

<b>TITLE:</b>	Randomized Trial of Peer-to-Peer Versus Pharmacist Education to Improve Older Adults' Vaccination Knowledge Through the Senior Center Model of Care
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# Merck Investigator Studies Program (MISP) Protocol Template

## Requirements for Submitting a Full Proposal

### Section #1 - MISP Protocol Identification

<b>Study Title:</b>	<b>Randomized Trial of Peer-to-Peer Versus Pharmacist Education to Improve Older Adults' Vaccination Knowledge through the Senior Center Model of Care</b>
<b>Request Date:</b>	May 2, 2016
<b>Institution Name</b>	Rutgers University
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## Section #2 - Core Protocol

### 2.1 Objectives & Hypotheses

The main goal of this project is to conduct a randomized trial to compare the efficacy and costs of two interventions to improve knowledge and beliefs regarding vaccine-preventable diseases. The interventions tested will be delivered to older adults in the Delaware Valley region using a senior center model of care and will compare a pharmacist-led didactic teaching (PHARM) to peer-to-peer teaching (PEER). The project will be conducted by Rutgers University in partnership with Thomas Jefferson University (TJU) and Center in the Park (CIP). CIP is a nationally-accredited senior center which has been recognized by the National Institute of Senior Centers (NISC) for its commitment to wellness and evidence-based health promotion. PHARM and PEER will be targeted towards African American (AA) communities and will address major vaccine-preventable diseases. Intervention content will be focused on zoster and pneumococcal infections but will compare and contrast influenza to these diseases to further participants' understanding of the differences between these diseases and vaccination recommendations.

#### 2.1 Objectives

- 1) Compare the efficacy of PHARM vs. PEER at improving participant's knowledge regarding vaccine-preventable diseases
- 2) Compare the efficacy of PHARM vs. PEER at improving participants' beliefs about vaccination
- 3) Measure the costs of PHARM and PEER from the senior center perspective
- 4) Compare the percent of participants taking activation step(s) to get vaccinated following receipt of PHARM vs. PEER
- 5) Determine the extent to which participants are satisfied with and trust the PHARM vs. PEER interventions

#### 2.1.1 Hypotheses

- 1) PHARM and PEER will **achieve similar improvements in older adults' knowledge** of vaccine preventable diseases (primary hypothesis)
- 2) PHARM and PEER will **improved beliefs about vaccine-preventable disease**
- 3) **PEER will be a lower cost approach** to educating participants in the senior center compared to PHARM
- 4) PHARM and PEER will result in similar rates of **participants taking one or more activation step(s)** to obtain vaccination
- 5) Participants will be highly **satisfied with the PHARM and PEER interventions**

## 2.2.1 Background and Rationale

Vaccination is the single best way to prevent common infectious diseases in older adults, including those caused by pneumococcus, zoster, and influenza. Though influenza vaccination programs are widespread, programs targeting pneumococcal and zoster infections are fewer. According to the Centers of Disease Control and Prevention (CDC), many adults remain unvaccinated for these diseases, including those at the highest risk of infection. For example, in 2013 the CDC estimated that only 59.7% of adults 65 years and older had ever received a pneumococcal vaccination.<sup>1</sup> In Pennsylvania the estimates are considerably lower. According to a 2004 Southeastern Pennsylvania Household Health Survey, only 51.9% of adults over 60 had ever received a pneumococcal vaccination. Furthermore, only 43.6% of the poor have ever had a pneumococcal vaccination and **only 41.6% of African Americans (AA) have ever received a pneumococcal vaccination** compared to 53.6% of Caucasians.<sup>2</sup> These values indicate concerning disparities in pneumococcal vaccination between AAs and whites.<sup>3</sup> These disparities could be exacerbated by **increased complexity of pneumococcal disease vaccination guidelines**; the Advisory Committee on Immunization Practices (ACIP) now recommends that older adults receive two different pneumococcal vaccinations (pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine).<sup>4</sup>

**There are similar population health concerns pertaining to zoster.** Nearly one-third of people will experience a zoster infection, i.e., shingles, in their lifetime.<sup>5</sup> Many will also experience ongoing sequelae of zoster such as post-herpetic neuralgia or ocular damage, both of which may interfere with activities of daily living.<sup>6,7</sup> Despite demonstrated efficacy, Food and Drug Administration Approval and ACIP recommendations, **many patients eligible for the zoster vaccine have not received it.** According to the CDC, in 2013, 24.2% of adults aged ≥60 years old reported receiving zoster vaccination to prevent shingles, an increase from the 20.1% in 2012.<sup>8</sup> While improved, the proportion of eligible adults receiving the herpes zoster vaccine remains below the Healthy People 2020 target of 30%.<sup>9</sup> Further, while whites aged ≥60 years had higher rates of zoster vaccination (27.4%) **African Americans (10.7%) and Hispanics (9.5%) had considerably lower rates.** To further understand zoster educational needs, we conducted a survey of Philadelphia senior center members in 2015. Findings confirm an unmet educational need for zoster education at the local level (see Appendix). These zoster data, considered together with similarly concerning pneumococcal vaccination data, reflect a **critical need to educate older adults to improve vaccination rates and reduce health disparities** among minority populations.

## 2.2.2 Significance of Selected Topic

Because vaccination rates among older adults are suboptimal, new models of care are needed. The senior center model of care uses a community-based senior center as the focal point of **access to an older population** and provides preventative health services through a facility the population **already attends.** Through our prior work, Jefferson and Center in the Park



have demonstrated that **senior centers can be an effective, engaging, and accessible hub for health promotion**. These efforts have included a depression support program, glaucoma detection program, diabetes adherence intervention, and pneumonia education and vaccination (described below under Preliminary Data).<sup>10-17</sup>

The proposed topic is significant because it will **further our prior work to yield effective, sustainable and scalable interventions to educate older adults about vaccination**. Though a prior intervention we tested (pharmacist-delivered pneumonia intervention) significantly improved vaccination knowledge, beliefs, and activation, the economic analysis of that program revealed that **it is resource intensive and costly** (\$119/participant). In fact, our implementation experience suggests that the intervention was cumbersome (required 3 components: pharmacist-delivered presentation, live actors skit, and pharmacist-led breakout sessions) and too time consuming for participants (approximately 3 hours of time required to attend the session). Older adults who participated in the study were cooperative, but the amount of time required made it **challenging to coordinate** with senior group calendars. Further, there were **space limitations** at some sites which were exacerbated by the intervention's **significant staffing requirements** (mean staff requirements per session were 3.6 pharmacists, 8.0 actors, 5.5 student assistants, and 2.0 community health workers).

This points to the **need for simpler, shorter, and cheaper vaccine education programs to be delivered using senior center models**. In the proposed study, we will **compare the efficacy of the main components** of the prior pneumonia intervention: pharmacist-led education compared to peer-to-peer education (e.g., role play exercises which are an adaptation of the live skit). We hypothesize that **both interventions will improve vaccination knowledge, beliefs, and activation, but that the peer to peer intervention will be less costly than the pharmacist-led education**. Given the tendency to consult with and trust peers regarding healthcare concerns, peer-to-peer education has long been recognized as a potential source of health promotion within communities. This has been particularly true among those that have inconsistent engagement with the healthcare system. Perhaps the most widely documented health promotion interventions have occurred within the African American population at venues that serve as cultural and/or religious centers of the community.<sup>18</sup> For example, African American owned barbershops represent cultural institutions that serve a loyal group of male patrons and that provides a forum for peers to openly discuss contemporary and relevant topics. Regarding health, these community venues have served as locations for successful peer to peer health promotion programs on hypertension, diabetes, depression, HIV/AIDS, sexually transmitted diseases and cancer among others.<sup>19</sup>

### **2.2.3 Preliminary Data**

The proposed study **builds upon the successful Jefferson/CIP research collaboration and the work completed through a prior Merck MISP-funded project**. That project was a single group observational cohort study

testing the effect of the Pharmacists' Pneumonia Prevention Program (PPPP) on participant's vaccination knowledge, beliefs, and activation. In addition, as described above, an economic analysis was conducted to measure PPPP's intervention costs and to identify opportunities for increasing its efficiency.

PPPP was delivered to **203 older adults at predominantly African American senior centers and other community based venues** in Philadelphia eight times in 2014, and consisted of: 1) a pharmacist-delivered 30 minute formal presentation, 2) a 10 minute culturally-sensitive live skit performed by senior center actors, 3) small group action planning facilitated by pharmacists, and 4) optional pneumococcal vaccination. Participants' pneumonia and vaccination knowledge, beliefs, and activation were measured at baseline, post-test, and 3 months.

Findings indicated that **PPPP significantly improved knowledge** of pneumococcal disease and immunization in an older, minority population using a novel senior center model of care. Specifically, there was a 54% increase in the total mean knowledge score among participants from baseline to 3 months. These findings are important because understanding pneumococcal disease and vaccination importance have consistently been linked to receipt of the vaccine<sup>20-26</sup>

In addition, an **increase in activation was observed among PPPP participants**. More than one-third of participants who had not received the vaccination or had an unknown vaccination status at the start of the program stated that they **received the vaccination as a result of PPPP participation**. Participants **also reported taking other activation steps** including speaking with physicians and pharmacists about pneumococcal disease and vaccination as well as engaging in conversations with family members and friends about the topic.

In addition to knowledge, beliefs about immunizations can influence a person's decision to receive a vaccine.<sup>27</sup> **At baseline in the PPPP study, 21% believed that the pneumococcal vaccine would prevent pneumonia. This proportion more than doubled following the program**, PPPP participants' trust in pharmacists also significantly improved; the proportion of participants who trusted pharmacists as immunizers was only 16% at baseline but increased to nearly 50% immediately after the program. However, participants' trust in pharmacists was consistently lower than of physicians at the measurement time points. This indicates that sustained trust in pharmacists as immunization providers is not something that can be attained through a single brief program. Trust takes time to build. **The proposed study will help to further this trust** through additional outreach and education.

**The economic analysis conducted as a part of the prior study revealed PPPP's costs to be \$119/per participant**. Resources were driven by costs of planning time (36.2%), program delivery (26.3%), and vaccine related expenses (23.8%). Vaccine costs were large despite only 18 attendees who received the vaccine (\$7,861 total, including acquisition costs and storage). These costs were high due to the acquisition prices of the product itself as well

	<p>as supply management by the institution's Investigational Drug Service. Findings point to the need for cheaper interventions that are at least equally effective. <b>The proposed study will compare the efficacy of two components of the PPPP: pharmacist education versus peer-to-peer education.</b> Each of these components is likely to be <b>less costly than PPPP, and easier to deliver.</b></p>
2.3 Study Design	<p>Randomized trial comparing outcomes in two intervention arms: Pharmacist-led (PHARM) vs peer-led (PEER) education</p> <p>Randomization to PHARM or PEER will occur by program date since we anticipate that randomizing at the participant level could lead to information sharing between participants, thereby compromising scientific integrity. In addition, randomizing at the participant level could lead to inefficiency since the staffing and space needs for the two interventions are different.</p> <p>The total number of participants will be 316.</p>
2.4 Study Flowchart	<p><b>Figure 1. Study Flowchart</b></p> <pre> graph TD     A[CIP recruits study candidates onsite and via telephone] --&gt; B[Assignment to study arm by program date]     B --&gt; C[Pharmacist-led didactic lecture ("PHARM")]     B --&gt; D[Peer-led small groups ("PEER")]          C --&gt; E["• Participants are consented using an IRB-approved consent form • Baseline assessments are administered • Pharmacist delivers a didactic lecture about vaccine-preventable diseases and vaccination"]     E --&gt; F[Post-program assessments are administered]     F --&gt; G[RU/TJU/CIP team administers 1 month follow-up assessments via telephone]          D --&gt; H["• Participants are consented using an IRB approved consent form • Baseline assessments are administered • Peer educators deliver an interactive educational program about vaccine-preventable diseases and vaccination"]     H --&gt; I[Post-program assessments are administered]     I --&gt; J[RU/TJU/CIP team administers 1 month follow-up assessments via telephone]          K[BASILINE] --&gt; L[POST-PROGRAM]     L --&gt; M[1 MONTH]   </pre> <p>The flowchart illustrates the study design. It begins with recruitment by CIP, followed by assignment to either the Pharmacist-led (PHARM) or Peer-led (PEER) arm. Both arms proceed through baseline assessments and interventions. The PHARM arm involves a didactic lecture, while the PEER arm involves an interactive program. Both arms then undergo post-program assessments and a 1-month follow-up assessment administered by the RU/TJU/CIP team via telephone.</p>



## 2.5 Study Procedures

### 2.5.1 Overview

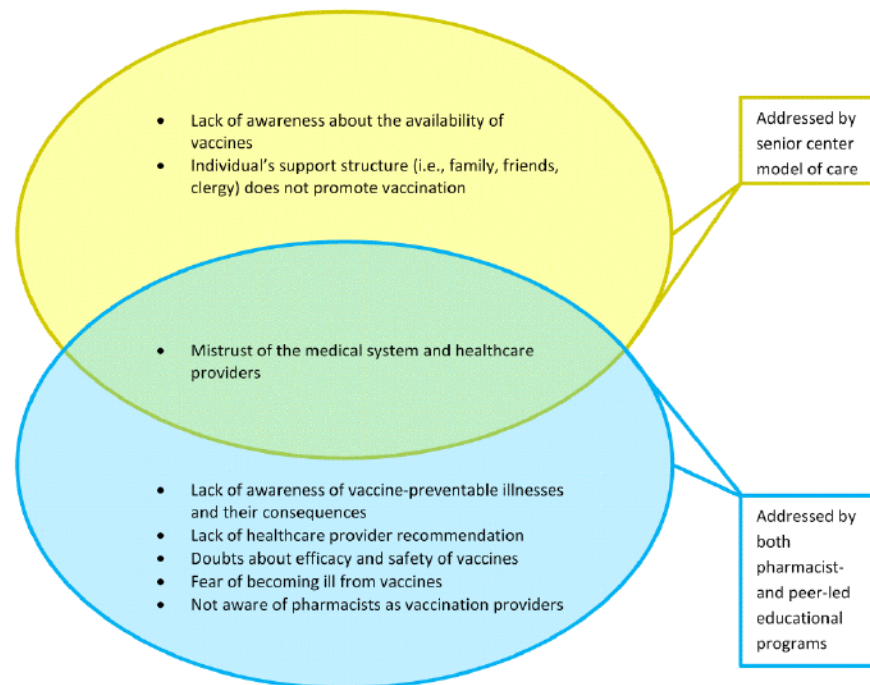
This study will **test two different vaccine educational programs delivered to older adults in the Delaware Valley region**. IRB approval and clinicaltrials.gov listing will be obtained prior to study initiation, and informed consent will be obtained in accordance with IRB requirements. The project will be conducted under the leadership of Dr. Laura Pizzi of Rutgers University, who will serve as Principal Investigator.

The PHARM and PEER interventions will be designed using the conceptual framework employed for our prior PPPP study (Figure 2). This framework was developed by our team based on a March 2015 CIP member survey in combination with findings from our previous work on a pharmacist-delivered pneumococcal vaccination program with CIP and a review of the medical literature. The framework outlines barriers to vaccination in the target population, and indicates which of these barriers can be addressed through a senior center model of care as well as which can be addressed through educational interventions.<sup>27-30</sup> The area of overlap indicates barriers which we believe can be addressed both by use of the senior center model of care and a pharmacist- and peer-led educational intervention.

**Inclusion criteria** are 1) Age  $\geq 50$ ; 2) can attend a 2-hour session (though both PHARM and PEER entail 60 minutes of intervention, an additional hour is needed to allow for informed consent and data collection); 3) speak and read English at  $\geq 4$ th grade level as determined by a brief reading passage; 4) cognitively intact as evidenced by an Abbreviated Mental Status Test score  $\geq 7$ .



**Figure 2. Potential Barriers to Vaccination in Older Adults to be Addressed by the Proposed Interventions**



The study will consist of two arms designed to educate participants about vaccine-preventable disease and vaccination: 1) PHARM will consist of a 60-minute didactic lecture delivered by a pharmacist and video clips pertaining to 3 vaccine-preventable diseases (zoster, pneumonia, and influenza), and 2) a peer-led intervention ("PEER") will consist of a 60 minute small-group session including roleplaying exercises on these three vaccine-preventable diseases. **The components of these interventions will be designed to address specific barriers in our framework.** The interventions will focus on pneumococcal disease and zoster but will include limited content on influenza because participants are likely to have questions about how the flu and its vaccination differ from pneumococcal diseases and zoster.

Because the primary goal of the program is participant education, **vaccination will not be included as a component of the program.** As noted, vaccine costs in our prior study were high, representing nearly a quarter of total program cost. In addition, only 10% of participants opted to get vaccinated through that program (though many reported receiving the pneumonia vaccination through other avenues, for example physician's office or community pharmacy). For the proposed study, **both PHARM and PEER groups will receive a listing of local vaccination sites**, including clinics and pharmacies within a 3 mile radius of the program location.

**PEER** will be delivered by 10 peer educators, each leading small groups of 5-6 participants, for a total of 158 PEER participants. **PHARM** will be

delivered to 3 groups of 50-55 participants, or possibly 6 groups of 25-30 participants for a total of 158 PHARM participants.

## **2.5.2 Detailed Description of Interventions and Procedures**

### **Pharmacist-Led Educational Intervention (“PHARM”)**

In the **PHARM intervention group**, participants will be given a 60-minute formal presentation on vaccine-preventable diseases to address knowledge and beliefs related to zoster, pneumonia, and influenza and to address barriers to receiving vaccination. In several studies, it has been demonstrated that those who believe it is wise to receive vaccinations and those that have discussed vaccination with their healthcare provider are more likely to receive a vaccine.<sup>31-33</sup>

**The presentation will be delivered by a pharmacist** (Dr. Schafer, TJU), be appropriate for participants’ educational level, and aim to establish an understanding of the vaccine preventable illnesses. The presentation will specifically discuss the following: causes, symptoms and potential complications of infection, risk factors for developing the infection, the incidence and prevalence of disease, modes of transmission, and disease prevention through vaccination.

To improve the interactivity of the presentation, brief **30-60 second video clips excerpted from interviews with community members and physicians will be shown. Community member clips** will consist of older adults from the AA population who have experienced vaccine-preventable infections. These clips will provide culturally relevant testimony to the program audience and reinforce participant understanding of concepts introduced during didactic teaching. Previous studies have demonstrated that using patient testimonials can influence a person’s healthcare decision making.<sup>34,35</sup>

### **Peer-Led Small Group Intervention (“PEER”)**

**Training of the PEER Educators:** Peer educators will be recruited from an experienced cohort of peer educators at CIP. CIP is an experienced provider of peer facilitated health education models. CIP staff has extensive experience recruiting and training peer educators. CIP has a core group of 8 volunteer peer leaders trained to facilitate CIP’s current health promotion programs: the 6 week Stanford University model *Chronic Disease Self-Management Program*; the *Diabetes Self-Management Program*; and, *Ask Me 3* (a health literacy program where peers educate the community to ask three simple questions of their healthcare provider). Additionally, CIP’s Living Well Players, a community health theater group comprised of older adults have used peer to peer approaches to develop and perform health education skits on a variety of topics including pneumonia (through our PPPP project).

A pharmacist (Dr. Schafer) will train the peer educators about vaccine-preventable diseases over the course of two didactic sessions. Following

this training, a third session will be held to train the peer educators on the script that they will deliver to participants. The script will include the key learning points to be taught by the peer educators to participants about vaccine preventable diseases and vaccination. The script will also include role-play exercises. In the role-play exercises, 3 vaccination-related scenarios (one for each disease- zoster, pneumonia, and influenza) will be delivered to illustrate situations participants might encounter when interacting with healthcare providers or friends/family. The skit and role-play exercises will be practiced as needed, under the leadership of CIP's project manager, to ensure that the peer educators are confident and consistent when delivering PEER.

After completing the training, peer educators' competency on PEER program content will be assessed through a formal multiple-choice knowledge test. Each peer educator must achieve a minimum score of 80% correct over all items assessed, and 100% correct for all items deemed "core" knowledge.

It is anticipated that 10 peer educators will be needed to deliver PEER. To ensure consistency in how the peer educators are trained, all 10 will be trained as a single cohort.

**Delivery of the PEER Intervention:** PEER will be run over a 60-minute session. On the day of the PEER program, participants will breakout into assigned small groups. During this session, peer educators will deliver the skit and complete the role play exercises. Participants will then be asked what key points they learned about vaccine-preventable diseases and vaccines. Finally, the peer educator will engage in a dialogue to clarify and summarize these key points.

### **Summary of PHARM and PEER Interventions and Procedures**

A summary of the PHARM and PEER interventions and procedures is provided below.

### **Figure 3. Summary of Interventions and Procedures**



	<pre> graph TD     A[RECRUITMENT AND CONSENT] --&gt; B[RANDOMIZATION]     B --&gt; C[PHARMACIST-LED DIDACTIC LECTURE "PHARM"]     B --&gt; D[PEER-LED SMALL GROUP "PEER"]     C --&gt; E[COMPONENT 1: PHARMACIST DIDACTIC PRESENTATION]     D --&gt; F[COMPONENT 1: PEER EDUCATOR PRESENTATION]     E --&gt; G[COMPONENT 2: COMMUNITY MEMBER VIDEO CLIPS]     F --&gt; H[COMPONENT 2: GROUP ROLEPLAY] </pre> <p><b>RECRUITMENT AND CONSENT</b></p> <p><b>RANDOMIZATION</b></p> <p><b>PHARMACIST-LED DIDACTIC LECTURE ("PHARM")</b></p> <p><b>COMPONENT 1: PHARMACIST DIDACTIC PRESENTATION</b></p> <ul style="list-style-type: none"> <li>• Presentation by pharmacist about vaccine-preventable diseases, covering the following topics:             <ul style="list-style-type: none"> <li>• Causes</li> <li>• Symptoms</li> <li>• Risk factors</li> <li>• Incidence and prevalence</li> <li>• Modes of transmission</li> <li>• Prevention and vaccination</li> </ul> </li> </ul> <p><b>COMPONENT 2: COMMUNITY MEMBER VIDEO CLIPS</b></p> <ul style="list-style-type: none"> <li>• Brief 30-60 second video clips excerpted from interviews with community members</li> <li>• 3 clips designed to provide culturally-relevant testimony to participants and reinforce understanding of concepts introduced during didactic presentation</li> <li>• Each clip will be followed by a 3-5 minute Q&amp;A session</li> </ul> <p><b>PEER-LED SMALL GROUP ("PEER")</b></p> <p><b>COMPONENT 1: PEER EDUCATOR PRESENTATION</b></p> <ul style="list-style-type: none"> <li>• Educational script presentation by trained peer educator about vaccine-preventable diseases, covering the following topics:             <ul style="list-style-type: none"> <li>• Causes</li> <li>• Symptoms</li> <li>• Risk factors</li> <li>• Incidence and prevalence</li> <li>• Modes of transmission</li> <li>• Prevention and vaccination</li> </ul> </li> </ul> <p><b>COMPONENT 2: GROUP ROLEPLAY</b></p> <ul style="list-style-type: none"> <li>• Roleplay exercises designed to present scenarios participants may encounter with a healthcare provider or with friends and family members, and demonstrate how to approach these scenarios</li> <li>• Roleplay will be followed by a 5-10 minute discussion and summary of key points</li> </ul>
2.6 Study Duration	<p>Total study duration is 18 months, allowing for developing PHARM and PEER interventions, training PEER educators, delivering both interventions, and reporting study results.</p>
2.7 Statistical Analysis and Sample Size Justification	<p><b>2.7.1 Overview of Statistical Analysis</b></p> <p>The design is a <b>randomized trial</b> with randomization to PHARM or PEER performed at the program date level. The primary outcome measure is a <b>between-group comparison of change in knowledge</b> for PHARM vs PEER at baseline vs. post-test and baseline vs. 1 month. Secondary measures include between group examinations of <b>beliefs, trust, and activation</b> at all 3 time points (baseline vs. post-test, and 1 month). We will also measure the <b>intervention costs of PHARM and PEER</b>, including program development, training, and implementation.</p> <p>The analytic sample will include <b>316 participants</b> who complete the study at one month.</p>



Study data will be recorded using paper forms and input into IBM SPSS for analysis. Electronic data will be password-protected by CIP while enrollment and data collection are ongoing. Files will be checked to ensure de-identification prior to sharing with the Rutgers investigators who will complete the analyses.

### 2.7.2 Definitions of Study Measures

Study measures will be assessed at baseline, immediately following the program (“posttest”), and 1 month after the program. The baseline and post-tests will be administered in person on the date of the intervention. The 1 month follow up will be administered by phone (with up to 4 attempts to reach the participant). It should be noted that the team considered a more distal follow up point (i.e., at 2 or 3 months), but based on experience with the prior PPPP study felt that an earlier follow up would make it easier to reach participants with **fewer call attempts**. **If the reviewers of this proposal conclude that 1 month is too soon for a follow up, we are willing to revise our plan to include a follow up at 2 or 3 months.**

#### **Knowledge and awareness of vaccine-preventable disease (Objective 1):**

**Knowledge and awareness about the target vaccine-preventable diseases** will be assessed with a 15-20 item inventory encompassing the following domains: susceptibility to infection, symptoms of disease, severity of illness, and vaccination with an emphasis on vaccine efficacy, safety, and eligibility. These items will be selected following a review of the literature since no single validated instrument exists to assess knowledge of all three target diseases.<sup>28,29,32,33,36-40</sup>

Similar to the prior pneumonia project, **pneumonia knowledge** will be assessed using an instrument developed by our group using previously published literature. The prior instrument consisted of 6 “check all that apply” questions. Each item correctly checked was worth 1 point, for a maximum possible score of 28 points (see Figure 4 for a summary). We plan to retain the same instrument for the proposed study in order to enable comparison of pneumonia knowledge between the studies. However, we will also add a module pertaining to **zoster knowledge** which takes the same form as the established instrument.

**Figure 4. Summary of Pneumonia Knowledge Instrument**

<b>Knowledge Assessment Questions</b>	<b>Maximum Number of Correct Responses Possible</b>
Who is at risk of getting pneumonia?	9
How can you catch pneumonia from an infected person who is near you?	4
Which of these are symptoms of pneumococcal disease?	5

I should call my doctor or get emergency help if I get any of the following problems after vaccination:	5
Which of the following are possible side effects of the pneumonia vaccine?	5
<b>TOTAL SCORE</b>	<b>28</b>

## **Beliefs about Vaccine-Preventable Diseases and Vaccination (Objective 2):**

Belief measures will include participants' beliefs about the target diseases and vaccination and trust in healthcare providers and peers as information sources. Multiple studies evaluating vaccinations in older and minority populations have found that people who do not receive certain vaccinations **are unaware of their risk of disease, do not believe they are susceptible to the disease, and are not aware of their eligibility to receive the vaccine or feel that the vaccine would not reliably prevent illness.** <sup>28,36-38</sup> In contrast, literature indicates that those who reported receiving a vaccination understood their susceptibility to infection, were aware of their eligibility to receive a vaccination, received a recommendation from a healthcare provider and felt that vaccination was the best way to prevent disease.<sup>28,40</sup>

Our prior PPPP study demonstrated that a pharmacist-delivered educational program can increase participants' trust in pharmacists both as vaccinators and sources of information, but that such gains are short term (limited to the post-test). This finding suggests that pharmacist-delivered information does not lead to sustained trust in pharmacists. However, peers may be more readily accepted as an information source in this population, which may contribute to sustained trust. Thus the change in beliefs from baseline to post test and one month after the intervention will be assessed in both the PHARM and PEER groups to determine whether the PEER group experiences a greater level of sustained trust vs. the PHARM group.

## **Cost Analysis (Objective 3):**

We propose to conduct a detailed cost analysis which **examines PHARM and PEER intervention costs in terms of what each of these two programs cost per program participant.** This will enable us to understand which approach, PHARM or PEER, is less costly to deliver. We hypothesize that PEER will be less costly than PHARM due to differences in staffing requirements. In fact, the main reason for inclusion of cost in the proposed study is to determine whether PHARM and PEER, each of which is less resource intensive than our prior pneumonia program, will be less costly but yield comparable efficacy.

Intervention costs for PHARM and PEER will be calculated as the monetary value of time and materials required to train involved personnel, and deliver PHARM and PEER as well as personnel travel costs. Data on personnel time requirements for delivering PHARM and PEER will be collected in real time by

trained staff members using time logs which document the time and staff members required for training and delivery of the program. These data will be monetized using the hourly wage rates plus fringe benefit costs of the involved personnel. Other costs include materials such as signage, a modest participant giveaway such as medication reminder cards and pill box, printing/duplication, and food/refreshments. All costs will be reported in \$US 2017, consistent with the intervention time period.

#### **Activation (Objective 4):**

Participant activation will be measured as percent of participants who report **taking one or more actions towards receiving vaccination** at one month post-intervention, such as discussion with a healthcare provider (physician/pharmacist) or friends/family and/or receiving vaccination for either pneumonia or zoster. For participants who report vaccination, we will report which (pneumonia, zoster, or both). Influenza vaccination activation will be excluded from this measure since influenza vaccination is widely promoted through other initiatives which could influence activation, such as onsite flu shots at CIP.

#### **Satisfaction (Objective 5):**

Satisfaction measures will include **participants' overall satisfaction** with the content and delivery of PEER vs PHARM, the extent to which the participant felt **engaged**, and their **satisfaction with information received**. Satisfaction will be measured only at post-test using a simple 5-10 item satisfaction survey adapted from our prior research.

#### **2.7.3 Sample Size Justification**

The sample size was calculated using G\*Power 3.0.10 and is based on the primary outcome measure (difference between change in mean knowledge score from baseline to 1 month for PHARM vs PEER). We plan to use a two-tailed independent samples t-test with  $\alpha=0.05$  to determine the between-group difference in mean knowledge scores at each timepoint. We seek to examine the difference, if any, in the effectiveness of the two approaches, PHARM and PEER; specifically, we wish to determine if the two approaches have similar results to within 20% difference expecting large variability (50% standard deviation). This difference is detectable at a power of 0.8 with 121 participants in each arm of the study. To ensure an adequate sample size, we scaled up the sample size calculation using the attrition rate from the prior pneumonia project. Attrition rate in PPPP was  $\frac{203-143}{203}=0.296 \approx 30\%$ ; thus scaling up by 30% yields a total sample size of 316 (158 in each arm).

As a secondary outcome, consistent with the prior pneumonia project, we plan to use a two-tailed paired samples t-test to determine the within-group difference in mean knowledge score between timepoints. However, because within-group differences are easier to detect than between-group differences, the sample size is powered to detect the 20% between-group difference.



<b>2.8 Specific Drug Supply Requirements</b>	None – vaccination is not included as a component of this study.
<b>2.9 Adverse Experience Reporting</b>	Not required since vaccination is not being offered through this study.
<b>2.10 Itemized Study Budget</b>	Provided as attachment.
<b>2.11 References</b>	<ol style="list-style-type: none"> <li>1. National Center for Health Statistics. Early Release of Selected Estimates Based on Data From the National Health Interview Survey. <a href="http://www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease201406.pdf">http://www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease201406.pdf</a>. Published June 2014. Accessed July 1, 2015.</li> <li>2. Community Health Data Base. Calling the Shots: Flu and Pneumonia Prevention. <a href="http://www.chdbdata.org/datafindings-details.asp?id=33">http://www.chdbdata.org/datafindings-details.asp?id=33</a>. Accessed 24 September 2012.</li> <li>3. Prioli K, Schafer J, Fields Harris L, McCoy M, Barber E, Marthol-Clark M, Pizzi LT. Awareness and beliefs about pneumococcal and influenza vaccination among older African Americans: Results from a survey of community-dwelling participants at an urban senior center. Poster presented at: The 18th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research; May 20, 2013; New Orleans, Louisiana.</li> <li>4. Tomczyk S, Bennett NM, Stoecker C, Gierke R, Moore MR, Whitney CG, et al. Use of PCV-13 and PPSV-23 vaccine among adults aged 65 and older: recommendations of the ACIP. MMWR. 2014;63(37):822-5.</li> <li>5. Forbes HJ, Thomas SL, Langen SM. The epidemiology and prevention of herpes zoster. Curr Derm Rep 2012;1:39-47.</li> <li>6. Yawn BP, Saddier P, Wollan PC, St Sauver JL, Kurland MJ, Sy LS. A population-based study of the incidence and complication rates of herpes zoster before zoster vaccine introduction. Mayo Clin Proc 2007;82:1341–9.</li> <li>7. Schmader KE, Johnson GR, Saddier P, et al. Effect of a zoster vaccine on herpes zoster-related interference with functional status and health-related quality-of-life measures in older adults. J Am Geriatr Soc 2010;58:1634–41.</li> <li>8. Williams WW, Lu P-J, O'Halloran A, et al. Noninfluenza vaccination coverage among adults—United States, 2013. MMWR Morb Mortal Wkly Rep 2015;64:95–102.</li> <li>9. U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. Healthy People 2020. Washington, DC. Available at <a href="https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives">https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives</a> . Accessed March 18, 2015.</li> </ol>



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<b>2.12 Publication Plan</b>	<p>The major publication goal of this project is to publish one original research manuscript in a relevant and credible peer reviewed journal such as the <i>American Journal of Public Health</i>, <i>Journal of the American Geriatrics Society</i>, or <i>Pharmacoeconomics</i>. Our target submission date will be April 2018.</p> <p>In addition, we plan to publish 2 scientific abstracts at relevant meetings:</p> <ol style="list-style-type: none"> <li>1. Main study findings to be submitted to the American Society for Health System Pharmacy Midyear Clinical Meeting (held annually in December) or Gerontological Society of America Annual Meeting (held annually in November)</li> <li>2. Cost findings to be presented at the International Society for Pharmacoeconomics and Outcomes Research Annual or European Congress (held annually in May and November, respectively)</li> </ol>
<b>2.13 Curriculum Vitae</b>	Each investigator's date stamped curriculum vitae has been submitted as an attachment through the Vision Tracker system.
<b>2.13 Protocol Submission for Investigator-Initiated Studies</b>	<p>U.S. protocols should be submitted by US investigators directly or through the Global Research Specialist at <a href="http://www.merckisp.com">www.merckisp.com</a></p> <p>Non U.S. protocols should be submitted to the MSD office by the investigators.</p>



## Appendix. Results of a Local Needs Assessment on Zoster

Because little was known about the local need specific to zoster vaccination, a survey was fielded to 58 older adults at CIP in 2015. The instrument consisted of 20 Likert Scale items assessing knowledge and perceptions of the zoster vaccine. Responses to selected Likert items are provided in Table 1.

The results demonstrate that there is **uncertainty regarding the efficacy of the zoster vaccine, with less than 50% of individuals agreeing that the vaccine can prevent shingles**. Additionally, many participants were **unsure whether or not their physician or pharmacist thought that a zoster vaccine was important for them**. They were also **unsure about whether they would want a zoster vaccine if they were eligible or if they would recommend the vaccine to another**.

**Table 1. Key Results from Likert Items in the CIP Member Survey on Zoster Vaccination**

Survey Item	Results
"The shingles shot keeps a person from getting shingles"	28/58 (48.3%) responded "completely agree" or "somewhat agree"  30/58 (51.7%) responded "somewhat disagree," "completely disagree," or "unsure/I don't know"
"My doctor thinks it is important for me to get the shingles shot"	31/58 (53.4%) responded "completely agree" or "somewhat agree"  27/58 (46.6%) responded "somewhat disagree," "completely disagree," or "unsure/I don't know"
"My pharmacist thinks it is important for me to get the shingles shot"	25/58 (43.1%) responded "completely agree" or "somewhat agree"  33/58 (56.9%) responded "somewhat disagree," "completely disagree," or "unsure/I don't know"
"If I am eligible, I would want to get the shingles shot"	29/58 (50%) responded "completely agree" or "somewhat agree"  29/58 (50%) responded "somewhat disagree," "completely disagree," or "unsure/I don't know"
"If my friend/family was eligible, I would encourage them to get a shingles shot"	31/58 (53.4%) responded "completely agree" or "somewhat agree"  27/58 (46.6%) responded "somewhat disagree," "completely disagree," or "unsure/I don't know"
"It would be easy for me to get a shingles shot if I wanted one"	40 (69%) responded "completely agree" or "somewhat agree"  18 (31%) responded "somewhat disagree," "completely disagree," or "unsure/I don't know"

A second key finding from the CIP member survey is that **while many believed that it would be easy to get a zoster vaccine if they wanted one, nearly one-third either disagreed with this statement or were unsure if they would be able to get the vaccine**. This finding also represents an opportunity for our program to provide access to the vaccine if participants are eligible.

The uncertainties uncovered in this survey represent opportunities for our program to **address these gaps** by educating this population on zoster vaccine efficacy as well as develop skills to engage their physicians and pharmacists in discussions about zoster and determine their vaccine eligibility.