in some populations.⁵⁹⁻⁶¹ However, the COVID-19 pandemic may also increase P/C levels of vaccine hesitancy due to ongoing exposure to anti-vaccine sentiment in social, political, media-related, and institutional environments.⁶²

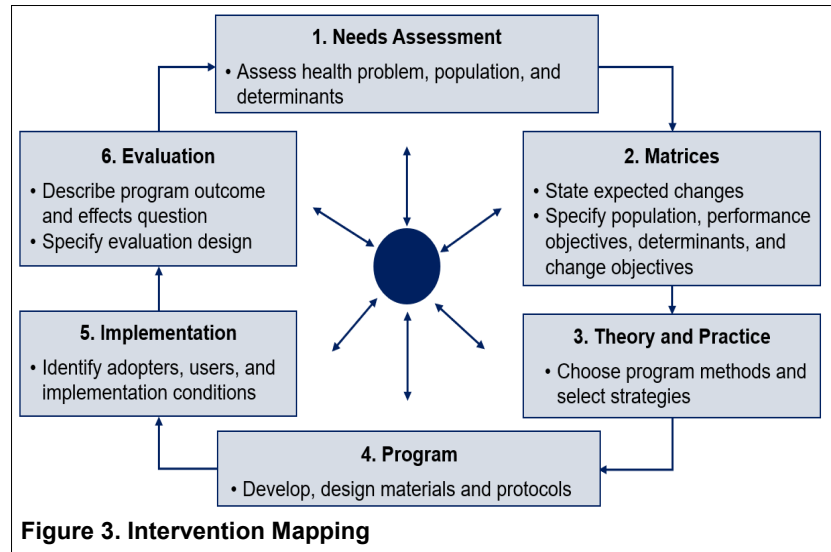
A.6. Multi-level interventions are needed to reduce HPV vaccination disparities. Solving complex public



health issues requires consideration of factors at multiple levels, including the individual (e.g., fear and fatalism), clinician (e.g., missed opportunities), clinic (e.g., limited operating hours), community, and society (e.g., low awareness and prioritization of vaccine). Current studies find that multi-level interventions are synergistic: interventions targeting P/C and HC teams achieve higher levels of HPV vaccine uptake than interventions targeting either group alone.^{12,36,63} However, *past studies lack adequate rigor because few multi-level interventions assessing HPV vaccine receipt have been developed and tested, and even fewer have been tested in rural settings.*^{37-39,63} Our study will develop and test effective multi-level intervention components for vulnerable populations. We will use intervention mapping (IM), developed by Bartholomew and others,⁶⁴ to identify factors and to plan each step of the intervention with the Intermountain West (IMW) HPV Vaccination Coalition (**Figure 3; Section C2; letters of support**).⁶⁵ The IM model has been implemented in multiple settings and uses six components for improved intervention outcomes: needs assessment, matrices, theory and practice, program, implementation, and evaluation.⁶⁴ IM is increasingly used to systematically plan preventive care interventions and ensure incorporation of stakeholder input at each step.⁶⁶⁻⁶⁸ We will apply IM to develop and test HPV vaccination patient reminders for P/C.

A.7. HPV reminder programs show promise, but face important barriers. Our team summarized the literature on HPV reminder programs with a subgroup of IMW HPV Vaccination Coalition members (**IM Step 1: Figure 3**).⁶⁵ Technology-based approaches hold several advantages, including broad availability, low cost, and use of formats both minimally intrusive and highly flexible.^{12, 69} Generally, patient reminders and strong provider recommendations (e.g., presumptive, bundled messages) offer the most promising evidence.¹² In an integrative review of the literature that included more than 50 studies, results found that improved HPV vaccination rates through text message reminder systems were found.⁷⁰ Reminder and recall systems demonstrate an untapped positive HPV vaccine intervention strategy for rural US settings.^{71, 72} However, several important gaps remain, including limited knowledge about differential improvement in combining technology-based interventions with human-delivered components.⁷³ Few previous studies have tested strong HC team recommendations with automated reminders.⁷⁴ Our study will fill these gaps by developing messages crafted by rural parents/caregivers, delivering them through recommended modes, testing the addition of live interactive components, and reporting intervention reach and effectiveness.

A.8. Summary and Impact. In 2020, only about 55% of US adolescents were up to date with HPV vaccination, a troubling fact given that timely vaccinations could prevent more than 90% of HPV-associated cancers and reduce cervical cancer incidence by up to 100%.^{16, 75, 76} Due to the COVID-19 pandemic, the 2021 HPV vaccination rates are expected to be lower than in 2020. Completion of HPV vaccination is *exceedingly low* in rural areas (49.2% nationally),^{16, 76} far below national averages and target rates. This study will target the groups least likely to undergo vaccination—those living in rural areas who have minimal education, low access to HC, lower incomes, and those of Hispanic ethnicity.⁷⁶ Our participatory approach will provide valuable information on translating evidence-based interventions to optimize HPV vaccination coverage in diverse rural clinics. Once implemented into practice, our intervention could significantly reduce disparities in HPV-associated cancers and cancer burden.



B. INNOVATION

This project builds upon Drs. Kepka (PI) and Coronado's (Co-I) history of successful collaborations with rural primary care clinics. The PREVENT Program will make unique scientific contributions in the following ways:

- **PREVENT is designed to address the needs of rural population subgroups.** A well-recognized limitation

of rural research is the lack of attention paid to population subgroups within rural communities. PREVENT will be the first to tailor its approaches to address the needs of the fastest growing rural population subgroup, Hispanic persons. This subgroup experiences a pronounced urban-rural disparity in HPV vaccination rates. PREVENT will accelerate the adoption of proven approaches in health systems with diverse rural clinics.

- **PREVENT will be tailored for language and culture, will be both practice and patient-centered.** Most previous studies have applied a one-size-fits-all approach to promoting HPV vaccination. While such approaches are important, they often cannot answer clinic administrators' critical questions, such as "*will this intervention work in my setting?*" or "*can I pare down this intervention and expect the same result?*" Our interventions will leverage existing resources (including electronic health records [EHR], state-level registries, and clinic/community services) and innovatively tailor the intervention for cultural factors and language.
- **PREVENT is designed for sustainability.** PREVENT will first adapt and test an intervention to promote HPV vaccine initiation and timely series completion in rural clinics. This approach allows for tailoring based on the best available evidence and local system preferences. It also aims to achieve long-term sustainability.
- **PREVENT will apply proven approaches to engage parents/caregivers and other stakeholders in all stages of the research process.** Building on our established partnership with a multi-state HPV Vaccination Coalition, our approach will involve P/C and HC teams and will consider state-of-the-art communication approaches—e.g. strong, presumptive recommendations bundled with other vaccine recommendations and reminders sent through preferred modes—while prioritizing the needs and preferences of end users.
- **PREVENT will incorporate innovative modalities for parent/caregiver engagement in Bootcamp Translation follow-up activities and will also include live interactive and tailored HPV vaccination reminders.** We will adapt text and phone-delivered messages using Bootcamp Translation (BCT), then iteratively refine them by gathering real time feedback on them from Hispanic and non-Hispanic white rural parents/caregivers. Furthermore, our Auto-Plus intervention includes an interactive web-based coaching tool that prompts patient navigators during live phone calls with P/C on how to best respond to varying types and levels of P/C vaccine hesitancy.

C. APPROACH

C.1. Project Overview: This two-stage study was designed in collaboration with Sea Mar Community Health Centers, an active member of Dr. Kepka's IMW HPV Vaccination Coalition.⁶⁵ The proposed project optimally aligns with the expertise of the study team and leverages our clinic partner's commitment to improving HPV vaccination and reducing disparities in HPV-related cancer incidence and mortality. Our study will test automated and live reminders for HPV vaccination (**Figure 4**). In Phase I (Years 1-2), we will refine intervention components and messages to increase HPV vaccination among rural C/A. **We will use a validated patient-engaged approach for P/Cs, BCT, with separate sessions conducted in English and Spanish.** In Phase II, we will conduct a P/C randomized controlled trial (**RCT**) that tests automated strategies (e.g., automated phone calls, text messages) and combined automated and interactive live strategies to prompt P/Cs of vaccine-eligible C/A to complete the next dose of the HPV vaccine (i.e. first, second, or third dose depending on age of C/A). The individual-RCT will include P/Cs of 1038 vaccine-eligible patients at 4 rural clinics in Washington (Rural-Urban Continuum Codes of 3-9). This trial could significantly reduce HPV-associated cancer disparities and can be sustained long-term.

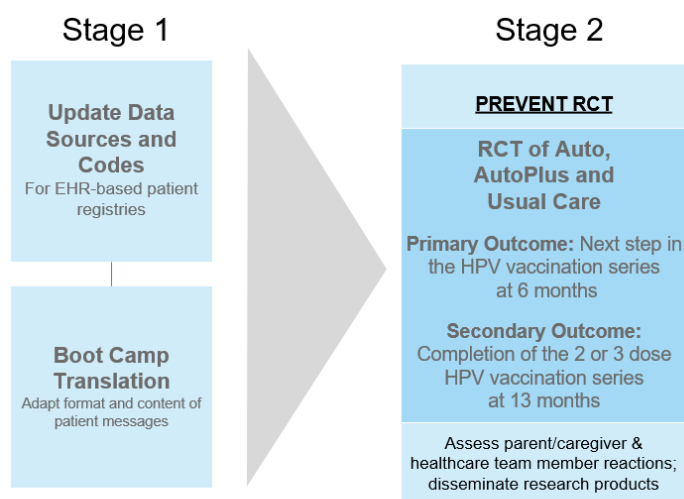


Figure 4. PREVENT Study Design.

EHR = electronic health records; RCT = randomized controlled trial; HPV = human papillomavirus

C.2. Research Team and Preliminary Data: Our multidisciplinary team includes investigators with a record of developing and testing multiple cancer prevention interventions; analysts with years of experience designing registries and reminder and recall systems; implementation scientists; and qualitative researchers. Dr. Kepka will lead this project in partnership with Dr. Coronado and Dr. Ricardo Jimenez, Medical Director at Sea Mar,

who has 28 years of experience at Sea Mar and collaborated on 3 previous quality improvement projects with Dr. Coronado. Dr. Noel Brewer (consultant) and Dr. Heather Brandt (consultant) will provide research expertise in HPV provider communication and dissemination and implementation science. Dr. Chelsey Schlechter (Co-I) is also an expert in dissemination and implementation science. Biostatistician Dr. Ben Haaland has more than a decade of experience designing, analyzing, and reporting on RCTs, and Drs. Erin Rothwell and Warner contribute expertise in qualitative methodologies. Dr. Turok, a primary care physician, has been one of Dr. Kepka's mentors and collaborators since she was a KL2 scholar (2013-15). Lastly, Dr. Echo Warner is an expert on text message-delivered research methodologies. Dr. Kepka has successfully collaborated with Dr. Brewer in the past⁷⁷ and has worked with Drs. Haaland, Rothwell, Brandt, Schlechter and Warner on many funded studies.^{65, 78-83}

Dr. Kepka is a health services researcher who leads a successful, independent program in HPV-related cancers, vaccination, and cancer screening among vulnerable populations. A national leader in HPV vaccination research, she has more than 15 years of experience collaborating with at-risk communities through community-based partnerships. At the Huntsman Cancer Institute, Dr. Kepka formed and directs the multi-state IMW HPV Vaccination Coalition (**Section C3**).⁶⁵ In partnership with the Coalition, Dr. Kepka conducted 14 focus groups involving HC team members and providers (HCP), community stakeholders, and P/Cs of children ages 11–17 years in rural Utah, Colorado, Nevada, Montana, and Arizona (N=140 participants; 3P30 CA042014-2958). Focus groups assessed system-level barriers and needed adaptations for implementing evidence-based HPV vaccination strategies in rural primary care clinics (**Table 1**).⁸⁴ The findings underscore P/Cs' uncertainty about which vaccines to get and providers' and stakeholders' desire for systems to remind P/Cs to obtain the vaccine. Dr. Kepka hosts monthly video-call meetings with partners (**Letters of support**).^{65, 82}

Table 1. Multi-level Barriers to HPV Vaccination in Rural Settings Identified in Rural Mountain West Focus Groups

Parent/caregiver challenges (n = 34)	N (%)
Uncertainty about which vaccines to get	12 (35.6)
Cost of vaccine	7 (21.1)
Time to clinic	5 (15.2)
Cost of clinic visit	5 (15.2)
Scheduling clinic appointment	4 (12.1)
Distance to clinic	1 (3.03)
Provider/stakeholder challenges (n = 99)	N (%)
No system to remind parents for 2nd dose	21 (21.2)
No records of previous vaccines for patient	13 (13.1)
No system to remind providers to talk with Parents/Caregivers	12 (12.1)
No standing orders for the HPV vaccine	8 (8.1)

Table 2. Selected Sea Mar Community Health Center Clinics*

Sea Mar Clinic Location	N patients (2019)	% Rural	% Hispanic	N patients ages 11-17 years	Among Patients Ages 11-12 Yrs.*		Among Patients Ages 13-17 Yrs.*	
					% HPV vac. Initiat.	% HPV vac. complet.	% HPV vaccine initiat.	% HPV vaccine complet.
Ocean Shores	2971	40.1	5.6	158	36.7	2.6	45.5	25.6
Aberdeen	3941	40.1	14.9	241	45.4	8.5	62.1	44.8
Elma	982	40.1	21.8	73	53.3	16.3	74.7	67.7
Yelm	4088	29.0	13.0	566	48.3	18.2	58.5	44.3

*Estimated 5% decline in HPV vaccination rates shown due to COVID-19 pandemic challenges

(through research subcontracts and impact fees) with over 18 community organizations; she has led or co-led more than 15 NIH-funded grants using community-engagement to improve health and HC in rural and Hispanic populations. Drs. Coronado and Kepka first collaborated on a pilot study to improve HPV vaccine awareness and knowledge among Hispanic P/C of age-eligible adolescents in rural Washington. **Radionovela to Improve HPV Vaccination** (PI: Coronado) developed and tested a community-informed HPV vaccination intervention that included a pamphlet and Spanish-language *radionovela*.^{85, 86} At the Center for Health Research, Dr. Coronado has led several practice-based cancer prevention initiatives. One initiative, focused on colorectal cancer (CRC) screening, **STOP CRC, demonstrated the feasibility of testing reminders at Sea Mar** (UH3CA188640; MPIs: Coronado, Green). As part of STOP CRC, Coronado's team designed a series of real-time EHR reports that relied on a library of user-expandable metrics to gather data from several sources.⁸⁷ An embedded Sea Mar sub-study tested various FIT reminders, including text messages, automated and live phone calls, letters and patient portal messages. Findings showed an overall FIT completion rate of 33%, with the highest completion observed the combination of automated *plus* live phone calls for Hispanic individuals

Dr. Coronado, an epidemiologist, is bilingual in English and Spanish and a national leader in practice-based cancer prevention research in safety net clinics. Dr. Coronado and her team have established formal collaborations

(49%).⁸⁸ The **Center for Hispanic Health Promotion: Reducing Cancer Disparities** (U54CA153502; Research Director: Coronado) engaged in a partnership with a rural health center to test a culturally-tailored cervical cancer screening curriculum developed using IM.⁸⁹⁻⁹¹ **SMARTER CRC** (UG3CA244298) focuses on improving CRC screening, follow-up, and referral to care in rural populations. The program has recruited 3 Medicaid Plans and 30 clinics, further demonstrating our success in partnering with rural clinics.

Preliminary Data Collected During the COVID-19 Pandemic. Since January 2021, we have interviewed 22 rural and rural Hispanic P/Cs in the Mountain West. These P/Cs have explicitly stated that they need targeted HPV vaccine intervention messages that answer specific concerns and counter misinformation. The rural and rural Hispanic P/Cs prefer text, emails, and phone calls to address vaccine hesitancy domains (**Figure 2**). In our recent survey of young adults ages 18-26 (n=2937), receiving information and reminders about the HPV vaccine from a HC professional was associated with receipt of the HPV vaccine for rural (76% v 24%, $P<.0001$) and Hispanic participants (73% v 28%, $p<.01$). Dr. Kepka and her team successfully pilot-tested a targeted HPV vaccination automated messaging campaign in rural Colorado that improved the intention of rural parents and caregivers to receive the HPV vaccine and complete the multi-dose series.⁸²

C.3. Research Design

C.3.a. Study Setting: Community participation is crucial to the success of studies and programs targeting underserved populations.⁹²⁻⁹⁵ PREVENT will be carried out in a 3-way partnership between Huntsman Cancer Institute, Kaiser Permanente Center for Health Research, and Sea Mar Community Health Centers. Through Sea Mar and the IMW HPV Vaccination Coalition's large network, the proposed trial can improve HPV vaccination rates, accelerate dissemination of findings, and lessen HPV-related cancer mortality.⁹⁶

Huntsman Cancer Institute (HCI): Headquartered in Salt Lake City, HCI is the only National Cancer Institute-designated comprehensive cancer center in the Mountain West. The Institute sponsors the IMW HPV Vaccination Coalition, formed by Dr. Kepka in 2014.⁶⁵ The Coalition brings together immunization program representatives, P/C, HCP, and community members who share the common goal of improving HPV vaccination rates. Initially formed with 100 members in Utah, Idaho, and Nevada, the Coalition now includes more than 400 members in 12 Mountain West states, including Washington and Oregon. Through cross-sector collaborations among diverse stakeholder communities, the Coalition is building a coordinated plan to implement innovative and evidence-based strategies to address regional barriers to HPV vaccination.⁶⁵

Kaiser Permanente Center for Health Research (CHR): A member of the Health Care Systems Research Network and Cancer Research Network, CHR has a long track record of successful practice-based research, including a history of productive collaboration with Sea Mar. Dr. Coronado began a partnership with Sea Mar in 2004, launching a pilot study to improve rates of CRC screening, using mailed FIT outreach.⁹⁷ Since that time, Dr. Coronado and Sea Mar have worked on 3 NIH-funded projects with sharing data across organizations.

Sea Mar Community Health Centers: Sea Mar is a federally qualified health center (**FQHC**) that operates 35 primary care clinics (4 rural clinics will participate in this trial; **Table 2**), serving more than 300,000 unique patients in Western Washington, of whom 70% have household incomes at or below the federal poverty level and about 40% are Hispanic persons.^{98, 99} Sea Mar is well equipped to serve as a partner in PREVENT (**IM Steps 1 & 2: Needs Assessment & Matrices**). Dr. Jimenez has engaged in efforts over the past 3 years to create systems to track and improve HPV vaccination rates. Community health and outreach staff in all Sea Mar clinics are fluent in Spanish and English. Sea Mar has strong technological resources to carry out this project, including the Epic EHR, with nearly complete data capture for vaccinations and demographic characteristics. Sea Mar maintains an ongoing contract with ClientTell (Valdosta, GA), who provides state-of-the-art automated telephone reminders for patients with upcoming appointments and delivered automated phone calls and text messages for the STOP CRC project (**Section C.2.**). The system, fully integrated in the EHR, notifies the user as to whether a phone message or text was received. Sea Mar also uses a patient portal that allows patients and P/C to view their health summaries and test results, request medical appointments, see vaccinations that are due, and communicate electronically and securely with their HCP. HPV vaccine events are recorded as laboratory procedures. Vaccines completed outside of Sea Mar are obtained from the *Washington State Immunization Information System (WA-IIS)*, through a bi-directional health information exchange. HPV vaccines for uninsured or Medicaid-eligible individuals <18 years old are covered through the Centers for Disease Control and Prevention's (**CDC**) Vaccines for Children Program.¹⁰⁰ Insurance covers all other vaccines. In addition to the four Sea Mar clinics that will participate in this trial, we can offer

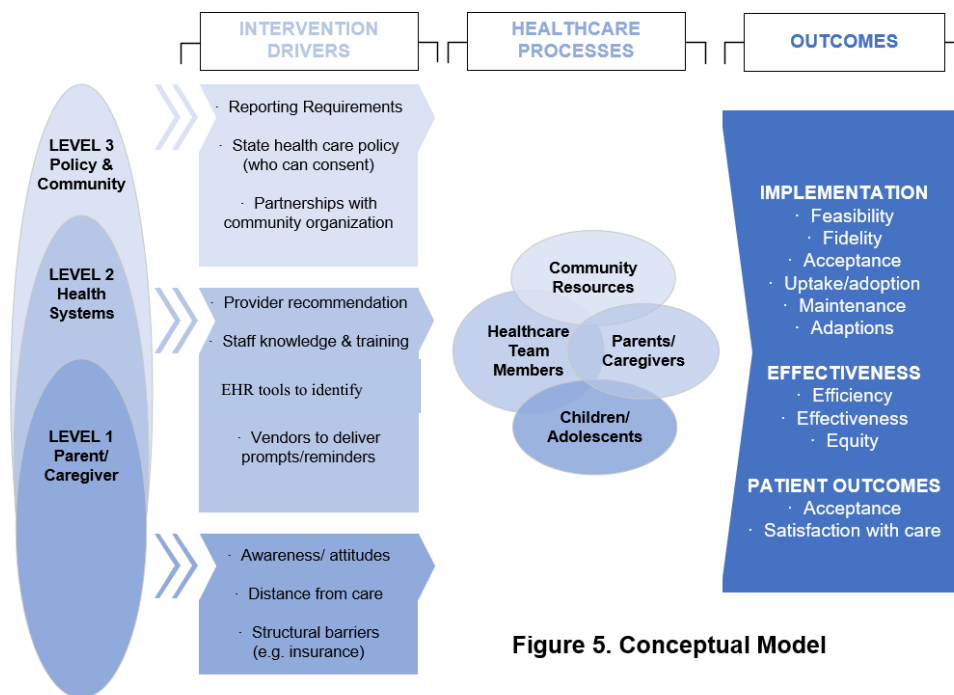


Figure 5. Conceptual Model

participation to an additional 30 Sea Mar clinics as alternate performance sites, and other rural clinics affiliated with the IMW HPV Vaccination Coalition are also available as performance sites (**Letters of Support**).^{65, 84}

C.3.b. Conceptual model (IM Step 3): We will use several frameworks and validated processes to guide PREVENT activities (**Figure 5**). IM outlines steps for organizing our efforts to adapt and implement research-tested interventions in new settings (**Figure 3**). Our participatory research methods engage multiple partners as equitable collaborators in the research process.^{101, 102} We will

use BCT to engage parents/caregivers in translating health information into concepts, messages, and materials that are understandable, meaningful, and engaging to the target population,^{103, 104} and to develop new messages that leverage national attention on vaccinations and public health prevention initiatives, as a result of the pandemic.^{103, 105} Dr. Coronado, trained as BCT facilitator, will use the method to culturally and linguistically adapt material and define intervention components. Applying the Proctor Implementation Framework, including RE-AIM Framework domains,¹⁰⁶⁻¹¹¹ we will gather quantitative data to assess the **Reach** and **Effectiveness** of the reminder intervention and gather qualitative data from P/C, HCP, and community organizations to identify clinic-level enhancements and assess barriers/facilitators to PREVENT's broad **Adoption, Implementation, and Maintenance**.¹¹²

C.4. Specific Aim 1: Design format and content of an intervention to promote adolescent HPV vaccine coverage that will consider unique information needs of diverse rural parents/caregivers.

We will use BCT to develop locally relevant intervention materials (e.g., reminder phone scripts for automated calls, text messages, and patient portal messages for P/C). Targeted promotional materials for HPV vaccination are available in Spanish and could be translated into other languages, as needed.⁹⁹ Newly designed messages and materials will seek to counter anti-vaccination sentiment by leveraging cancer prevention, vaccine effectiveness, and vaccine safety messages. BCT methods will provide the framework to tailor HPV vaccination messages for rural and Hispanic IMW P/C. (**IM Step 4**).

C.4.a. Bootcamp Translation: BCT, a method for engaging diverse stakeholders in a consensus-building process,^{103, 104} has been used by our team to actively develop and adapt study interventions.^{105, 113} It uses an iterative, flexible schedule of face-to-face meetings combined with short, focused teleconferences in a process that addresses 2 questions: *"What do we need to say in our message to the community (newly HPV vaccine-eligible adolescents and adolescents who have not completed the HPV vaccination series)?"* and *"How do we deliver that message to our community?"* BCT emphasizes no wrong answers and no hierarchy of expertise. The process requires 15-20 hours of participant time over 3-6 months.

We will recruit P/C (i.e., participants) for BCT sessions by working with Sea Mar's project manager to generate a list of potential P/C of patients across the 4 clinics. Eligible participants: a] are P/C of C/As ages 11-17 (age eligible for HPV vaccination); b] P/C with active clinic patients (i.e., have been seen in the clinic in the last 12 months); and c] P/C who speak either English or Spanish. About 1038 patients in the 4 rural Sea Mar partner clinics (**Table 2**) meet these criteria. We will select participants to achieve a mix of HPV vaccination behaviors (from never vaccinated to up-to-date), sex of parent, sex of child, age, and language. We will send letters to prospective participants on clinic letterhead (in English and Spanish). Within 2 weeks, we will make follow-up

calls to discuss BCT and conduct a brief intake survey. We will recruit 6 participants from each clinic (24 total): 12 whose preferred language is English and 12 whose preferred language is Spanish. Two Sea Mar providers (Dr. Gibbs and Ms. Torres) and 2 members of the Coalition (Dr. Shannon and Ms. Jaquette) will participate.

Dr. Coronado will lead the project team in applying Bootcamp Translation. **We will conduct 2 parallel sessions, one in English and one in Spanish, with approximately 14 participants per session** (12 patients, 2 Sea Mar staff). The in-person or live Zoom presentation will consist of an expert presentation by Drs. Kepka and Coronado (for the Spanish-language presentation) with input from Drs. Brewer and Brandt. They will share research on the safety and effectiveness of the HPV vaccine and social norms about vaccination. They will educate participants about the six different types of cancers that are prevented by the HPV vaccine among women and men in the United States. Drs. Kepka and Coronado will also present up-to-date evidence on effective messaging by clinicians (e.g., using presumptive statements, bundling HPV vaccine recommendations with recommendations for other vaccines)¹¹⁴⁻¹¹⁷ as well as novel formats for educational messages (e.g., digital videos, narratives).^{51, 118}

Participants will be assigned to a Spanish-language or English-language text message group, as appropriate, to provide iterative feedback to the research team on HPV vaccination messages over a 3-month period. Our clinical partners in rural communities emphasized the high prevalence of mobile phone use among the parents/caregivers in their communities for seeking and sharing health information, and nationally 95% of adults ages 18-49 have a smartphone, including the majority of Hispanics (85%) and rural residents (80%).¹¹⁹ Further, obtaining feedback from P/C about the suitability of HPV vaccine messages through text messaging will facilitate more specific and tailored feedback from participants, increased accessibility for individuals who may have limited access to meet in-person,¹²⁰ and provides an opportunity where individuals may feel more comfortable sharing their opinions and perceptions than they would during a face-to-face or synchronous online experience. Text messages **will emphasize individual involvement and personal meaning to enhance retention and promote engagement**. Text messages between study staff and BCT participants will occur through the text messaging Twillio, which we have previously used to pilot HPV vaccine reminders. Text messages will be designed to elicit feedback on the HPV vaccination messages (which are suitable for girls vs. boys, English vs. Spanish speaking parents/caregivers) that are developed during the Bootcamp sessions, on reminder scripts (i.e., automated call scripts, text messages, patient portal messages), and on key intervention components (e.g., reminder type, number, sequence). The text messages will occur two times per week. This process can be automated using the text-messaging tool Twillio. Each text will ask participants to provide their feedback via text response. Messages will be pilot tested.¹²¹

Because the BCT process is interactive and iterative, recording and transcribing sessions is often impractical. Instead, field notes will be taken by our team in English and/or Spanish during each session and shared during weekly meetings of the project team. Reminder materials tailored through BCT and proposed protocols for the intervention will be reviewed by members of the IMW HPV Vaccination Coalition and tested during study Aim 2. Following BCT, we will finalize our trial protocol, including procedures for the Auto and the Auto-Plus arms of the intervention, and will finalize methods for data coordination, management, and ongoing monitoring. Because our goal is to craft materials and messages that are motivating for English- and Spanish-speakers, we do not anticipate directly translating materials from English to Spanish. Instead, we rely on BCT and native speakers to craft messages from the ground up; this approach was successful in prior research.¹¹³ We aim for a broad scale-up, all English and Spanish materials will be reviewed by the Sea Mar marketing and communications office for appropriateness and equivalency.¹²² **C.4.b. Update Data Sources and Codes:** In preparation for the RCT, we will define automated codes to manage interventions so that P/Cs of vaccine eligible C/As, who receive initial HPV vaccination, are prompted to receive follow-up vaccine on time. Dr. Coronado, a community clinic EHR data expert, will lead this work.

Inclusion and Exclusion Criteria and Data Sources: Working with clinic staff, our research team will use patient-level inclusion and exclusion criteria based on current HPV vaccine guidelines to determine P/C participant eligibility. These criteria will consider previous HPV vaccination history, clinic visits (as a proxy for patient enrollment), clinical conditions that influence CDC HPV vaccine recommendations (e.g., pregnancy), age (11-17), and other factors.¹²³ For this study, language will also be a criterion, as we plan to conduct the intervention in English and Spanish. We anticipate that EHR systems at our 4 clinics will likely provide complete information on vaccination status for HPV and other vaccines (e.g., Tdap, meningococcal). *The Washington State Department of Health maintains accurate, up-to-date information on vaccination status in the WA-IIS, and*

patient-level immunization data are already routinely provided to Sea Mar through a health information exchange.¹²⁴ As part of Aim 1, we will perform sensitivity analysis, cross tabulation, and targeted chart audits (of up to 100 charts from each clinic) to assess the agreement between HPV vaccine events found in the EHR and in the state-level vaccine registries, recognizing that previous studies have reported agreement ranging from 96% to 99%.¹²⁵ Epic offers existing tools for documenting external procedures and discrete code-based fields for categorizing laboratory events and needed follow-up. We will provide support and training to enter these data within our clinics' EHR, to assure complete data when possible.

C.5. Aim 2: Test a set of automated reminders (defined during Aim 1) on timely receipt of next needed HPV vaccine dose and on series completion.

We hypothesize that Auto and Auto-Plus interventions will be more effective than usual care, and Auto-Plus will be more effective than Auto at increasing receipt of the next needed HPV vaccine dose and on series completion. We will implement and evaluate the intervention in 4 clinics using an individual-RCT design (**IM Steps 5 and 6**). Our quantitative evaluation will assess intervention effectiveness and reach. We will gather P/C-, patient- and HCP-level data to identify possible program enhancements, as well as barriers and facilitators to adoption, implementation, and maintenance.

C.5.a. Convene Teams and Train Staff: Each participating clinic will convene an implementation team comprised of a clinic champion, clinic coordinator, and relevant laboratory and administrative personnel whom we will select for their ability to facilitate the intervention within the clinic settings. Once the team is formed, members of the PREVENT research team and clinic staff will train the participating clinics in delivering the intervention. Staff training will take place during a half-day session (with additional phone support) and will address procedures for identifying P/C of eligible patients and tracking automated outreach (e.g., automated phone calls, text messages). Clinics will receive training specific to the Auto-Plus components, such as the live phone call and patient navigation protocols using as computer assisted interactive system.

C.5.b. Intervention Process: Focused on HPV vaccine initiation. Through BCT, we will select a set of HPV vaccine initiation reminders to encourage uptake among age- and vaccine-eligible adolescents. Reminders could include letters (with strong provider recommendations, and bundled recommendations), text messages with links to digital stories, patient and/or P/C narratives, letters, automated phone calls, or email messages. Because we hope to implement this trial as part of standard care, our study will apply to obtain a waiver of informed consent, which was successful in STOP CRC because intervention components are similar to primary health care settings' standards of care and imply minimal risk (**See Section C.2**). Sea Mar analysts will create a real-time list of patients due for an initial HPV vaccine dose, and the clinic outreach coordinator will review the list and remove any patients missing telephone number or address (if a mailed intervention is selected). P/C of remaining children and adolescent patients (i.e., participants) will be individually randomized to either Auto or Auto-Plus intervention or UC, in a 1:1:1 ratio. The PREVENT study will only target one child/adolescent per parent/caregiver (siblings will be excluded from intervention assessments). In Sea Mar clinics, 87% of phone numbers of patients eligible for CRC screening (aged 50-75) could receive text messages; we expect a higher percentage for the younger cohort in this trial.⁸⁸ Participant lists will be sent to Sea Mar's communications vendor (ClienTell) for delivery of automated HPV vaccine initiation prompts; the UC group will not receive tailored reminders but will only receive opportunistic vaccine reminders that are delivered during clinic visits or MyChart EHR-based patient portal reminders. As in STOP CRC, real-time participant lists will be refreshed to discontinue reminders for P/C of patients who have received a given vaccine dose.

Consistent with the desire of clinic staff to integrate this project into their standard workflows, we will use automated codes to manage interventions so that eligible patients get initial HPV vaccines on time and P/C are prompted to repeat vaccination, as recommended. Our EHR tools rely on Reporting Workbench, a population management tool in Epic which will be customized to include tools needed for tracking completion of HPV vaccination at the 4 intervention clinics.¹²⁶ The registry will list patients' HPV vaccination history as well as key demographic variables for the intervention (e.g., name, address, preferred language). We will select a cohort of approximately 1,038 P/C of patients from the 4 clinics, randomized to intervention arms (UC, Auto, and Auto-Plus) stratified by clinic, sex, and language preference (English, Spanish, other) to ensure a nearly balanced distribution of clinic, sex, and language preference among study arms. The registry will generate 2 real-time reports: 1] HPV vaccination outcomes (i.e., date of vaccination events, and whether the event represents series initiation, second dose, and/or series completion); and 2] PREVENT intervention activities (i.e., date of

Table 3: Schedules of Measures (part.=participants; T=time, Y=year; M=month)				
Variable	Data source	How measured	Proctor/ RE-AIM domain	T
Aim 1: Bootcamp Translation (BCT)				
Rural parent-/ caregiver- & provider-driven adaptations/ program acceptance	Parents / providers	Notes from BCT sessions	Adaptations, Acceptance	Y 1
Aim 2: PREVENT Randomized Controlled Trial (RCT)				
Reach of RCT – primary outcome (next needed HPV vaccine dose)	EHR; vendor logs	N part. receive program/ N anticipated, reasons	Reach	6 m
Reach of RCT – secondary outcome (completion of HPV vaccine series)	EHR; vendor logs	N part. receive program/ N anticipated, reasons	Reach	6 m
Effectiveness of RCT – primary outcome	EHR	N C/A complete next HPV vaccine dose/ N anticipated	Effectiveness	6 m
Effectiveness of RCT – secondary outcome	EHR	N C/A complete all doses of HPV vaccine ² / N anticipated	Effectiveness	13 m
Aim 3: Tertiary and Qualitative Outcomes				
Moderators (e.g., sex of parent, sex of child, age, ethnicity, etc.)	EHR data	Effectiveness of intervention by presence of moderator	Equity	6 m
Parent/caregiver reactions	Interviews	Coded transcripts	Acceptance	Y 3
Provider/staff reactions	Interviews	Coded transcripts	Acceptance, Adoption, Implementation, Maintenance	Y 3
Parent/caregiver/child	EHR/Administrative data	Delivery/receipt of interventions as intended	Fidelity	Y 3
Clinic-, community-level barriers / facilitators to implementation/ sustainability	Interviews	Coded transcripts	Adaptations, Acceptance, Maintenance	Y 3

mailing, date of automated phone calls, text messages, patient portal messages). We will use reports to monitor and maintain quality assurance during intervention implementation, and Reporting Workbench to automate patient-specific mass mailings for P/C, and HPV vaccine orders.

Automated Intervention (Auto): Auto intervention participants will be eligible for outreach delivered using automated phone calls, text or email messages with the mode, frequency, timing of reminders, and message content refined using BCT. Automated outreach may also include innovative communication strategies, such as text-linked videos, P/C, or patient narratives (based on BCT). Auto outreach to P/C will invite P/Cs to attend free HPV vaccination visits and will emphasize family-friendly hours.

Automated Intervention Plus (Auto-Plus): Auto-Plus intervention participants will be eligible for automated reminders, plus additional P/C prompts for patients who do not undergo vaccination within 3 weeks. These prompts may be delivered via live phone call outreach or patient navigation.

Working with clinic leadership and using the findings BCT, activities will be selected from a list of possible options from the National HPV Vaccination Roundtable (previously chaired by Dr. Brewer), and our ranking of the effectiveness of language- and culturally-tailored intervention materials. Recommended interventions:

- Live phone call outreach: Live phone call outreach allows outreach staff to answer P/C questions, ease vaccination resistance, and facilitate appointment scheduling in real-time. Sea Mar outreach staff are already trained in motivational interviewing, and we prompt them in HPV-specific communication techniques (i.e., presumptive language, bundled recommendations, as appropriate).
- Interactive web-based coaching tool: Live calls will be facilitated by an interactive web-based coaching tool that prompts patient navigators during live phone calls with P/C on how to best respond to varying types and levels of P/C vaccine hesitancy. This tool will be developed by Drs. Kepka and Coronado in partnership with HCI's bioinformatics core. P/C identified vaccine hesitancy barriers may fall within the broad domains related to vaccine confidence, vaccine complacency, and vaccine convenience (**Figure 2**).
- Patient navigators: trained staff who promote healthful behaviors by addressing barriers to care. Navigators can respond to the cultural needs of their patients—such as values of *personalismo* or *respeto*.^{127, 128}

C.5.c. Intervention Process: Focused on HPV vaccine series completion. The BCT process will define the format (mode and frequency) and content of messages to promote vaccine series completion. The clinic-level analysts will generate real-time lists of patients who have initiated the HPV vaccine and are due for a follow-up dose, stratified by age group (11–14 vs. 15–17). The list will include adolescents age 11–14 years who have completed an initial dose of the HPV vaccine and are due for a second dose (within 6-12 months) and those aged 15–17 who are due for a second or third dose. While Auto and Auto-Plus interventions for series

completion may use some of the same components as vaccine initiation (automated calls, live calls, text messages, emails, and mailings), some notable differences will likely exist. HPV vaccine initiation may bundle recommendations for HPV and for other needed vaccines (e.g., “[Patient name] is due for the following vaccines: HPV; meningococcal; Tetanus, Diphtheria, Pertussis”), whereas series completion will not need bundled messages. Series completion reminders will include scheduling and appointment reminders.⁶⁹

C.5.d. Evaluation: Based on our previous research and conversation with clinic staff, we have designed Phase I to include multiple components. Using the Proctor Implementation and RE-AIM frameworks, we will track intervention reach and effectiveness. We will conduct one-on-one interviews with participants and debrief interviews with HCP to illuminate persistent barriers to HPV vaccination uptake and factors important to program acceptability, maintenance, and sustainability. **Table 3** summarizes these measures.

Program Effectiveness: We will assess intervention effectiveness for each of the three study arms, calculated as the proportion of eligible children/adolescents who received any HPV vaccine within 6 months and 13 months (series completion by one year) of randomization. We will assess the proportion of C/A who initiated HPV vaccination, those who received the next needed dose and the percent who completed the series.

Study Design: We propose a 3-arm RCT to compare rates of completing the next step in the HPV vaccination series at 6 months and completing the HPV vaccination series at 13 months between Auto, Auto-Plus, and UC arms. P/C of C/A who have not completed the HPV vaccination series will be randomized 1:1:1 to study arms, with separate randomizations within each clinic (Ocean Shores, Aberdeen, Elma, or Yelm) and patient-level HPV vaccination initiation status (series initiated or not initiated). Participants will be assessed for eligibility and, if eligible, enrolled within the 4 clinics at their first visit time during the 12-month study period, with a total participant time on study of 13 months, for a total of 25 months of enrollment, execution, and follow-up.

Statistical Approaches: The primary comparisons are between the rates of completing the next step in the HPV vaccination series at 6 months in the Auto, Auto-Plus, and UC arms (Primary Outcome), and between the rates of completing the HPV vaccination series at 13 months (Secondary Outcome). Completing the next step in the vaccine series and completing the vaccine series outcomes will be compared via logistic generalized estimating equations (GEE) models,^{129, 130} with bias-reduced robust sandwich variance estimators¹³¹ clustered by clinic. These logistic GEEs will be adjusted for P/C and patient features that may influence HPV vaccination series next step and completion, including age, sex, race/ethnicity, rurality, and HPV vaccination initiation status at study enrollment. Models comparing the Auto, Auto-Plus, and UC groups, will also include study arm. Comparisons between the study arms of the next-step and series-completion endpoints will be performed separately. For each endpoint, pairwise differences between arms will be assessed with a Bonferroni correction to achieve type I error control at 0.05, with $p < 0.017 = 0.05/3$ needed for statistical significance. Pre-defined subgroup analyses will be performed by P/C and/or patient sex, age group, race/ethnicity, rurality, and HPV vaccination initiation status at study enrollment, and each of these characteristics will be assessed for effect moderation. Since next step completion and series completion will be captured via the EHR and the state-wide vaccine registry, we anticipate little missing data for these outcomes. Statistical Analysis and Power:

Based on the **Table 2**, there are 1038 patients in the appropriate age range, of whom <50% will have completed the HPV vaccination series, for at least 519 patients within the eligible age range who have not yet completed the HPV vaccination series, with at least 173 in each study arm. 173 participants per study arm will ensure >80% power for detecting rate differences for both the next step endpoint and series completion endpoint exceeding 0.17, under the Bonferroni statistical significance benchmark of $p < 0.017$. If the completion endpoint rate is 50% in the Auto-Plus arm and is 33% in the UC arm (rate difference 0.17), then the proposed study will have 80% power for detecting a difference by arm. Moderators: We will assess differences across study arms in our secondary outcome: missed opportunities, defined as patients who receive other recommended vaccinations, but not HPV. We will also explore possible moderators of effectiveness: age (11–14, 15–17), ethnicity (Hispanic vs. non-Hispanic white), sex (male vs. female vs. other), language (Spanish vs. English), poverty status (<100% Federal Poverty Level vs ≥100% Federal Poverty Level), and insurance status (commercial vs. Medicaid vs. other). Thus, we will consider **sex a biological variable**, an important distinction because of differing rates of HPV vaccination and barriers faced by adolescent males and females.¹³²⁻¹³⁵ By assessing differences in effectiveness **across the life course of ages 11–14 and 15–17**, we will understand differences in groups for whom 2 doses and 3 doses of the vaccine is recommended. Each potential moderator will be tested separately by considering its main effect and interaction with study arm in the logistic mixed effects models (Aim 2). Evidence of differential intervention effectiveness will be supported by an overall test of

the potential moderator by study arm interaction effects.

C.6. Specific Aim 3: Assess implementation outcomes and identify multi-level barriers and facilitators to implementation.

We will accomplish this aim using mixed methods assessment (**IM Steps 5 and 6**) and assessing implementation outcomes from administrative and EHR data. With guidance from Dr. Brewer (consultant), we will conduct qualitative assessment that will consist of P/C interviews conducted 6 months following randomization in Phase II of the PREVENT study as well as HCP interviews conducted in Year 4. The assessments will gather P/C and HC team member reactions to the intervention and recommended areas for improvement, including provider- and clinic-level practices that could enhance the program and organizational-level factors that influence adoption, implementation, and maintenance over time. **C.6.a. Parent/Caregiver Interviews:** During the intervention-testing stage, we will conduct one-on-one interviews to elucidate factors related to non-adherence to HPV vaccination recommendations (e.g., awareness, anti-vaccination norms) among English- or Spanish-speaking P/C who received HPV reminders. One-on-one interviews can help identify salient constructs related to health behavior and are recommended for sensitive topic areas.¹³⁶ About 40 P/C who received reminders during the previous 6 months will participate in the interviews. An interview guide will be developed based on study team expertise, BCT experiences, process notes taken during meetings, a literature review, and factors hypothesized to influence implementation and effectiveness outcomes derived from the Proctor and RE-AIM frameworks. We expect that 40 interviews will suffice to obtain both the breadth and depth of information and data saturation.¹³⁷⁻¹³⁹ Interviews will be held either by phone or in person at the clinic and will last about an hour. Participants will be offered a stipend (\$25) as a token of appreciation. Eligible participants, identified using clinic records, will be mailed an introductory letter (including a phone number for the project office), then called by phone. Interviews will be digitally recorded using password-protected devices, professionally transcribed, and imported into ATLAS.ti for data management and analysis. Bilingual study team members (Dr. Coronado and Ms. Rivelli) and a qualitative methodologist (Dr. Rothwell) will content analyze the interviews.¹³⁹⁻¹⁴¹ A subset of transcripts will be reviewed to develop a codebook, applying codes to passages of transcript text, then iteratively reviewing code reports to identify common themes. Team members will meet regularly to discuss differences in coding and themes until consensus is reached; inter-rater reliability will be established by between-coder agreement in coded text. High-level summaries of acceptability/maintenance will occur. **C.6.b. Provider/Staff Interviews:** Staff interviews will address clinical practices, plans for adaptations and stakeholder attributes that influence implementation and long-term maintenance, using questions informed by Proctor and RE-AIM, and based on instruments developed by Weiner et al., Brownson et al. and others.¹⁴²⁻¹⁴⁵ We will ask about the HPV Vaccination Roundtable's evidence-based HPV vaccination recommended practices (i.e., standing orders, EHR provider prompts, family-friendly office hours, immunization champion(s), strong recommendation, provider feedback, vaccination recommendation at every visit, and team huddles).¹⁴⁶ Debrief interviews with HCP will be conducted by phone and audio-recorded, and will last about 45 minutes. Recorded interviews will be transcribed, and analyzed according to the process described above for P/C interviews, involving design and application of a codebook, iterative review of reports against actual transcripts, and development of summarized themes (acceptance, adoption, maintenance, and future recommendations). **C.6.c. Intervention Fidelity:** Administrative and EHR data will be used to obtain the extent to which interventions were delivered and received as intended. Metrics include intervention fidelity (e.g., proportion of C/A that received/interacted with outreach staff and patient navigators, received/interacted with interventions).

C.7. Potential Challenges and Alternative Solutions: By design, we are conducting this research in 4 clinics, so will likely encounter barriers inherent to research in real-world delivery systems, such as changes in operating conditions or practice guidelines. The registry tools we will develop will be flexible to such changes. Our selection of P/C of eligible patients relies partially on data from other vaccination sites; nevertheless, we will cross-reference our EHR list with immunization registry data, minimizing the possibility of outreaching to P/C of patients who are not due. Clinic drop-out and slower-than-anticipated participant recruitment can hamper study progress; nevertheless, we can recruit from among the other 30+ clinics that Sea Mar operates, and Coalition partner clinics (**Letters of Support**). To prevent contamination, only one child per household will be targeted with the P/C intervention components.

C.8. Conclusion: Timely HPV vaccinations could prevent more than 90% of HPV-associated cancers.^{75, 76} This study will target the groups least likely to undergo vaccination, US rural and rural Hispanic communities.⁷⁶

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