Organization: University of Rhode Island

C. MAIN SECTION OF THE PROPOSAL

I. OVERALL GOAL AND OBJECTIVES

I.a. OVERALL GOAL

To provide adult pneumococcal immunization education, and coordinate vaccination efforts among Health Care Professionals, which will improve the pneumococcal vaccination rate and subsequently, decrease the burden of pneumococcal disease in Rhode Island's adult population.

I.b. OBJECTIVES

The most significant challenge with adult vaccinations, as opposed to childhood vaccinations, is improving adult vaccination awareness among Health Care Professionals (HCPs), including pharmacists, physicians, physician assistants, and nurse practitioners. Currently, vaccine status assessment in adults by HCPs is not routine.[1-4] Moreover, a major concern with adult vaccination is that patients often receive care at multiple locations, which may not always be coordinated.[1] Additionally, patients are unaware of their immunization status and eligibility to receive pneumococcal vaccination.

To accelerate the adoption of recent United States Advisory Committee on Immunization Practices (ACIP) pneumococcal vaccination guidelines and ultimately improve the quality of care provided to patients, outreach, coordination and education of HCPs is essential.[5] The burden of such an intervention may be reduced through the use of Statewide large-scale, high-contact, lower-cost providers, such as community pharmacies and community health centers. In Rhode Island, the need to improve pneumococcal vaccination is focused on education and coordination efforts, as local pharmacists report that financial and storage barriers are not major concerns associated with pneumococcal vaccination.

Objective 1: Education. Improve adult pneumococcal vaccination rates in Rhode Island from 71.7% (Behavioral Risk Factor Surveillance System [BRFSS] data, 2010) to the state and Healthy People 2020 goal of 90%, by increasing knowledge and awareness of pneumococcal immunization recommendations and opportunities through education.[6]

i. **We will educate Health Care Professionals (HCPs) across the state through Academic Detailing.** Our education outreach will include community pharmacists, and HCPs at free clinics, diversity (non-English speaking) clinics, and ambulatory settings including primary care facilities. This objective will be accomplished by utilizing our existing team of Faculty and College partners (i.e., Preceptors and Adjunct Faculty) with multiple practice sites throughout the state.

ii. **We will educate citizens across the state, with a focus on the elderly, smokers and underserved racially, ethnically and linguistically diverse (REL) communities.** Our educational outreach to the community will include diversity centers, community centers and clinics, senior centers, and senior housing centers. Citizens with diverse backgrounds

are underserved in Rhode Island because of limitations in outreach. Moreover, educational efforts from community leaders, focused on REL populations are demonstrated to have a positive impact on vaccination rates. This will be accomplished through our existing and long-standing Pharmacy Outreach program (circa 1988) and Drug Information Center (circa 2004) which have established and strong relationships in REL communities. These groups will serve as "Vaccine Promoters".

Objective 2: Coordination and Communication. Improve coordination of care regarding pneumococcal vaccination between Health Care Practitioners, while also facilitating communication of pneumococcal vaccination status between patients and Health Care Professionals.

i. **We will provide a Pneumococcal Vaccination Coordination Materials.** This will include, wallet record cards, template letters, and vaccination reminder postcards to community pharmacies for their patients in order to facilitate coordination of care and communication with the patients' primary care provider.
ii. **We will conduct Public Service Announcements (PSA). PSA's will include** radio ads using media outlets throughout Rhode Island that will target the ≥65 population and smokers. The 30 second radio ads (300 runs) will highlight the importance of receiving the pneumococcal vaccine and encourage discussion of vaccination status between patients and Health Care Professionals by providing explicit examples of communication. We will coordinate this effort with the Department of Health's Ocean State Adult Immunization Coalition who have developed similar ads for statewide vaccination.

Objective 3: Outcomes. Quantify the effectiveness of our multifaceted education and coordination of care intervention.

i. **We will assess the change in incidence of invasive pneumococcal disease in Rhode Island** as our primary outcome, between the pre-intervention baseline period and the follow-up post-intervention period.
   We will also evaluate the impact of the intervention on pneumococcal disease hospitalizations in the state.
ii. **Our comprehensive set of secondary outcomes will assess:** (1) changes in pneumococcal vaccination rates, (2) the impact of education and coordination efforts among patients and health care professionals, and (3) results dissemination, including a step-by-step implementation guide detailing our education and coordination efforts, as well as a summary of lessons learned.

II. TECHNICAL APPROACH

II.a. *CURRENT ASSESSMENT OF NEED IN TARGET AREA*

Pneumococcal Disease and Importance of Prevention. Infections from *Streptococcus pneumoniae* (or pneumococcus) are among the leading causes of illness and death worldwide.[7,8] Pneumococcus causes a number of disease processes, the most common of which include pneumonia (70% of cases), bacteremia (16.8% of cases), and meningitis (6.0% of

cases).[9] In the United States, pneumococcus is responsible for over 500,000 cases of pneumonia and 175,000 hospitalizations annually.[8,10,11] The mortality rate of pneumococcal pneumonia is 5-7%, and may be even higher in elderly patients.[11] In the United States in 2010, there were an estimated 40,000 cases of invasive pneumococcal disease (e.g. bacteremia and meningitis) with over 4,000 resultant deaths.[9] Despite appropriate antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is still about 20% among adults and may be as high as 60% in the elderly population.[8] Of even greater concern in the elderly is pneumococcal meningitis which has a fatality rate of up to 80% in this population.[8] It is estimated that 3,000 - 6,000 cases of pneumococcal menigitis occur per year in the United States.[11]

Greater than half of all cases of pneumococcal disease in adults occur in non-vaccinated patients with an indication for pneumococcal vaccination.[12] This is extremely concerning, because people with ACIP indications for pneumococcal vaccination are twice as likely to die as those without indications if they develop invasive pneumococcal disease.[13] Despite this grave reality, pneumococcal vaccination rates remain below national goals. In 2009, the rate of pneumococcal vaccination in adults aged 65 years and older was only 61%, well below the Health People 2020 goal of 90%.[14] Additionally, early release data from the 2011 National Health Interview Survey, suggests that over 100 million persons with existing pneumococcal indications may be currently unvaccinated.[15]

A number of deaths during the 2009 outbreak of the novel influenza A (H1N1) virus were caused by secondary pneumococcal infections.[16] In an analysis of 34 autopsy cases of patients who died during this pandemic, half showed signs of secondary bacterial infections by post mortem lung culture and histological evaluation. In this study, pneumococcus was among the most common bacterial causes of these secondary infections. Thus, pneumococcal vaccination can help prevent secondary pneumococcal infections and resultant illness and death during influenza outbreaks.[17]

Need for Outreach in Elderly (≥65), Smokers and Immunocompromised Populations. Substantial evidence demonstrates that healthy adults ≥65 years of age and younger patients who have immunocompromising conditions, asplenia (functional or anatomic), cerebrospinal fluid leaks, and cochlear implants or have certain chronic illnesses, such as heart disease, diabetes, pulmonary disease, alcoholism, cirrhosis, , have an increased risk of pneumococcal disease.[18-21] Thus, the 23-valent pneumococcal polysaccharide vaccine (PPSV23) has been recommended for use in these populations for many years. In 2009, patients with asthma and current cigarette smokers ages 19 to 64 were also recommended to receive a one time dose of PPSV23.[22] Although, 13-valent conjugate pneumococcal vaccine (PCV13) was approved by the United States Food and Drug Administration for use in adults aged 50 and older, it has not been recommended by the ACIP for use in healthy adults.[23] In June 2012, the ACIP did add recommendations for use of PCV13 in adults aged 19 and older with immunocompromising conditions, asplenia (functional or anatomic), cerebrospinal fluid leaks, or cochlear implants.[5] New recommendations were released in October 2012 and the ACIP now recommends both

PPSV23 and PCV13 for individuals aged 19 and older with immunocompromising conditions, cerebrospinal fluid leaks, or cochlear implants.[5]

Need for Outreach in Underserved Racially, Ethnically and Linguistically Diverse (REL) Communities. Underserved communities may stand to benefit the most from vaccination yet suffer the greatest loss when they are not vaccinated. Health education is most commonly disseminated in English, which non-English speakers or readers may find difficult to understand. The underinsured, low-income groups, or those not connected to services may not even be aware that they are at increased risk of developing pneumococcal disease, nor may they be aware that vaccinations are available to prevent this disease. Additionally, many groups are distrustful of public health messages because of historical family beliefs of discrimination or negative experiences with public agencies. Therefore, coordination with community and diversity center leaders is a critical component for successful and sustainable vaccination promotion among this community.

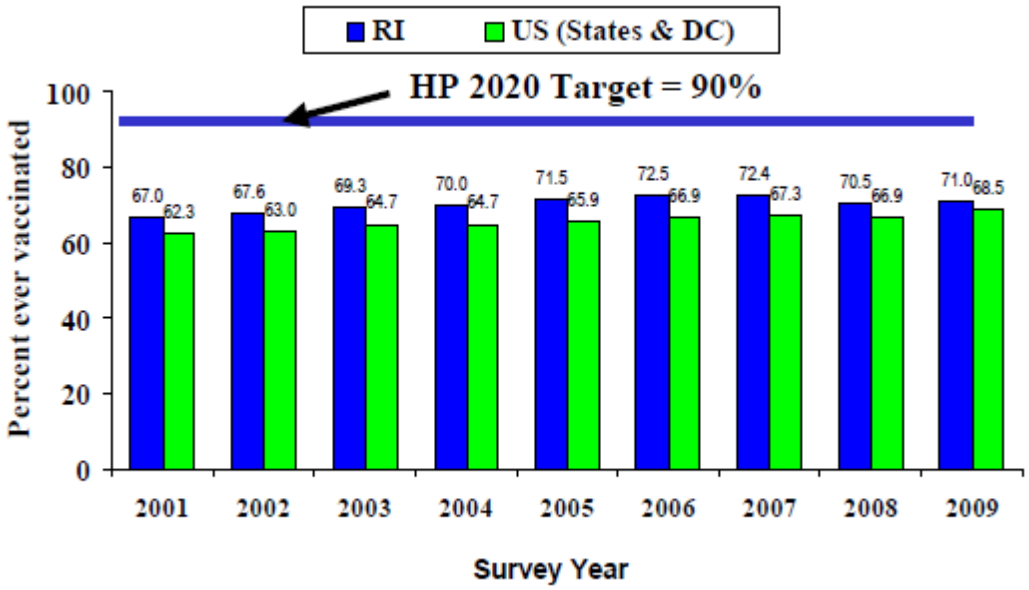
Local Significance. In Rhode Island, the incidence of invasive pneumococcal disease has increased in recent years, from 9.1 per 100,000 in 2007 to 11.9 in 2010.[24,25] The 2010 incidence of invasive pneumococcal disease was markedly higher in Rhode Island compared to the national rate, at 11.9 versus 8.8 per 100,000 population. The same trend was observed for incidence rates adjusted by age and gender. In 2010, the incidence of pneumococcal disease among females was 13.1 per 100,000 population in Rhode Island, compared to a national incidence of 8.5 per 100,000 population. Among males the incidence rate was 10.4 and 9.1 per 100,000 Rhode Island and national population respectively. Among patients 60 years of age and older, the Rhode Island invasive pneumococcal disease incidence rate in 2010 was 34.3 per 100,000 population (60-69 years 22.9/100,000, 70-79 years 27.5/100,000, ≥80 year 52.5/100,000). Nationally, the 2010 incidence rate was only 23.9 per 100,000 population in patients greater than or equal to 65 years old. These baseline data demonstrate the burden and importance of invasive pneumococcal disease in Rhode Island and the significance our proposed multifaceted education and coordination intervention in this population.

Rhode Island's Nationally Recognized Efforts. In 2007, Rhode Island became the first state to develop a statewide program that centralized distribution of adult vaccines and developed universal adult vaccination policies.[26] This Adult Immunization Program was formed through collaborations between the Rhode Island Department of Health, the Primary Care Physician Advisory Committee, insurers, Centers for Medicare & Medicaid Services, College of Pharmacy Faculty, and the Ocean State Adult Immunization Coalition to reduce barriers to adult immunization and to improve vaccination rates, including pneumococcal vaccination. This group facilitated passage of legislation in 2007 that requires the Department of Health to distribute vaccine to RI providers at no cost, thus eliminating cost as a barrier to vaccination. This program benefits providers in that it stabilized the supply of vaccines and eliminated the financial burden of vaccine purchase, thus making it easier for all providers to offer adult vaccines. Further, the program benefited the public greatly by improving access to vaccines in a wide range of settings, including community pharmacies, and through the establishment of adult vaccine programs that target at-risk populations.

This Rhode Island immunization program, in collaboration with University of Rhode Island College of Pharmacy Faculty, has been recognized for its innovation and has won several awards including the Association of State and Territorial Health Officials (ASTHO)'s 2008 Vision Award and the Center for Disease Control and Prevention's Immunization Excellence Award in 2008.[26] Despite the great successes of this program, pneumococcal vaccination rates for adults aged 65 and older have not significantly improved since implementation of the program in 2007 (Figure 1). Pneumococcal vaccination rates for this population have remained stable over time, at around 70%.

According to Behavioral Risk Factor Surveillance System (BRFSS) data, the rate of pneumococcal vaccination in adults aged 65 and older in 2010 was 71.7%.[6] While this percentage is about 10% higher than national rates, the rates of vaccination in the State remain well below the Healthy People Goal of 2020.

Figure 1: Pneumococcal Vaccination in Lifetime - Adults 65 Years of Age or Older: 2001-2009[26]



Source: Behavioral Risk Factor Surveillance System (BRFSS), 2001-2009, CDC

To continue focusing on immunization across the state, in 2012, the University of Rhode Island College of Pharmacy took part in a statewide campaign to increase pneumococcal vaccination awareness and access among Rhode Island's community pharmacists. This campaign was set forth because of pneumococcal vaccination data collected by the Rhode Island Behavioral Risk Factor Surveillance System in 2008. This data demonstrated that only 61.3% and 78.5% of adults aged 65-74 and ≥75 years, respectively, had ever received pneumococcal vaccination, thus falling short of the Centers for Disease Control and Prevention's Healthy People 2020 Goal of 90% pneumococcal vaccination rates among those aged 65 and older. In post-campaign surveys, 65% of pharmacists (16/30) were able to better identify new indications for

vaccination and 90% of pharmacists (27/30) provided more pneumococcal vaccinations after participation in the program as compared to before participation. The majority of participants (76%) found that Centers for Disease Control and Prevention screening cards were helpful to identify patients eligible for pneumococcal vaccination.

Primary Targeted Population. Our intervention will directly target two audiences in Rhode Island: (1) health care professionals, including community based pharmacists, physicians, physician assistants, and nurse practitioners and; (2) specific patient populations including the elderly, smokers, and underserved racially, ethnically and linguistically diverse communities. This multifaceted education and coordination of care approach has been designed to take advantage of Rhode Island's geographic size, optimizing the inter-connectedness of health care professionals, patients, and other stakeholders. Our education outreach will include community pharmacists, and HCPs at free clinics, diversity (non-English speaking) clinics, and ambulatory settings, including primary care facilities. Patient education will focus on diversity centers, community centers and clinics, senior centers, and senior housing centers. Residents of Rhode Island will directly benefit from our multifaceted intervention to educate practitioners and patients on pneumococcal vaccination and improve coordination of care between practitioners, while also facilitating communication between patients and health care professionals. These direct benefits include increased vaccination rates and subsequently reduced morbidity and mortality due to invasive pneumococcal disease in Rhode Island.

A major focus of this grant will be targeting the underserved racially, ethnically and linguistically diverse (REL) communities. According to 2010 Rhode Island census data, 5.7% of households in Rhode Island were linguistically isolated. According the Centers for Disease Control and Prevention (CDC) Snap Shots of State Population Data (SNAPS), the 6 languages spoken at home among Rhode Islanders (> 5000), are English only (788,565), followed by Spanish (79,440), Portuguese (37,435), French (19,355), Italian (13,760) and Mon-Khmer, and Cambodian (5,570). Through previous experience with the College of Pharmacy's Outreach Program's and Drug Information Center's deep-rooted connections in these REL community settings, much has been learned about barriers confronting patients who do not speak English as their first language, particularly those of Asian descent, which make up nearly 6,000 Rhode Islanders. Many of the community members rely on their community centers for guidance and assistance, because of limited access to health care professionals who speak their language. Strong relationships in these centers already exist with community leaders. These centers are a logical targeted approach to reach populations who may have or perceive barriers to vaccination (Appendix A; Letters of Support/Commitment).

II.b. *INTERVENTION DESIGN AND METHODS*

Objective 1: Education. To improve adult pneumococcal vaccination rates in Rhode Island from 71.7% (Behavioral Risk Factor Surveillance System [BRFSS] data, 2010) to the state goal of 90%, by increasing knowledge and awareness of pneumococcal immunization recommendations and opportunities through education.[6]

We will apply a multifaceted approach that targets both patients and Health Care Professionals (i.e., pharmacists, nurses, nurse practitioners, physician assistants and physicians). Our major focus will be in community pharmacies (CVS, Rite Aid, Target, Walgreens, and local independent pharmacies), senior and community centers (via College's Pharmacy Outreach Program), with additional focus on Health Care Professionals among underserved Racially, Ethnically and Linguistically Diverse (REL) communities in our state's free clinics, family van program, and diversity (non-English speaking) community centers. This objective will be accomplished by utilizing our existing team of Faculty and College partners (i.e., preceptors and adjunct Faculty) with clinical sites throughout the state (Appendix B). Currently we have formal College partners and or Faculty in 40% (23/59) of CVS Pharmacies, 39% (18/46) of Rite Aids, 100% (4/4) of Targets, and 60% (15/25) of Walgreens. (Appendix A).

By utilizing an academic detailing approach, our trained Vaccine Promoters (Faculty and College partners) will visit community pharmacies and HCPs focusing on REL communities to provide face-to-face, unbiased, evidence-based education about pneumococcal vaccination. Studies clearly demonstrate that academic detailing can change prescribing practices and most importantly improve patient care.[27-31]

The Role of Academic Detailing. By definition, academic detailing is "university or non-commercial-based educational outreach which involves face-to-face education to prescribers by trained health care professionals". The goal of academic detailing is to provide education consistent with medical evidence or guidance documents. Many of today's ambulatory care providers have become disengaged from local hospital and academic centers. These materials will provide information pertaining to vaccine reimbursement (e.g. Medicaid, Medicare, private insurers, Department of Health incentive programs), and guidelines to identify eligible patients. We will also have available information regarding the State's Department of Health reimbursement and vaccination program. Knowledge of these programs already exists among our Vaccine Promoters at the College. However, monthly meetings and/or teleconferences will be held for updates and review. In addition, a Project Nurse Manager and the Drug Information Service will be available by phone between the hours of 8:30am to 4:30pm to coordinate efforts among Vaccine Promoters regarding educational materials (facsimile or ordering additional materials), and other questions regarding vaccine access and reimbursement.

Pneumococcal Vaccine Eligibility Pathway. Because of the intricacies of age and disease co-morbidities that affect a patient's vaccination status, Health Care Professionals who recommend and/or administer immunizations may be unsure if their patients meet criteria for vaccination. Additionally, providers may have questions regarding administration of the pneumococcal polysaccharide vaccine versus the pneumococcal conjugate vaccine and when additional dosages are indicated. Moreover, recent changes to pneumococcal vaccination recommendations add further complexity.[5] Therefore, we have created a simple to follow pathway that primary care providers and pharmacists can utilize to easily and efficiently determine if patients meet the criteria for pneumococcal vaccination (Appendix C; Educational Pathways).

Educational Materials. We will utilize and develop educational materials from the Immunization Action Coalition (IAC), which is an organization whose mission is to "increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public".[32] Currently, the IAC's website for health professionals Immunize.org is "the largest resource for practical, user-friendly immunization information" available.[32] The website provides informational handouts for health care professionals and patients (in over 13 different languages including Hmong, Spanish, and French) free of charge, and encourages users to reproduce and redistribute the materials.

Vaccine Information Statements. By Federal law, immunizers are required to provide a Pneumococcal Polysaccharide Vaccination Information Statements (VIS). The Immunize.org website provides a Pneumococcal Polysaccharide VIS, which defines indications for pneumococcal polysaccharide vaccine (PPSV) and indications for additional doses.[33] We will provide and disseminate copies of the Pneumococcal Polysaccharide VIS to primary care offices and community pharmacies throughout the state. This information statement is translated in French, Spanish, Hmong, Cambodian, Vietnamese, and Laotian.[33] Translations to Portuguese and Italian are not available; however, both the Socioeconomic Development Center of South East Asia (Hmong, Cambodian, Vietnamese) and the University of Rhode Island Language Faculty will be utilized to provide these translations. Translated versions will be printed and supplied to all diversity and free clinics. The IAC does not provide Vaccine Information Statements for the 13-valent conjugate pneumococcal vaccine (PCV13). As such, we will utilize resources from the CDC to make PCV13 VIS following the recommendations for use of the PCV13 by the Advisory Committee on Immunization Practices.[5]

Increased Communications Electronically. Over the next several years an increasing number of primary care providers will be utilizing Rhode Island's Currentcare program, which is the state's electronic health information exchange. In our efforts to enhance documentation and communication of patients' immunization status, we will seek to align our activities with the work of the Rhode Island Quality Institute, which is the regional health information organization responsible for deploying the Currentcare system. Currentcare will soon serve as the state's core source for accessing patients' health records electronically; and patients' immunization history, whether delivered in a PCP office or a community pharmacy, will be readily viewable by pharmacists, or any other provider authorized to utilize the system. While the complete integration of immunization histories within the Currentcare system is not a specific objective of our proposal, we will work in concert with the Rhode Island Quality Institute to ensure that our activities to promote immunization and related documentation parallel ongoing activities to implement Currentcare.

Educate citizens across the state, with a focus on elderly, smokers and underserved racially, ethnically and linguistically diverse (REL) communities. Our educational outreach to the community will include diversity centers, community centers and clinics, senior centers, and senior housing centers. Citizens with diverse backgrounds are underserved in our state due in part to limitations in outreach. Educational efforts focused in specific racial and ethnic populations have been demonstrated to increase vaccination rates.[34] This will be accomplished

through our existing, long-standing relationships developed by the Pharmacy Outreach program (circa 1988) and Drug Information Center (circa 2004; See Leadership and Organizational Capacity). Faculty, students, and staff from these units will serve as "Vaccine Promoters".

Objective 2: Coordination and Communication. Since patients often receive care at multiple locations that may not be coordinated, our Vaccine Promoters will also provide education materials to Health Care Professionals throughout Rhode Island to assist with *coordination of care*. Through College of Pharmacy Faculty and College Partners (i.e., Preceptors and Adjunct Faculty) with clinical appointments at each of the state's Diversity and Free clinics (e.g. Family Van), and each of the major local community pharmacies (Rite Aid, Target, CVS, and Walgreens), we will provide ongoing academic detailing to HCPs. These efforts will focus on providing vaccination schedule reminders to HCPs, increasing awareness on the importance of documentation and communication to patients' PCPs, and training HCPs to empower patients to know their immunization status for communication to their PCPs.

Wallet Card. In an effort to empower patients, we will disseminate laminated Pneumococcal & Vaccination cards that will be distributed and completed by the person providing the vaccine at the time of vaccination. The patient will be informed that their immunization status will be documented on this card, and patients will be instructed to carry the card with them and to present this card to their PCPs, for a confirmation that vaccination occurred. This process will provide PCPs with additional verification, coinciding with existing regulation requiring immunizers to provide PCPs with a mailed letter within 14 days of vaccination. An additional beneficial aspect of the wallet card is that its use may serve as a reminder to the PCP about the importance of pneumococcal vaccination.

Wallet cards will be printed in English (alone or in combination with) Spanish, Italian, Portuguese, Laotian, Cambodian, French and Hmong. The cards will allow patients to self-screen for the pneumococcal and influenza vaccines (e.g. age, chronic disease, etc). This card will include the Vaccine Information Statement (VIS) and Federal requirements (vaccine name, site of admin, date, lot#, expiration date). This will be distributed to community pharmacies and PCP offices throughout the state. This card will also include a toll-free number (8:30am to 4:00pm) to the Project Manager/Coordinator, which patients may call for additional information regarding the vaccination.

A pneumococcal vaccination wallet card will be provided to patients who will require pneumococcal vaccination in the next 5 years, and will highlight the patient's indication for vaccination. We will indicate whether the patient should receive 23-valent pneumococcal polysaccharide vaccine (PPSV23) or 13-valent conjugate pneumococcal vaccine (PCV13). The wallet card will also serve as a "receipt" for patients who received their pneumococcal vaccination, and which vaccination the patient received (PPSV23 or PCV13). Patients can share this card with all of their HCPs, thus serving to improve coordination between multiple providers. For patients who require subsequent pneumococcal doses, the card will highlight this need and document when the patient should get their next dose.

Additionally, this wallet card will have a section to document 5 years of influenza vaccinations. Each year when patients receive their influenza vaccination, they will also be reminded about pneumococcal vaccinations. Patients can review their wallet card, to determine when they need pneumococcal vaccination. Patients can also share their card with their yearly influenza immunizer, and these providers can help patients determine if pneumococcal vaccination is indicated.

Communication to PCPs. Furthermore, communication via fax or mailing will be sent by the immunizer to the PCP within 14 days of the patient's immunization, per Rhode Island vaccination regulations: *Title; 23.13 The immunizing pharmacist shall provide written notification of a patient's immunization to the primary care provider, if known, within fourteen (14) days.*

Identifying Eligible Patients. In addition to Educational Pathways (Appendix C), auxiliary labels can be used to help alert patients that they are eligible for pneumococcal vaccination. As such, we will disseminate pneumococcal vaccination auxiliary labels to community pharmacies throughout the state. These labels, which we will purchase from the American Pharmacists Association, can be placed on prescriptions for heart disease, diabetes, asthma or chronic obstructive pulmonary disorder, and smoking cessation. Additionally, labels can be put on packs of cigarettes.[35]

Public Service Announcement (PSA). We will develop a 30 second radio public service announcement. This announcement will empower patients (focus group will be age >65 and smokers) to inquire about pneumococcal vaccination in their encounters with Health Care Professionals, including community pharmacists. The ads will play on-air and on-line on the two most popular stations in Rhode Island (PRO-FM and WWLI). We will purchase 300 total spots for this announcement to run.

II.c. EVALUATION DESIGN

The goal of vaccination is to prevent morbidity and mortality, particularly invasive disease. *As such, the primary outcome of our multifaceted intervention program is to assess changes in the incidence of invasive pneumococcal disease in Rhode Island.* Invasive pneumococcal disease is a reportable disease nationally and in our state. Invasive disease is confirmed by isolation from blood, cerebrospinal fluid, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, or another normally sterile site. In Rhode Island, pneumococcal disease must be reported within 4 days of recognition. To calculate incidence, we will use Rhode Island census data for our denominator. Further, we will report age, race, and gender adjusted incidence rates that can be compared to national rates. Changes in incidence between the pre-intervention baseline period and the follow-up post-intervention period at Months 12 and 24 of the project period will be evaluated. We expect to see a decline in the incidence of invasive pneumococcal disease in Rhode Island as a result of our intervention.

The Rhode Island Department of Health report form can be found in Appendix D. The report form collects the following patient information: age, gender, race, ethnicity, vital status, hospital admission status, date of illness onset, signs and symptoms, underlying medical conditions, and immunization status. As such, we will describe changes in invasive pneumococcal disease, stratified by these aforementioned patient characteristics. Though certain data elements may be missing from some report forms (e.g. underlying medical condition, date of illness onset), we will clearly identify this missing data.

We will also assess pneumococcal disease from hospital discharge data collected by the state.[36] Discharge data is captured from 5 teaching hospitals providing general acute care, 6 other general acute-care hospitals, 2 psychiatric teaching hospitals, and 1 rehabilitation hospital. The data are collected by means of a statewide reporting system that was established as of October 1, 1989 by regulations promulgated by the Rhode Island Department of Health under its licensure authority (Rhode Island General Laws 23-17-10). Available data include patient demographics, clinical diagnoses, length of stay, and costs, as well as overall number of discharges and number of days of care. Pneumococcal disease will be identified from the following diagnosis codes: 481 (pneumococcal pneumonia), 038.2 (pneumococcal septicemia), and 320.1 (pneumococcal meningitis). Although under ascertainment is a concern when using diagnosis codes in infectious diseases, assessing invasive pneumococcal disease from both reportable disease forms (laboratory confirmed) and hospital discharges should provide a clear picture of disease trends pre- and post-intervention.

To further assess the effectiveness of our approach to improving pneumococcal vaccination in Rhode Island through education and coordination of care, we will evaluate a range of outcomes, including impacts on immunization rates and other measures assessing the effectiveness of program components. Our secondary outcomes include (1) changes in pneumococcal vaccination rates, (2) the impact of education and coordination efforts among patients and Health Care Professionals, and (3) results dissemination, including a step-by-step implementation guide detailing our education and coordination efforts, as well as a summary of lessons learned. Baseline vaccination rates (pre-intervention) and follow-up rates (post-intervention) will be captured from the Rhode Island Behavioral Risk Factor Surveillance System. Since this survey, conducted through random-digit dialed telephone interviews, only includes a sample of Rhode Island residents, we will also attempt to capture pre- and post-intervention vaccination rates at participating clinical sites, including community pharmacies and clinics, where data are available. We expect to observe an increase in pneumococcal vaccination rates in Rhode Island as a result of our intervention.

During the study period, we will capture the number of administered pneumococcal vaccinations from community pharmacies and clinics. Additionally, we will work with immunizers to assist them in tracking the number of immunizations provided, overall and according to key patient characteristics (e.g. REL status). Our Vaccine Promoters will measure baseline vaccination rates at their sites and subsequently capture changes in vaccination rates over the study period. At some sites, such as community pharmacy locations, it may be difficult to quantify the eligible population (i.e. denominator). In these cases, we will work with vaccine

providers and their organizational representatives to determine which data may be available for assessing site-specific immunization rates at baseline and following the implementation of our intervention. For example, a community pharmacy retailer may be able to identify older patients having chronic diseases by analyses of prescription dispensing data. Percent changes in vaccination will be calculated for each year. Where data are available, stratified analyses will present rates according to patient race, ethnicity, language spoken at home, and patient risk factors for pneumococcal disease. We will also track the number of sites that implement a formalized and sustained process for identifying and immunizing at-risk patients through documentation and reporting functions.

We will assess the effectiveness of the educational campaign directed toward patients and HCPs through survey development and administration. These surveys will be developed during the initial phase of the project period. Domains of survey measurement will include content understanding, educational material ease of use, implementation adherence by HCPs, changes in vaccination practices, and utilization of coordination materials (e.g. wallet card, direct notifications). Surveys of HCPs will also aid in determining if their immunization programs improved in quality and effectiveness as a result of our initiative, and the extent of HCP engagement. Patient surveys will be administered at diversity centers, community centers and clinics, senior centers, and senior housing centers measuring the content understanding and utility of educational materials, including the public service announcement and auxiliary labels, and subsequent intent to vaccinate.

Our project outcomes will be broadly disseminated through conference presentations and journal publications. The dissemination of our project results will include a detailed step-by-step guide for other states that may be seeking to implement an education and coordination of care pneumococcal vaccination program. Further, we will share the results of our intervention in future practitioner and patient educational materials. And lastly, we will develop a summary of lessons learned, or what worked and what didn't, for dissemination.

III. DETAILED WORKPLAN AND DELIVERABLES SCHEDULE

The coordination and implementation of this grant will be through the University of Rhode Island's College of Pharmacy, and include monthly live meetings with the Rhode Island Department of Health's Adult Vaccination Program Members. Our proposed project will be carried out over 30 months. The first 4 months will focus on designing the educational materials, as well as the collection of baseline data and development of surveys to be administered to patients and Health Care Professionals. After the sixth month, educational interventions and academic detailing will begin (including PSAs), and be continued monthly. Upon completion of educational interventions, assessment and outcome data will be analyzed.

Timeline. *This 30 month project will start January 1, 2013 and be completed July 1, 2015. The timeline is detailed in the table below.*

Table 1: Project Timeline

Activity	Month 0-6	Month 6-12	Month 12-24	Month 24-30
Obj. 1: Designing educational materials and public service announcements	← →			
Obj. 1: Educational interventions and academic detailing		←	→	
Obj. 2: Coordination efforts and tracking of coordination		←	→	
Obj. 3: Collection of baseline data, development of surveys to be administered to patients and Health Care Professionals	← →			
Obj. 3: Collection of follow-up data on invasive pneumococcal disease, vaccination activities, administration of surveys to patients and HCPs		←	→	
Obj. 3: Analyses			←	→
Dissemination: (1) presentations at national meetings, (2) publication submission to a high impact journal, and (3) other presentations, including a step-by-step guide and lessons learned			←	→