

Title: Driving Technology-Enhanced Immunization Outreach in the Los Angeles Safety-Net

Abstract:

The Los Angeles County Department of Health Services (DHS) recognizes the disparities in pneumococcal vaccination rates within minority and safety-net patient populations. A review of electronic records for patients eligible for pneumococcal vaccinations found only 10% had received PCV13 or PPSV23 pneumococcal vaccine. We propose a three-pronged approach designed to increase pneumococcal immunizations within DHS. When proven successful, this generalizable approach will be scalable across multiple health care networks and systems. Program components include:

- Electronic identification of at-risk adults
- Automated interactive multi-modal outreach, communication and scheduling
- A Pneumococcal immunization protocol that expands which caregivers are able to vaccinate patients

DHS has created a standardized pneumococcal immunization protocol for administration and proper sequencing of PCV13 and PPSV23 vaccines. This approach allows non-provider staff to determine eligibility, order and administer pneumococcal vaccines. In addition to staff education, we will translate the protocol into an electronic algorithm that will identify potential vaccination-eligible patients. We will create a bilingual automated system that contacts patients via email, text message, and phone to provide pneumococcal immunization outreach and electronically negotiate vaccination appointment scheduling.

The Center for Community Health and Evaluation, a nationally respected health service research group external to DHS, will be an integral part of study design, measurement and analysis of outcomes. The evaluation will be conducted utilizing an interrupted time series for major outcomes. A small group of patients will undergo qualitative and quantitative structured interviews to provide deeper understanding of immunization facilitators and barriers. Findings will be disseminated to community and academic partners.

Goal: The Los Angeles County Department of Health Services (LAC DHS) will increase the pneumococcal immunization rate for the underserved through a three-pronged approach that includes (1) an immunization protocol that expands which caregivers are able to vaccinate patients, (2) electronic identification of at-risk adults, and (3) automated multi-modal outreach and scheduling. Utilization of standardized Interdisciplinary Practice Approved protocols will enable non-provider staff to order and administer pneumococcal vaccines safely, efficiently, and effectively.

Objectives:

1. Create and implement an algorithm to identify patients eligible for pneumococcal immunization.

The care gaps in pneumococcal vaccination described in this RFP are amplified within LAC DHS's safety-net, predominantly Hispanic patient population.¹ LAC DHS does not have a consistent, automated method to identify patients who are eligible for pneumococcal immunizations. We will create an algorithm to identify eligible patients and recommend appropriate pneumococcal vaccine(s) to be administered. The benefits of an algorithm are (1) that it will be easy to update and refine inclusion/exclusion criteria as pneumococcal vaccination recommendations evolve; (2) patients can be uniformly identified using the same criteria across the more than 340,000 continuity patients empaneled to Patient Centered Medical Homes (PCMH) across the county; (3) it can be integrated into and capitalized on existing LAC DHS infrastructure; and (4) it provides a foundation for a generalized solution scalable across health care networks and systems.

2. Educate providers on the indications for and sequencing of PCV13 and PPSV23 vaccine through use of a standardized pneumococcal immunization protocol.

We created a standardized pneumococcal immunization protocol that allows provider and non-provider clinical staff to facilitate and expedite patient care (Appendix A). We will educate staff on the appropriate use of, indications for, and sequencing of PCV13 and PPSV23 vaccines. Patient outreach will include pneumococcal immunization education designed for safety-net, minority, and Spanish-speaking populations. This program will be broadly implemented across more than 140 LAC DHS Patient Centered Medical Homes (PCMHs) that care for more than 340,000 patients. The design will address a number of system, provider, and patient barriers noted in this RFP. Broad education and spread efforts combined with patient communication infrastructure designed for low socioeconomic and minority patients will result in sustainable system level change.

3. Establish and evaluate bilingual multi-modal automated outreach mechanisms targeted to safety-net patients that will result in scheduled immunization appointments.

LAC DHS' successful track record with multi-modal automated outreach to safety-net patients will be the foundational platform upon which we will create an automated, bilingual outreach tool for pneumococcal immunization.²⁻⁵ Eligible patients will receive interactive communication delivered via email, text message, and voice. The communication will include features that allow the patient to self-schedule an immunization appointment and transmit data back to LAC DHS that indicates if the patient has immunization questions. Data collected through these

outreach methods will be used in parallel with existing LAC DHS registries and appointment systems.

4. *Integrate electronic pneumococcal immunization data into LAC DHS health systems.*

There is no systematic, electronic method to identify and automatically contact LAC DHS patients in need of pneumococcal vaccination. Funding provided by this grant will result in integration of pneumococcal-related data into existing electronic health systems (i.e., who should be vaccinated, when a patient will be vaccinated, if a patient has already been vaccinated or has declined). This will result in an increased number of patients who receive immunizations and allow us to better understand reasons for and patterns of vaccination variability.

5. *Increase the number of LAC DHS patients who receive pneumococcal immunization.*

The mission of LAC DHS is “to ensure access to high-quality, patient-centered, cost effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.” The program described in this application aligns directly with our mission. Pfizer funding will enable us to provide high quality, patient-centric care consistent with national recommendations by improving provider awareness and utilizing patient outreach methods that are specifically designed to integrate into patient’s routines.

Technical Approach:

Our proposal addresses all areas of interest enumerated in this RFP. We will focus our efforts on at-risk adult patients in the Los Angeles Safety-Net. Our intervention is a multi-disciplinary effort with a foundation of evidenced-based health information technology²⁻⁵ and clinical interventions^{6,7} that, if successful, will directly improve patient care. Our approach is designed for system-wide change that encompasses education, patient identification, outreach, scheduling and vaccine administration.

Needs Assessment:

The population seen at LAC DHS facilities is multicultural and diverse; 15% of patients are African Americans and 65% are Hispanic/Latinos. Many LAC DHS patients have multiple chronic conditions, are non-native English speakers, and remain uninsured or underinsured (43%) at higher rates than state or national levels.^{8,9} Social problems (i.e., poor social/community support, chronic homelessness) compound the impact of disease in this population. Within LAC DHS, more than 40% of patients have diabetes, heart failure, or asthma, and one or more other chronic conditions.^{8,10} Improving the quality and coordination of immunization care for high-need, high-cost patients is crucial to reducing health care disparities among vulnerable populations.^{11,12} Funding from Pfizer will enable us to comprehensively address disparities in pneumococcal immunizations within our patient population.

Current immunization data are captured across multiple systems from multiple data sources and aggregated by analysts. Funding from this grant will support a streamlined approach to understanding gaps in pneumococcal vaccinations. A review of electronic sources of patients revealed that of those eligible for the pneumococcal vaccine, only 10% had received

the appropriate vaccination. This low rate is likely a combination of low immunization rates and poor electronic capture of immunization. This care gap potentially affects more than 65,000 patients.

The US median (inclusive of all races/ethnicities) for appropriate pneumococcal immunization is approximately 69%.¹³ Estimates of pneumococcal vaccination rates for African Americans nationally range from 46% - 61%.¹³⁻¹⁵ Estimated pneumococcal immunization rates for Hispanics nationally range from 19% to 59%.^{1,13-15} Within Los Angeles County, across all socio-economic and insurance statuses, pneumococcal vaccination rates among Hispanics are 28%.¹⁶ Analysis of racial differences in LAC DHS pneumococcal rates were not conducted, in part due to current difficulty aggregating disparate data sources.

Primary Audience: Both LAC DHS patients and clinicians benefit from this project. Patients benefit from improved communication, improved health outcomes due to reduced pneumococcal disease, and a more integrated healthcare system that can track their individual circumstances. LAC DHS Clinicians will benefit from time savings via enhanced electronic medical records, improved patient-provider communication, and targeted training and education. A Key Stakeholder Analysis is included in Table 1.

Program Design and Methods: Our program consists of a three-pronged design to increase pneumococcal immunization rates in LAC DHS. The approach includes utilization of a standardized protocol in parallel with provider education, electronic identification of at-risk adults, and automated multi-modal outreach and scheduling. Our intent is to roll out interventions, staggering implementation across clusters of PCMHs, in 30-day intervals. This will allow for site-specific modifications and improvements based on staff feedback to ensure optimal utility. The staggered approach will also mitigate the confounding effect of global temporal changes in vaccination rates.

Provider Education and Standardized Protocol: One barrier to optimal pneumococcal vaccination is provider knowledge deficits. The details of vaccine indications and exclusions, proper sequencing of PPSV23 / PCV13 and knowledge of motivational interviewing techniques to overcome patient resistance to vaccination are all important components of a successful program.⁶ Co-Investigators Dr. Campa, the LAC DHS ACN Director of Primary Care, and Dr. Tran, ACN Associate Director of Continuous Quality Improvement, will lead education efforts with providers that address these barriers.

We created a structured pneumococcal vaccine order and documentation form (Appendix A). This protocol includes a decision-support algorithm that organizes a complicated decision process and helps guide the user through the maze of the 2013 Advisory Committee on Immunization Practices (ACIP) recommendations for adult pneumococcal immunization. In order to maximize broad use, it is written as an Interdisciplinary Practices Committee (IDPC) standardized procedure that allows implementation by nurses without a specific provider order. The Adult Pneumococcal Immunization form is used to assess eligibility, order and administer pneumococcal vaccines. It includes all of the following: (1) Inclusion and exclusion criteria for both special populations and patients with chronic conditions for both Prevnar (PCV13) and Pneumovax (PPSV23); (2) Ordering one or more vaccines; (3) Documentation of

vaccine administration or reasons it was not administered. The protocol is approved for broad dissemination by the LAC DHS Ambulatory Care Network (ACN) Interdisciplinary Practices Committee and is available on the LAC DHS intranet.

Pfizer support will enable us to educate PCMH staff through a series of Pneumococcal Immunization Education events, taught by LAC DHS Health Education staff. These education events will include the appropriate use of, indications for, and sequencing of PCV13 and PPSV23 vaccines, utilizing our protocol as a tool, methods for discussing vaccinations with patients in the safety-net, and will employ case study tests for staff to apply the information being disseminated. We will also conduct an ACN-wide presentation that will be recorded and available on our intranet for future viewing. Throughout the progress of this grant, on-site refreshers with case study application assessments, performed by local medical directors or their designees, will reinforce education efforts.

Electronic Identification of At-Risk Adults: Morbidity and mortality from Pneumococcal disease can be reduced if we appropriately immunize patients. We will create an electronic algorithm to identify which of our 340,000 empaneled patients are potentially eligible for pneumococcal vaccination. To accomplish this goal, we will translate the paper based protocol (Appendix A) to work automatically “behind the scenes” of our electronic health registry.

Automated Multi-Modal Outreach, Education, and Scheduling: LAC DHS is uniquely situated to leverage technology for the creation of a scalable and sustainable automated system that provides remote interactive communication and patient self-scheduling. The system, built on the ARMS infrastructure, is the *Immunization Outreach Automated Remote Monitoring System (IO-ARMS)*. It will provide patient communication via text message, phone, and email and will be secure web-service based to allow broad interoperability.

Current immunization outreach is primarily based on human resource driven interventions.^{1,6,17} They are effective, but are costly, consume limited resources, and have limited sustainability. Mobile tele-health programs, similar to our proposed system, have high rates of success with African Americans and Hispanic/Latinos, particularly among women.^{19,20} Patients report that these systems increase communication with providers without interfering with daily routines.¹⁸⁻²⁰ Automated tele-health programs have resulted in improved health outcomes and compliant health behaviors.¹⁹⁻²⁶

LAC DHS has a strong track record of successfully integrating technology for improved clinical care in the safety-net. Building on the success of structured telephone support and tele-monitoring to reduce hospitalizations and improve health outcomes,²⁻⁵ with a technology partner,²⁷ we have created an Automated Remote Monitoring System (ARMS). This technology is a cost-effective, proven technique for improved clinical performance, with positive fiscal and satisfaction outcomes that have demonstrated efficacy for patients regardless of education and technology experience.²⁸⁻³⁰ This technology reduces disparities and improves health outcomes regardless of race, ethnicity and social class.²⁶⁻²⁸

We have demonstrated the utility of ARMS for both Heart Failure and Depression; both applications highlight its ability to facilitate low-cost, high impact care. The Heart Failure Automated Remote Monitoring System (HF-ARMS) is a data collection tool that uses automated speech recognition system that is able to provide multiple simultaneous outbound calls to

patients on a scheduled and triggered basis. Communication results with details of the patient interaction are made available via a secure web interface in real-time to care providers. Over 92% of data collected by the HF-ARMS were clinically equivalent to data collected by human researchers. 80% of satisfaction survey respondents preferred the HF-ARMS calls to less frequent human monitoring. Patients reported protective effects of using the HF-ARMS, suggesting that regular cognitive prompts reinforced healthy behaviors. On average, successful HF-ARMS calls lasted 2.34 minutes at a cost of \$0.85 per call. A demonstration line to experience HF-ARMS interaction can be called at 1-888-283-3716; the caller will be asked to respond as "George."

The automated remote monitoring technology used by the HF-ARMS was adapted for the R18, "Care Management Technology to Facilitate Depression Care in Safety Net Diabetes Clinics" (1R18AE000054-01). The Depression Automated Remote Monitoring System (D-ARMS) is a bilingual system that gathers patient PHQ-9 scores, behavior responses, and information about antidepressant medication use and cognitive behavior therapy activities. Preliminary data show that patients randomly assigned to use the D-ARMS have significantly improved PHQ-9 depression scores (differences-in-differences ANOVA test, $p < 0.05$) and are less likely to have persistent major depression (Pearson Chi-Square test, $p < .01$), baseline measure to six month follow up, when compared to patients in usual care.

Capitalizing on our success with the HF-ARMS and D-ARMS,²⁻⁵ the Immunization Outreach Automated Remote Monitoring System (IO-ARMS) will contact patients that the algorithm determines potentially eligible for pneumococcal immunizations via a combination of email, text message, and automated phone call. The communication will inform the patient of their eligibility, provide a brief message on the importance of pneumococcal immunization, ask if the patient has received the immunization outside of LAC DHS, allow the patient to indicate if they'd like to speak with an LAC DHS care team member to ask questions, and prompt the patient to self schedule an appointment to receive the immunization. Based on previous ARMS experience, we believe this patient-centric approach will educate patients about pneumococcal immunizations, directly (through messaging in the ARMS communication), and indirectly through a "halo" effect whereby patients become more cognizant of pneumonia risks and vaccination benefits.⁴ The cost of these communications is expected to average less than fifty cents per communication.

Evaluation Design: A quasi-experimental design will be used to test two main hypotheses, (H1) *there will be an increased rate of identified patients who receive PCV13 or PPSV23 vaccine, and (H2) automated outreach and communication will significantly drive the increased rate of pneumococcal immunization for the target population.* The main patient interventions, electronic identification of patients eligible for pneumococcal vaccinations and IO-ARMS messaging to these patients, will be implemented broadly across all LAC DHS PCMHs, targeting a population of 65,000 patients. In order to reduce bias, the evaluation of this project will be conducted by the Center for Community Health and Evaluation, Group Health Research Institute.

Data Sources: We will utilize a combination of existing data sources, supplemented by patient survey data. Existing LAC DHS data sources include our Enterprise Data Repository which contains appointment/scheduling data, visit data, and encounter (ICD9 & CPT4) data.

Data Collection and Analysis Plan: Changes in rates of immunizations will be measured using a quasi-experimental interrupted time-series design (ITS) (data captured at baseline and every 3 months) to assess changes in outcomes for all of the domains of interest. Our goal is to examine whether pneumococcal immunization-related outcomes improved over time and identify the degree to which improved outcomes can be attributed to one of more of the intervention arms we are examining. Pneumococcal immunization automated communication is pioneering work. As such, we will assume moderate size of treatment effects in calculating statistical power. Power to evaluate program effects was determined with G*Power (V3.1) software. All power calculations were done at two-tailed $\alpha = .05$. To estimate our ability to detect statistically significant outcomes we set power at .80 power and used Cohen's conventional standards for effect sizes with $f=0.1$ for small effect size and $f=.25$ for medium effect size.^{31,32} Based on this analysis, our proposed sample size of 65,000 is sufficiently powerful to detect both medium and small effects. Racial/ethnic and gender differences will be reported but comparisons may lack the statistical power to assess significant differences dependent on any trends in attrition.

Interrupted time-series (ITS) design allows for analysis of repeated or multiple measures over time relative to a sentinel index date. One advantage of ITS design is that it allows for the statistical investigation of potential biases in the estimate of the effect of an intervention, including Secular trend, cyclical or seasonal effects, duration of the intervention, random fluctuations and statistical challenges related to the underlying distribution of the specific outcome measures of interest.

To implement the ITS design we will estimate separate generalized estimating equation (GEE) regressions with each unique outcome as the dependent variable in each equation. Covariates will include patient level socio-demographic and socio-economic variables (e.g. age, gender, race/ethnicity), and baseline pneumococcal vaccination need (i.e., eligible and vaccinated/not vaccinated). GEE allows us to adjust for the impact that individual patients will be seen by the same provider and at the same clinic and our estimates of standard regression efforts will account for this clustering. The function and form of each equation will depend on the specific outcome measure, with the factors we need to consider including: the frequency with which the data are collected, the underlying distribution of the measure (e.g. is the variable continuous or categorical), and the source of the data (i.e. are they from self-report surveys or from electronic information systems maintained by LAC DHS?).

We will use a mixed-method (covering qualitative and quantitative data) survey on a sample sub-population that receives automated messaging ($n=150$; 75 randomly selected from those who receive IO-ARMS automated messaging and subsequently received pneumococcal immunizations; 75 patients randomly selected from those who received automated messaging and did not receive the vaccine). Themes identified from these responses maybe followed up through focus groups or individual interviews with patients. This sub-population will provide context for observed overall trends in data.

Patients will be included in the received IO-ARMS messaging + received pneumococcal immunization group if they complete an immunization within 16 weeks post messaging.

Surveys will be administered either in person or over the phone within 4 weeks post immunization completion. Members of PCMH teams will be invited to complete surveys to measure their satisfaction, how the interventions integrate into workflow, and their perceived knowledge of pneumococcal immunizations.

Qualitative data collection and analysis will consist of open-answer responses from sub-groups of patients who were contacted by the IO-ARMS who did (n=75) and did not (n=75) receive a pneumococcal vaccination following the IO-ARMS contact. Based on themes identified in these interviews we may opt to conduct semi-structured interviews or focus groups with patients and care providers. Following recommendations by Crabtree and Miller, interviewers will be culturally similar to respondents, we will conduct focus groups with respondents who are demographically similar, and if conducted, interviews or focus groups will be in the respondent's language of choice (English or Spanish).^{25,26}

This project will focus on the LAC DHS Patient-Centered Medical Homes (PCMH) who are responsible for ongoing and coordinated care to maximize health outcomes. The PCMH team is led by a primary care provider (MD, DO, or NP) and includes nurses, care managers, certified medical assistants, and clerks. Each full-time provider has a panel of approximately 2,000 member-equivalents. LAC DHS PCMHs use i2i, a patient registry, to enhance patient care and population-based management. Care management programs support implementation of standard interventions for patients with chronic conditions, ensure coordination of care between health care settings, and conduct health maintenance/prevention activities. The goal of the PCMH is to provide proactive management of patient care needs based on risk assessments, and achieved through maximization of disease-specific interventions and preventive care improvement, while ensuring appropriate utilization in a resource-constrained environment.

Control for Exogenous Variables: We will first generate descriptive statistics by patient and clinic for each variable to assess distributional properties to inform in support of subsequent analyses. Missing data, outliers, or other unusual features that may be influential will be systematically identified for all the variables. Psychometric properties of all the measurement scales included in the project will be examined to ensure valid comparisons across the program conditions. Analyses will be carried out according to the intention-to-treat rule consistent with standard practice in most clinical trials. Preliminary analyses are also performed to compare descriptive and clinical baseline characteristics across the treatment conditions to investigate the baseline differences. When variables differentiate treatment groups at baseline are identified, it is necessary to include them as covariates in the analysis to remove potential confounding effects. It is also statistically useful to include covariates that explain outcome variance and do not differentiate between groups because such variables increase statistical power.

Analyses for hypothesis testing related to the evaluation of IO-ARMS effects will be carried out according to the intent-to-treat rule consistent with standard practice in clinical trials. Preliminary analyses will be performed at each assessment to carefully examine relationships within the cross-sectional data. Investigation of the main effects of IO-ARMS on outcomes will be conducted at each follow-up. Baseline outcome measures will be treated as one of the covariates variables to control for potential baseline differences. We will then

conduct repeated measures analyses of profiles across time to examine the effects of program conditions on trends of outcome measures. Comparison of group means on continuous scales will be conducted using the family of statistical techniques based on the generalized linear model (e.g., ANOVA/ANCOVA, regression analysis, t-test).

Basic cross-sectional data analyses performed at each major follow-up assessment point will use ANCOVA with the baseline measurement as the covariate. Longitudinal (repeated measures) analyses of continuous scales will be performed for follow-up points (at 3-month intervals) using the general linear mixed model with repeated measures (SAS Proc Mixed). The MIXED procedure in SAS is a very general regression model that permits considerable flexibility in specifying the nature of the co-variances among the dependent measures, allows time dependent, within-cell covariates, and operates on incomplete (i.e., missing data) matrices. Key outcome variables to be compared in this proposed study are continuous, but many lend themselves to clinically meaningful categorization, and some of the most important outcomes are naturally dichotomous. SAS/MIXED procedure is an appropriate analytical approach for continuous outcome variables. For dichotomized outcomes, the SAS/GLIMIX procedure will be used. Analyses of rates will be performed using Mplus. A particular strength of the Mplus statistical package for the current project is that it can estimate multiple logit and probit polytomous regression models with ordered categorical outcomes. Mplus permits very flexible regression modeling, including hierarchical (e.g., mixed model repeated measures) factorial analyses on both continuous and this kind of ordered categorical outcome even if there is missing data. When the assumption of constant odds ratios between adjacent outcome categories is warranted, this methodology provides an elegant approach to multiple regression modeling (if not, separate analyses will be performed on full adherence and nonadherence).

Empirical data from interviews will be independently coded by the designated research team members at a very general level in order to condense the data into analyzable units. Segments of transcripts will be assigned codes based on a priori (i.e., questions in the interview guide) or emergent (i.e., issues raised by the respondents themselves) themes, and will be assigned more than 1 code. Transcripts will be independently coded by at least 3 team investigators. Disagreements in assignment or description of codes will be resolved via investigator discussion and enhanced code definition. The final consensus code list will include numbered themes, issues, behavior accounts, and opinions related to sociocultural, organizational, and system characteristics that influence care training/activation and pneumococcal immunization receipt. Two investigators will separately review final coded transcripts to ensure agreement in applied codes. Based on these codes, we will generate categories arranged in a treelike structure connecting transcript segments grouped into separate categories or “nodes.” Nodes and trees will be used to examine the association between different a priori and emergent categories and to identify previously unrecognized categories. The frequency with which these categories occur together, either as duplicate codes assigned to the same text or as codes assigned to adjacent texts in the same conversation, will be recorded, and specific examples of co-occurrence will be illustrated with transcript texts.

All steps will be made to avoid statistical bias with respect to qualitative and quantitative analysis. We will follow national recommendations for avoiding or minimizing operational bias in the following ways.³³ We will maintain the same criteria for patient eligibility for the duration of the project, unless changes are made to national pneumococcal

immunization guidelines. We will work to identify potential sources of bias during the design phase. The potential effect of operational bias sources will be quantified, and if possible mitigated. The restriction of any study personnel from knowing selection information will be considered and decided through a deliberative democratic discussion prior to project implementation. Sources of bias, both operational and statistical, will be weighed against the possible benefits. These processes will be transparent

Projected Change in Population:

1. 10% increased rate of patients who receive PCV13, PPSV23 or a combination of the two from baseline.
2. Significant increase from baseline in pneumococcal immunization knowledge, specifically the appropriateness of PCV13 and PPSV23, among providers.

Target Audience Engagement Analysis: Stakeholder engagement will be measured through successful automated contact, narrowed care gaps, patient and provider satisfaction, and provider attendance at immunization education outreach efforts.

Project Findings Dissemination: LAC DHS is home to a Practice Based Research Network and a member of several community and academic organization that include the AHRQ PBRN Research Network, the California HealthCare Foundation Chronic Care Improvement Network, of which we are a founding member, and the two local Centers for Translational Science Institutes (CTSIs) housed at the University of Southern California and University of California, Los Angeles; we will disseminate findings through these networks in addition to pursuing publishing and presentation at academic conferences.

Research findings-sharing strategies include: publication of findings in academic peer reviewed journals; publication of findings on patient outcomes from computer-based decision support and documentation systems in academic peer reviewed journals; and presentation of findings at academic conferences.

Work Plan and Deliverables: The project will be implemented over a 2.5 year (30 month) period. The project's implementation will be conducted in three phases, "Build," "Execution," and "Report." The Build Phase includes the clinical content review and finalization of the protocol, the creation of the patient eligibility algorithm, the creation of provider education curriculum, and the creation of the IO-ARMS. The Execution Phase includes the launch of the aforementioned tools and processes, data collection from various stakeholders, and data analysis. The Report Phase includes dissemination of findings to Pfizer and various stakeholders, including community and academic partners. Details of the work plan and deliverables can be found in Table 2.

Appendix A: Adult Pneumococcal Immunization Protocol

County of Los Angeles **Adult Pneumococcal Immunization** Department of Health Services

Assessment (see back of form for sub-group definitions)	
<p style="text-align: center;">Special Populations</p> <p><input type="checkbox"/> Pneumovax (PPSV23) pneumococcal vaccine not recommended</p> <ul style="list-style-type: none"> • Previously received vaccine <u>or</u> • Received PPSV23 within the past year <p><input type="checkbox"/> Pneumovax (PPSV23) pneumococcal vaccine not recommended</p> <ul style="list-style-type: none"> • Received vaccine within the past 5 years <u>or</u> • Received 2 lifetime doses one of which was at 65 years of age or older <u>or</u> • Received 2 doses and less than 65 years of age <p>Stop the assessment, check "Do not administer vaccine", sign and date below</p>	<p style="text-align: center;">Chronic Conditions and General Population</p> <p><input type="checkbox"/> Pneumovax (PPSV23) pneumococcal vaccine not recommended</p> <ul style="list-style-type: none"> • Received vaccine within the past 5 years <u>or</u> • Received 2 lifetime doses one of which was at 65 years of age or older <u>or</u> • Received vaccine and less than 65 years of age without any chronic disease <u>or</u> • Receiving chemotherapy or radiation therapy <p>Stop the assessment, check "Do not administer vaccine", sign and date below</p>
<p><input type="checkbox"/> Pneumovax (PPSV23) pneumococcal vaccine indicated</p> <ul style="list-style-type: none"> • If not previously vaccinated with PPSV23 <u>AND</u> <ul style="list-style-type: none"> ○ Never received PPSV23 <u>or</u> ○ One year or more since last PPSV23 <u>or</u> ○ PPSV23 vaccination status unknown <p><input type="checkbox"/> Pneumovax (PPSV23) pneumococcal vaccine indicated</p> <ul style="list-style-type: none"> • If not previously vaccinated with PPSV23 and 8 weeks since PCV13 <u>or</u> • If previously received one dose PPSV23 and 5 or more years since administration <u>or</u> • If previously received two doses PPSV23 and 5 or more years since administration and patient is 65 or older <u>or</u> • PPSV23 vaccination status unknown 	<p><input type="checkbox"/> Pneumovax (PPSV23) pneumococcal vaccine indicated</p> <p>If patient is either:</p> <ul style="list-style-type: none"> • 65 years or older <u>or</u> • 19 years or older with any chronic condition(s) (see back of form) <u>or</u> • Resides in or will be discharged to a long-term care facility <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Not previously vaccinated with PPSV23 <u>or</u> • If 65 years or older, 5 or more years since last dose and none given at 65 years or older yet <u>or</u> • PPSV23 vaccination status unknown

Vaccine Order/Standardized Procedure Decision (May be given concurrently with influenza vaccine. If both PCV13 and PPSV23 are indicated, DO NOT administer at the same time. Administer PCV13 first, followed by PPSV23 at least 8 weeks later)

Do not administer pneumococcal vaccine

Administer pneumococcal vaccine

Pneumovax (PPSV23) vaccine 0.5 mL IM **OR** **Pneumovax (PPSV23) vaccine 0.5 mL IM**

PCV13 Follow-up: Make clinic appointment for no sooner than 8 weeks from vaccine administration date for dose of Pneumovax (PPSV23) vaccine if never received PPSV23

MD/NP/RN/PharmD/LVN Print Name: _____ Signature: _____ Date: _____ Time: _____

ADMINISTRATION RECORD: Entered into CAIR

If administering with influenza vaccine do not administer both vaccines in the same site.
 Give only when temperature has been less than 38.6°C (101.4°F) for at least the prior 12 hours.
 Do not give pre-operatively or within 24 hours of operative procedure.

<p>Pneumovax (PPSV23) vaccine</p> <p><input type="checkbox"/> R <input type="checkbox"/> L deltoid (22-25g, 1-1.5 inch needle)</p> <p>Manufacturer: Wyeth Lot # _____</p>	<p>Pneumovax (PPSV23) vaccine</p> <p><input type="checkbox"/> R <input type="checkbox"/> L deltoid (22-25g, 1-1.5 inch needle)</p> <p>Manufacturer: Merck Lot # _____</p>
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Vaccine information statement (version date: _____) has been given, explained and questions answered

RN/PharmD/LVN/CMA Print Name: _____ Signature: _____ Date: _____ Time: _____

<p>VACCINE NOT ADMINISTERED:</p> <p><input type="checkbox"/> Patient/guardian refused _____ vaccine(s), provider notified</p> <p><input type="checkbox"/> Pneumovax (PPSV23) vaccine not available</p> <p><input type="checkbox"/> PCV13 vaccine not available</p> <p><input type="checkbox"/> Vaccine information sheet (VIS) given</p> <p><input type="checkbox"/> Health Services Info Line (800) 427-8700 given</p> <p>RN/PharmD/LVN/CMA Signature: _____ Date: _____ Time: _____</p>	
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Table 1: Key Stakeholder Analysis

<u>STAKEHOLDER</u>	<u>RELATIONSHIP TO PROGRAM</u>	<u>ENGAGEMENT and IMPACT</u>
<p>LAC DHS Patients Eligible for Pneumococcal Immunizations whose Medical Home is LAC DHS and who have received care from LAC DHS</p>	<p>Patients at risk for pneumococcal disease are the primary audience for this program; they will be the primary recipient/beneficiaries of the planned interventions.</p>	<p>Our immunization outreach automated system will identify, communicate with and schedule pneumococcal immunizations with eligible patients. Patient opinions and feedback will be collected regularly and incorporated into project structure. Patients will benefit from technology developments and provider educational interventions. At the close of the study, a findings briefing targeted to patients and their families will be disseminated. It is expected that this program will increase Pneumococcal Immunizations.</p>
<p>LAC DHS Care Team this includes all members of the Patient-Centered Medical Home (PCMH): Primary Care Provider - (MD or NP), RN Care Giver, RN Care Manager, Health Coordinator (Certified Medical Assistant), and Clerk</p>	<p>PCMH-based care team members will be represented in project leadership and contribute to the development of intervention tools and methods. Tools specifically for providers will be developed. Educational components of this program will ensure providers have appropriate knowledge of pneumococcal immunizations.</p>	<p>Care team partners will give input and feedback at all stages of the project. At the close of the study, a targeted briefing for care team members will be disseminated. It is expected that care team knowledge of pneumococcal immunizations will increase.</p>
<p>LAC DHS Leadership is committed to ensuring access to high quality, patient-centered, cost-effective health care to LA County residents through direct services at DHS facilities and through collaboration with community and university partners.</p>	<p>LAC DHS Leadership is invested in the outcome of this project. Scalability will translate to improved patient-centric, quality of care improvements.</p>	<p>Regular updates will be made to LAC DHS leadership. At the close of the study, an executive summary with implications for sustainability and scalability across LAC DHS will be presented to leadership.</p>
<p>Health Care Providers Beyond LAC DHS will begin to see a greater number of newly insured patients in 2014 due to implementation of the Medi-Cal Expansion components of the Affordable Care Act.</p>	<p>Providers beyond LAC DHS serve patients that experience the same disparities and barriers to appropriate pneumococcal immunizations.</p>	<p>LAC DHS is home to a Practice Based Research Network and Project Leaders are members of several professional organizations. We will share findings and best practices with the broader health care community at the close of the study through professional presentations, publications, and academic lectures.</p>

Table 2: Work Plan and Deliverables - Grant Time Period: July 2014 – Dec 2016 (30 months)

Activities	Milestones	Deliverables	Months	Due Date
IRB submissions	Completed IRB application and approvals	IRB approval letters	1-2	Aug 2014
Review Pneumococcal Immunization Protocol for any updates	Completed Protocol	Finalized Protocol	1-2	Aug 2014
Design and Build IO-ARMS	Clinical and Non-clinical content development	"Go-Live" of IO-ARMS	1-10	April 2015
	Modules of communication construction			
	Voice recordings of communication modules			
	Quality Assurance testing			
Design patient identification eligibility algorithm for pneumococcal vaccination	Completion of algorithm and integration into system	Completed algorithm	1-6	Dec 2014
Design and implement PCMH Pneumococcal Immunization education elements	Education training curriculum developed and implemented	Report with copies training materials	1-7	Jan 2015
Launch identification eligibility algorithm for pneumococcal vaccination	Algorithm implemented	Report on launch of algorithm	7	Jan 2015
Launch IO-ARMS communications to patients following study design methodology (for 15 months)	IO-ARMS communications implemented	Report on launch and progress of IO-ARMS	10-24	Jul 2016
Patient data collection, conduct interrupted time series data pulls for analysis	Completion of data collection	Report on progress of data collection	7-24	Jul 2016
Provider data collection, conducted 6 months post implementation, at 6 month intervals	Completion of data collection	Report on progress of data collection	13-24	Jul 2016
Completion of 10 Pneumococcal Immunization Education events taught by program staff and LAC DHS's Nursing Education Department	Completion of 10 events	Report on success of Pneumococcal Immunization Education events	1-6	Dec 2014
Data collection from sub-study patients	Completion of data collection from 150 sub-study patients	Report on progress of data collection	7-24	Jul 2016
Final Data analysis	Data analysis completed	Notification of data analysis completion	26-28	Oct 2016
Write final report, disseminate findings	Final report completed	Final Report	28-30	Dec 2016

Organizational Detail

Leadership and Organizational Capability

The mission of Los Angeles County Department of Health Services (LAC DHS) is “to ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.” As the second largest safety-net provider in the country, LAC DHS employs over 21,000 individuals and serves 800,000 patients annually with 2.7 million ambulatory care, 280,000 emergency department, 230,000 urgent care visits, and 75,000 inpatient admissions.

The LAC DHS Ambulatory Care Network is home to a Primary Care Practice Based Research Network (PBRN) established in 2011. The Ambulatory Care Network PBRN aims to promote community and university partnerships and facilitate collaborative research to improve clinical practice in the Los Angeles County safety net that will help ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents. We are an official member of an organized network of networks which include the California Improvement Network (CIN), Community Clinics of Los Angeles County (CCLAC), and the proposed Southern California Primary Care Practice Based Research and Learning Center.

LAC DHS operates four hospitals, inclusive of two acute care level 1 trauma centers, one acute rehab center, and is academically affiliated with both the USC and UCLA Schools of Medicine. In addition, LAC DHS operates two Multi-Service Ambulatory Care Centers, six Comprehensive Health Centers, and supports over 160 community-based clinics.

Center for Community Health and Evaluation CCHE is part of Group Health Research Institute, which is nationally recognized for research on the delivery of health services and outcomes of health care. Based in Seattle, Washington, CCHE serves foundations and health organizations throughout the United States. Aided by an extensive network of long-term affiliations with individual experts, universities, and other health care institutions, CCHE has pioneered many of the techniques today considered standard in evaluation of community-based interventions, such as case study methodology, use of logic models, and innovative approaches to measuring the community environment. CCHE has extensive experience conducting evaluations, with an emphasis on projects that involve collaboration and participatory approaches and promote program improvement.

Project leadership will draft a governance plan that articulates the roles of project team members that utilizes a Deliberative Democratic Theory approach.³⁴ This process uses concepts of democracy to arrive at justifiable conclusions and judgments about program success. It aspires to arrive at program conclusions by 1) considering all relevant interests, values, and perspectives; 2) engaging stakeholders in extended dialogue; and 3) promoting extensive deliberation. The governance plan will be revisited on a routine ongoing basis throughout the study aimed at meeting the needs of all major stakeholders. The final governance plan will be

disseminated among core stakeholder partners, who will be given the opportunity to comment and make revisions.

Staff Capability

The proposed research team includes UCLA and LAC DHS affiliated clinical experts, health technology innovators, a large public safety net health care system and research program, and participation of patients eligible for pneumococcal vaccination. LAC DHS has an active Research and Innovation division within the Ambulatory Care Network (ACN:R&I) that has developed and begun to facilitate technology-based patient-provider communication systems and defined pneumococcal immunization care protocols. The study PI, Dr. Nina Park, is the Chief Medical Officer for the Ambulatory Care Network, LAC DHS. She has a strong background in the implementation of technology-based QI efforts. Dr. Park is also a Health Sciences Associate Clinical Professor of Medicine at the David Geffen School of Medicine at UCLA.

Dr. Cheadle will lead evaluation efforts. Dr. Cheadle is the Director of The Center for Community Health and Evaluation (CCHE) at the Group Health Research Institute (GHRI) is an expert in methods of community-based research, in particular evaluations of comprehensive community initiatives and community- and organization-level systems change initiatives. He has experience in evaluating data-driven clinical quality improvement initiatives and doing the data analysis for those evaluations.

Dr. Fishman will serve as an evaluator with Dr. Cheadle. Dr. Fishman is a health care economist with expertise in designing and conducting analyses of health service use and cost and the organization of health care systems with a specific emphasis on primary care including extensive analyses of the implementation and outcomes associated with the patient centered medical home model of primary care delivery. Dr. Fishman is also an expert on the organization and management of large databases for use in health services research. As part of a comprehensive research program on costs and outcomes associated with different clinical and behavioral health states and conditions, Dr. Fishman has examined the cost implications of a variety of modifiable health behaviors and addictive disorders including alcohol abuse and chemical dependency, tobacco use, over-weight and obesity, as well as behavioral health issues including depression and anxiety disorders. This research has allowed Dr. Fishman to gain expertise in the analysis of health care use and cost data related to the examination of how health behaviors impact health service use and health care outcomes, as well as the empirical methods best suited to assess health service use and cost and outcomes over time as well as at any point in time. Dr. Fishman has a PhD in Economics from the University of Washington and is Scientific Investigator at the Group Health Research Institute and an Associate Professor at the University of Washington's Department of Health Services.

Dr. Campa is LAC DHS ACN Director of Primary Care. In this role, he oversees the implementation of the Patient-Centered Medical Home (PCMH) model across the Department of Health Services. Dr. Campa is in a key position to influence the role out of programs within the PCMH. As the Director, Quality Improvement/Patient Safety/Risk Management, Dr. Tran has substantial experience driving quality improvement programs across the LAC DHS

Ambulatory Care Network. Drs. Campa and Tran will lead education efforts with providers and oversee PCMH staff education efforts in coordination with LAC DHS Health Education staff.

Dr. Gross-Schulman will serve as a co-investigator and Dr. Agrawal will serve as a clinical contributor. They will provide clinical oversight, will advise on training and education efforts, and will update clinical information as guidelines and recommendations become available. Dr. Gross-Schulman has substantial experience on the development and implementation of clinical ARMS and oversees the ACN's disease management programs. In addition, Dr. Gross-Schulman led the development of the paper-based algorithm. Dr. Agrawal is experienced with the implementation of electronic patient identification and tracking measures. He has leadership experience training providers in the LAC DHS PCMH environment.

The IT elements of this program will be overseen by Mr. Scheib and Mr. Wang. Both have several years of experience implementing and integrating Health Information Technology programs within LAC DHS, including ARMS. They will be supported by additional LAC DHS IT support and will work in concert with the vendor providing ARMS services.

The Project Coordinator, Ms. Myerchin Sklaroff, will be responsible for coordinating study activities between sites and stakeholders. This includes facilitating meetings and communications, serving as point of contact for questions and problems, ensuring that the subcontractor adheres to the scope of work, tracking study expenditures, and distributing study materials, correspondence, and reports. Ms. Myerchin Sklaroff has significant experience with community outreach and program facilitation at the local, national, and international level. Ms. Myerchin Sklaroff has coordinated three other studies that specifically use the ARMS technology.

Internal Revenue Service

Date: August 30, 2006

OLIVE VIEW UCLA EDUCATION AND
RESEARCH INSTITUTE INC
14445 OLIVE VIEW DR ADMIN BLDG
SYLMAR CA 91342-1437 000

Department of the Treasury
P. O. Box 2508
Cincinnati, OH 45201

Person to Contact:

Ms. K. Hilson ID 31-07340
Customer Service Representative

Toll Free Telephone Number:

877-829-5500

Federal Identification Number:

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SEP 5 2006

Dear Sir or Madam:

**OLIVE VIEW-UCLA
EDUCATION & RESEARCH INSTITUTE**

This is in response to your request of August 30, 2006, regarding your organization's tax-exempt status.

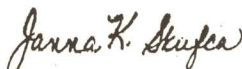
In March 1965 we issued a determination letter that recognized your organization as exempt from federal income tax. Our records indicate that your organization is currently exempt under section 501(c)(3) of the Internal Revenue Code.

Our records indicate that your organization is also classified as a public charity under sections 509(a)(1) and 170(b)(1)(A)(vi) of the Internal Revenue Code.

Our records indicate that contributions to your organization are deductible under section 170 of the Code, and that you are qualified to receive tax deductible bequests, devises, transfers or gifts under section 2055, 2106 or 2522 of the Internal Revenue Code.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

Sincerely,



Janna K. Skufca, Director, TE/GE
Customer Account Services

ERI

Olive View-UCLA Education & Research Institute

14445 Olive View Drive – Research Administration Office
Sylmar, CA 91342-1495

Telephone (818) 364-3434 Fax (818) 364-3465

Website www.ovuclaeri.com

April 24, 2014

Pfizer Independent Grants for Learning & Change

Subject: “Driving Technology-Enhanced Immunization Outreach in the Los Angeles Safety-Net”
Nina Park, M.D., Principal Investigator

The Olive View-UCLA Education & Research Institute (ERI) is pleased to support Dr. Nina Park’s grant application entitled “Driving Technology-Enhanced Immunization Outreach in the Los Angeles Safety-Net.”

If funded, the ERI will serve as the fiduciary agent for this grant. The ERI is a private, non-profit 501(c)3 responsible for conducting research and education activities at Olive View-UCLA Medical Center and its related health centers.

If you have any questions, please contact me at (818) 364-3434 or denisestritt@ovuclaeri.com.

Regards,
Denise



Denise Tritt, CIM, CRCP
Business Manager/Human Protections Administrator
OV-UCLA Education & Research Institute
14445 Olive View Drive – Research Administration Office
Sylmar, CA 91342-1495

(818) 364-3434 Telephone
(818) 364-3465 Fax

Website: www.ovuclaeri.com

Letters of Commitment

1. Alex Li, MD – Los Angeles Department of Health Services, Ambulatory Care Network
2. Allen Cheadle, PhD – Center for Community Health and Evaluation, Group Health Research Institute
3. John Harding, PhD – 4Patient Care



Health Services
LOS ANGELES COUNTY

April 23, 2014

**Los Angeles County
Board of Supervisors**

Gloria Molina
First District

Mark Ridley-Thomas
Second District

Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

Nina J. Park, M.D.
Chief Medical Officer
Ambulatory Care Network
Los Angeles County Department of Health Services

Dear Dr. Park,

On behalf of the Department of Health Services (DHS), I would like to express strong support for your application being submitted to Pfizer Independent Grants for Learning & Change for technology-enhanced pneumococcal immunization outreach. This project will significantly benefit the underserved population in Los Angeles County, who are disproportionately at risk for community acquired pneumonia.

As providers of high quality care to people most in need and as the second largest US publically supported safety net care system, it is our responsibility to recognize and address the disparities in pneumococcal immunizations. We believe that your approach of an electronic algorithm to identify in-need patients, an automated pneumococcal immunizations messaging and self-scheduling system delivered to patients, and protocol-driven staff education efforts will substantially improve vaccination rates while integrating into DHS workflow.

I am happy to commit the access and make available the resources submitted in your project's budget that are necessary for success. We welcome this opportunity to better serve our patient population.

Sincerely,

Alexander K. Li, MD
Chief Executive Officer
Ambulatory Care Network



Alexander K. Li, MD
Chief Executive Officer

Nina J. Park, MD
Chief Medical Officer

Quentin O'Brien
Chief Operations Officer

Jeffrey Guterman, MD
Chief, Research and Innovation

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To ensure access to high-quality, patient-centered, cost-effective health care to Los Angeles County residents through direct services at DHS facilities and through collaboration with community and university partners.

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April 25, 2014

Nina J. Park, MD
Chief Medical Officer
Ambulatory Care Network
Los Angeles County Department of Health Services

Dear Dr. Park,

We are pleased to offer our support and participation in the proposal being submitted to Pfizer Independent Grants for Learning & Change for pneumococcal immunization outreach. The proposed work will offers a technology-driven approach to reducing disparities in pneumococcal immunization rates and will greatly benefit patients.

The Center for Community Health and Evaluation at the Group Health Research Institute has extensive experience working with safety-net health organizations around evaluations of their innovative programs. We are currently working with LAC DHS around the evaluation of an initiative for reducing cardiovascular events in patients with diabetes. For the proposed project we are happy to commit the resources submitted in your project's budget, and to draw on the analytical capacity and biostatistical support at GHRI, to conduct the evaluation analysis of project outcomes.

We look forward to participating in this project.

Sincerely,

Allen Cheadle, PhD, Director
Center for Community Health and Evaluation



4/29/2014

Nina J. Park, MD
Chief Medical Officer
Ambulatory Care Network
Los Angeles County Department of Health Services

Dear Dr. Park,

I would like to offer my strongest support for the proposed study being submitted to Pfizer Independent Grants for Learning & Change for pneumococcal immunization outreach. We are excited to continue our relationship with Los Angeles County Department of Health Services, with has resulted in the use of two similar systems for automated remote monitoring, focused on Heart Failure and Depression.

I share the commitment to this project, and am extremely excited about joining forces with LAC DHS to conduct this research. With 4PatientCare's technological expertise, our contributions to this project will bring benefit and allow us to achieve our goals of improving patient care. I understand that our role will include regularly scheduled meetings with the rest of the team over the course of the grant period. All 4PatientCare staff are fully dedicated to offering the necessary support to facilitate the successful acquisition and completion of this research grant. For the proposed project we are happy to commit the resources submitted in your project's budget.

Best,

A handwritten signature in blue ink that reads "John Harding".

John Harding, Ph.D.
Vice President
4Patient Care, Inc.

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