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Pneumococcal Pneumonia in the Older Adult: Increasing Patient Education and Vaccination

Jessica E. Valletta

University of Massachusetts Amherst

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Pneumococcal Pneumonia in the Older Adult: Increasing Patient Education and Vaccination

Jessica E. Valletta

UMass College of Nursing

Capstone Chair:	<u>Dr. Pamela Aselton</u>
Capstone Committee Member:	<u>Dr. Raeann Leblanc</u>
Capstone Mentor:	<u>Vanessa Sheehan, FNP</u>
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Table of Contents

Abstract	3
Introduction and Background	4
Problem Statement	6
Literature Review	6
Standing Orders Program.....	6
Methods.....	7
Results and Synthesis of the Evidence.....	8
Summary of Evidence.....	13
Theoretical Framework	14
Lewin’s Change Theory.....	14
Theory Application in Implementation.....	15
Project Design and Methods	16
Planning Model: CHIP.....	17
Needs Assessment.....	18
<i>Community of Interest</i>	18
Organizational Analysis.....	19
<i>Identifying the Key Stakeholder</i>	19
<i>Resources, Facilitators and Barriers</i>	19
Project Implementation	21
Ethics and Human Subjects Protection.....	21
Project Timeline.....	22
Project Evaluation	25
Data Analysis and Results.....	25
Discussion.....	31
Study Limitations.....	34
Conclusion	35
References	36
Appendices	42

Abstract

Background: Pneumococcal disease is a transmitted infectious illness that results in serious complications and death every year in the United States. Given their increased susceptibility to the potential complications of this disease, patients aged 65 and older are considered to be high-risk, but vaccination compliance for this population remain well below state and national goals.

Purpose: The purpose of this project was to increase pneumococcal vaccination rates among adults aged 65 and older in a primary care clinic by increasing patient education.

Methods: An educational intervention was implemented within a large primary care practice located in Central Massachusetts. Educational materials were distributed within the clinic, including posters, vaccine information sheets, and flyers. Cumulative vaccination rates for pneumococcal pneumonia among the target population were analyzed pre and post intervention to evaluate project impact. Mixed methods were used for analyzing project results.

Results: Results demonstrated a nearly 10% increase in cumulative vaccination rates after project implementation. There also proved a statistically significant relationship between patient education and rates of vaccination exists ($p < .0001$).

Conclusion: The project's findings demonstrate that increasing patient education in the primary care setting can improve rates of vaccination against pneumococcal pneumonia in vulnerable patient populations.

Keywords: pneumococcal, pneumonia, patient education, standing order programs, vaccination, immunization, barriers, older adults.

Introduction and Background

Introduction

Vaccines are arguably one of the most powerful medicines available to patients to prevent illness and reduce infectious disease morbidity and mortality. The Centers for Disease Control and Prevention (CDC) (2014) recommends routine vaccinations from birth through adulthood to provide a lifetime of protection against vaccine preventable diseases. Notable increase in average life expectancy during the last century is associated with decreased rates of infectious disease mortality attributable to vaccinations. As one of the most cost-effective clinical preventive services, investment into vaccines yields a high return (U.S. Department of Health and Human Services [HHS], 2014). Currently, the Advisory Committee on Immunization Practices (ACIP) recommends twelve different immunizations for adults ages 19 and older, including two specific to preventing pneumonia: Pneumococcal polysaccharide vaccine (PPSV-23) and Pneumococcal conjugate vaccine (PCV-13) (CDC, 2015).

Pneumococcal disease is an easily transmitted, significantly infectious illness that results in massive expense, complications and death every year in the U.S. (American Lung Association [ALA], 2010). High-risk patients aged 65 and older are more susceptible to potential complications associated with pneumonia as it often exacerbates underlying illnesses. Older individuals are more likely to experience respiratory failure, sepsis, lung abscesses or even death. Pneumococcal disease claims the lives of one in every four to five people over the age of 65 that contracts it and in 2013, was responsible for 53,282 deaths in the U.S.; together with influenza it is currently the fifth leading cause of death in the older adult (NFID, 2015). Community-acquired pneumonia is responsible for 350,000-620,000 hospitalizations for older adults annually and survival rates among this population are lower than younger individuals; furthermore, those

who may survive the initial illness sustain a higher-than-normal morbidity rate in forthcoming years. With the baby boomer generation aging, it is anticipated that disease incidence will rise proportionately. The CDC (2011) has estimated that by the year 2030 the number of U.S. adults 65 years and older will have doubled to approximately 71 million; simultaneously, life expectancy will continue to increase, introducing a greater opportunity for these diseases to wreak their havoc on society.

Background

Pneumococcal disease places a financial burden on the U.S.; in 2004 an estimated four million episodes of illness resulted in direct medical costs of \$3.5 billion, half of which (\$1.8 billion) were related to care of patients aged 65 and older (Huang et al., 2011). It is projected that pneumococcal pneumonia hospitalizations will increase by 96% between 2004 and 2040. Without intervention the increasing demand for healthcare services will double in coming decades, and the total cost of pneumococcal pneumonia will increase by \$2.5 billion annually (Wroe et al., 2012). However, approximately 70 million adults considered high-risk remain unvaccinated (CDC, 2013). *Healthy People 2020* maintains a target goal of a 90% vaccination rate for pneumonia in adults 65 years and older, but with current data exhibiting a suboptimal total of 59.7%, disparities in vaccination rates clearly exist (CDC, 2013; HHS, 2014).

A multitude of factors contribute to whether an individual will seek medical treatment, including vaccination. Health service or treatment must be perceived by the individual to be important, beneficial to their wellbeing, easily available and affordable (ALA, 2010). From a global perspective, lack of resources and infrastructure play a large role in barring efforts to promote preventive care. In certain developing countries, citizens struggle to pay for basic medical procedures and consider anything greater than basic a luxury (Pfizer, 2012). Within the

U.S. issues pertaining to cost appear to be less concerning for patients than personal awareness or beliefs (ALA, 2010). Reported barriers have also included a lack of awareness of the disease and/or vaccine, competing priorities, time restraints, incomplete or unobtainable immunization histories and delivery challenges within the health care system (Rehm et al., 2012). With coverage levels not attaining nationwide goal, infectious disease still remains prevalent in society and there is a consequential need to develop, understand and promote interventions in primary care that will increase immunization rates. This quality improvement DNP project investigated the feasibility of increased patient education having an impact on pneumococcal pneumonia vaccination rates among patients 65 and older in a primary care setting.

Problem Statement

Risk of serious health complications from pneumococcal pneumonia among U.S. patients' ages 65 and older has been made evident by consistently high morbidity and mortality rates from vaccine preventable pneumococcal pneumonia related to suboptimal vaccination coverage resulting from a multitude of perceived personal and logistical barriers among patients and providers alike.

Literature Review

A search of the literature was conducted to identify and critique existing methods to improve pneumococcal vaccination rates among patients aged 65 years and older. The review further sought to identify patient and provider perceived barriers to immunization.

Standing Orders Program

Standing orders programs (SOP) as recommended by the ACIP allow non-provider personnel to assess the vaccination status of patients and administer vaccines without an individual physician order. An outline of the ACIP's report on their recommendations is

available to review in Appendix A. The Immunization Action Coalition (2014) has developed a multitude of SOPs allowing eligible staff (i.e. nurses and pharmacists) within approved states the autonomy to identify and subsequently vaccinate individuals that meet specified criteria; standing orders already exist for both pneumococcal vaccines (PPSV23 and PCV13) with an ultimate goal of reducing overall morbidity and mortality from pneumococcal disease. A copy of the existing orders protocol is provided in Appendix B. The review specifically identifies current evidence within the literature pertaining to SOPs, including barriers to implementation and successes achieved when said barriers are eliminated.

Methods

The initial search included the following databases: PubMed and Google Scholar. Prior to undergoing the search, texts published by experts in systematic reviews were utilized for reference on database selection and search term development. Medical Subject Headings (MeSH) terms included a varying combination of the following: *pneumococcal, pneumonia, vaccination, immunization, rates, improving, interventions, and older adults*. Two additional terms were later included to further expand the search: *standing order programs* and *SOP*. After an initial review was undergone, the DNP student chose to isolate and explore literature pertaining specifically to the interventional use of Standing Order Programs (SOP) and the benefits increased patient education has on increasing vaccination rates.

Inclusion criteria consisted of full-text articles published in the English language within the past 5 years (2010-2015). Retrospectively, a larger time span may have been beneficial as there were limited publications available. Articles were filtered to focus on the community setting in order to maximize primary care relevance. Those non-specific to adults 65 years of age and older were used sparingly but not omitted, as some provided high-quality analysis of

SOP implementation. Studies focusing on interventions other than standing order programs were not evaluated, unless the intervention was used in combination with a standing order. Initial search yielded 482 articles, which were further delineated into 15 sources, each scrutinized according to specific criteria of reliability, validity and applicability to future research and practice scenarios. Nine articles were chosen for final synthesis and major patterns and gaps across the literature pertaining to this possible intervention were identified.

Results and Synthesis of the Evidence

The Johns Hopkins Nursing Evidence-based Practice Rating Scale (JHNEBP) was utilized to assess methodological quality of the literature. For the quantitative studies, internal/external validity and reliability were taken into account, while credibility, transferability and generalizability were considered in reviewing the qualitative.

Benefits to Vaccination. Multiple studies have validated the claim that vaccination against pneumonia will decrease risk for potential complications (CDC, 2015). In a study of approximately 85,000 adults 65 years and older in the Netherlands, researchers found PCV-13 was effective at preventing invasive pneumococcal disease and 45% effective at preventing pneumococcal pneumonia (Mangen et al., 2015). Bonten et al. (2015) conducted a similar study among 84,496 adults within the United States in which one group was vaccinated and the other was not. Just as in the study by Mangen et al., researchers identified a positive correlation between pneumococcal vaccination and rates of illness: Community-acquired pneumonia was diagnosed in 49 vaccinated individuals versus 90 in the unvaccinated placebo group (vaccine efficacy, 45.6%; 95.2% CI, 21.8 to 62.5); invasive pneumococcal disease was recognized in 7 individuals of the PCV13 group and 28 in the placebo (75.0%, 95% CI, 41.4 to 90.8). Both studies demonstrate that pneumococcal vaccination is effective in preventing disease.

A single dose of PPSV-23 is recommended routinely for adults 65 and older as an effective means of preventing invasive pneumococcal disease (ACIP, 2010). However, data on the vaccine's effectiveness against community-acquired pneumonia is inconsistent and various studies have been unable to provide adequate evidence proving PPSV-23 effective against non-invasive pneumococcal pneumonia (NPP) among older adults in the community (Huss et al., 2009; Moberly, Holden, Tatham & Andrews, 2008). The addition of PCV-13 into the older adult population is predicted to improve coverage against this type of pneumonia and studies are being undergone for further exploration (Smith et al., 2012). Currently, the ACIP recommends immunocompetent older adults receive both vaccines as a way to broaden their coverage against varying strains of pneumonia. Patients 65 and older that have previously been vaccinated with PPSV-23 should receive a single dose of PCV-13 at least one year after having received the PPSV23. For those adults 65 and older that have not received either pneumococcal vaccination, a single dose of PCV-13 should be given first, followed by a dose of PPSV-23 six to twelve months later.

Efficacy of Standing Order Protocol Use. Current literature suggests use of SOPs as an effective means of raising rates of vaccinations (Appel, 2011). The United States Preventive Services Task Force (USPSTF) recommends the use of SOPs as a highly graded preventive tool and members of the American Academy of Family Physicians (AAFP) further support belief in SOP efficacy. Evidence demonstrates a direct correlation exists between implementation of an SOP and increased vaccination rates (Albert et al., 2012; Bardenheier et al., 2010; Nowalk et al., 2014; Zimmerman et al., 2011). Nowalk et al. (2014) conducted an observational study among providers from four diverse primary care practices (Level II, Grade B). Utilizing group interviews and surveys as reliable tools to measure outcomes, researchers implemented use of an

SOP toolkit and found PPSV rates of high-risk adult patients increased from 25% to 40% in just one year. Results of the study indicated minimal effect on the older adult population, revealing inconsistency in the study's findings. However, influenza vaccination rates exhibited significant improvement in three out of four sites overall (22% vs.33%, $p < .001$), justifying the researchers' claims of SOPs positively impacting rates of vaccination.

Similarly, Bardenheier, Shefer, Lu, Remsburg and Marsteller (2010) also yielded positive results from their cross-sectional study of a randomized sample of 11,939 nursing home residents 65 years and older (Level I, Grade A). Aiming to assess the impact of SOPs vs. alternative programs on influenza vaccination rates, the researcher identified a positive relationship between use of standing orders and greater vaccination coverage (66.7% versus 62.0%, respectively, $P < .01$). In congruence with the previous study's conclusions, Middleton et al. (2008) also proved that utilization of an SOP is a cost-effective method for increasing rates of pneumococcal vaccination among hospitalized elderly patients. Newly admitted patients to a 1,094 bed tertiary-care hospital were screened for PPSV eligibility and then offered the vaccine resulting in overall vaccination rates increased by 30.5%. More research will be beneficial in analyzing the impact of SOPs on alternative outpatient locations.

In continued support of the previous findings, Smith and Metzger (2011) conducted an experimental pre-test/post-test study among 300 randomly selected adult patients of two separate Internal Medicine units. The sample was isolated into two groups of 150 patients with the purpose to determine if a multifaceted vaccine protocol inclusive of standing orders would increase rates of screening and vaccination among eligible patients. The overall screening rate was similar between both pre and post-implementation groups (96% vs. 93%). However, the rate of vaccination was significantly different (19.1% to 74.2%, respectively). Within their

analysis, researchers highlighted findings from a prospective, randomized controlled study conducted by Dexter et al. (2004) in which patients designated to an electronic standing order group had higher rates of vaccination against pneumonia opposed to a group using electronic reminders as an intervention (51% vs. 31%, respectively, $p < 0.001$). Methods of measurements for both studies were reliable and data successfully demonstrate noteworthy findings consistent with previous studies included in this review: Standing order programs are an effective method of increasing vaccination rates.

Correlates of SOP Use. Despite proven benefit to increasing vaccination rates, consistent underutilization of SOPs signifies barriers exist to implementation. In a nationally represented sample of 880 physicians, Albert, Nowalk, Yonas, Zimmerman and Ahmed (2012) indicated only 23% of providers reported consistent use of SOPs (Level I, Grade A). The researchers aimed to identify factors either promoting or impeding the use of SOPs. Reliability was strengthened through use of a survey that is national in scope and maintains a high provider response rate, while the questionnaire was rooted in concepts from various theoretical models. Investigators determined that consistent SOP use for influenza and pneumonia vaccination was significantly impacted by provider awareness of ACIP recommendations and/or Medicare regulations as those reporting consistent use of SOPs were typically more aware of said regulations and recommendations. The same team conducted an additional study among 1,640 providers and findings were similar, identifying the two variables mostly highly associated with a provider's likelihood of using SOPs as awareness of recommendations to use them and agreement with their efficacy (Zimmerman, Albert, Nowalk, Yonas & Ahmed, 2011). Both of these studies concluded providers who used them found they are beneficial; however, they also bring to light a need for greater awareness and methods to increase use of SOPs in primary care.

Comparative findings were elicited by researchers Zimmerman et al. (2011) who conducted a quasi-experimental study among a stratified random sample of 1,640 providers within the U.S. (Level II, Grade B). Consistent SOP use was reported slightly higher than the previous study at 42.4%. The percentage of providers aware of ACIP/Medicare recommendations and regulations was 35.8% in the group not currently using SOPs, compared to 70.9% in the group that was aware. These findings further justify that awareness is critical to ensure successful implementation of an SOP and increase rates of vaccination; to be considered however, the method of data collection via survey is limited to self-report. Regardless, methods that will increase use of SOPs are implicated for future research.

Barriers to Immunization. A multitude of barriers related to vaccine delivery exist within society as perceived by both patients and providers. Much of the current literature aims to identify these barriers and address potential methods of alleviating them in attempts to raise vaccination rates. A common theme across the literature is missed vaccine opportunities and the contribution it has to low vaccination rates. In one retrospective study of 1,072 female girls between the ages of 18-24, it was found that 33.7% of the girls who did not receive their second vaccine in the series had at least one identifiable missed opportunity (Richards, Peters & Sheeder, 2014). Similarly, Nowalk et al. (2005) conducted a cross-sectional analysis of 4,000 patients in multiple primary care practices over a span of four years, yielding results with high sensitivity and generalizability. The researchers identified an average of 10.7 +/- 7.3 missed opportunities for vaccination of adults 65 and older against pneumococcal pneumonia during the period of one year.

Specific to provider and patient reported barriers, a survey conducted amongst 238 OB/GYN U.S. medical residents reported barriers to immunization, which included uncertainty

over vaccine recommendations, safety and efficacy and a lack of time to properly inform patients of the risk and benefits to vaccination (Fay, Hoppe, Schulkin & Eckert, 2014). It should be noted that these results are limited to providers of a medical specialty and may not be applicable to all providers. Rehm et al. (2012) summarized similar findings elicited from a multidisciplinary task force meeting on ways to increase pneumococcal vaccination rates among older adults. Barriers to vaccination included lack of awareness of the vaccine or disease, health care system delivery challenges and competing priorities that restricted the time available for vaccine discussion. Researchers Suryadevara et al. (2013) identified similarly expressed barriers in their study and attempted to eliminate them and improve rates of vaccination. They partnered with the Salvation Army to educate families on childhood immunizations and by doing so, rates of vaccination increased from 28% to 45%. Although further study specific to barriers against pneumococcal pneumonia vaccination in the older adult population is warranted, each of these articles successfully highlighted the significance of missed opportunities on vaccination rates.

Summary of Evidence

As research has demonstrated, disparities in pneumonia vaccination rates exist among the older adult population. Despite the known efficacy and availability of vaccines, millions remain unvaccinated (ALA, 2010). Barriers to full immunization do exist, but sufficient evidence proves they are surmountable. Development and implementation of this program will address ways in which health care providers can begin rectifying the issue, starting with the simple task of increasing their awareness to existing recommendations and patient awareness to vaccine benefits; successful intervention will aid in minimizing this disparity by expanding provider's abilities to offer patient services aligned with nationally established goals for prevention and control against vaccine preventable disease. Vaccinations help to eliminate health disparities

while simultaneously advancing health equity among the population. Utilizing detailed screening and not relying solely on the providers will help reduce the number of missed opportunities within this vulnerable population, and implementation of SOPs will positively affect vaccination rates.

Theoretical Framework

Lewin's Change Theory

In order to successfully motivate a collaborative team and advance toward achieving an optimal goal, one must be familiar with the concept of change and its theoretical underpinnings (Zaccagnini & White, 2014). Developed by 'the father of social psychology', Kurt Lewin, the Change Theory of Nursing recognizes change as a constantly evolving factor of life, driven by a dynamic balance of forces working in opposing directions (Lewin, 1951; Lewin, 1975; Zaccagnini & White, 2014). The social scientist believed driving forces facilitated change by pushing individuals in the desired direction, while restraining forces pushed individuals in opposite directions, consequently preventing it (Kritsonis, 2005). Lewin's theory is based on the belief that change process must go through three stages: unfreezing, moving, and refreezing (Lewin, 1951; Lewin, 1975; Zaccagnini & White, 2014).

The first stage is unfreezing. This step in the process identifies needs of an individual or group, while simultaneously preparing those involved to move forward from the existing situation, or status quo, to an improved level of practice. The unfreezing phase helps to identify a potential method that will allow people to let go of counterproductive processes and is necessary to overcome strains of individual resistance and group conformity. Kritsonis (2005) recognizes three ways unfreezing can be achieved: a) increase the driving forces which will aid in redirecting behavior away from the existing situation or status quo; b) eliminate restraining

forces responsible for hindering movement from the existing equilibrium; c) formulating a combination of the two previous methods.

Once those involved are motivated to change, the second stage in the process can take place: moving. The movement phase zeroes in on what exactly needs to be changed. It involves addition of driving forces as a means of motivating and empowering individuals/the group to adopt a new and improved perspective; additionally, this phase attempts to minimize opposing forces that pose potential barriers to achieving the desired change (Lewin, 1951; Lewin, 1975; Zaccagnini & White, 2014). The focus here is to move the target system to a new level of equilibrium with the assistance of competent leader (Kritsonis, 2005).

The final stage, freezing, involves making the change permanent and cannot successfully occur until the change has been implemented (Lewin, 1951; Lewin, 1975; Zaccagnini & White, 2014). The purpose of this stage is to stabilize the new equilibrium by maintaining a balance between driving and restraining forces, and if this is done poorly, or not at all, the risk for reverting back to old behaviors is high (Kritsonis, 2005). To ensure completion of this stage, leaders must consistently reinforce the new level of practice and promote continued use by members.

Theory Application in Implementation

A comprehensive breakdown of the theory's major concepts and their applicability to the capstone project are reviewed below. Driving forces were identified as supporting evidence-based research, improved patient outcomes and decreased hospitalizations, decreased healthcare costs, and improved patient/staff safety. Restraining forces included lack of perceived benefit, fear of adverse effects and lack of perceived severity of illness and provider's lack of awareness to how little patients knew of this disease and available vaccines.

Unfreezing phase. Achieving this step required an increase in driving forces and decrease in restraining forces. This was accomplished by providing more educational materials on pneumococcal pneumonia and allowing patients the opportunity to ask questions and voice concerns during office visits. Engaging patients instilled a sense of empowerment, helping them to overcome their resistance to change and gain a greater understanding of how important the need for change was (Sutherland, 2013). Additionally, this time was used to discuss existing statistics with staff and providers, making them more aware of the need for increased education.

Moving phase. The moving phase included implementation of the intervention. During this time, posters were placed in the waiting room; flyers were placed in each exam room and handed out to patients at both check-in and check-out, in addition to provision of VIS forms. Patients were encouraged to read the available material and ask questions during their visit in order to increase their knowledge of pneumococcal pneumonia and recognize the benefits of vaccination.

Freezing phase. Bozak (2003) identifies the need for the theory's final stage to include stability and evaluation, which the DNP student achieved through the provision of ongoing support of all stakeholders during implementation of the intervention. Adequate follow-up with patients and providers/staff offered a chance for feedback and ensured the new equilibrium was maintained.

Project Design and Methods

The project design looked at benchmark change in cumulative vaccination rates through use of an educational intervention aimed at both patients and the clinic. Pre and post intervention data was analyzed to assess the impact of the project. Project data was analyzed using mixed qualitative and quantitative methods. The project intervention ran from November

2015 through February 2016. Data regarding immunization rates for pneumococcal disease in the target population adults age 65 years and older was gathered and analyzed pre and post-implementation, quantifying the number of eligible patients that received vaccination at each time interval and comparing results; this was completed with the assistance of the Information Technology department.

Planning Model: CHIP

The Community Health Improvement Process (CHIP) provides a systematic approach for how communities can identify and manage prevalent health issues in specified populations (IOM, 1997; Layde et al., 2012). The model is separated into two cycles to further delineate key elements (Appendix C). The first cycle, identification and prioritization, aided the DNP student in conducting the needs assessment and determining which health issue needed to be addressed; it is comprised of 3 core elements:

- Form a community health coalition
- Prepare and analyze community health profiles
- Identify critical health issues

Completion of the first cycle indicated a need for improving pneumonia vaccination rates.

Subsequently, the student was able to initiate the second cycle of analysis and implementation, addressing seven additional elements:

- Analyze health issue
- Inventory resources
- Develop health improvement strategy
- Identify accountability
- Develop indicator set

- Implement strategy
- Monitor process and outcomes

The CHIP model provided a framework for guiding the implementation of the capstone project and the assessment of outcomes for the future.

Needs Assessment

Community of Interest. The chosen site for implementation was a group medical practice established in Central Massachusetts with 14 sites providing primary care and satellite sites providing specialty services. Project implementation occurred at only one of the primary care locations. The selected practice had a panel of approximately 12,000 patients, ranging from young adults to elderly, and nine providers: six MDs and four APRNs. The providers saw on average anywhere between 80 and 130 patients a day for a combination of well and sick visits. Demographics within the practice were consistent with the surrounding town of Westborough, representing a dominantly middle to upper class Caucasian and Indian population. The target population for project implementation included adults 65 years of age and older eligible for pneumococcal vaccination within the primary care setting; patients were excluded if they were new to the practice within the previous three months.

Utilizing the feedback of multiple providers within the department through verbal discussion, it was determined that an intervention focusing on increasing vaccination rates was desired. Most providers felt that the numbers of patients receiving the currently recommended vaccinations were lacking and wanted to see these numbers increase; although, there were a select few that did not feel their numbers were far off from national baselines. Many patients felt improved efforts needed to be made by healthcare offices to remind patients when they are due for vaccines. Interviewed individuals felt that if they forgot to ask about a vaccine they may

have seen on TV (i.e. the new CDC recommendations for PCV13) it may not have necessarily been recommended during the visit. Statistical data was gathered to accurately demonstrate vaccination rates within this department. Additionally, further investigation was undergone to highlight missed opportunities for vaccinating patients and identifying existing barriers (i.e. during a regular office visit vs. physical). This information assisted the DNP student in identifying gaps or deficits comparatively speaking.

Organizational Analysis

Identifying the Key Stakeholder. The key stakeholder for this project was a Master's prepared FNP who works closely with her supervising physician, a family medicine doctor with nearly 40 years of experience in primary care. On average she sees 15-20 patients a day, primarily 18 years and older, for both well and sick visits. Although she does not have a panel of her own, she is well known to patients throughout the office and they often seek her care directly.

Resources, Facilitators and Barriers. Resources necessary to complete the capstone project included: time, location, materials and email communication. Time was managed throughout the entire process to account for development, implementation and analysis of the quality improvement project. A specific location was necessary to implement the project and approval to utilize this site was necessary to obtain. Email was necessary to stay in constant contact with project stakeholders, particularly the IT department. Materials included the supplies necessary for poster construction, paper and printer for flyer production and Vaccine Information Sheets, all of which helped facilitate information to patients. Poster supplies were obtained on the DNP student's budget, while the rest of the material was made available by the project site. Each of these interventional tools was beneficial in facilitating communication about

pneumococcal pneumonia between patients and providers.

Vaccine Information Sheets (VIS) developed by the CDC were already being provided to patients in adherence to national regulations. The CDC ensures these informational sheets are up-to-date; the PCV-13 VIS was most recently updated in November of 2015 and PPSV-23 in April of 2015. Each of these is available in multiple patient languages and written in layman's terms for patients to comprehend. They explain to patients, parents or legal representatives of the individual being vaccinated, what the risks and benefits are to vaccination and address many of the commonly asks questions associated with the vaccination.

Existing standard workflow processes within the office facilitated the project. Trained nurses were available to administer vaccines or answer patient's questions. A designated nursing room allowed a space for patients to receive vaccines without having to wait and delay rooming of other patients, which was a perceived barrier expressed amongst office staff. The office maintained stock of all necessary materials to facilitate vaccine administration, including PCV-13 and PPSV-23 vaccines, needles, gauze and band aids. Additionally, a crash cart with all items necessary for an emergency was readily available and appropriate staff was knowledgeable of its contents. VIS forms were already present in all exam rooms and the nursing room; open communication between DNP student and staff ensured that these were consistently offered to patients.

Potential barriers to project implementation were identified as provider/staff reluctance, lack of knowledge of vaccination coverage and an assumption of patient's lack of perceived need and severity of illness. Some providers were reluctant to rescind responsibilities of identifying eligible patients, while some expressed concern over it being the nurse's sole responsibility to decide whether or not vaccination was appropriate. Staff and providers identified their lack of

knowledge of vaccination coverage was a barrier to facilitating adequate monitoring of vulnerable patients. Data gathered for pre-implementation analysis was provided to staff and providers to accurately depict vaccination rates within the department and demonstrate a need for improvement.

It was determined that due to Internal Medicine and Pediatric departments combining for their annual flu clinic implementation during the clinic was too large of an undertaking. The additional requirements on staff mentally, physically and financially were deemed too overwhelming. It was determined among student and key stakeholder that the SOP would be best implemented as a part of the standard daily workflow. By October, significant barriers to implementation became evident. The company was undergoing a major layoff, management was reconstructing itself and employees at all levels were under great amounts of stress. By November, the clinical nurse lead, and another key stakeholder for the project, resigned. This was detrimental to project implementation as this nurse leader had been in support of the project and was helping facilitate nursing's adaptation. The DNP student met with the key stakeholder and practice manager in December to discuss plausible solutions.

Project Implementation

Ethics and Human Subjects Protection

The chosen methods of design and evaluation were submitted to the UMass Amherst Institutional Review Board and determined to be exempt given the proposed activities were not considered research under the human subject regulations (Appendix D). To avoid violation of HIPPA laws, the student at no time had access to any patient's protected health information and their confidentiality was maintained. To alleviate potential for representation of human subject research, the project was limited to the use of existing and/or prospectively collected de-

identified patient data; IT gathered and supplied all necessary data for analyzing.

Project Timeline

A flow chart was developed to identify the program's major processes and is available for review in Appendix E. Constant reference to the original timeline and flowchart were made throughout the implementation process, allowing the student opportunities to acknowledge obstructing factors and ensure programmatic needs of the project were effectively being addressed.

Pre-intervention. The DNP student had previously met with both the project's key stakeholder and office practice manager in late August 2015 and was granted permission to implement the project at their location. Discussion at that time included the following key points that pertained to the proposed project's design and evaluation methods:

- Outcome goal: Determine if the intervention demonstrates a relationship between the health intervention program and the health outcome of the population (increased pneumonia vaccination rates among adults age 65 and older).
- Project design: Quasi-experimental, pre and post-intervention.
- Methods of evaluation:
 - i. Quantitative data analysis/interpretation: 1) Pre and post intervention evaluation of the statistics pertaining to vaccination rates among patients 65 and older within the practice.
 - ii. Qualitative: Provision and review of patient and provider responses to an open-ended survey regarding the proposed intervention.

Communication with the IT department via email and phone occurred and data on current pneumococcal immunization rates for patients within the target audience was made

available to the student. All data were given de-identified patient codes so as not to compromise patient confidentiality.

By the end of October 2015 the project's tactile materials were constructed to promote project awareness. Flyers on pneumococcal pneumonia and vaccine promotion in patients 65 and older were designed, printed and offered to patients during both check-in and check-out; they were also hung in patient exam rooms (Appendix F). A poster board presentation with similar information was created and placed in the office waiting room for patients to view. The office previously had vaccine information sheets available for both PCV-13 and PPSV-23 in the nursing treatment room. The DNP student collaborated with staff and was able to have materials placed in all patient exam rooms by the end of October 2015. By mid-October a PowerPoint presentation on pneumococcal pneumonia was developed and a copy of the pneumococcal pneumonia vaccine eligibility screening tool developed by the Immunization Action Coalition (2015) was printed and copied for providers and staff to review at the first educational session (Appendix G). In addition, a survey was constructed to gain feedback from attendees at the educational session (Appendix H). The survey included questions specific to the content of the DNP student's presentation and three open-ended questions pertaining to the proposed capstone as a whole.

During the early phases of implementation the company underwent a large layoff and scheduling conflicts occurred frequently due to structural changes and a need to address pressing issues within the company. As a result, the DNP student was not able to present the project as anticipated. Rather, multiple conversations were had between student and individual staff that would be affected by the project, including nurses, providers, medical assistants and secretaries. Despite ample support from key stakeholders and an overall desire within the office to improve

pneumococcal vaccination rates, mostly everyone were significantly less receptive to the idea that this would require a change in the workflow process.

At the onset of the project the DNP student had engaged in multiple conversations with the clinical nurse supervisor who was in strong support of carrying out a standing orders program; however, by the end of October she had resigned and remaining staff nurses adamantly refused to adopt the proposed project. Concerns were raised regarding recent layoffs and budget cuts placing too significant of a strain on their already understaffed team and they did not want to assume the responsibilities that came with a standing orders program. Validation of their concerns was provided and it was acknowledged that a change in project focus was necessary. In the best interest of all participants involved in the project, it was decided that the DNP student would remove the existing intervention of a standing orders program and place emphasis on the educational component of the project. By increasing the presence of informational material on pneumococcal pneumonia and available vaccinations, the hope was that immunization rates would raise.

During Intervention. During this interval the DNP student maintained supervision and offered support to patients and staff as necessary. Periodic inspection of the project site was conducted by the student to ensure that posters were visible to patients, VIS forms were consistently being offered and flyers were being offered to patients appropriately. Service utilization outputs were tracked, such as the number of materials developed for the implementation of the project and overall work flow, and a running log of project activities was maintained.

Post-intervention. Interpersonal information system outputs were requested and included all reports generated by IT. The final report was generated and supplied to the student

via email. Inputs and outputs to the service utilization plan were reviewed and quantified during this phase as necessary. This included tracking of program coverage through collection of de-identified patient data via IT to determine if the target audience had been reached successfully. Results were analyzed to determine the effectiveness and future applicability of the quality improvement project. During the months of March and April 2016 the program was evaluated and discussions regarding program intervention delivery were had between the student and project facilitators. Dissemination of project findings is projected to occur at the College of Nursing Scholarship Day, held on May 5, 2016 at the University of Massachusetts Amherst.

Project Evaluation

Data Analysis and Results

The project identified three major goals, each of which had associated objectives and specific measurable outcomes utilized to achieve the overarching goals of the project (Appendix I). Analysis and interpretation of the data collected from IT was undergone to assess whether project goals were met and complete a program evaluation.

Goal I: Identify a multidisciplinary team within primary care to design and implement a program that meets both state and federal regulatory requirements and national vaccination goals. Each of the objectives and measurable outcomes for this goal were specific to implementation of a standing orders program. Given an SOP was not successfully implemented, objectives could not be met, and this goal by default was considered unattained. However, an alternative educational program was successfully implemented.

Goal II: Ensure all eligible adults age 65 and older in primary care are effectively motivated and informed of current pneumococcal vaccination recommendations and provided an opportunity for vaccination. Again, failure to implement an SOP within the

office was a significant deterrent to satisfying all measurable outcomes of this goal. However, despite the fact that original measurable outcomes were not met, the individual objectives were; therefore, this goal was arguably achieved.

Objective i: Establish baseline data for vaccination rates of patients aged 65 and older in the practice. Baseline data was successfully obtained from IT by October 2015. From a total clinic panel of 10,601 patients, it was established that 2,049 met the inclusion criteria for the project. Of the eligible patients, 1,636 were shown to have previously received either one or both of the available pneumococcal pneumonia vaccines. This objective was successfully met.

Objective ii: Identify and eliminate missed vaccine opportunities. Although this objective was not met with regards to the specified outcome measures, the DNP student did engage in individual in-depth interviews with providers and patients during the pre-intervention phase of the project to discuss barriers to vaccination and gain feedback on why they believed opportunities were missed. Critical analysis of provider and patient responses was conducted. The two most common responses elicited from providers included frequent need to prioritize other concerns during office visits and the subsequent lack of adequate time to discuss the vaccine with their patients; however, providers expressed feeling methods to alleviate these barriers were scarce. Similarly, patients felt dependent on their providers to raise the discussion of vaccines. Lack of disease and vaccine awareness was also a major barrier identified by patients.

Objective iii: Increase patient awareness of pneumococcal disease and vaccine availability. Nearly 100% of adult patients 65 and older had flyers readily available to them at check-in. Informational flyers and an educational poster board were constructed by September 2015 and made available for patient viewing by October 2015. Additionally, patient and provider

responses to open-ended discussion yielded positive feedback. The patients approached all expressed an appreciation for the increased presence of educational material and providers noted patients inquiring about the vaccine more frequently than previously. The data was obtained sporadically and patient responses were not tracked; therefore, critical analysis of these results could not be completed.

Goal III. Reduce overall morbidity and mortality caused by pneumococcal disease among adults age 65 and older in primary care. In order to adequately assess outcomes and evaluate whether the goal was met at project completion, the DNP student requested four specific data sets from the IT department to evaluate project impact; they included (a) the total number of patient's on the clinic's panel; (b) the total number of those patients 65 years and older not new to the practice within the last three months; (c) the total number of those patients 65 years and older that have received either or both pneumococcal vaccines (PCV-13 and PPSV-23); (d) the total number of those patients 65 years and older that have not received either vaccine. IT conducted two separate reports to reflect data before and after intervention. Table 1 provides a comparative summary of results for each individual dataset before and after intervention and reveals the nearly 10% increase of cumulative vaccination rates among the target population after project implementation.

Table 1

Data Comparing Pneumococcal Vaccination Rates in Adults 65 and Older Within Primary Care Before and After an Educational Intervention

Dataset	Pre-Intervention	Post-Intervention	Cumulative % ^a	
			Pre	Post
Total # of patients in clinic	10,601	10,816		
Total # of patients \geq 65 y/o ^b	2,049	1,994		
Vaccinated ^c	1,636	1,788	79.84%	89.67%
Unvaccinated ^c	413	208		

Note. De-identified patient data collected from Reliant Medical Group, Active Patient Panel reports: November 2015 and February 2016.

^a Cumulative percentages were calculated specifically utilizing pre and post-intervention samples separately.

^b Only patients that met inclusion criteria (adults age 65 and older, not new to the practice within the previous 3 months and eligible to receive either vaccine without contraindication).

^c Total # calculated from patient sample that met inclusion criteria; these totals do not reflect the vaccination rates for the entire clinic's panel; includes both PCV-13 and PPSV-23. Individuals were counted only once as "vaccinated" regardless if they had received both or either vaccination multiple times.

Objective i: Expand immunization services. The measurable outcome for this objective aimed to have at least 75% of patient's age 65 and older complete screening and receive a pneumococcal vaccine if determined eligible under the standing orders. This outcome was realistically unattainable as an SOP was not implemented.

Objective ii: Increase the annual immunization rates of adults age 65 and older who are vaccinated against pneumonia in primary care. Primary data analysis was conducted using a chi-square test to determine whether increased patient education was directly related to increased vaccination rates. Nominal values included 1) before vs. after project intervention, and 2) how many patients were and were not vaccinated against pneumonia. Utilizing the statistics

from Table 1, results indicated there was a statistically significant relationship between patient education and rates of vaccination $\chi^2 (1) = 73.74, p < .001$.

Descriptive analysis of the February 2016 active patient report yielded clinically significant results. Approximately 1,788 (89.67%) patients age 65 and older in the primary care clinic had received either, or both, the PCV-13 and PPSV-23 vaccines, compared with 1,636 (79.84%) in November 2015 ($p < .0001$). There was an overall increase of 9.83% in cumulative vaccination rates from project baseline. Furthermore, the number of those unvaccinated was nearly cut in half after project implementation was complete (see Figure 1).

Prior to the intervention, vaccination rates for the clinic among the target population were 10.16% below *Healthy People 2020* benchmark goal of 90%; the intervention minimized that gap to only 0.33% (see Figure 2). The objective's measurable outcomes called for a 20% improvement of cumulative vaccination rates and a match to the *Healthy People 2020* goal of 90%; therefore, the objective could only be observed as partially met.

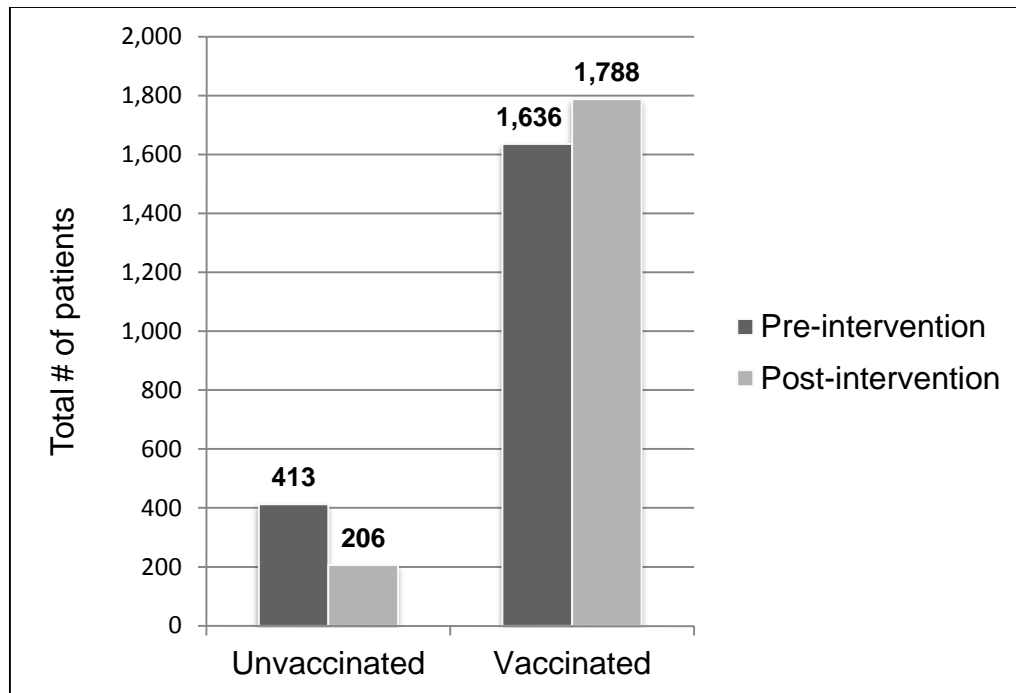


Figure 1. Patient pneumococcal vaccination status pre and post an educational intervention.

The bar graph compares pneumococcal vaccination rates among patients 65 years and older in a primary care setting. Individuals were considered vaccinated if they had received either, or both, PCV-13 and PPSV-23 and unvaccinated if they had received neither. The decrease in number of unvaccinated patients is consistent with the increase of total patients vaccinated. Relative to the sample sizes before intervention ($n=2,049$) and after intervention ($n=1,994$), there was an overall cumulative vaccination rate increase of 9.83% among the total number of eligible patients vaccinated before and after project implementation (79.84% to 89.67%, respectively).

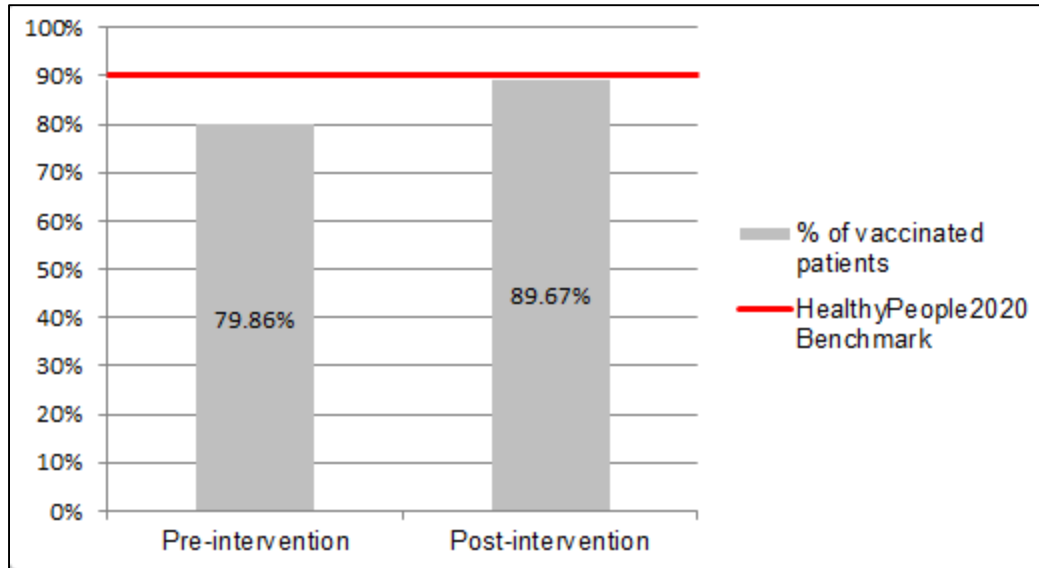


Figure 2. Pre and post intervention cumulative pneumococcal vaccination rates compared to the target goal of *Healthy People 2020*.

This bar graph is a quantitative comparison of cumulative pneumococcal vaccination rates among the sample population before and after the educational intervention was implemented. Patients included in the sample were adults 65 and older that were not new to the practice within the previous 3 months. Results clearly demonstrate the 9.8% increase from baseline. The results are displayed in relation to their achievement of Healthy People's 2020 benchmark goal of 90%, which is indicated by the red target line.

Discussion

Despite the fact that not all project objectives were met in terms of instituting standard orders the project did demonstrate the benefits of increased patient education on rates of vaccination. Although the initial goal of implementing an SOP was not achieved, the fact that an alternative educational intervention was planned and implemented in accordance with both national and state guidelines cannot be discredited. The U.S. Department of Health and Human Services (HHS) has established numerous initiatives and programs designed with the same

overarching goal in mind: strengthening adult vaccination. This project aligned specifically with objectives and indicators of Healthy People 2020 and the Agency for Healthcare Research and Quality. The project also built on existing initiatives at the state level as specified by the Massachusetts Department of Public Health (MDPH) (Executive Office of Health and Human Services, 2015). As is the case with many of state projects, development of this capstone project followed recommendations of the CDC, including implementation of measurable increases and reduction of disparities in adult immunization rates (CDC, 2015). Results of the project support previous studies that determined cumulative vaccination rates increased with the use of an educational intervention (Kemp, 2008; Yu, 2015). These successes implicate both immediate and long-term achievement of a major project goal: Reduce overall morbidity and mortality caused by pneumococcal disease in the target population.

The *Healthy People 2020* target goal of 90% vaccination in this population lay right outside of reach and suggests that sustained efforts to improve cumulative vaccination rates through patient education are necessary. However, it is of interest to note that 41 patients were excluded from the data analysis post-intervention as they were new to the practice within the previous three months. Of these, 31 were vaccinated with either, or both, PCV-13 and PPSV-23. If data were to be collected on pneumococcal vaccination rates without consideration to this exclusion criteria, the true total number of vaccinated patients 65 and older within the clinic would be 1,819 (1,788 + 31); therefore raising the clinic's cumulative vaccination rate to 91.22% and exceeding the Healthy People 2020 benchmark goal of 90%.

The project goal to expand immunization services could understandably not be met, strictly because achievement of the measurable outcome required implementation of an SOP. However, by preventing missed vaccination opportunities in the future, eliminating barriers to

immunization and increasing overall patient awareness on pneumococcal pneumonia, the project's outcomes certainly aid in the expansion and improvement of vaccination services within the primary care clinic. The project identified patient and provider barriers that were largely consistent with those identified in previous qualitative studies (Albert et al., 2012; Appel, 2011; Burns & Zimmerman, 2006; Hurley et al., 2014; Rehm, 2012; Richards et al., 2014). Furthermore, the project's findings also support the use of patient education as a quality tool for removing certain barriers (Suryadevara et al., 2013). This reinforces the notion that improved efforts to identify barriers to immunization are necessary to improve pneumococcal vaccination rates among adults 65 and older in primary care (Rehm, 2012). Further research on methods to eliminate common barriers to vaccination is necessary.

Similar to previous research findings, providers felt that the increased education resulted in more patients mentioning the vaccine during visits and patients reported feeling better informed of the disease and vaccines (Smith & Metzger, 2011; Suryadevara et al., 2013; Yu, 2015). Additionally, critical analysis of the responses clearly supported prior researcher's claims that increased presence of educational material in primary care clinics subsequently increased the amount of patients inquiring about the vaccines (Nowalk et al., 2014). It should be noted that open-ended discussion was conducted among random patients and providers and may have limited generalizability; furthermore, future studies of a similar nature would benefit from tracking the number and responses of individuals interviewed to analyze data more accurately and avoid potential threats to project validity. Regardless, the project's findings underscore the need to increase patient education on pneumococcal pneumonia and available vaccinations.

Results of this DNP project also add to existing literature suggesting that Lewin's Theory of Change can be utilized as framework to motivate acceptance of change among both patients

and providers. Lewin's theory argues that in order for change to be successful, three phases must occur: unfreezing, moving and freezing (Lewin, 1951; Lewin, 1975; Zaccagnini & White, 2014). The provider's acknowledgment of driving and restraining forces to immunization throughout the unfreezing and moving phases reminded them of the integral role they play in ensuring patients are well informed of vaccine recommendations. Of equal importance, the framework also guided patients in recognizing and accepting responsibility of their role in maintaining their health; thus improving the level of practice among both entities. The clinic has proven able to adopt Lewin's theory and could benefit from continued efforts in identifying and eliminating gaps in healthcare quality by utilizing the framework.

Study Limitations. This study was subjected to several limitations. Most significantly, the implementation of a standing orders program was unsuccessful due to changes in the workplace. The initial implementation of an SOP seemed feasible for both student and project key stakeholders but structural barriers within the company were too significant to overcome. Additionally, the loss of support from the nurse lead resulted in significant resistance from the nurses, whose participation was crucial to project success. Future studies of a similar nature would benefit from greater involvement of multidisciplinary stakeholders to act as liaisons between student and staff.

Limitations also existed within the study's methods and designs. First, the pre-post intervention design was most feasible given timing and logistical constraints; however, without follow-up it lacks the ability to evaluate long-term effectiveness of the intervention. Second, participants were recruited from a convenience sample, lacking randomization or inclusion of a control group. Inability to control variables limits the ability to make casual inferences and leaves question surrounding whether there may have been alternative explanations for the

project's outcomes. Third, being that the project was constrained to one primary care location findings may be limited in generalizability. However, comparative results to previous studies with similar patient population's leads the DNP student to speculate it was a fairly accurate depiction of the population, thus strengthening the project's external validity. Future research should consider the effect of these limitations on the study's findings and address them accordingly.

Conclusion

Primary care providers uphold a pivotal role in preventive health maintenance, including immunizations. This DNP project aimed to assess the feasibility of implementing a theory-driven, evidence-based educational intervention to increase rates of pneumococcal pneumonia in adults 65 and older within the primary care setting. Results indicated that by increasing the presence of educational material and introducing greater opportunities for patients to seek information, the DNP student was able to increase cumulative rates of pneumococcal vaccination (PCV-13 and PPSV-23) in the at risk population by nearly 10%. Furthermore, the project elicited findings supportive of previous research, indicating that educational interventions aimed at both patients and providers, are a plausible means of dismantling barriers and increasing cumulative rates of vaccination in high-risk patient populations.

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Appendix A

Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Sara Tomczyk, MSc^{1,2}, Nancy M. Bennett, MD^{3,4}, Charles Stoecker, PhD⁵, Ryan Gierke, MPH², Matthew R. Moore, MD², Cynthia G. Whitney, MD², Stephen Hadler, MD², Tamara Pilishvili, MPH² (Author affiliations at end of text)

On August 13, 2014, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of 13-valent pneumococcal conjugate vaccine (PCV13 [Pneumovax 13, Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer Inc.]) among adults aged ≥65 years. PCV13 should be administered in series with the 23-valent pneumococcal polysaccharide vaccine (PPSV23 [Pneumovax 23, Merck & Co., Inc.]), the vaccine currently recommended for adults aged ≥65 years. PCV13 was approved by the Food and Drug Administration (FDA) in late 2011 for use among adults aged ≥50 years. In June 2014, the results of a randomized placebo-controlled trial evaluating efficacy of PCV13 for preventing community-acquired pneumonia among approximately

85,000 adults aged ≥65 years with no prior pneumococcal vaccination history (CAPiTA trial) became available and were presented to ACIP (1). The evidence supporting PCV13 vaccination of adults was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and determined to be type 2 (moderate level of evidence); the recommendation was categorized as a Category A recommendation (2). This report outlines the new recommendations for PCV13 use, provides guidance for use of PCV13 and PPSV23 among adults aged ≥65 years, and summarizes the evidence considered by ACIP to make this recommendation.

Epidemiology of Pneumococcal Disease Among Adults Aged ≥65 Years

Streptococcus pneumoniae (pneumococcus) remains a leading infectious cause of serious illness, including bacteremia, meningitis, and pneumonia, among older adults in the United States. Use of a 7-valent pneumococcal conjugate vaccine (PCV7) since 2000 and PCV13 since 2010 among children in the United States has reduced pneumococcal infections directly and indirectly among children, and indirectly among adults. By 2013, the incidence of invasive pneumococcal disease (IPD) caused by serotypes unique to PCV13 among adults aged ≥65 years had declined by approximately 50% compared with 2010, when PCV13 replaced PCV7 in the pediatric immunization schedule (3). However, in 2013 an estimated 13,500 cases of IPD occurred among adults aged ≥65 years (3). Approximately, 20%–25% of IPD cases and 10% of community-acquired pneumonia cases in adults aged ≥65 years are caused by PCV13 serotypes and are potentially preventable with the use of PCV13 in this population (3,4).

PCV13 Vaccine in Adults

On December 30, 2011, PCV13 was approved for use among adults aged ≥50 years to prevent pneumonia and invasive disease caused by *S. pneumoniae* serotypes contained in the vaccine. The new use for Prevnar 13 was approved under FDA's accelerated approval pathway, which allows for earlier approval of products that provide meaningful therapeutic benefit over existing

Recommendations for routine use of vaccines in children, adolescents, and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children and adolescents are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetrics and Gynecology (ACOG). Recommendations for routine use of vaccines in adults are harmonized with recommendations of AAFP, ACOG, and the American College of Physicians (ACP). ACIP recommendations adopted by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report (MMWR). Additional information regarding ACIP is available at <http://www.cdc.gov/vaccines/acip>.

treatments for serious and life-threatening illnesses (5). FDA defined “meaningful therapeutic benefit over existing treatments” as protection of adults aged ≥ 50 years from nonbacteremic pneumococcal pneumonia or nonbacteremic pneumococcal pneumonia combined with protection from IPD (7). On June 20, 2012, ACIP recommended routine use of PCV13 for adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leak, or cochlear implants (6). The ACIP decision to recommend PCV13 use among adults aged ≥ 65 years was deferred until data became available on 1) the impact of PCV13 use in children on disease in adults (i.e., indirect effects) and 2) the efficacy of PCV13 against noninvasive pneumococcal pneumonia among adults. In accordance with accelerated approval requirements, a randomized placebo-controlled trial (CAPiTA trial) was conducted in the Netherlands among approximately 85,000 adults aged ≥ 65 years during 2008–2013 to verify and describe further the clinical benefit of PCV13 in the prevention of pneumococcal pneumonia (1). The results of the CAPiTA trial demonstrated 45.6% (95% confidence interval [CI] = 21.8%–62.5%) efficacy of PCV13 against vaccine-type pneumococcal pneumonia, 45.0% (CI = 14.2%–65.3%) efficacy against vaccine-type nonbacteremic pneumococcal pneumonia, and 75.0% (CI = 41.4%–90.8%) efficacy against vaccine-type IPD among adults aged ≥ 65 years (1).

Two randomized, multicenter, immunogenicity studies conducted in the United States and Europe among older adults showed that PCV13 induced an immune response as good as or better than that induced by PPSV23 (7,8). Functional antibody responses were measured 1 month after vaccination using an opsonophagocytic activity (OPA) assay. In adults aged 60–64 years with no prior pneumococcal vaccination, PCV13 elicited OPA geometric mean antibody titers (GMTs) to the 12 serotypes common to both vaccines that were comparable with, or higher than, responses elicited by PPSV23 (7). In adults aged ≥ 70 years who previously had been immunized with a single dose of PPSV23 ≥ 5 years before enrollment, PCV13 elicited OPA responses that were comparable with those elicited by PPSV23 for two serotypes and higher for 10 serotypes (8).

Immunogenicity studies evaluating responses to PCV7 and PPSV23 administered in series showed a better immune response when PCV7 was administered first (9–12). An evaluation of immune response after a second pneumococcal vaccination administered 1 year after the initial study doses showed that subjects who received PPSV23 as the initial study dose had lower OPA antibody responses after subsequent administration of PCV13 than those who had received PCV13 as the initial dose followed by a dose of PPSV23, regardless of the level of the initial OPA response to PPSV23 (9). Studies evaluating the immune response after a sequence of PCV7 or PCV13

What is currently recommended?

In 2010, the Advisory Committee on Immunization Practices (ACIP) approved revised recommendations that all persons should be vaccinated with 23-valent pneumococcal polysaccharide vaccine (PPSV23) at age 65 years. In 2012, ACIP made recommendations for use of 13-valent pneumococcal conjugate vaccine (PCV13) and PPSV23 for adults aged ≥ 19 years with immunocompromising conditions.

Why are the recommendations being modified now?

PCV13 was approved by the Food and Drug Administration in late 2011 for use among adults aged ≥ 50 years. In June 2014, the results of a randomized placebo-controlled trial showing efficacy of PCV13 against community-acquired pneumonia among approximately 85,000 adults aged ≥ 65 years became available and were presented to ACIP. The evidence supporting PCV13 vaccination of adults was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and determined to be type 2 (moderate level of evidence); the recommendation was designated as a Category A recommendation.

What are the new recommendations?

Both PCV13 and PPSV23 should be routinely administered in series to all adults aged ≥ 65 years. The recommendations for routine PCV13 use among adults aged ≥ 65 years will be reevaluated in 2018 and revised as needed. ACIP recommendations for routine use of PCV13 in adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leak, or cochlear implants remain unchanged.

followed by PPSV23 with intervals of 2, 6, and 12 months or 3–4 years demonstrated that after the PPSV23 dose, antibody levels were higher than the pre-PCV baseline, and a noninferior response was observed when compared with post-PCV antibody levels (9–12). None of the studies were designed to evaluate the optimal interval between vaccine doses.

Safety of PCV13 was evaluated in approximately 6,000 PPSV23-naïve and PPSV23-experienced adults aged ≥ 50 years (13). Overall incidence of serious adverse events reported within 1 month of an initial study dose of PCV13 or PPSV23 did not differ between the two vaccines and ranged from 0.2% to 1.7%. From 1 to 6 months after an initial study dose, the overall incidence of serious adverse events ranged from 1.2% to 5.8% among persons vaccinated with PCV13 and 2.4% to 5.5% among persons vaccinated with PPSV23. Rates of reported serious adverse events in the treatment groups were similar among studies that enrolled PPSV23-naïve subjects and studies that enrolled PPSV23-experienced subjects. Common adverse reactions reported with PCV13 were pain, redness, and swelling at the injection site; limitation of movement of the arm in which the injection was given; fatigue; headache; chills; decreased appetite; generalized muscle pain; and joint pain. Similar reactions were observed in adults who received PPSV23 (13).

Indirect effects from PCV13 use among children, if similar to those observed after PCV7 introduction, might further reduce the remaining burden of adult pneumococcal disease caused by PCV13-types. A preliminary analysis using a probabilistic model following a single cohort of persons aged 65 years demonstrated that adding a dose of PCV13 to the current PPSV23 recommendations for adults aged ≥ 65 years, compared with current PPSV23 recommendations, would lead to additional health benefits (14). This strategy would prevent an estimated 230 cases of IPD and approximately 12,000 cases of community-acquired pneumonia over the lifetime of a single cohort of persons aged 65 years, assuming current indirect effects from the child immunization program and current PPSV23 vaccination coverage among adults aged ≥ 65 years (approximately 60%). In a setting of fully realized indirect effects assuming the same vaccination coverage, the expected benefits of PCV13 use among this cohort will likely decline to an estimated 160 cases of IPD and 4,500 cases of community-acquired pneumonia averted among persons aged ≥ 65 years (14).

CDC will assess the implementation and impact of the recommendation for PCV13 use among adults aged ≥ 65 years, including coverage with PCV13 and PPSV23, and impact of PCV13 on vaccine-type IPD burden and community-acquired pneumonia. Monitoring disease trends among adults who do not receive PCV13 might help quantify indirect effects and the long-term utility of routine PCV13 use among adults. ACIP will be updated routinely on changes in the burden of IPD and community-acquired pneumonia among adults during the next 3 years to determine the need for revisions to the adult PCV13 recommendations.

PPSV23 in Adults

A single dose of PPSV23 is recommended for routine use in the United States among adults aged ≥ 65 years (15). Effectiveness of PPSV23 in preventing IPD in adults has been demonstrated, but the data on the effectiveness of this vaccine in preventing noninvasive pneumococcal pneumonia among adults aged ≥ 65 years have been inconsistent. PPSV23 contains 12 serotypes in common with PCV13 and 11 additional serotypes. In 2013, 38% of IPD among adults aged ≥ 65 years was caused by serotypes unique to PPSV23 (3). Given the high proportion of IPD caused by serotypes unique to PPSV23, broader protection is expected to be provided through use of both PCV13 and PPSV23 in series. ACIP considered multiple factors when determining the optimal interval between a dose of PCV13 and PPSV23, including immune response, safety, the risk window for protection against disease caused by serotypes unique to PPSV23, as well as timing for the next visit to the vaccination provider.

ACIP Recommendations for PCV13 and PPSV23 Use

Both PCV13 and PPSV23 should be administered routinely in series to all adults aged ≥ 65 years (Box).

Pneumococcal vaccine-naïve persons. Adults aged ≥ 65 years who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23. The dose of PPSV23 should be given 6–12 months after a dose of PCV13. If PPSV23 cannot be given during this time window, the dose of PPSV23 should be given during the next visit. The two vaccines should not be coadministered, and the minimum acceptable interval between PCV13 and PPSV23 is 8 weeks.

Previous vaccination with PPSV23. Adults aged ≥ 65 years who have previously received ≥ 1 doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. A dose of PCV13 should be given ≥ 1 year after receipt of the most recent PPSV23 dose. For those for whom an additional dose of PPSV23 is indicated, this subsequent PPSV23 dose should be given 6–12 months after PCV13 and ≥ 5 years after the most recent dose of PPSV23 (15).

Potential Time-Limited Utility of Routine PCV13 Use Among Adults ≥ 65 Years. The recommendations for routine PCV13 use among adults aged ≥ 65 years will be reevaluated in 2018 and revised as needed.

ACIP recommendations for routine use of PCV13 in adults aged ≥ 19 years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leak, or cochlear implants remain unchanged (6).

Coadministration with Other Vaccines

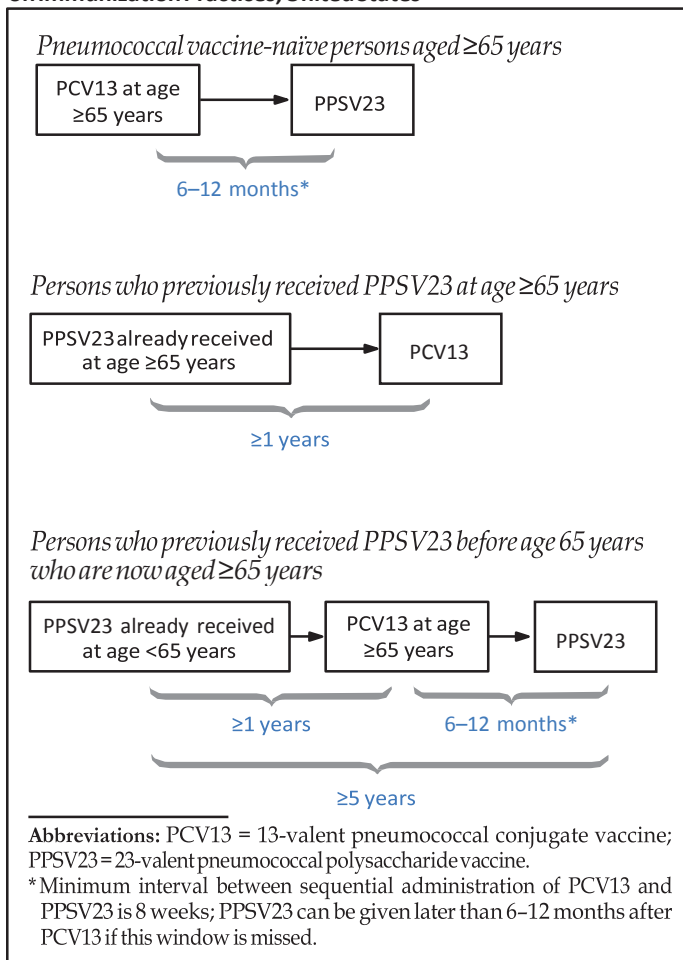
Concomitant administration of PCV13 and trivalent inactivated influenza vaccine (TIV) has been demonstrated to be immunogenic and safe. PCV13 can be coadministered with TIV in an adult immunization program. However, a randomized double-blind trial found slightly lower pneumococcal serotype-specific geometric mean concentrations and lower proportion achieving at least a fourfold rise in hemagglutination inhibition assay titer for one of three influenza subtypes (influenza A[H3N2]) with PCV13 plus TIV compared with PCV13 alone or TIV alone among adults aged ≥ 65 years (16). Currently, no data are available on coadministration with other vaccines (e.g., tetanus, diphtheria, and acellular pertussis vaccine or zoster vaccine) among adults.

Precautions and Contraindications

Before administering PCV13, vaccination providers should consult the package insert for precautions, warnings, and contraindications. Vaccination with PCV13 is contraindicated in persons known to have a severe allergic reaction (e.g., anaphylaxis) to any component of PCV13 or PCV7 or to any diphtheria toxoid-containing vaccine.

Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax,

BOX. Sequential administration and recommended intervals for PCV13 and PPSV23 for adults aged ≥ 65 years — Advisory Committee on Immunization Practices, United States



or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (<http://vaers.hhs.gov>).

Acknowledgments

ACIP members (membership roster for July 2014–June 2015 available at <http://www.cdc.gov/vaccines/acip/committee/members-archive.html>). ACIP Pneumococcal Work Group.

¹Epidemic Intelligence Service, CDC; ²National Center for Immunization and Respiratory Diseases, CDC; ³Pneumococcal Vaccines Working Group, Advisory Committee on Immunization Practices; ⁴School of Medicine and Dentistry, University of Rochester Medical Center, Rochester, New York; ⁵Department of Global Health Systems and Development, Tulane University of Public Health and Tropical Medicine, New Orleans, Louisiana (Corresponding author: Tamara Pilishvili, tdp4@cdc.gov, 404-639-3585)

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Announcement

Now Available Online: Final 2013–14 Influenza Vaccination Coverage Estimates for Selected Local Areas, States, and the United States

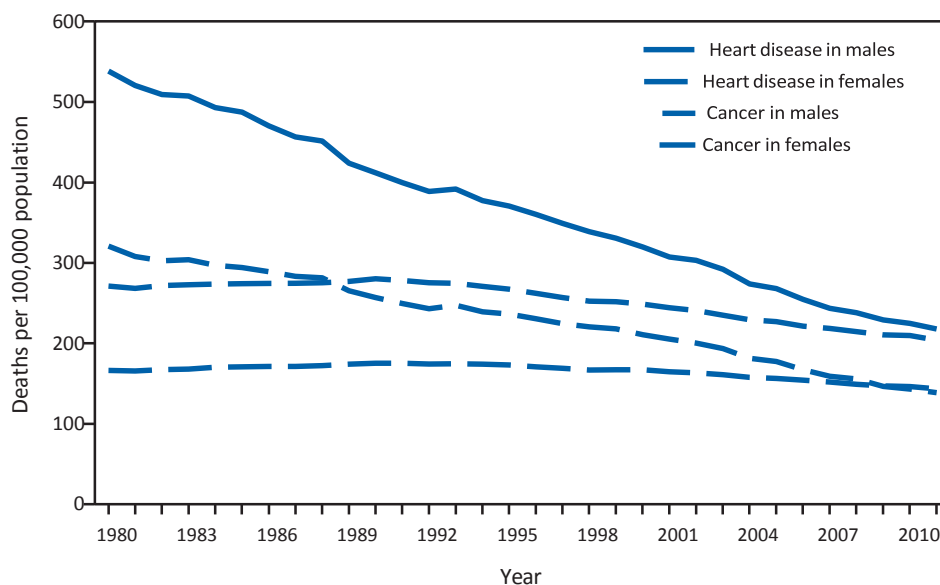
Final 2013–14 influenza season vaccination coverage estimates are now available online at FluVaxView (<http://www.cdc.gov/flu/fluview>). The online information includes estimates of the cumulative percentage of persons vaccinated by the end of each month, from July 2013 through May 2014, for select local areas, each state, each U.S. Department of Health and Human Services region, and the United States overall.

Analyses were conducted using National Immunization Survey influenza vaccination data for children aged 6 months–17 years and Behavioral Risk Factor Surveillance System data for adults aged ≥ 18 years. Estimates are provided by age group and race/ethnicity. These estimates are presented in an interactive report (<http://www.cdc.gov/flu/fluview/interactive.htm>) and complemented by an online summary report (<http://www.cdc.gov/flu/fluview/coverage-1314estimates.htm>).

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Age-Adjusted Death Rates* for Heart Disease and Cancer,[†] by Sex — United States, 1980–2011



* Per 100,000 population.

[†] As the underlying cause of death, heart disease is coded as 390–398, 402, and 404–429 for the period 1980–1998, and I00–I09, I11, I13, and I20–I51 for 1999–2011. As the underlying cause of death, cancer is coded as 140–208 for the period 1980–1998 and C00–C97 for 1999–2011, based on the *International Classification of Diseases, Ninth and Tenth Revisions*.

During 1980–2011, age-adjusted death rates for heart disease in males and females decreased steadily. The rate decreased 59.5% for males and 56.8% for females. In contrast, the rate from cancer first increased 3.4% for males and 5.3% for females during 1980–1990 and then decreased 27.2% for males and 18.0% for females by 2011. For females, the rates for cancer (147.4 per 100,000 population) surpassed the rates for heart disease (146.6) in 2009. The death rate for heart disease in males remained slightly higher (218.1) than the death rate for cancer (204.0) in 2011.

Source: National Vital Statistics System. Mortality public use data files, 1980–2011. Available at http://www.cdc.gov/nchs/data_access/vitalstatsonline.htm.

Reported by: Jiaquan Xu, MD, jax4@cdc.gov, 301-458-4086.

Appendix B

Standing Orders for Administering Pneumococcal (PPSV23 and PCV13) Vaccine to Adults

Purpose: To reduce morbidity and mortality from pneumococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet any of the criteria below.

Procedure

1. Identify adults in need of vaccination with pneumococcal conjugate vaccine (PCV13) based on the following criteria:
 - a. Age 65 years or older with no or unknown history of prior receipt of PCV13
 - b. Age 19 through 64 years with no or unknown history of prior receipt of PCV13 and any of the following conditions:
 - i. candidate for or recipient of cochlear implant; cerebrospinal fluid leak
 - ii. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - iii. immunocompromising condition (e.g., HIV infection, congenital immunodeficiency, hematologic and solid tumors)
 - iv. immunosuppressive therapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids, radiation therapy)
 - v. organ or bone marrow transplantation; chronic renal failure or nephrotic syndrome
2. Identify adults in need of vaccination with pneumococcal polysaccharide vaccine (PPSV23) based on the following criteria:
 - a. Age 65 years or older with no or unknown history of prior receipt of PPSV23
 - b. Age 19 through 64 years with no or unknown history of prior receipt of PPSV23 and any of the following conditions:
 - i. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
 - ii. chronic pulmonary disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma)
 - iii. diabetes mellitus, alcoholism or chronic liver disease (cirrhosis), cigarette smoker
 - iv. any of the conditions specified in categories 1.b. above
3. Identify adults in need of an additional dose of PPSV23 if 5 or more years have elapsed since the previous dose of PPSV23 and the patient meets one of the following criteria:
 - a. Age 65 years or older and received prior PPSV vaccination before age 65 years
 - b. Age 19 through 64 years and at highest risk for serious pneumococcal infection or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories 1.b.ii.–1.b.v. above)
4. Screen all patients for contraindications and precautions to pneumococcal vaccine:
 - a. **Contraindication:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of pneumococcal vaccine (PPSV or PCV13) or to a vaccine component. For a information on vaccine components, refer to the manufacturer's package insert (www.immunize.org/package-inserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precaution:** moderate or severe acute illness with or without fever
5. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). While only the VIS for PCV13 is required by federal law, it is prudent to also provide the VIS for PPSV23 to patients receiving PPSV23. For both vaccines, document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
6. Administer vaccine as follows:
 - a. For adults identified in 1. above, administer 0.5 mL PCV13 intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
 - b. For adults identified in 2. and 3. above, administer 0.5 mL PPSV23 vaccine either intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle or subcutaneously (23–25g, 5/8" needle) in the posterolateral fat of the upper arm.
 - c. For adults in need of both PCV13 and PPSV23, administer PCV13 first, followed by PPSV23 in 6–12 months. (Note: for adults with immunocompromising conditions or functional or anatomic asplenia, give PPSV23 8 weeks following PCV13.) If previously vaccinated with PPSV23, give PCV13 at least 12 months following PPSV23. Do not give PCV13 and PPSV23 at the same visit.

(Note: A 5/8" needle may be used for IM injection for patients who weigh less than 130 lbs [60kg] for injection in the deltoid muscle, only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle.)

- 7. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
- 8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical proto- col available, as well as equipment and medications.
- 9. Report all adverse reactions to PPSV23 and PCV13 to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Disease Control and

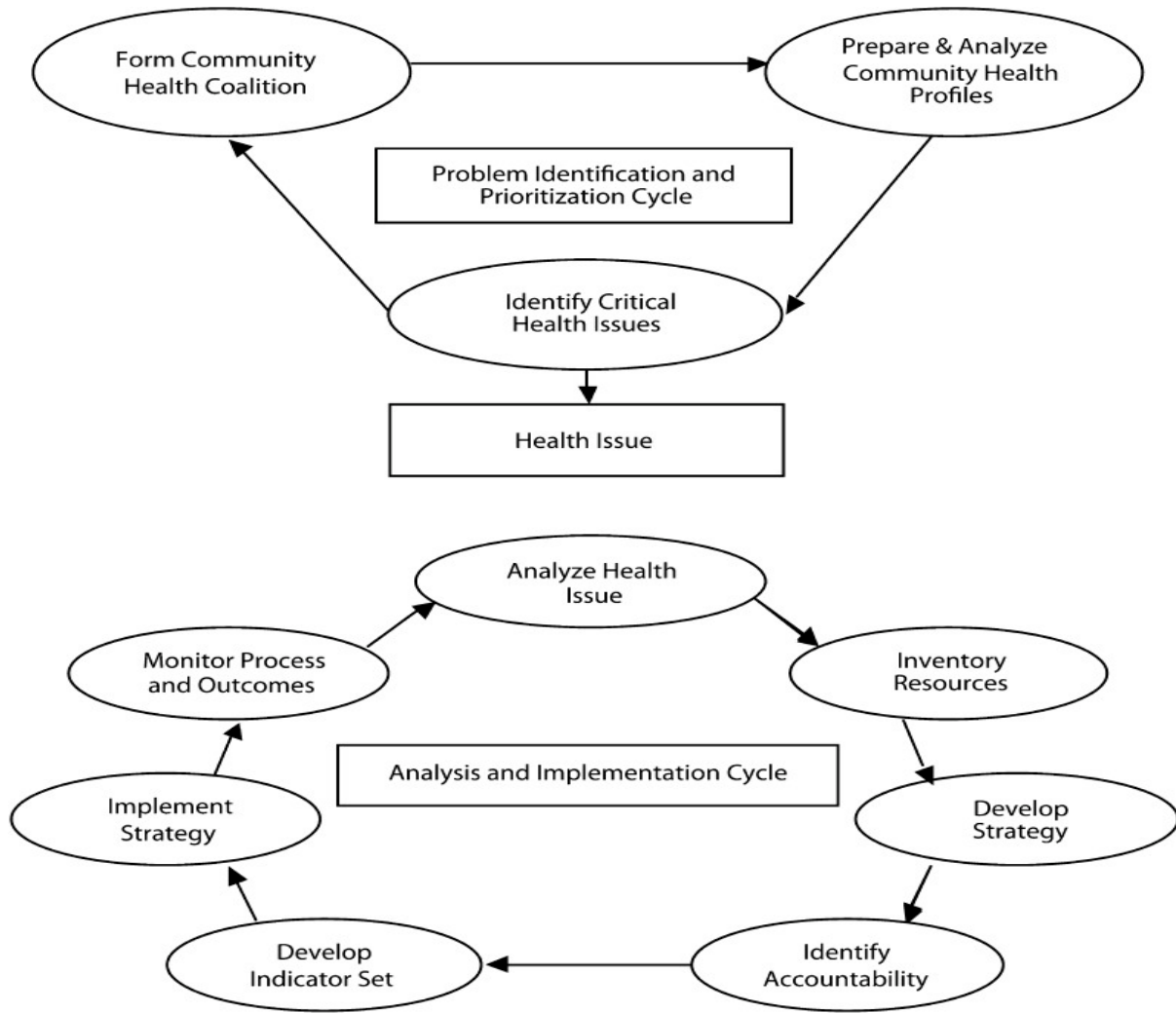
Technical content reviewed by the Centers for Prevention

Immunization Action Coalition Saint Paul, Minnesota · 651-647-9009 · www.immunize.org · www.vaccineinformation.org

www.immunize.org/catg.d/p3075.pdf · Item #P3075 (10/14)

Appendix C

Community Health Improve Process (CHIP)



Adapted from “Improving Health in the Community: A Role for Performance Monitoring,” by J.S. Durch, L.A. Bailey, and M.A. Stoto, 1997, *International Journal of Health Planning and Management*, 13(2), p. 191-192. Copyright 1997 by the National Academy Press.

Appendix D

**University of Massachusetts Amherst**

108 Research Administration Building
70 Butterfield Terrace
Amherst, MA 01003-9242

**Human Research Protection Office
Research Affairs**

Telephone: 545-3428
FAX: 577-1728

MEMORANDUM

To: Jessica Valletta
From: Human Research Protection Office
Date: September 21, 2015

Project Title: Improving Pneumonia Vaccination Rates in Older Adults: Implementation of Standing Orders Program

IRB Number: 15-011

The Human Research Protection Office (HRPO) has evaluated the above named project and has made the following determination:

- The activity does not involve research that obtains information about living individuals.
- The activity does not involve intervention or interaction with individuals OR does not use identifiable private information.
- The activity is not considered research under the human subject regulations. (Research is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge.")
- The activity is determined to meet the definition of human subject research under federal regulations, but may qualify for exemption. If uncertain as to whether the scope of the research falls within an exempt category, please contact the HRPO for guidance. Exempt determinations must be made by the IRB.
- The activity is determined to meet the definition of human subject research under federal regulations and is not exempt. The research must be reviewed and approved by the IRB and requires submission of applicable materials.

Information regarding Types of Review for human subject research protocols may be found at <http://www.umass.edu/research/irb-guidelines-levels-review>

For additional information, please contact the Human Research Protection Office at 545-3428.

Cc: OGCA

Appendix E

Flow Chart of Program Processes

Educate Key Stakeholders

- **Provide project manager and site chief with cost/benefit analyses**
- **Conduct educational/training session with staff/providers**
- **PowerPoint presentation on pneumococcal pneumonia, benefits to vaccination and the benefits to the proposed project**
- **Increase providers awareness of ACIP recommended standing orders for PPSV-23/PCV-13 vaccines; offer copy**
- **Post-educational session surveys, including open-ended questions, to assess opinions and willingness to participate**
- **Address potential barriers and methods to eliminate them**
- **Remain available to address questions/concerns of staff/providers**

**Promote Project Awareness Among Patients**

- **Provide patients with Vaccine Information Sheets**
- **Hang and distribute flyers with pertinent information regarding pneumococcal pneumonia and the importance of vaccination**
- **Encourage providers and staff to educate patients on pneumococcal pneumonia and vaccination during any available and appropriate opportunity**

**Implement/Evaluate Intervention**

- **Gather and analyze pre/post-intervention de-identified data on pneumococcal vaccination rates among target population**



Assess program effectiveness and future applicability; share findings with key stakeholders and student's capstone committee

Appendix F

Pneumococcal Disease: Are You and Your Loved Ones Protected?

What Is Pneumococcal Disease?

Pneumococcal disease is one of the leading causes of death throughout the world. It is an easily transmitted, significantly infectious illness cause by a common bacteria *pneumococcus*, and results in massive expense, complications (i.e. pneumonia, meningitis or sepsis) and

death every year in the U.S. (American Lung Association [ALA], 2010). Nearly **one million** people will develop pneumococcal pneumonia in the U.S. in the next year and 5 to 7 percent of them will die; the death rate is even higher in adults 65 years of age and older.

*Pneumococcal disease claims the lives of **one in every four to five** people over the age of 65 that contracts it.*

Did You Know?

Adults 65 and older are at a higher risk.

As humans age our immune defenses become weaker, making us more susceptible to illnesses such as pneumonia. Patients suffering from chronic diseases are further limited in their ability to fight infection and suffer a greater risk for potential complications. According to

the CDC (2011), 80% of older adults are diagnosed with a chronic illness and 50% with two or more.

FAST FACT:

Patients 65 and older have the highest expenditures of pneumonia among all age groups in the U.S.

Why Vaccinate?

...

Getting vaccinated is the **most effective and safest way to protect yourself and your loved ones.**

Many studies have demonstrated pneumococcal vaccination to effectively protect against invasive and noninvasive pneumococcal disease.

Vaccines aid in protecting your body against various strains of bacteria.

There are two currently recommended vaccines for older adults:

- Pneumococcal Polysaccharide (PPSV23)
- Pneumococcal Conjugate (PCV13)

Some strains of pneumococcal are resistant to antibiotics, making infections difficult to treat.

Prevention through
vaccination

Appendix G

Screening Checklist for Contraindications to Vaccines for Adults

For patients: The following questions will help us determine which vaccines you may be given today. If you answer “yes” to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Are you sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Do you have allergies to medications, food, a vaccine component, or latex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you ever had a serious reaction after receiving a vaccination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Have you had a seizure or a brain or other nervous system problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. For women: Are you pregnant or is there a chance you could become pregnant during the next month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Have you received any vaccinations in the past 4 weeks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form completed by: _____ Date: _____
 Form reviewed by: _____ Date: _____

Did you bring your immunization record card with you? **yes** **no**

It is important for you to have a personal record of your vaccinations. If you don't have a personal record, ask your healthcare provider to give you one. Keep this record in a safe place and bring it with you every time you seek medical care. Make sure your healthcare provider records all your vaccinations on it.

Information for Health Professionals about the Screening Checklist for Contraindications To Vaccines for Adults

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references listed at the bottom of this page.

1. Are you sick today? [all vaccines]

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events (1). However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as upper respiratory infections or diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Do you have allergies to medications, food, a vaccine component, or latex? [all vaccines]

If a person has anaphylaxis after eating gelatin, do not administer MMR or varicella vaccine. A local reaction to a prior vaccine dose or vaccine components (e.g., latex) is not a contraindication to a subsequent dose or vaccine containing that component. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf. For an extensive list of vaccine components, see reference 2.

An egg-free recombinant influenza vaccine (RIV3) may be used in people age 18 years and older with egg allergy of any severity who have no other contraindications. People younger than age 18 years who have experienced a serious systemic or anaphylactic reaction (e.g., hives, swelling of the lips or tongue, acute respiratory distress, or collapse) after eating eggs can usually be vaccinated with inactivated influenza vaccine (IIV); consult ACIP recommendations (see reference 3).

3. Have you ever had a serious reaction after receiving a vaccination? [all vaccines]

History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses (1). Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder? [LAIV]

The safety of intranasal live attenuated influenza vaccine (LAIV) in people with these conditions has not been established. These conditions, including asthma in adults, should be considered precautions for the use of LAIV.

5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? [LAIV, MMR, VAR, ZOS]

Live virus vaccines (e.g., LAIV, measles-mumps-rubella [MMR], varicella [VAR], zoster [ZOS]) are usually contraindicated in immunocompromised people. However, there are exceptions. For example, MMR vaccine is recommended and varicella vaccine should be considered for adults with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/ μ L. Immunosuppressed people should not receive LAIV. For details, consult the ACIP recommendations (1, 4, 5).

6. In the past 3 months, have you taken medications that weaken your immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments? [LAIV, MMR, VAR, ZOS]

Live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement (1, 3). To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see reference 6. LAIV can be given only to healthy non-pregnant people younger than age 50 years.

7. Have you had a seizure or a brain or other nervous system problem? [influenza, Td/Tdap]

Tdap is contraindicated in people who have a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years. An unstable progressive neurologic problem is a precaution to the use of Tdap. For people with stable neurologic disorders (including seizures) unrelated to vaccination, or for people with a family history of seizure, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with the following: 1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap; 2) Influenza vaccine (IIV/LAIV): if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccinate with IIV if at high risk for severe influenza complications.

8. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? [LAIV, MMR, VAR]

Certain live virus vaccines (e.g., LAIV, MMR, VAR, ZOS) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines. (1)

9. For women: Are you pregnant or is there a chance you could become pregnant during the next month? [MMR, LAIV, VAR, ZOS]

Live virus vaccines (e.g., MMR, VAR, ZOS, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, inactivated poliovirus vaccine should not be given during pregnancy; however, it may be given if risk of exposure is imminent and immediate protection is needed (e.g., travel to endemic areas). Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester. (1, 3, 4, 5, 7, 8)

10. Have you received any vaccinations in the past 4 weeks?

[LAIV, MMR, VAR, yellow fever] People who were given either LAIV or an injectable live virus vaccine (e.g., MMR, VAR, ZOS, yellow fever) should wait 28 days before receiving another vaccination of this type. Inactivated vaccines may be given at any spacing interval if they are not administered simultaneously.

References:

1. CDC. General recommendations on immunization, at www.cdc.gov/vaccines/pubs/acip-list.htm
2. Table of Vaccine Components: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/exciipient-table-2.pdf.
3. CDC. Prevention and control of seasonal influenza with vaccines: Recommendations of the ACIP—2014–2015 Influenza Season at www.cdc.gov/mmwr/pdf/wk/mm6332.pdf, pages 691–7.
4. CDC. Measles, mumps, and rubella—vaccine use and strategies for elimination of measles, rubella, and congenital rubella syndrome and control of mumps. *MMWR* 1998; 47 (RR-8).
5. CDC. Prevention of varicella: Recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2007; 56 (RR-4).
6. Tomblyn M, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic stem cell transplant recipients: a global perspective. *Biol Blood Marrow Transplant* 15:1143–1238; 2009 at www.cdc.gov/vaccines/pubs/hematocell-transplts.htm.
7. CDC. Notice to readers: Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. *MMWR* 2001; 50 (49).
8. CDC. Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants: Recommendations of the ACIP. *MMWR* 2008; 57 (RR-4).

Appendix H

**Educational Component #1: Post-session
Questionnaire**

Thank you for taking a few moments of your time to complete the brief questionnaire below. Your honest feedback is encouraged and **extremely valuable**; it ensures successful implementation of a project that will address your needs, while also providing long-term benefits to both the office and its valued patients.

Please rate the following statements on the extent to which you agree or disagree:

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The material presented during this session was educational and applicable to my job.					
The information increased my awareness of how significant the problem of suboptimal pneumococcal vaccination rates is.					
The student clearly identified the problem and proposed intervention for addressing the problem.					
I think a Standing Orders Program will help to increase rates of pneumococcal vaccination amongst our patients 65 and older.					
I am confident that staff will be able to successfully implement a Standing Orders Program.					
Patients will be receptive to this project.					

1.) What, if any, are your concerns regarding the proposed intervention?

2.) Do you feel that a Standing Orders Program will work effectively at your site? Why or why not?

3.) Please provide any feedback that you believe will be beneficial in making this project a success for the staff, patients and student:

Appendix I

Goals and Objectives of Proposed Capstone Intervention

Goal I. Identify a multidisciplinary team within primary care to design and implement a program that meets both state and federal regulatory requirements and national vaccination goals.

Objective	Outcome Measures
<p>i. Increase staff and provider awareness of the significance of the problem (i.e. suboptimal pneumococcal vaccination rates among adults 65 and older) and justify the need for the chosen intervention.</p>	<p>a. An educational session/practice meeting will be conducted within the first 1-2 weeks of the semester (middle to end of September).</p> <p>b. A post-educational session questionnaire will be distributed to staff to determine if the presentation was successful in achieving this objective. At least 80% of participants will provide feedback.</p> <p>a. A practice meeting will be conducted within the first week of student beginning final capstone rotation; at the close of the meeting 90% of participants will be educated on HCP, system and patient barriers previously identified by the student in current evidence-based research.</p>
<p>ii. Increase provider and staff awareness of potential barriers to achieving targeted vaccination rates</p>	<p>b. A survey will be conducted at the end of the meeting – at least 60% of providers and staff will agree that a SOP can help alleviate at least one barrier.</p> <p>a. 90% of the practice’s providers (MDs and NPs) and clinical staff will be provided a copy of the Immunization Action Coalition’s standing orders for administration of PPSV23 and PCV13 to adults.</p>
<p>iii. Increase provider and staff awareness of recommendations and regulations regarding SOPs for vaccines</p>	<p>b. 90% of providers and staff will provided a copy of the Massachusetts Department of Public Health – Model Standing Orders for both PPSV23 and PCV13.</p> <p>c. 90% of providers will be informed of the recommendations by Advisory Committee on Immunization Practices (ACIP) and Centers for Medicare and Medicaid on the use of SOPs.</p> <p>a. 80% of key stakeholders will attend two separate educational sessions between 9/9 and 11/1 that will address all components of objective.</p>
<p>iv. Increase pertinent stakeholder’s knowledge of project’s key components, including the following secondary objectives:</p> <p>iv-1.1 Immunization practices</p> <p>iv-1.2 <i>HealthyPeople 2020</i> objectives</p> <p>iv-1.3 CDC eligibility criteria for</p>	<p>b. At the end of the in-service a post-session questionnaire will be distributed; at least 80% of attendees will complete it.</p> <p>a. An SOP will be implemented by November 2nd, 2015.</p>

<p>PPSV23 and PCV13 vaccines</p> <p>iv-1.4 Core concepts of disease risk criteria for target population</p> <p>iv-1.5 Utilization and analysis of patient data in EHR</p> <p>iv-1.6 Vaccine order procedures.</p>	
<p>iv. Establish, implement and evaluate a standing orders program that will be utilized and accessible by appropriate key stakeholders.</p>	<p>b. By Spring 2016, at least 60% of providers and staff will express willingness to utilize SOPs in the future.</p>

Goal II. Ensure all eligible adults age 65 and older in primary care are effectively motivated and informed of current pneumococcal vaccination recommendations and provided an opportunity for vaccination.

Objective	Outcome Measures
<p>i. Establish baseline data for vaccination rates of patients aged 65 and older in the practice</p>	<p>a. Baseline data will be gathered and reviewed prior to the 2015-2016 influenza season</p>
<p>ii. Identify and eliminate missed vaccination opportunities</p>	<p>a. By 10/15/15, 75% of providers will assess their schedule for a previous work week and identify at least 3 patients that were due for a pneumococcal vaccine but it wasn't discussed</p> <p>b. Providers will report discussing pneumococcal vaccination with at least 75% of eligible patients by the end of the 2015-2016 influenza season</p> <p>c. 60% of providers will report assessing and discussing vaccination status at every clinical encounter</p>
<p>iii. Increase patient awareness of pneumococcal disease and vaccine availability.</p>	<p>a. 90% of adult patients 65 and older or their patient representatives will be provided a flyer and screening tool on pneumococcal disease and vaccination upon check-in.</p> <p>b. Flyers will be hung in all exam rooms by the end of September 2015</p> <p>c. An educational poster regarding pneumococcal disease and vaccination will be hung in the waiting room by the end of September 2015</p>

Goals Related to Population

Goal III. Reduce overall morbidity and mortality caused by pneumococcal disease among adults age 65 and older in primary care.

Objective	Outcome Measures
i. Expand immunization services	a. At least 75% of patients age 65 and older will complete screening and be administered a pneumococcal vaccine if determined to be eligible.
ii. Increase the annual immunization rates of adults age 65 and older who are vaccinated against pneumonia in primary care.	a. In line with <i>HealthyPeople 2020</i> , a target 90% of the practice's patients aged 65 and older will have received a pneumococcal vaccination by the end of the 2015-2016 influenza season.
	b. Improve practice's pneumococcal vaccine coverage by at least 20% before the end of the 2015-2016 influenza season