

## A. COVER PAGE

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**Title: Science-Based Communication to Decrease Disparities in Adult Pneumococcal Vaccination Rates**

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**Notable Definitions and Abbreviations:**

- **REL** = racially, ethnically and linguistically diverse
- **CDC** = Centers for Disease Control and Prevention

**Abstract**

Minority adult populations are at a higher risk for invasive pneumococcal disease when compared to the general population. These subpopulations also have significantly lower vaccination rates when compared to the general population. Therefore, the goal of this project is to increase pneumococcal vaccination rates in minority adult populations. To accomplish this goal we will develop sustainable, science-based communications targeting these disparate populations. This novel messaging will be shared through Community Pharmacies to be used nationally to increase adult pneumococcal vaccination rates and decrease invasive pneumococcal disease across minority populations. We will test which science-based vaccine messages most effectively resonates with minority populations and measure the impact of the dissemination of this messaging on vaccination status, invasive pneumococcal disease rates, and motivation to vaccinate.

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**C. REVIEWER COMMENTS – none.**

## D. PROJECT PROPOSAL AND PLAN

### D.1. OVERALL GOAL AND OBJECTIVES

**GOAL:** To develop sustainable, science-based communications targeting minority adult populations. This novel messaging will be utilized in community pharmacies and clinics nationally to increase adult pneumococcal vaccination rates and decrease invasive pneumococcal disease across diverse populations.

**BACKGROUND.** One of the most significant barriers in improving vaccinations rates among disparate populations of adults is overcoming ingrained attitudes and apathy<sup>1</sup>. In 2013, pneumococcal vaccination rates among adults aged  $\geq 65$  years was 59.7%, falling short of the Healthy People 2020 goal of 90%.<sup>2</sup> Coverage was noted as higher in whites (63.6%) when compared to 39.2% for Hispanics or Latinos, and 48.7% for blacks.<sup>2</sup> *Importantly, adjusting for access and quality of health care does not eliminate the vaccination coverage disparities across minority groups*<sup>3</sup>. Consequently, the National Vaccine Advisory Committee called for approaches that identify and overcome attitudinal barriers to adult pneumococcal vaccination in racially and ethnically diverse subpopulations. Currently, vaccine promotion materials utilize standard messaging in a “one size fits all” approach. General informational messaging is not always sufficient for overcoming these types of negative attitudes.<sup>4</sup> Therefore, messaging that is focused on overcoming the attitudinal barriers to adult pneumococcal vaccination in racially, ethnically and linguistically diverse sub-populations is of critical importance.

To accelerate pneumococcal vaccination in adult minority populations, and ultimately improve the quality of care provided to patients, we aim to **identify** the nature of common myths and misconceptions (vaccination hesitancy) towards receiving pneumococcal vaccination across racial and ethnic subpopulations, **test** which science-based persuasive messages most effectively counter each attitudinal barrier, and then **tailor** science-based vaccination messages to overcome the subpopulation’s attitudinal obstacles in order to **improve** vaccination. By increasing vaccination rates and reducing disparities across racial/ethnic groups, we expect to observe subsequent decreases in the burden of pneumococcal disease morbidity and mortality in the United States adult population. ***Our focus areas will be*** Hispanics or Latinos, and blacks which represent the largest ethnic and racial subpopulations with a documented current pneumococcal vaccination rate of less than or equal to 50%.<sup>5</sup> This will be accomplished by the following objectives:

**Objective 1: Identify Barriers.** A survey focused on adult pneumococcal vaccination hesitancy in minority populations is needed. Nearly all of the published survey research evaluates vaccine attitudes in the general population, with a focus on children’s vaccines.<sup>6</sup>

- **We will investigate ingrained attitudes and apathy regarding pneumococcal vaccination in the general adult population focusing particularly on barriers in Hispanics or Latinos, and blacks.** This will be accomplished by developing a nationally representative survey that will identify the nature and extent of common myths and misconceptions towards receiving adult pneumococcal vaccination across minority populations. This survey, developed by well-respected survey experts on our research team will be administered by a national

survey house experienced in over-sampling unique subpopulations.

**Objective 2: Test Persuasive Communication.** It is important to pinpoint the persuasive advantage of using newly identified targeted messages over current standard approaches to communicate about adult pneumococcal vaccination.

- **We will craft science-based targeted messages about adult pneumococcal vaccination and test their persuasive efficacy against conventional vaccine information.** We will develop a series of controlled experiments embedded in a second nationally representative survey to test which science-based vaccine messages most effectively overcome vaccination hesitancy identified in our first survey. These survey experiments (administered by the same national survey house) will test which science-based vaccine messages most effectively overcome the various attitudinal myths and misconceptions. Embedding randomized experiments in a nationally representative survey has distinct advantages; because the experiments use a probability sample for the subject pool, rather than a more narrow and unrepresentative pool of subjects, the results of the analysis display a high degree of national generalizability.<sup>7,8</sup>

**Objective 3: Create and Distribute Educational Messages.** It is essential to disseminate newly developed patient focused educational materials so that this information can be utilized nationally to increase adult pneumococcal vaccination rates and ultimately decrease invasive pneumococcal disease across minority populations.

- **We will use our new understanding about the adult pneumococcal vaccination messages to develop and disseminate educational materials (posters, brochures and Public Service Announcements) to Community Pharmacies that serve minority populations.** We will work with Walgreens Pharmacy, a national leader and financial supporter of initiatives that serve multi-cultural populations, and eliminate barriers to care. Specifically, we will send educational materials for use in community pharmacies that serve minority populations in Rhode Island, Washington, DC (lowest ranking of pneumococcal vaccination nationally), Illinois (second lowest ranking), New York (fifth lowest ranking of pneumococcal vaccination nationally), and New Jersey (sixth lowest ranking) as they will directly benefit from our messages.

**Objective 4: Measure Impact of Messaging.** Evaluating the impact of newly targeted messaging with both quantitative and qualitative data is necessary.

- **We will measure the effectiveness of messaging dissemination; this will be assessed from (1) vaccination status, (2) invasive pneumococcal disease rates, and (3) motivation to vaccinate.** Our primary outcome will be change in adult pneumococcal vaccination. Using a quasi-experimental design (interrupted time series), we will ascertain within state zip code differences in vaccination status among the subpopulations of interest from the Behavioral Risk Factor Surveillance System (BRFSS). This will be compared between the pre-intervention and post-intervention periods. We will also assess changes in burden of non-vaccination by tracking invasive pneumococcal disease as a secondary outcome. Lastly, we

will conduct a pilot field experiment of our message in a real-world clinical setting (locally) as compared to the standard message and evaluate motivation to vaccinate.

## 2. TECHNICAL APPROACH

### 2a CURRENT ASSESSMENT OF NEED IN TARGET AREA

**Pneumococcal disease and vaccination rates in the United States.** Pneumococcal disease remains a substantial burden among older adults in the United States. A recent analysis estimated that pneumococcus was responsible for 4 million illness episodes, 445,000 hospitalizations and 22,000 deaths annually in the United States.<sup>9</sup> National estimates of invasive pneumococcal diseases for 2013, were 33,900 cases and 3,700 resultant deaths.<sup>10</sup> Also in 2013, pneumococcal vaccination rates in white, black and Hispanic/Latino adults were reported. Among adult's aged  $\geq 65$  years, pneumococcal vaccination rates were slightly under 60% falling short of the Healthy People 2020 goal of 90%.<sup>2</sup> Vaccination coverage was noted as higher in whites (63.6%) when compared to 39.2% for Hispanics or Latinos, and 48.7% for blacks.<sup>2</sup>

**Pneumococcal disease in minority populations.** The burden of pneumococcal disease in blacks and Hispanics or Latinos is substantial, due to lower vaccination rates coupled with a higher prevalence of pneumococcal risk conditions.<sup>11</sup> Blacks and Hispanics or Latinos are more likely to have chronic medical conditions, including asthma, diabetes, and cardiovascular disease and stroke, than whites.<sup>12-14</sup> Invasive pneumococcal disease disproportionately affects blacks. In the United States, the rate of invasive pneumococcal disease in blacks is 15.5 cases per 100,000 population as compared to 9.9 cases per 100,000 population in whites.<sup>10</sup> Rates of bacteremic pneumonia due to pneumococcus are also higher among blacks as compared to whites.<sup>15, 16</sup> Higher rates of invasive pneumococcal disease have also been described in Hispanics than in whites.<sup>17</sup>

**Disparities in Pneumococcal Vaccination.** Racial and ethnic disparities in pneumococcal vaccination have a substantial public health impact. Despite the huge burden of pneumococcal disease, pneumococcal vaccination rates for black and Hispanic or Latino adults aged  $\geq 65$  are 15% and 24% lower, respectively, compared to whites.<sup>2</sup> There is also a substantial gap for younger at-risk Hispanic adults where vaccination rates are approximately 5% lower compared to whites.<sup>2</sup> ***As there are almost 4 million black (non-Hispanic) and 3.3 million Hispanic adults aged 65 and older in the US, the elimination of racial and ethnic disparity in pneumococcal vaccination could result in a significant reduction of unnecessary illness episodes and deaths due to pneumococcus in these subpopulations.***<sup>18</sup> It is essential that the gaps in vaccination coverage for blacks and Hispanics or Latinos be closed to reduce the morbidity and mortality due to invasive pneumococcal disease for these subpopulations nationally. ***Gaps in vaccination coverage leave too many black and Hispanic or Latino adults at risk for pneumococcal disease.***<sup>11</sup>

**Need for Outreach in Disparate Populations.** 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. In Hispanic communities where English is limited among adults, it's ideal that vaccination messaging be delivered in Spanish.<sup>11</sup> 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. In fact, four out of five adults in the United States responded that they did not know about pneumococcal disease.<sup>11</sup> Therefore, more education about the disease is needed for people to understand that they need to protect themselves through vaccination.<sup>11</sup> This education must be delivered through culturally competent, relevant, simple and easy to understand messages. Additionally, many disparate populations are distrustful of public health messages because of historical family beliefs of discrimination or negative experiences with public agencies. Blacks value discussion with their personal physicians when making health care decisions, while for Hispanics the most common source of health information is from other medical professionals.<sup>19, 20</sup> Messages must thus reinforce the value of vaccination in a culturally competent manner.

**Lack of Efficacy in Current Messaging.** According to a recent National Vaccine Advisory Committee report, the most significant barrier in improving vaccinations rates among subpopulations of adults is overcoming ingrained attitudes and apathy. Consequently, there is a national call to better identify and understand attitudinal barriers to adult pneumococcal vaccination in racially and ethnically diverse subpopulations. Currently, vaccine promotion materials available for use on the Centers for Diseases Control and Prevention (CDC) and immunize.org, website provide general messaging in English and Spanish with a standard “one size fits all” approach<sup>21, 22</sup>. Research conducted to evaluate adult vaccination rates to date consistently suggest that vaccination rates increase simply if the patients physician recommends vaccination.<sup>23</sup> While this data is promising, disparate populations may not always seek the primary health care they need. In fact, Hispanics are less likely to seek and receive health-care services than non-Hispanic whites.<sup>24, 25</sup> Additionally, disparate adults may be more likely to live in communities where access to primary care providers is an issue. Therefore, for all healthcare providers every interaction with disparate at-risk adults should be an opportunity to vaccinate or promote vaccination.<sup>11</sup> The tide is largely changing as health-care providers are suggesting that patients receive their vaccinations at local community pharmacies. Also, due to the Affordable Care Act (ACA) signed into law March 2013, affordable and accessible Health Care should be available for all Americans. Adults 19 years and older who are enrolled will be eligible to receive pneumococcal vaccination as recommended by the ACIP without any cost-sharing requirements. Therefore, we should see a significant reduction in previous barriers to vaccination stemming from access to care, providers and insurance concerns.

It is well researched, that general informational messaging is not always sufficient for overcoming these types of negative attitudes.<sup>4</sup> Therefore, messaging that is focused on overcoming the attitudinal barriers to adult pneumococcal vaccination in minority populations is of great importance. To accelerate pneumococcal vaccination in adults, and ultimately improve the quality of care provided to patients, it is necessary to identify, test, tailor and distribute targeted messages designed to overcome the attitudinal barriers to immunizations in minority adult populations.

**Assessment of Team - Rhode Island's Current Efforts to improve adult pneumococcal vaccine Rates.** The University of Rhode Island faculty is uniquely positioned to implement this grant. The College of Pharmacy, under the leadership of Kerry LaPlante (PI) is completing a two and a half year grant focusing on addressing educational and coordination barriers for adult pneumococcal disease prevention in Rhode Island. To date, with the collaboration of the Rhode Island Department of Health, this group has had great success implementing the objectives of the grant which include; 1) Pneumococcal vaccination pathways, patient education pamphlets and a vaccination wallet card translated into Chinese, Laotian, Hmong, Spanish and Cambodian to help improve coordination of care (please refer to the supplemental materials that we uploaded to the grant portal with our letter of intent, as well as Appendix C). Her team also put together a 30 second PSA about pneumococcal vaccination in Spanish and English which aired 227 times on 6 radio stations throughout RI to an estimated audience of 368,895 (listen on "additional uploads" section in Pfizer submission portal). This team has attended 23 public health events, 73 senior events, impacting approximately 2,636 seniors and an estimated 5,170 Rhode Islanders. **Overall, the estimated Patient Population Impacted to Date from this work is 1,100,852.** Also, pharmacy faculty have visited 102 pharmacies and Health Care Providers throughout the state of RI to provide academic detailing regarding the new pneumococcal vaccination guidance. We have also incorporated our pneumococcal pathways into six of Rhode Islands' largest hospitals and national Rite Aid pharmacy headquarters has requested to use our pathway (see Appendix C) in all of their stores. **Overall our Health Care Professional Population Impacted to Date (Rhode Island estimates only) is 1,552 providers/pharmacists.** The team is finalizing our outcomes by obtaining data on the incidence of invasive pneumococcal disease in RI from 2004 through Nov 2014 through our collaboration with the Rhode Island Department of Health, and vaccines ordered from community pharmacies in Rhode Island (obtained with approval from Pfizer's legal team via Verna Welch, PhD, MPH).

## **2b. PROJECT DESIGN AND METHODS**

**OBJECTIVE 1: IDENTIFY ATTITUDINAL BARRIERS.** We will identify the specific vaccination hesitancy barriers towards receiving adult pneumococcal vaccination within ethnic and racial subpopulations as well as overall population attitudinal barriers.

### **Survey development and implementation.**

We will develop and administer a nationally representative survey that will identify the nature and distribution of common myths, misconceptions and other negative attitudes towards receiving adult pneumococcal vaccination across subpopulations. We will utilize information from past studies that focused on attitudes toward vaccines when developing this survey instrument.<sup>26-29</sup> A survey focused on adult pneumococcal vaccination in disparate populations is needed because much of this past survey research considers vaccine attitudes in the general population, with a focus on children's vaccines.<sup>6, 30</sup> We will conduct a probability sample survey of U.S. residents employing an oversampling technique that increases the sample size of our ethnic and racial subpopulations. This oversampling allows for independent analysis of targeted subgroups that would otherwise comprise only a small proportion of the sample. We will also compare the subgroup results with the entire U.S. population; post-stratification sample weighting based on population parameters drawn from the U.S. Census will be used to

ensure the representativeness of the sample survey when we conduct analysis intended to generalize to the entire U.S. adult population. This objective will be accomplished by utilizing our existing team of faculty experts and by hiring the University of New Hampshire Survey Center, a professional academic survey research firm that routinely conducts public health and political data collection focused on disparate populations..

**Probability sample survey.** Our probability sample survey assessing the myths, misconceptions and other attitudinal barriers towards receiving adult pneumococcal vaccination will provide a snapshot that is generalizable to all residents of the United States with a known degree of sampling error (approximately +/-3% for overall sample & +/-6% for the black and Hispanic or Latino sub-samples, with 95% confidence). Probability sample surveys give every unit of analysis, in our case residents of the United States, some known probability of being included in the sample. Members of the research team are nationally and internationally known experts in survey research methodology, survey design, analysis and survey implementation (Drs. Hutchison and Krueger). As is routinely done in public opinion research, we will contract with a professional academic survey research house that has the facilities, software, and staff to undertake the data collection (See University of New Hampshire's Survey Center letter of support and Organizational Detail section).

**Ensuring appropriate subpopulation sample sizes.** We will focus on black and Hispanic or Latino subpopulations; the 2013 U.S. Census shows that blacks and Hispanic or Latinos comprise 13.2 and 17.1 percent of the U.S. population respectively.<sup>31</sup> In a nationally representative sample survey, the typical size of the black and Hispanic or Latino subsample would be too small for many types of stand-alone subgroup analyses. Therefore, we will conduct an oversample of blacks and Hispanic or Latinos to increase the sample size of these ethnic and racial subpopulations, with Spanish speaking interviewers available for non-English speaking residents. Oversampling of subpopulations is an intensive but routine procedure that can be set in place when we contract with the survey research house. The end result will be a survey with 1000 total respondents, comprised of a nationally representative survey of 800 U.S. residents (with racial and ethnic groups proportional to their size in the U.S. population), an additional oversample of 100 blacks and an additional oversample of 100 Hispanics or Latinos. This initial survey is designed to explore, identify, and compare attitudinal barriers across ethnic and racial groups. The exploratory nature of the initial survey does not require large and expensive oversamples to identify key fault lines across disparate subpopulations. Nonetheless, oversampling racial and ethnic subpopulations distorts the composition of the overall national sample. We still seek to compare the patterns found in the black and Hispanic or Latino subpopulations to a nationally representative sample of all U.S. residents. For this we will use post-stratification sample weighting based on population parameters drawn from the U.S. Census. This post-stratification weighting procedure is widely used to correct for the racial and ethnic imbalance caused by the oversample.

**Survey questions.** We will undertake a multifaceted approach in the initial survey that seeks to identify the attitudinal barriers towards receiving adult pneumococcal vaccination. We will begin by reviewing past studies and surveys that assess barriers to health care adoption generally and vaccination specifically.<sup>30</sup> Next, through face-to-face, telephone, and electronic conversations we will get the perspective of pharmacists and trusted community leaders in



health care (Rhode Island Department of Health) whom have extensive experience in offering adult vaccinations, and working with disparate populations. Our approach will be to reach out to our College's pharmacy preceptors (over 1000 pharmacists) that serve minority populations in community pharmacies (via Dr. Orr's national connections with Walgreen's Pharmacy and URI annual preceptor meetings each March). Through this exploratory and developmental investigation, members of the team will construct the survey questions, led by team member (Dr. Krueger), who has considerable experience designing survey instruments. We will take care to include a diverse mix of easy to grasp open-ended and close-ended questions including but not limited to various aspects of trust, science, religion, views toward government, gender roles, awareness/knowledge, aging norms, views toward health care and providers, family, time and transportation constraints, community leadership, core values, civic and family duties, risk/safety/side effect perceptions, alternative medicines and diets, as well as financial and opportunity costs.

**Analysis of survey data.** Members of the survey team are known experts in survey research with a combined 21 years' worth of experience in survey methodology and questionnaire design. They also have widely published academic books and peer reviewed articles that analyze public opinion surveys, including major health surveys such as The National Survey of Family Growth (NSFG) sponsored by the U.S. Department of Health and Human Services. Brian Krueger (Co-PI), has been contracted to analyze surveys for such institutions as the National CBS News and the World Wildlife Fund.

**Statistical analysis.** Software such as STATA and SPSS will be used to recode, clean and analyze these data. We expect most of the analysis of attitudinal barriers will involve descriptive statistics and cross-tabulations, but the research team is well versed in more advanced techniques such as reliability analysis, index and scale construction, data reduction and multivariate statistics should these be useful for exploring and comparing the attitudinal barriers towards receiving Adult Pneumococcal Vaccination.

**OBJECTIVE 2: TEST PERSUASIVE COMMUNICATION.** We will develop a series of controlled experiments embedded in a second nationally representative survey to test which science-based vaccine messages most effectively overcome the various attitudinal myths and misconceptions identified in our first survey.

#### **Survey development and implementation.**

Our second probability sample survey assessing messages that can overcome attitudinal barriers towards receiving adult pneumococcal vaccination will provide information that is generalizable to all residents of the United States with a known degree of sampling error (approximately +/-2% for overall sample & +/-5% for the black and Hispanic or Latino subsamples, with 95% confidence). We will again conduct an oversample of blacks and Hispanic or Latinos to increase the sample size of these ethnic and racial subpopulations, with Spanish speaking interviewers available for non-English speaking residents. Because the second survey involves the critically important message testing stage, the black and Hispanic or Latino oversamples are much larger than the first exploratory survey. The end result will be a survey with 1600 total respondents, comprised of a nationally representative survey of 1000 U.S. residents, an oversample of 300 blacks and an oversample of 300 Hispanics or Latinos. When

developing the proposed budget for our two surveys we communicated with the Survey Center at the University of New Hampshire about the likely cost of our survey research design.

**We will craft science-based targeted messages about Adult Pneumococcal Vaccination and test their persuasive efficacy against conventional vaccine information.** We will identify the specific science-based messages that are most appropriate for ethnic and racial minority subgroups. To determine the control group messages we will use both the CDC crafted informational language as well as the PSA language used in the Principal Investigator's previous work on adult pneumococcal vaccination<sup>21</sup>. This approach pinpoints the persuasive advantage of using this project's newly identified targeted messages over current standard approaches to communicating about adult pneumococcal vaccination.

**Apply communication theory.** To determine the specific approaches to messaging intended to overcome attitudinal barriers identified in the initial exploratory survey (Objective 1), we will be informed by psychological, public opinion and communication theories. One cannot be wedded to only one theoretical paradigm; the project is problem-based (reducing disparities in adult pneumococcal vaccination) and not primarily intended to test any one theory. We have published numerous books and articles that apply a diverse range of cognitive,<sup>32</sup> emotion,<sup>33</sup> public opinion/messaging<sup>34</sup> and communication<sup>35</sup> theories; we will use this rich understanding to guide choices regarding the best way to enhance messages. Directed by the results from our first survey (Objective 1) that identifies the attitudinal barriers, we will use best practices and relevant theories to craft persuasive messages, including but not limited to frameworks focused on personalization,<sup>36</sup> control over self,<sup>37</sup> message source,<sup>38</sup> verbal acuity and literacy levels,<sup>5</sup> prospect theory's loss versus gain frames,<sup>39</sup> cognitive processing<sup>40</sup> and the ethno-cultural construction of disease.<sup>41</sup>

***The following is an example of how we might use a relevant theory when considering messages that promote adoption of Adult Pneumococcal Vaccination:*** Elaboration likelihood theory suggests that some past public health campaigns such as smoking cessation, healthy eating, and physical activity promotion require fundamental and deep changes to lifestyle, which can only be accomplished by messaging that triggers central processing.<sup>40</sup> When the central processing system is engaged, only arguments that resist deterioration and remain deeply persuasive are likely to be effective at inducing long-term behavioral changes. Education materials designed around slogans and modifications of message framing are not likely to successfully induce persistent changes to these habitual behaviors. On the other hand, messaging that activates peripheral processing could be used to encourage someone to go for one walk or try kale for the first time. For many (perhaps most) individuals, it is likely that the decision to get the adult pneumococcal vaccination would fall under the peripheral processing system, particularly if considered at the point of the provider. Peripheral processing involves lower degrees of cognitive examination and messaging cues and frames can have greater effects on short-term attitudinal changes or snap judgments.

**Embed experimental design into survey.** This second survey will contain standard close ended questions as well as questions written as randomized experimental designs, which have been shown to be effective in testing public health communications.<sup>42</sup> Because exposure to the experimental stimulus (vaccine message) is randomly assigned, the results should display a high

degree of internal validity. Embedding randomized experiments in a nationally representative survey has further advantages; because the experiments use a probability sample for the subject pool, rather than a more narrow and unrepresentative pool of subjects, the results of the analysis display a high degree of national generalizability.<sup>7,8</sup> In the initial exploratory survey that identifies the myths, misconceptions and other attitudinal barriers towards adult pneumococcal vaccination, we might find that blacks or Hispanics/Latinos disproportionately indicate that getting vaccinated is not a priority because they are too busy working to support or otherwise helping their family.<sup>43</sup> Messages focused narrowly on their own self-interest by appealing to their own health outcomes may fail because the message is not sensitive to the familial context. For this specific type of attitudinal barrier we might construct and test a message that primes respondents to consider how their receiving the adult pneumococcal vaccination could help their family, not simply themselves.<sup>44</sup> The following is an example of an embedded survey question experiment, with one third of the sample randomly assigned to receive no treatment, one third randomly assigned to receive treatment A, and one third randomly assigned to receive treatment B.

**Control:** Pneumonia causes life-threatening severe fever and weakness. If your health care provider told you that a free Adult Pneumococcal Vaccination could prevent you from getting Pneumonia, how likely would you obtain the vaccine?

**Answers:** *Very likely, likely, somewhat likely, not very likely, not at all likely.*

**Treatment A:** Pneumonia causes life threatening severe fever and weakness **that may require your family to care for you.** If your health care provider told you that a free Adult Pneumococcal Vaccination could prevent you from getting Pneumonia, how likely would you obtain the vaccine?

**Answers:** *Very likely, likely, somewhat likely, not very likely, not at all likely.*

**Treatment B:** Pneumonia causes life threatening severe fever and weakness **that may require your family to take time off to care for you.** If your health care provider told you that a free Adult Pneumococcal Vaccination could prevent you from getting Pneumonia, how likely would you obtain the vaccine?

**Answers:** *Very likely, likely, somewhat likely, not very likely, not at all likely.*

In this hypothetical example, if we found that treatment A and/or B prompts a much higher level of vaccine acceptance than the control information about personal health risks, then we would consider incorporating similar family focused language into the final messaging materials.

**OBJECTIVE 3: Create and Distribute Educational Messages. We will use our new understanding about the adult pneumococcal vaccination messages to develop and disseminate educational materials (posters, brochures and Public Service Announcements) to community pharmacies that serve minority populations.**

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We will use our new understanding about the adult pneumococcal vaccination messages to develop and disseminate educational materials (posters, brochures and Public Service

Announcements) to Community Pharmacies that serve minority populations so that this information can be utilized nationally to increase adult pneumococcal vaccination rates and decrease invasive pneumococcal disease across minority populations. We will work with Walgreens Pharmacy, a national leader and financial supporter of initiatives that serve multi-cultural populations, and eliminate barriers to care. Specifically, we will send educational materials for use in Walgreens pharmacies (at minimum) that serve minority populations in Rhode Island, Washington, DC (lowest ranking of pneumococcal vaccination nationally), Illinois (second lowest ranking), New York (fifth lowest ranking of pneumococcal vaccination nationally), and New Jersey (sixth lowest ranking) as they will directly benefit from our messages.

In Table 1 (next page), we list the Walgreen's pharmacies that we will target with our educational materials in each of the five states. Using demographic data from the 2010 U.S. Census organized by zip codes with over 1000 residents, we identify five areas with the highest concentrations of African American populations and Hispanic/Latino populations, respectively<sup>45</sup>. Using the store locator search function on the Walgreen's website <http://www.walgreens.com/storelocator/find.jsp?tab=store%20locator&requestType=locator> to find stores with the closest proximity to these areas, we identified the target stores for distribution of our educational materials. In most cases, we chose the store closest in proximity to the identified zip code but in those instances where we had already selected a store, we used the next closest store so each store will only receive one set of messaging materials. The average store proximity to the identified population areas is 0.79 miles with no store further than 3.8 miles away.

**Creation of educational materials.** We will design large color posters; brochures and post-cards that apply the evidence based strategic communication shown to best overcome the attitudinal barriers towards adult pneumococcal vaccination. As with our previous grant, we will work with the graphic designer at the University of Rhode Island to integrate these messages in a format that creates vivid and appealing materials. Readability is one of the chief barriers in health communication, with studies routinely showing that the average nutrition, disease prevention, and substance abuse educational materials require reading acuity between 10<sup>th</sup> and 12<sup>th</sup> grade levels.<sup>4</sup> Health education materials that have even an 8<sup>th</sup> grade reading level excludes one quarter of the U.S. adult population, with recent studies showing that a majority of health educational material remain above the target 6<sup>th</sup> grade level.<sup>46</sup> This issue is particularly important in our study, as we seek to identify and distribute materials to reduce disparities in underserved subpopulations. Accordingly, we will use best practices as it relates to font size and readability of our written materials by using the SMOG readability index to ensure accessibility across a wide audience. The SMOG index has been shown to be superior to other readability indices for healthcare education material.<sup>47</sup> The pamphlets and posters created will facilitate 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 subpopulations residing in regions with low rates of pneumococcal vaccination nationally.

A major focus of this grant will be targeting the underserved racially, ethnically and linguistically diverse (REL) communities with messages appropriate for these minority populations. Because this grant focuses on black and Hispanic or Latino subpopulations, the materials will be distributed in English and Spanish.

**Table 1: List of Target Walgreens Pharmacies for Distribution of Educational Materials**

|                                      | State                | ZIP Code | % African American | % Age 65 or older                     | Target Walgreens Pharmacy                         |
|--------------------------------------|----------------------|----------|--------------------|---------------------------------------|---------------------------------------------------|
| Highest African American Populations | District of Columbia | 20019    | 95.0%              | 12.2%                                 | 6498 Landover Rd, Landover, MD 20785              |
|                                      |                      | 20020    | 95.0%              | 10.5%                                 | 801 7th St NW, Washington, DC 20001               |
|                                      |                      | 20032    | 90.0%              | 8.2%                                  | 1517 Mount Vernon Ave, Alexandria, VA 22301       |
|                                      |                      | 20018    | 85.1%              | 19.0%                                 | 111 Michigan Ave NW Suite, Washington, D.C. 20010 |
|                                      |                      | 20017    | 71.4%              | 17.9%                                 | 1329 University Blvd E, Takoma Park, MD 20912     |
|                                      | Illinois             | 60620    | 97.7%              | 16.0%                                 | 1213 W. 79th St, Chicago, IL 60620                |
|                                      |                      | 62205    | 97.7%              | 15.6%                                 | 2510 State St, East St Louis, IL 62205            |
|                                      |                      | 60621    | 97.3%              | 11.6%                                 | 650 W. 63rd St, Chicago, IL 60621                 |
|                                      |                      | 60619    | 96.8%              | 16.5%                                 | 8628 S. Cottage Grove Ave, Chicago, IL 60619      |
|                                      |                      | 62207    | 96.1%              | 14.1%                                 | 1201 Camp Jackson Rd, Cahokia, IL 62206           |
|                                      | New Jersey           | 07112    | 91.1%              | 10.2%                                 | 1303 N. Broad St, Hillside, NJ 07205              |
|                                      |                      | 07018    | 87.9%              | 11.1%                                 | 508 Main St, East Orange, NJ 07018                |
|                                      |                      | 08045    | 87.7%              | 17.1%                                 | 100 White Horse Pike N, Magnolia, NJ 08049        |
|                                      |                      | 07017    | 85.7%              | 12.3%                                 | 240-250 Central Ave, Orange, NJ 07050             |
|                                      |                      | 07108    | 85.3%              | 9.0%                                  | 361 Bergen St, Newark, NJ 07103                   |
|                                      | New York             | 11411    | 90.4%              | 17.3%                                 | 11907 Springfield Blvd, Cambria Heights, NY 11411 |
|                                      |                      | 11412    | 89.6%              | 13.4%                                 | 11255 Farmers Blvd, St. Albans, NY 11412          |
|                                      |                      | 11413    | 88.9%              | 13.5%                                 | 21914 Merrick Blvd, Springfield Gardens, NY 11413 |
|                                      |                      | 11203    | 88.3%              | 14.8%                                 | 5001 Church Ave, Brooklyn, NY 11203               |
|                                      |                      | 11434    | 85.7%              | 13.1%                                 | 12704 Guy R Brewer Blvd, Jamaica, NY 11434        |
| Rhode Island                         | 02907                | 18.3%    | 6.9%               | 533 Elmwood Ave, Providence, RI 02907 |                                                   |
|                                      | 02860                | 16.3%    | 11.4%              | 100 Broad St, Pawtucket, RI 02860     |                                                   |
|                                      | 02905                | 15.0%    | 9.2%               | 1763 Broad St, Cranston, RI 02905     |                                                   |
|                                      | 02841                | 14.2%    | 0.1%               | 12 E. Main Rd, Middletown, RI 02842   |                                                   |
|                                      | 02908                | 14.1%    | 9.0%               | 295 Academy Ave, Providence, RI 02908 |                                                   |
|                                      | State                | ZIP Code | % Hispanic/Latino  | % Age 65 or older                     | Target Walgreens Pharmacy                         |
| Highest Hispanic/Latino Populations  | District of Columbia | 20010    | 30.1%              | 7.8%                                  | 4225 Connecticut Ave NW, Washington, DC 20008     |
|                                      |                      | 20011    | 21.2%              | 14.3%                                 | 2041 Georgia Ave NW, Washington, DC 20060         |
|                                      |                      | 20005    | 16.8%              | 7.1%                                  | 1325 14th St NW, Washington, DC 20005             |
|                                      |                      | 20009    | 15.1%              | 6.8%                                  | 1217 22nd St NW, Washington, DC 20037             |
|                                      |                      | 20012    | 11.2%              | 18.2%                                 | 3524 Connecticut Ave NW, Washington, DC 20008     |
|                                      | Illinois             | 60165    | 88.1%              | 5.9%                                  | 6 E. North Ave, Northlake, IL 60164               |
|                                      |                      | 60804    | 86.6%              | 5.9%                                  | 5932 W. Cermak Rd, Cicero, IL 60804               |
|                                      |                      | 60632    | 84.2%              | 6.6%                                  | 4385 S. Archer Ave, Chicago, IL 60632             |
|                                      |                      | 60639    | 75.9%              | 6.7%                                  | 4817 W. Fullerton Ave, Chicago, IL 60639          |
|                                      |                      | 60505    | 73.6%              | 6.7%                                  | 9 N. Union St, Aurora, IL 60505                   |
|                                      | New Jersey           | 07087    | 84.6%              | 10.5%                                 | 3508 John F Kennedy Blvd, Union City, NJ 07087    |
|                                      |                      | 07513    | 79.0%              | 7.8%                                  | 639 E. 18th St, Paterson, NJ 07501                |
|                                      |                      | 08861    | 76.4%              | 9.4%                                  | 520 Convery Blvd, Perth Amboy, NJ 08861           |
|                                      |                      | 07093    | 75.6%              | 11.8%                                 | 6012 Kennedy Blvd W, West New York, NJ 07093      |
|                                      |                      | 07055    | 71.0%              | 7.8%                                  | 101 President St, Passaic, NJ 07055               |
|                                      | New York             | 10455    | 74.8%              | 8.8%                                  | 2817 3rd Ave, Bronx, NY 10455                     |
|                                      |                      | 11368    | 73.8%              | 7.3%                                  | 10314 Roosevelt Ave, Corona, NY 11368             |
|                                      |                      | 10454    | 73.5%              | 9.0%                                  | 135 E. 125th St, New York, NY 10035               |
|                                      |                      | 11237    | 72.7%              | 6.1%                                  | 5411 Myrtle Ave, Ridgewood, NY 11385              |
|                                      |                      | 10034    | 72.2%              | 10.6%                                 | 133-141 Dyckman St, New York, NY 10040            |
| Rhode Island                         | 02863                | 60.3%    | 8.7%               | 385 Cottage St, Pawtucket, RI 02861   |                                                   |
|                                      | 02907                | 58.5%    | 6.9%               | 335 Prairie Ave, Providence, RI 02905 |                                                   |
|                                      | 02909                | 55.8%    | 6.4%               | 1 Pocasset Ave, Providence, RI 02909  |                                                   |
|                                      | 02905                | 36.2%    | 9.2%               | 1763 Broad St, Cranston, RI 02905     |                                                   |
|                                      | 02908                | 33.5%    | 9.0%               | 354 Admiral St, Providence, RI 02908  |                                                   |

**Note:** Demographic data are based on the "Profile of General Population and Housing Characteristics, 2010" dataset collected by the United States Census. The data is available at: <<http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml>>. The Walgreens store locations are based on proximity to the ZIP codes.

**Public Service Announcement (PSA).** Using our new understanding about the science-based **Adult Pneumococcal Vaccination** messages, we will develop two different 30 second radio public service announcement (one for black and one for Hispanic/Latinos). This announcement will empower patients to inquire about pneumococcal vaccination in their encounters with Health Care Professionals, including community pharmacists. The ads will be available for download via MP3 formatting on our colleges [Drug Information Website](#) (location of exciting vaccine educational materials) and distributed via web link to all interested community pharmacies for use inside the pharmacy.

**Objective 4: Measure Impact of Messaging & Pilot Field Experiment.**

The effectiveness of the messaging dissemination will be assessed from (1) vaccination status, (2) invasive pneumococcal disease rates, and (3) motivation to vaccinate. Our primary outcome will be change in adult pneumococcal vaccination. Using a quasi-experimental design (interrupted time series), we will ascertain within state differences in vaccination status among the subpopulations of interest from the Behavioral Risk Factor Surveillance System (BRFSS) between the pre-intervention and post-intervention periods. We will also assess changes in burden of non-vaccination by tracking invasive pneumococcal disease as a secondary outcome. Lastly, we will conduct a pilot field test of our message in a real-world clinical setting as compared to the standard message and evaluate motivation to vaccinate. This will provide us with hands on experience in the community pharmacy setting that we can share when developing a Best Practices manuscript.

**Changes in vaccination and pneumococcal disease rates.** To measure message dissemination outcomes, we will request data from the BRFSS, notifiable disease reports, and hospital discharge data, where available, for each of the five states (files will contain zip code information). Vaccination status will be ascertained by race and ethnicity for each interview month and year. Invasive pneumococcal disease is a reportable disease nationally. Invasive disease is confirmed by isolation from blood, cerebrospinal fluid, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, or another normally sterile site. To calculate monthly incidence, we will use census data for our denominator. We will also assess pneumococcal disease from hospital discharge data collected by each state. Pneumococcal disease will be identified from the following diagnosis codes: 481 (pneumococcal pneumonia), 038.2 (pneumococcal septicemia), and 320.1 (pneumococcal meningitis). Using invasive pneumococcal disease data from both reportable disease forms (laboratory confirmed) and hospital discharges should provide a clear picture of disease trends during the pre-intervention and post-intervention periods. We will map vaccination and invasive pneumococcal disease rates by race and ethnicity. We will also map our dissemination efforts (Objective 3) and overlay these with changes in vaccination and pneumococcal disease. Mapping will be done at the county and zip code level (where available).

**Statistical analysis.** We will use interrupted time series methods to assess within state changes in vaccination status and disease rate over time. There will be at least 24 time points for the pre-intervention period (monthly rates for 2 years) and 12 time points for the post-intervention period. In order to identify an appropriate interrupted time series model, we will first plot the data. We will assess the presence of autocorrelation with a visual inspection of the plotted data and residuals, a review of the autocorrelation check for white noise, and the Durbin

Watson statistic. Stationarity will be assessed with the Dickey-Fuller unit root test for each outcome, and if stationarity is present, we will transform the data by differencing from the previous month. These steps will allow us to determine whether an autoregressive integrated moving average (ARIMA) model is needed or whether segmented regression is sufficient. If an ARIMA model is indicated, we will evaluate autoregressive first order and mixed autoregressive moving average candidate models. Once an appropriate model is identified, manual backward elimination (threshold for retention,  $p < 0.05$ ) will be used to identify the best parsimonious model. We will repeat these analyses for each state. We will compare motivation to vaccinate between the standard and newly developed message groups with chi-square or Fisher's exact tests as appropriate. Results will be presented overall and by race and ethnicity. Analyses will be performed using SAS (SAS Institute Inc., Cary, NC, Version 9.3).

**Pilot Field Study.** We will partner with vaccine providers at two different Walgreen's community pharmacies in Providence, Rhode Island. We selected two different pharmacies in Providence, Rhode Island that specifically serves a large African American population (533 Elmwood Ave, Providence, RI - 18.3% African American) and a large Hispanic / Latino population (385 Cottage St, Pawtucket, RI - 60.3% Hispanic/Latino). We (Dr. Orr and Advanced Pharmacy Practice Students on rotation) will conduct a field experiment using hand held tablets (ipads) that will randomly offer patients either the standard message about Adult Pneumococcal Vaccination or our newly developed message. Patients will receive the developed message (Objectives 2) and then be asked whether they would want to ask their vaccine provider/pharmacist for more information about receiving the vaccine today. This research design identifies the advantage or disadvantage of using our messages relative to current standard approaches to communicating about vaccines. If successful, this evidence would be made widely available nationally to inform best practices about communicating about Adult Pneumococcal Vaccination.

## **2c. EVALUATION DESIGN**

The goal of this project is to develop and disseminate sustainable, science-based communications targeting minority populations. Our evaluation design captures the impact of this messaging. In terms of changes in vaccination status and invasive pneumococcal disease rates, there will be 36 time points for analysis, with at least 24 baseline observations. Assuming a lag-one autocorrelation in the pre-intervention series of 0.15, we will have 87% power to detect a 1.25 standard deviation change between the pre-intervention and post-intervention periods. For the field experiment, we will have 88% power to detect a 15% increase in motivation to vaccinate with a sample size of 250 participants ( $n=125$  new message,  $n=125$  standard message). This calculation assumed 10% of the standard message group would express a desire to learn more about pneumococcal vaccination at that time. Additionally, we assumed 80% of participants would represent one of the minority populations of interest, which would result in 80% power to detect a 15% increase in motivation to vaccinate. The power calculations were completed using the McLeod-Hipel Times Series Package and Open Epi.

Our findings would be made widely available nationally, to inform best practices for adult pneumococcal vaccination messaging. The project outcomes will be broadly disseminated through conference presentations and journal publications. 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.

### **3. DETAILED WORKPLAN AND DELIVERABLES SCHEDULE**

#### **PROJECT TIMELINE.**

The coordination and implementation of this grant will be through the University of Rhode Island's College of Pharmacy, with monthly live meetings with the collaborators. This will be a 29-month study. The first 4 months will focus on designing the survey instrument while working with the University of New Hampshire Survey Center. After the 6th month (January 2016), the first survey will be conducted, followed by analysis and messaging designs for the second survey to be conducted in summer of 2016. Following the second survey analysis, the collaborators will design the education materials to be distributed in December of 2016. After which time we will conduct our outcomes assessment.

#### **REQUESTED BUDGET.**

Total budget amount: \$706,173 in total costs (direct and indirect); \$154,475 in indirect (28%), \$290,729 in personnel (faculty/coordinator salary), \$116,769 in fringe, \$120,000 to conduct two distinct and robust surveys (plus indirects) and \$24,200 in supplies and travel.



**TIMELINE.**

This 29 month project will start August 1, 2015 and be completed December 31, 2017. The timeline is detailed in table 1 below.

**Table 1: Project Timeline**

| <u>Activity</u>                                                                                                                                                           | <u>Month 0-6</u> | <u>Month 6-12</u> | <u>Month 12-24</u> | <u>Month 24-29</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|-------------------|--------------------|--------------------|
| <b>Obj. 1:</b> Survey Development: identifying the specific attitudinal barriers towards receiving adult pneumococcal vaccination within ethnic and racial subpopulations | ←→               |                   |                    |                    |
| <b>Obj. 2:</b> Test messaging                                                                                                                                             | ←→               |                   |                    |                    |
| <b>Obj. 3:</b> Create and Distribute Educational Messages.                                                                                                                |                  |                   | ←→                 |                    |
| <b>Obj. 4:</b> Measure impact of messaging and pilot field study to develop best practices.                                                                               |                  |                   | ←→                 |                    |
| <b>Dissemination of Results:</b> (1) presentations at national meetings, (2) publication submission to a high impact journal                                              |                  |                   |                    | ←→                 |

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## APPENDIX C:

# Supplemental Materials



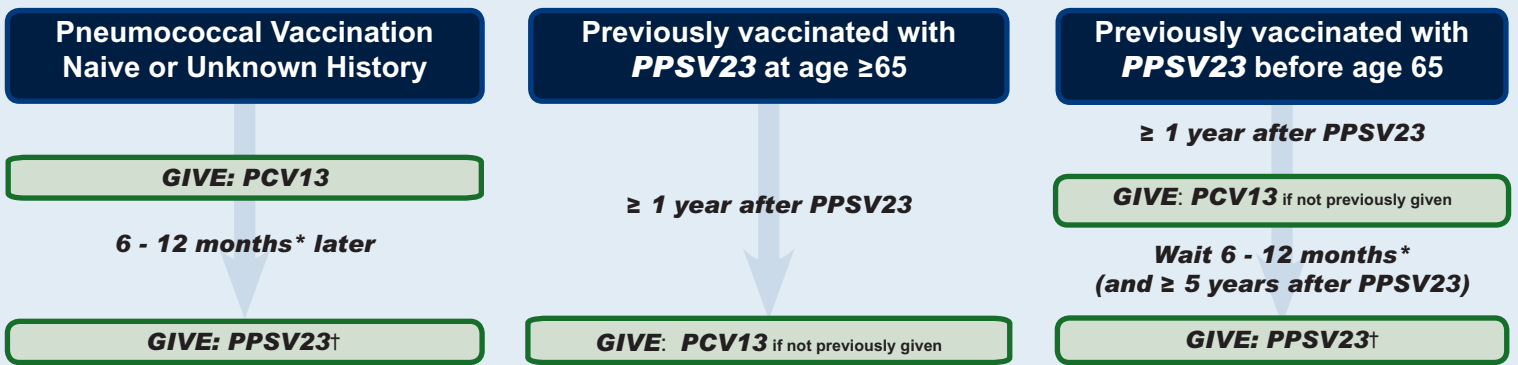
# Pneumococcal Vaccination Recommendations

## Adults ≥ 19 Years<sup>1-3</sup>

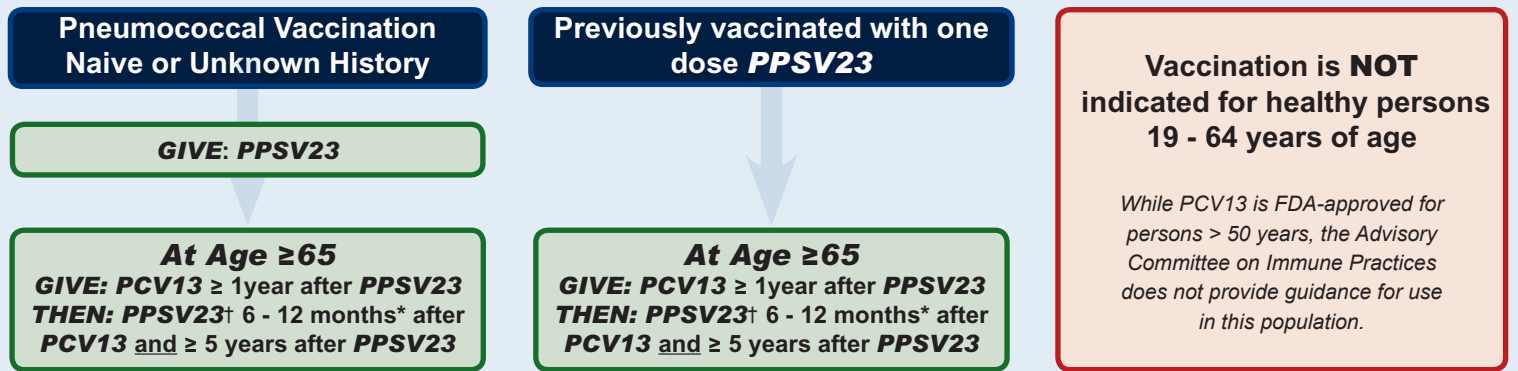
(Including updated recommendations for the use of PCV13 in Adults)

THE UNIVERSITY OF RHODE ISLAND COLLEGE OF PHARMACY  
DRUG INFORMATION SERVICES  
401-874-9188

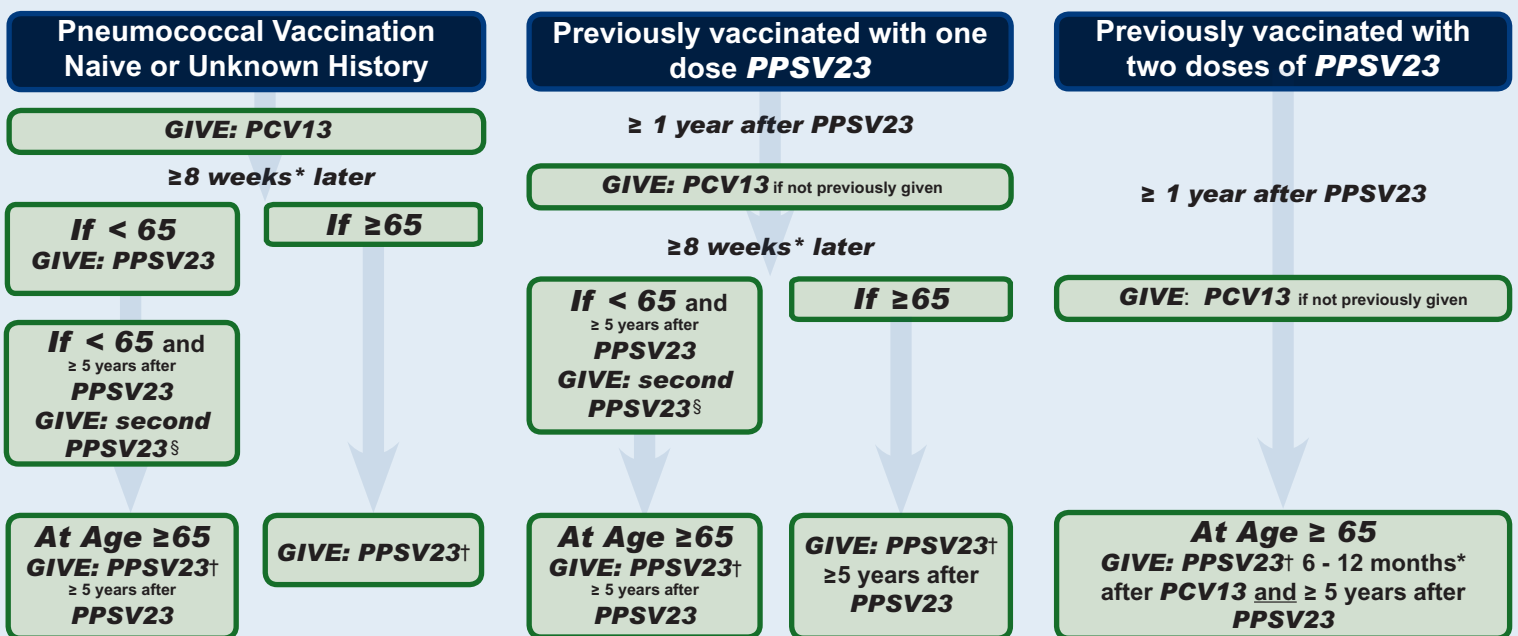
### Healthy Adults ≥ 65



### ADULTS ≥ 19 with UNDERLYING MEDICAL CONDITIONS (see chart on back) OR who SMOKE or live in a NURSING HOME



### ADULTS ≥ 19 with IMMUNE COMPROMISING CONDITIONS (see chart on back), OR ASPLENIA (including sickle cell anemia), CEREBROSPINAL FLUID LEAK, or COCHLEAR IMPLANT



\* Minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks. For Medicare reimbursement interval must be 11 months. Please refer to page 4.

† The ACIP (Advisory Committee on Immunization Practices) recommends only 1 dose of PPSV23 at age ≥65. Revaccination is not necessary.

§ A second PPSV23 for patients with cerebrospinal fluid leak, or cochlear implant is not required.

PPSV23=23-Valent Pneumococcal Polysaccharide Vaccine (Pneumovax®23)

PCV13=13-Valent Pneumococcal Conjugate Vaccine (Prevnar 13®)



# Pneumococcal Vaccination Recommendations

## Adults ≥ 19 Years<sup>1-4</sup>

THE UNIVERSITY OF RHODE ISLAND COLLEGE OF PHARMACY

DRUG INFORMATION SERVICES  
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(Including updated recommendations for the use of PCV13 in Adults)

### PCV13 and PPSV23 Indications for Adults ≥ 19 Years\* by Risk Group<sup>2,3</sup>

| Risk Group                                                                                             | Underlying Medical Condition                                                  | PCV13 (Pneumovax®13) | PPSV23 (Pneumovax®23) |                                      |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------|-----------------------|--------------------------------------|
|                                                                                                        |                                                                               | Recommended          | Recommended           | Revaccinate 5 years after first dose |
| Persons with normal immune function                                                                    | Cigarette smoker                                                              |                      | ✓                     |                                      |
|                                                                                                        | Chronic heart disease†                                                        |                      | ✓                     |                                      |
|                                                                                                        | Chronic lung disease§                                                         |                      | ✓                     |                                      |
|                                                                                                        | Diabetes mellitus                                                             |                      | ✓                     |                                      |
|                                                                                                        | Cerebrospinal fluid leak                                                      | ✓                    | ✓                     |                                      |
|                                                                                                        | Cochlear implant£                                                             | ✓                    | ✓                     |                                      |
|                                                                                                        | Alcoholism                                                                    |                      | ✓                     |                                      |
|                                                                                                        | Chronic liver disease, cirrhosis                                              |                      | ✓                     |                                      |
| Persons with functional or anatomical asplenia<br>(Please refer to reference 3 for specific guidance.) | Sickle cell disease or other hemoglobinopathy∞                                | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Congenital or acquired asplenia∞                                              | ✓                    | ✓                     | ✓                                    |
| Immunocompromised persons<br>(Please refer to reference 3 for specific guidance.)                      | Congenital or acquired immunodeficiency¶                                      | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | HIV infection                                                                 | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Chronic renal failure                                                         | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Nephrotic syndrome                                                            | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Leukemia                                                                      | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Lymphoma                                                                      | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Hodgkin disease                                                               | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Generalized malignancy                                                        | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Iatrogenic immunosuppression**<br>(Both high and low level immunosuppression) | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Solid organ transplant                                                        | ✓                    | ✓                     | ✓                                    |
|                                                                                                        | Multiple myeloma                                                              | ✓                    | ✓                     | ✓                                    |
| Hematopoietic stem cell transplant                                                                     | Please refer to reference 2 for specific guidance                             |                      |                       |                                      |

† Including congestive heart failure and cardiomyopathies, excluding hypertension.

£ If feasible, administer PCV13 and PPSV23 ≥ 2 weeks before *planned* cochlear implant surgery at appropriate intervals as described in the algorithm on the front page.

∞ For PPSV23 naive patients *planning* splenectomy: Give PCV13; wait at least 8 weeks then give PPSV23. Do not give PPSV23 within 2 weeks of *planned* splenectomy.

§ Including chronic obstructive pulmonary disease, emphysema, and asthma.

¶ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

\*\* Those requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation.

**Drug Information Services 401-874-9188 Monday - Friday 8:30 am - 4:00 pm EST**

**REFERENCES:**

1. Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC. Advisory Committee on Immunization Practices (ACIP) Recommended Immunization Schedules for Persons Aged 0 Through 18 years and Adults Aged 19 Years and Older - United States, 2013. MMWR Surveill Summ. 2013;62 Suppl 1:9-19.
2. CDC. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep. 2012;61(40):816-819.
3. CDC. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥ 19 years: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep. 2014;63(37):822-825.
4. Rubin LG, Levin MJ, Davies EG, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis. 2014;58:e44-e100. doi: 10.1093/cid/cit684.

### **Facts About Pneumococcal Disease:**

- *Streptococcus pneumoniae* bacteria (i.e., pneumococci) are usually found in the upper respiratory tract of most people.
- Pneumococcal disease most commonly presents as a serious infection in the lungs (pneumonia), blood (bacteremia), or brain (meningitis). The annual U.S. case estimate for invasive pneumococcal disease (bacteremia and/or meningitis) is 40,000 and 4,250 deaths.
- Pneumococcal disease most often occurs in older people as well as in people with a predisposing condition (e.g., immunosuppression, pulmonary disease, heart disease, diabetes). The disease rates for adults in these groups can be more than 20 times those for adults without high-risk medical conditions.
- PPSV23 is 60–70% effective in preventing serious pneumococcal disease; it does not provide substantial protection against all types of pneumonia (viral and bacterial). It is not a “pneumonia” vaccine.

### **Frequently Asked Questions:**

#### **Question: Can I get the influenza and pneumococcal vaccines at the same time?**

Yes. These vaccines can be given at the same time. If giving two IM vaccinations, separate by one inch in the body muscle to reduce likelihood of local reactions overlapping.

#### **Question: If patients who are in a recommended risk group for PPSV23 or PCV13 aren't sure if they have previously received these vaccines, should healthcare providers vaccinate them?**

Yes. If patients do not have a documented vaccination history for these two vaccines and their records are not readily obtainable, you should administer the recommended doses. Extra doses will not cause harm to the patient.

#### **Question: Is an egg allergy a contraindication for PCV13 or PPSV23?**

No. Both vaccinations are safe for persons with egg allergies.

#### **Question: If my state has a registry, do I still need to give patients vaccine record cards?**

Yes. Patient-held cards are an extremely important part of a person's medical history. The person may move to an area without a registry, and a personal record may be the only vaccination record available. In addition, even within a state, all healthcare providers may not participate in the registry, and the personal record card would be needed.

#### **Question: My patient has had laboratory-confirmed pneumococcal pneumonia. Does he/she still need to be vaccinated with PPSV23?**

Yes. There are more than 90 known serotypes of pneumococcus (23 serotypes are in the current vaccine). Infection with one serotype does not necessarily produce immunity to other serotypes. As a result, if the person is a candidate for vaccination, he/she should receive it even after one or more episodes of invasive pneumococcal disease.

#### **Question: Why is pneumococcal vaccination recommended for smokers and asthmatics?**

In 2008, the Advisory Committee on Immunization Practices (ACIP) reviewed new information that suggests that asthma is an independent risk factor for pneumococcal disease among adults. ACIP also reviewed new information that demonstrates an increased risk of pneumococcal disease among smokers. Consequently, ACIP recommends to include both asthma and cigarette smoking as risk factors for pneumococcal disease among adults age 19 through 64 years and as indications for PPSV23.



# Pneumococcal Vaccination Information Sheet

PCV13 (Pneumovax® 23) and PPSV23 (Pneumovax® 23)

## PPSV23 (Pneumovax®23)

### Manufacturer:

Merck  
[www.merckvaccines.com/Products/Pneumovax/Pages/home](http://www.merckvaccines.com/Products/Pneumovax/Pages/home)

### How Supplied:

0.5mL Single Dose Vial  
Multi-Dose (5 dose Vial)

### Storage and Handling:

Refrigerate on Arrival  
Store at 2°C to 8°C  
DO NOT FREEZE  
Discard after the expiration date

### Special instructions:

None

### Route of Administration:

0.5mL IM or SQ

## PCV13 (Pneumovax®13)

### Manufacturer:

Pfizer  
<http://www.pfizerpro.com/hcp/prevnar13>

### How Supplied:

Prefilled Syringe  
(10 per Package)

### Storage and Handling:

Refrigerate on Arrival  
Store at 2°C to 8°C  
DO NOT FREEZE  
Discard after the expiration date

### Special instructions:

Shake well to obtain a homogeneous white suspension

### Route of Administration:

0.5mL IM ONLY

## Insurance Carrier Information:

Medicare [www.medicarenhic.com](http://www.medicarenhic.com) 1-866-801-5304\*

BCBS of RI [www.bcbsri.com/providers](http://www.bcbsri.com/providers) 401-274-4848 1-800-230-9050

UnitedHealthCare [www.unitedhealthcareonline.com](http://www.unitedhealthcareonline.com) 1-877-842-3210

RI Department of Health State Supplied Vaccination Program [www.health.ri.gov/resources/immunization/](http://www.health.ri.gov/resources/immunization/)

## Contraindications and Precautions:

- Do not give PPSV23 or PCV13 to patients who have a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PCV13, PPSV23, or one of their components.
- Do not give PPSV23 and PCV13 simultaneously. For vaccine naive patients, give PCV13 first, followed by a dose of PPSV23 at least 8 weeks later† (current recommendations are 6-12 months later, see page 1). For patients who have already received PPSV23, give PCV13 12 months after the most recent dose of PPSV23.
- Vaccine Co-administration: (1) all vaccines used for routine vaccination in the United States can be given on the same day; (2) an inactivated vaccine can be administered either on the same day as or at any time before or after another inactivated or a live vaccine; and (3) any 2 LIVE vaccines that are not given on the same day must be spaced at least 4 weeks apart. Zoster vaccine is a live, attenuated vaccine; injectable influenza vaccine and pneumococcal polysaccharide vaccine are inactivated vaccines. So these 3 vaccines can be given on the same day or at any time before or after each other. They should be given as separate injections, not combined in the same syringe.

## Side Effects:

- Most common side effects from either PPSV23 or PCV13 are soreness and redness at the injection site, lasting 1-2 days.

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\* An initial pneumococcal vaccine may be administered to all Medicare beneficiaries who have never received a pneumococcal vaccine under Medicare Part B. A different, second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered). Please note that the "interval" between the two different pneumococcal vaccines must be 11 or more months (per Medicare reimbursement), not 8 weeks or 6 months as in the ACIP recommendations.

Acquired from [www.immunize.org](http://www.immunize.org) on September 4, 2013. We thank the Immunization Action Coalition.

† CDC. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥ 19 years: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep. 2014;63(37):822-825.