

A. Cover Page

1. *Title:* Increasing Immunization Coverage in Adolescents by Partnering with Dental Providers

Grant ID #: 15422277

2. Abstract:

In an integrated medical-dental healthcare delivery system, we will test if a strong dental provider recommendation, coupled with clear step-by-step instructions for getting vaccinated, will improve adolescent vaccination rates. The Kaiser Permanente delivery system in Oregon and Washington (KPNW) has close to 17,000 11-to-17 year old members who have both dental and medical insurance. Sixty percent of these members had at least one dental visit in 2013. Our intervention will 1) develop scripts for dental providers, 2) provide brochures or flyers for patients and their parents, and 3) give “assisted referral” to the closest location (e.g. nurse treatment desk) offering vaccinations. Using a randomized controlled design, we will assign 8 of the 16 dental offices in KPNW to the education-plus intervention condition and 8 to the control condition. To evaluate the impact of our intervention, we will monitor vaccination coverage rates using a comprehensive electronic medical record. We will also survey parents of a select set of teens on their recent visits to the dental clinic, inquiring whether the provider recommended one or more vaccines, how they felt about the recommendation coming from a dental versus a medical provider, and whether or not they intend to vaccinate their child. We will also survey the providers to assess changes in their knowledge, behaviors, and beliefs. If successful, the proposed intervention will lead to strong recommendations for vaccination from dental providers, fewer missed opportunities for vaccination, and increased vaccination coverage rates.

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B. Proposal

1. Overall Goal & Objectives:

Using an integrated medical-dental healthcare delivery model, we will develop and assess a multi-level intervention to promote recommendation of adolescent vaccines in the dental setting. The study will occur in the Kaiser Permanente delivery system in Oregon and Washington (KPNW). If successful, the proposed intervention will lead to strong recommendations for vaccination from dental providers, fewer missed opportunities for vaccination, and increased vaccination coverage rates. Provider recommendation is a strong predictor of adolescent vaccine acceptance, particularly for HPV vaccination.^{1,2} We will:

1. Understand current dental providers' knowledge, attitudes, beliefs (KAB), and current clinical practices with regard to recommended adolescent vaccines.
2. Develop an educational program to increase providers' KAB about adolescent vaccines.
3. Develop an intervention to prompt dental providers to make strong recommendations for adolescent vaccinations and provide information and tools for parents to act on them.
4. Assess the utility, acceptability, and effectiveness of the program and, if successful, disseminate the program to other dental offices and practitioners.

Drs. Naleway and Henninger are long-time successful partners with the CDC in assessing adolescent vaccine uptake, safety, and effectiveness. Their work has improved understanding of factors associated with adolescent vaccine uptake and completion within our health-care delivery system, and has laid the foundation for the proposed intervention.^{3,4} Kaiser Permanente is committed to providing recommended preventive care and vaccinations to its members. In recent years, rates of vaccine refusal and delay have increased, and this proposed study will allow us to utilize additional providers, dental providers, within our delivery system to increase adolescent vaccination coverage rates.

Our study will be the first to engage dental-health providers as vaccination partners. Partnering with dental practitioners holds tremendous potential because they see hard-to-reach adolescent patients and, often, parents of these adolescents, twice a year for routine cleanings and examinations. Dental providers now have a strong incentive to recommend adolescent vaccinations because HPV vaccine could prevent many of the oral cancers they see and treat. Our study could lead to increased opportunities for vaccination by providing dental providers with the tools they need to effectively communicate about and promote vaccination to their patients.

2. Technical Approach:

Current Assessment of Need in Target Area

A large challenge to vaccinating adolescents is that they have fewer routine medical visits than younger children.⁵⁻⁷ However, most adolescents receive preventive dental care at least twice a year. Therefore, engaging dental providers to strongly recommend vaccination may create new opportunities for vaccinating adolescents. We have a unique opportunity to

engage dental providers in vaccination promotion, and to assess the results, because at KPNW the medical- and dental-care delivery systems are integrated. Additionally, a comprehensive electronic medical record (EMR) is available to capture patient visit information and vaccinations. This EMR system is available to all KPNW medical and dental providers and researchers.

KPNW has 46,154 members 11-17 years of age; 58% have medical coverage only, 37% have both medical and dental, and 5% have dental coverage only. Among adolescents with both medical and dental coverage, about 60% had at least one dental visit in the previous year and the mean number of dental visits in the past year in this group was 2.07 (range 0-24).

Thirty-five percent of adolescents with dual coverage and no medical visit in the past year had at least one dental visit. These dental visits represent missed opportunities to promote vaccination to these hard-to-reach adolescents.

Current rates of vaccination are somewhat higher in patients who have both medical and dental coverage versus medical coverage alone (Table 1). Although adolescent vaccination rates for KPNW are fairly consistent with national rates, there is still room for improvement and we are currently below Healthy People 2020 targets.⁸

Table 1. Vaccination rates among 11-17 Year old Kaiser Permanente Northwest Members*

Membership Type	Number	HPV [†]	Tdap [†]	MCV4 [†]	Influenza [†]
Medical	26,839	58%	78%	75%	62%
Medical/Dental	16,887	61%	84%	80%	67%
National Estimates [‡]		54% female; 21% male	85%	74%	
Healthy People 2020 Targets for vaccination coverage ⁹		80% in females 13-15 years (3 doses)	80% in children 13-15 years (1 dose)	80% in children 13-15 years (1 dose)	80% in children 13-17 (annually)

*As of Jan 1, 2014[†]; includes any vaccination since 1/1/05[‡] From National Immunization Survey (NIS)-Teen, 2012⁸

Dental providers, including dentists and hygienists, will be the primary audience for this intervention; these providers are already involved in addressing some “care gaps” at KPNW. Support staff can print a care-gap report from the EMR for scheduled patients which displays preventive-care recommendations (e.g., mammograms, pap tests, vaccinations that are due or overdue) and which is given to patients during their dental visit. KPNW supplies dental providers with a suggested generic script to accompany these reports, e.g., “In support of your overall health, here is a reminder from your primary-care provider.” However, the extent to which dental providers are using (or are comfortable with using) the care-gap reports and script is unknown. Furthermore, scripts specific to recommending adolescent vaccination have not yet been developed.

Project Design and Methods

The primary objective of the proposed project is to develop a multi-level intervention to encourage dental providers to make a strong vaccine recommendation to patients and their

parents. Our project includes assessments of baseline and post-intervention dental provider KAB and a survey of parents shortly after their adolescent's dental visit. We will also use the KPNW EMR to monitor changes in vaccination coverage rates. We will work in partnership with the Permanente Dental Associates Clinical Effectiveness Committee to discuss study operations and implementation, to develop appropriate materials for patients and parents, and to disseminate and communicate findings to dental providers throughout our network and beyond.

At baseline, we will conduct a brief online survey of the ~200 KPNW dental providers (dentists, dental hygienists) regarding their current KAB, current clinical practices, and comfort with current clinical practices related to the four vaccines routinely recommended for young adolescents. These four vaccines are the ones we will study for this proposal: Tdap, meningococcal, HPV, and influenza. We will utilize a previously published survey for family physicians and pediatricians,¹⁰ which will be adapted for use with dental providers. We will survey providers from all dental clinics throughout the region.

KPNW dental clinics are located throughout the Portland, OR-Vancouver, WA metropolitan area. Eight of the sixteen dental clinics are located in or near a Kaiser Permanente medical facility and regularly see pediatric patients. We will randomly assign all 16 dental offices in KPNW to either the control condition (i.e., usual care, as described above) or to the education-plus intervention condition. We will further classify each clinic by location (i.e., in/near medical clinic vs. not in/near medical clinic), and number of adolescent patients seen.

We will then develop an educational program and intervention to encourage dental providers to make strong recommendations regarding adolescent vaccination. We will implement the educational component of the program in the intervention clinics over a three-month period and will cover basic information regarding each vaccine, the diseases each vaccine prevents, and the importance of vaccinating during early adolescence. We will utilize existing educational materials adapted from the Centers for Disease Control and Prevention (CDC) website for health providers (<http://www.cdc.gov/vaccines/who/teens/for-hcp.html>), as well as the HPV-vaccine specific "You are the Key to Cancer Prevention" campaign (<http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html>). Control clinics will not receive the educational program.

The intervention component of our program will include three primary parts: 1) development of scripts for dental providers, 2) brochures or flyers for patients/parents for dental waiting rooms, and 3) "assisted referral" to the closest location (e.g. nurse treatment room) offering vaccinations.

In collaboration with our dental co-investigator we will develop scripts specific to adolescent vaccination to help providers make strong recommendations. We will make special efforts to ensure scripts are appropriate to the dental setting, and multiple versions will be piloted to increase the likelihood that providers are comfortable making the recommendations. We will offer the scripts and training to all providers including hygienists and dental assistants, but we will specifically recommend dentists as the preferred providers for making the recommendation to patients.

For patient/parent brochures and flyers, we will utilize existing CDC or KPNW materials. These materials will be reviewed with the Permanente Dental Associates group and KPNW Communications, and will be adapted as needed.

Assisted referral will involve providing the patient/parent with printed information (i.e., address, map, instructions for checking in at nurse treatment) of the closest location to obtain their vaccinations. KPNW members can receive all of their vaccinations within the health plan with no additional out-of-pocket costs or co-pays. Members can schedule appointments with their primary care providers to discuss and receive vaccinations, or they can walk in to one of the KPNW nurse treatment rooms without an appointment to receive a vaccination according to “standing order” protocols. We also administer large numbers of influenza vaccinations during our walk-in flu shot clinics available to members beginning in early fall each year. Our study co-investigator will help facilitate communications about this study with the medical delivery system. The Co-investigator currently serves on several operational committees within the health plan where he can provide frequent updates about study implementation and ensure cooperation with medical departments routinely providing vaccinations, including pediatrics, family medicine, and the nurse treatment rooms.

The intervention program will be implemented in intervention clinics only, starting in August, 2015 and will continue for a period of one year (see Study Timeline). Control clinics will not receive the intervention materials, and providers at intervention clinics will be advised not to share these materials with colleagues in control clinics throughout the duration of the study.

Evaluation Design

Qualitative Implementation Interviews

We will assess the fidelity of our intervention (i.e., determine if the target audience was fully engaged in the project), in two primary ways. First, we will conduct quarterly implementation interviews with 3-5 dental providers in the intervention clinics to assess utility and acceptability of the intervention, as well as to review any unanticipated barriers to implementation. Implementation interviews will be conducted by research staff experienced in qualitative interviewing techniques (see Organizational Detail section) using an implementation interview format previously used in other qualitative research studies at KPNW.¹¹ We will consider on-going revisions to intervention components as needed if we identify weaknesses in the effectiveness of the program and/or materials.

Parent Survey

As second assessment of fidelity, we will conduct a brief mailed paper survey of ~150 parents within one week of their child’s dental appointment. We will randomly select parents of adolescents with recent visits to the dental clinic and survey them about whether or not the provider recommended one or more adolescent vaccines. We will describe the number of missed opportunities for vaccine recommendation as reported by the parents. We will also ask them how they felt about receiving the recommendation from a dental versus a medical provider, and whether or not they intend to vaccinate their child.

To evaluate the impact of our intervention, we will monitor changes in vaccination rates pre- and post-implementation as the primary outcome measure. We will also conduct a follow-up survey (adapted from the baseline survey) of dental providers in both intervention and control clinics to assess changes in KAB and clinical practices.

Vaccination Data

We will use our EMR to collect information about vaccinations received. All vaccines given to KPNW members are recorded in an immunization registry database. This database contains information about the type of vaccine, vaccination date, manufacturer, lot number, and site and route of administration. Vaccines given in the past or outside of the health plan can also be recorded in the registry. Parent or patient vaccine refusal or delay is also documented using ICD-9 codes in the V64.0 group.

In addition to the KPNW registry, we are able to capture data from ALERT IIS, the State of Oregon immunization information system. This will allow us to capture vaccines given outside our health plan (e.g., at county health departments or women's health clinics). ALERT IIS historically captured only childhood immunization data but has recently expanded to capture adolescent and adult vaccinations as well. We successfully incorporated ALERT data into our recent Vaccine Safety Datalink study of HPV vaccine uptake.¹² We also expect to have access to the State of Washington immunization registry data this fall. This will allow us to capture data on our members who receive vaccinations outside of KPNW in Washington State.

Analysis of Post-Intervention Vaccination Rates

As part of our formal evaluation of the intervention, we will calculate and compare pre- and post-intervention vaccination rates for our intervention and control clinics using an interrupted time series design.¹³ We can identify individual adolescent patients with visits to dental clinics in the year prior to and the year after implementation. We can link these patients to our vaccine registry and will extract information about Tdap, HPV, MCV4, and influenza vaccinations received during the periods of interest.

We will calculate monthly clinic-specific vaccination coverage rates by dividing the number of adolescents receiving each vaccine by the count of patient visits per clinic as the denominator. For influenza vaccination, we will restrict our analysis to the six-month period (September through March) pre- and post-intervention when influenza vaccine is usually available. We will compare the monthly vaccination rates by clinic (intervention vs. control) using multilevel segmented regression, which is commonly used to examine changes in rates across time comparing rates prior and post implementation¹⁴⁻¹⁷ and will model site as a random effect. The model will yield an estimate of the level and slope across time of vaccination rates prior to implementation of the intervention in both arms and changes in the level and slope of rates after the intervention implementation in both arms. The change in level provides an estimate of the immediate effect of the intervention, and the change in slope provides an estimate of the effect of the intervention across time after implementation. We will look for potential effect moderators such as clinic location (in/near medical office vs. not) and size of clinic by including the product of these variables with arm into the models.

Twelve data points pre- and post-intervention is the minimum number used in similar segmented regression analyses used to inform policy at the system-level and adequate to detect modest effects.^{15,16,18} Our power will be more limited to detect differences in influenza

vaccination rates with only 6 months of observation pre- and post-intervention and to examine the moderator variables.

We expect vaccination rates at our control clinics to increase during the assessment period as providers and the health plan try to meet new HEDIS measures for HPV vaccination. We also expect that there may be some study contamination as patients may be seen at multiple dental clinics within our system and a small number of providers practice in more than one clinic.

Provider Survey

To determine whether the intervention affected provider knowledge, behaviors and beliefs, we will test for differences in residualized change between the intervention and control arms while controlling for the clustering of providers within clinics using generalized estimating equation (GEE) modeling.^{19,20} The dependent variable will be the change in the outcome from baseline to follow-up, and the independent variables will include arm and baseline outcome. We will adjust for the clustering of providers nested within clinics by specifying an unstructured working covariance structure and using robust standard errors. Assuming the outcomes are normally distributed, we will use an identity link with Gaussian distribution for all outcomes; otherwise we will specify an alternative functional form more appropriate to the data. A significant effect for arm would indicate that providers at the intervention and control sites differed in their change in knowledge, behaviors and/or beliefs after adjusting for baseline values.

Dissemination Plan

Although this study will be conducted in an integrated health- and dental-care delivery system serving a population in the Pacific Northwest, the outcomes of this project will be generalizable to other integrated health care systems where identifying vaccination gaps, recommending vaccination in the dental care system, and monitoring outcomes via an EMR can be implemented fully. For example, the Health Partners Foundation in Minnesota has more than 600 physicians and more than 60 dentists working in a similar integrated system. Marshfield Clinic Health System, which serves patients in over 50 Wisconsin locations, and many Federally-Qualified Health Centers (FQHCs) also provide integrated medical and dental care. These integrated systems are ripe for promoting the engagement of dental providers in raising rates of adolescent vaccination.

Many components of this intervention could also be adopted in private practices. Educational brochures and other parent resources could be easily incorporated in private dental practice settings. Vaccination education specifically geared toward dental providers can also be adopted in a stand-alone dental setting. Dental providers care about their patients overall health and we predict they will be extremely interested in recommending adolescent vaccinations, especially vaccinations linked to HPV. The body of evidence is growing rapidly larger and stronger that HPV causes a large number of head and neck and oral cancers, and the incidence of these cancers is increasing.²¹

3. Detailed Workplan and Deliverables Schedule:

Table 2 shows a detailed study work plan and deliverables schedule. The first six months of the project will be

focused on study start-up tasks and conducting the baseline provider survey. The next six months of the project will involve working with our dental collaborators to develop, pilot, and then implement the intervention in the intervention clinics. During this period, we will also finalize the Parent Survey for “real time” use throughout the intervention phase of the study.

The intervention will be implemented during the late summer/early fall of 2015, to ensure that the intervention is in place prior to influenza vaccination availability in our region (typically October of each year). The intervention will continue through October 2016 to allow for a full year of participation by our intervention clinics prior to conducting the follow-up assessment. During the intervention period, we will conduct quarterly interim assessments to determine the effectiveness and utility of the intervention materials. These assessments will include examining changes in vaccination-coverage data, feedback from provider implementation interviews, and parent-survey data. Feedback will be summarized and offered to providers at the intervention clinics and intervention materials and procedures will be refined as appropriate.

During the final six months of the project, we will conduct the final assessment of changes in vaccination coverage, conduct the provider follow-up survey, prepare a summary report for our dental collaborators, disseminate study materials to control clinics as appropriate, and begin work on manuscripts for publication.

Unless another schedule of reporting is requested from Pfizer, we will provide detailed written progress reports every six months, which will include final versions of all study materials developed up to that point.

QUARTER	STUDY TASKS	DELIVERABLES
<p align="center">YEAR 1 Nov 2014-Jan 2015</p>	<p>Project Start-Up:</p> <ul style="list-style-type: none"> • Project kick-off meeting • IRB and compliance approvals • Collect baseline vaccination coverage data • Assign clinics to intervention vs. usual care 	<ul style="list-style-type: none"> • IRB and compliance approvals • Study Manual of Procedures (MOP)
<p align="center">Feb 2015-Apr 2015</p>	<p>Baseline Provider survey:</p> <ul style="list-style-type: none"> • Finalize provider survey in collaboration with dental co-Investigator • Survey dental providers • Summarize findings of survey 	<ul style="list-style-type: none"> • Final version of baseline Provider Survey • Progress report to Pfizer by April 30, 2015.
<p align="center">May 2015-July 2015</p>	<p>Piloting Phase:</p> <ul style="list-style-type: none"> • Use information from survey, existing CDC materials, and input from dental collaborators to develop provider education/intervention program 	<ul style="list-style-type: none"> • Provider education program • Intervention materials • Final version of Parent Survey

	<ul style="list-style-type: none"> • Pilot education program and intervention in 1-2 intervention clinics • Finalize educational program and intervention materials 	
Aug 2015-Oct 2015	Implementation Phase: <ul style="list-style-type: none"> • Implement education and intervention program in all intervention (n=8) clinics 	<ul style="list-style-type: none"> • Annual report to Pfizer by October 31, 2015.
YEAR 2 Nov 2015-Jan 2016	Intervention Phase: <ul style="list-style-type: none"> • Continue intervention in all intervention clinics 	<ul style="list-style-type: none"> • Final version of implementation interview
Feb 2016-Apr 2016	<ul style="list-style-type: none"> • Continue intervention in all intervention clinics • Interim Assessment 1: <ul style="list-style-type: none"> • Assessment of changes in vaccination coverage with feedback to intervention providers • Implementation interviews with providers • “Real time” parent surveys • Revision/refinement of intervention as appropriate 	<ul style="list-style-type: none"> • Progress report to Pfizer by October 31, 2016.
May 2016-July 2016	<ul style="list-style-type: none"> • Continue intervention in all intervention clinics • Interim Assessment 2 	
Aug 2016-Oct 2016	<ul style="list-style-type: none"> • Continue intervention in all intervention clinics • Interim Assessment 3 	<ul style="list-style-type: none"> • Final version of Provider Follow-up Survey • Annual report to Pfizer by October 31, 2016.
YEAR 3 Nov 2016-Jan 2017	Follow-up Phase: <ul style="list-style-type: none"> • Final assessment of changes in vaccination coverage • Conduct follow-up provider survey 	
Feb 2017-Apr 2017	Project Wrap-Up Phase: <ul style="list-style-type: none"> • Summary report of findings to dental program • Manuscript preparation and dissemination activities 	<ul style="list-style-type: none"> • Final report to Pfizer by April 30, 2017.

C. Organizational Detail

1. Leadership and Organizational Capability:

The Center for Health Research

The Center for Health Research (CHR) is an academic-model organization that conducts independent research in a wide variety of areas including health services, public health, cancer screening, and many others. A significant portion of our research is conducted in the setting of a real-world delivery system. Through CHR's relationships with KPNW physicians and access to the comprehensive EMR linked to individual members' health records, we have a unique capacity for innovative, large-scale research. KPNW serves approximately 480,000 members and includes one of the largest dental plans in the United States, with about 200,000 members in northwest Oregon and southwest Washington. About 21% of members are under the age of 18. Medicare members represent about 14% of KPNW's population. KPNW members are demographically representative of the service area.

The CHR provides investigators with strong, centralized support for research operations activities. Data collection, processing, and analysis functions are carried out by centralized research operations departments, including the Survey Research Department (behavioral assessment/mental health interviewing, and recruitment), Data Coordination, Research Analysis, Programming, and Computer Operations. The CHR Biostatistics Core provides support and consultation to research projects on study design, data management, and data analyses. Staff in the Behavior Assessment and Change (BAC) department have extensive training in counseling and are all master's-level clinicians. BAC staff are experts in participant recruitment, adherence and retention measures, qualitative interviewing, and focus-group facilitation.

The CHR's organizational approach ensures that well-qualified staff are available as needed during the life cycle of a research project. Other centralized support staff include financial analysts, editors, secretaries, and graphic artists.

KPNW maintains administrative and clinical databases that are available to CHR investigators. In addition, CHR has developed and continues to maintain other databases that are used exclusively for research purposes. These databases are populated by data from KPNW's electronic administrative systems, from CHR's research data systems, and from the health plan's computerized clinical information system, HealthConnect. KP HealthConnect is the automated clinical information system used in all Kaiser Permanente medical facilities across the organization's eight regions. It is the world's largest private deployment of an electronic medical record system, and it contains detailed information on health problems, physical findings, tests ordered, medications prescribed, therapies ordered, and progress notes. KPNW data systems are linked using members' unique health record numbers, which never changes. These databases have allowed CHR investigators to conduct innovative population-based research for nearly five decades. Data contained in these systems are strictly protected by well-established confidentiality procedures. All research using data derived from these systems is subject to rigorous institutional, scientific, and human subjects' protection review.

Kaiser Permanente Dental Care Program

The Kaiser Permanente Dental Care Program in the Northwest region employs more than 130 dentists and specialists at 16 dental offices, making it one of largest group-dental practices in the U.S. The dental plan includes prepaid coverage for comprehensive preventive and restorative dental services; oral surgery; and periodontal, endodontic, orthodontic, prosthodontic, and implant services. The Dental Tracking System maintains all administrative and clinical data on all dental office visits in KPNW's Dental Care Program. This electronic dental tracking system is updated at each visit and includes demographic and benefit information, along with dental services provided and current and past treatment plans. Kaiser Permanente Northwest is the only KP region with an integrated dental care program. The program began as a federally funded demonstration project in the late 1960s and continues to partner with the Center for Health Research on pragmatic clinical trials and other studies. PDA is a member organization of the National Dental Practice-Based Research Network, through which the CHR has conducted about 20 studies to date.

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