

**Pfizer Medical Education Group
HEALTHY PEOPLE 2020**

**Grant Proposal by
University of Connecticut School of Pharmacy
&
Yale-New Haven Hospital**

Overall Goal & Objectives

S. pneumoniae is the most common cause of pneumonia (community acquired) with 15% of patients developing invasive disease. In the US in 2010, invasive pneumococcal infection caused an estimated 4,000 deaths. As studies have shown, a sizable portion of hospital admissions, and the associated morbidity and mortality are potentially preventable through vaccination. Currently, administration of the pneumococcal vaccine is suboptimal despite efforts to increase vaccination rates in both outpatient and inpatient settings.

In order to meet Centers for Medicare & Medicaid Services (CMS) pneumococcal immunization measure, IMM-1, which mirrors the goals of Healthy People 2020, Yale-New Haven Hospital (YNHH) has created a systematic approach to identify and vaccinate all patients that meet the criteria set by CMS. Although this approach has captured more at-risk patients in need of vaccination, vaccination rates have only marginally increased due to high patient refusal rates (40%). Therefore, the objective of this study is to identify reasons why patients decline the pneumococcal vaccine. Following the identification of the reasons why patients refuse the pneumococcal vaccine, the goal is to implement formalized strategies to increase the rate of patient's acceptance to receive the pneumococcal vaccine. These strategies may include targeted education for health-care professionals on why patients refuse pneumococcal vaccination and tools to help health-professionals mitigate the reasons for vaccine refusal. Additionally, patient education efforts will be tailored to the patient's reason for refusal.

Technical Approach

Currently, YNHH has a pharmacy and therapeutic committee approved protocol for a pharmacist and nurse driven pneumococcal vaccination process. At-risk patients for vaccination are identified by the Advisory Committee on Immunization Practices (ACIP) and the CMS IMM-1 measure specifications. The current protocol at YNHH is highly effective at identifying at risk patients with greater than 99% of these patients receiving an order for pneumococcal vaccination.

Overall compliance with the CMS IMM-1 vaccine measure at YNHH is approximately 80%. This includes 40% of patients who are documented as having refused, 30% who receive vaccination and 10% who have documentation of prior receipt of the vaccine. The refusal rate of 40% adversely impacts meeting the Department of Health and Human Services (HHS) Healthy People 2020 goal of achieving a 90% vaccination rate for adults greater than 65 years of age and a vaccination rate greater than 60% in high risk adults between the ages of 18 and 64.

In order to reach the Healthy People 2020 goal, YNHH will need to improve vaccination rates among the significant percentage of patients who currently decline the pneumococcal vaccination when offered. After analysis of why patients decline pneumococcal vaccination, targeted education will be developed for health care professionals and patients. Upon successful implementation of these strategies at YNHH they will be extended to the entire Yale-New Haven Health-System, which includes Greenwich Hospital, Bridgeport Hospital, and St. Raphael's campus at YNHH.

The strategies developed in the Yale-New Haven Hospital initiative will be incorporated into the certification process of pharmacist immunizers as part of the currently available certificate program, "Immunization Training for Pharmacists". The certificate program will be conducted by The University of Connecticut School of Pharmacy, is an accredited ACPE provider of continuing pharmacy education. In addition to training current pharmacists, this certification will be integrated into the University of Connecticut School of Pharmacy's curriculum. A toolkit of the strategies developed from this initiative will be disseminated via the school's Continuing Education website for continuing education credit. The state of Connecticut requires all pharmacist immunizers to obtain continuing education in immunizations annually.

Current Assessment of need in target area

Compliance with CMS IMM-1 measure was used to estimate overall pneumococcal vaccine in our overall patient population. The first quarter of 2012 (January to March) the overall compliance rate with pneumococcal vaccination was 61%. The rate of vaccination in the patient population age 65 and older was 73% and the rate in patients less than 65 with a risk factor was 47%. Both of these individual vaccination rates are suboptimal compared to the Healthy People 2020 objective.

Since compliance with the CMS goal includes patient refusal of vaccination as meeting the CMS measure, a more in depth review of the vaccination process was initiated. A retrospective chart review of all orders entered into the electronic medical record during May, June and July was performed. Over that quarter, 3122 pneumococcal vaccine orders were entered on high-risk patients. High risk patients, consistent with the CMS and ACIP definitions are those patients who are greater than 65 years of age, immunosuppressed (i.e. HIV), smokers, live in an extended care facility, diagnosed with

diabetes, COPD/asthma, liver disease, congested heart failure, chronic kidney disease, and sickle cell. Of the 3122 orders, 39.5% were documented as patient refused vaccination; 30.5% were documented as patient received vaccination; and 12.6% had previously received vaccination. While the compliance rate for the CMS IMM-1 measure improved to 82.6%, this includes a 40% rate of patient refusal. Consequently, we have identified that the one of the greatest barriers to achieving the Healthy People 2020 goal is patient refusal of pneumococcal vaccination. Therefore, this group of patients is our target population for this proposed study.

The primary audience targeted for this intervention is all patients identified by the ACIP and CMS IMM-1 measure, based on their risk factors, age, and vaccination history. In the inpatient setting the following patient care units will be excluded: intensive care, psychiatric, maternity, and pediatric and all other patient units will be included. The target hospital clinics will be the primary care center (PCC), Women's Center, Yale Medical Group, Transplant Clinic, and Winchester Chest Center. These diverse areas will represent the patient population from which the reasons for refusal will be identified. Following analysis of why patients refuse vaccination, targeted interventional strategies will be implemented in the above inpatient and outpatient areas. After successful application of these interventions at YNHH, it will be extended to the entire YNNH health-system. The formalized strategies and resources created will be disseminated by the University of Connecticut School of Pharmacy through continuing education activities. Additionally our study of the interventions will be submitted to a peer review journal for national and international audiences.

Intervention Design and Methods

This project builds upon our prior development of a pharmacist and nurse driven protocol for pneumococcal vaccination during their hospital admission or clinic visit. Given the high rate of vaccine declination, an intervention focused on identifying the reasons for vaccine refusal and education to eliminate these barriers is the next logical step in achieving the HHS Healthy People 2020 objective for patients cared for at YNHH.

The project will require multiple sequential phases to develop the targeted interventions in order to reduce the rate of vaccine refusal. The first phase is to identify reasons for patient refusal. Phase II will utilize the analysis of phase I data to educate both health-care providers and patients in order to reduce the rates of vaccine refusal. During phase III and IV, the education and strategies will be expanded to the other YNHH hospitals, state of Connecticut as a whole and national/international audience.

Evaluation Design

The practice gap will be determined via the identification of at-risk patients who refuse pneumococcal vaccination during their most recent visit to the clinic or hospital. Vaccine refusals will be documented in the patients' electronic medical record by a nurse, physician, pharmacist, or licensed practical nurse (LPN) offering the vaccine. A daily report of patients who refused will be run by a pharmacist and LPNs via the vaccine charting documentation in the electronic medical record. For both inpatient and outpatient, the pharmacist and LPNs will verify that these patients meet the criteria set by ACIP and CMS and are not excluded due to their location (i.e. patient was transferred to an ICU). In both settings, the number of new patients identified daily will be documented in an excel file for data

collection purposes. Each month a report will be generated of the number of refusals, which will be compared to the number of vaccines administered that month. This will quantify the number of refusals and help identify the target gap that needs assessment.

The study will require a minimum of 70 patients in the intervention phase to confirm a statistically significant reduction of 70% in the refusal rate with an 80% power and alpha value of 0.05. A multivariate analysis will be done to assess predictors and reasons for decline. This will aid in identify which types of patients are more likely to refuse and their reason for refusal.

The target audience of our intervention is the 40% of patients that initially refuse to receive the pneumococcal vaccine. We expect to see a 70% decrease in these refusal rates from baseline.

We will determine if the target audience, those who initially refused the vaccine, was fully engaged by their acceptance or refusal to receive vaccine at the end of our intervention. Each patient will be asked a standard set of questions identifying the reason for their refusal. Based on the patient's reason a direct response educating the patient will be provided in effort to overcome their concerns. At the end, the patient will be asked whether they are willing to receive the vaccine and their response will be an assessment of the effectiveness of our intervention and their engagement through out the process.

The success of this intervention at YNHH will result in application of the project throughout the Yale-New Haven Health-System (YNHHS) which includes Bridgeport Hospital, St Rafael's and Greenwich Hospital. Moreover, the results and toolkit information will also be disseminated throughout the country by submission of the manuscript in national journal publications. The American Pharmacist Association has a strong interest in pharmacist immunizations and the Journal of the American Pharmacist Association (JAPhA) will be a primary target for publication.

Detailed Workplan

During phase I, in order to assess the reason for refusal, a standardized questionnaire will be created by the study team members. The questions will be extrapolated from the most common reasons for patient refusal encountered by the LPNs during their routine vaccination. These questions will then be validated on the first 30 patients who have documented refusals in the electronic medical record. The questionnaire will include basic patient characteristics (age, gender, ethnicity) level of education, their area of residence (zip code), patient's knowledge of the pneumococcal vaccine, patient's knowledge of pneumonia, patient's opinion of whether they are at risk for developing pneumonia, reason(s) why they are refusing the vaccine. A one-on-one interview between the study team member and the patient who declined the vaccination offered will be conducted using the standard questionnaire. The questions will be asked in an open-ended manner to avoid leading a patient to particular answer. In the inpatient setting, the study team member will visit the patient, while in the outpatient setting the study team members will call the patient at home. The questionnaire is a tool designed to accurately identify and capture all the reasons for refusal. The data obtained from the questionnaire will be entered into Excel for analysis. Unique patient identifiers will be removed prior to data entry in Excel. The database will be stored on a password protected file on a secure YNHH server. This phase will be conducted in the winter of 2013.

During phase II, a series of interventions will be developed and designed to address the common reasons why patients decline the vaccine. The interventions will include development of accredited continuing education (CE) for health care providers (pharmacists, nurses, and physicians) on the patient barriers identified. The goal of the CE is to inform health care providers of patient reasons for decline to receive the pneumococcal vaccine and also to provide tools and strategies for addressing these reasons. For example, the interventions may include: counseling techniques, health disparity and cultural competence training. At the end of the CE, there will be case based questions to facilitate large group discussions on how to identify patient specific barriers and utilize strategies provided. This will allow us to assess their understanding and ability to effectively use the tools given in order to increase vaccination rates. We will also observe healthcare workers execute these strategies in order to ensure they are used appropriately and allows us to provide direct one-on-one feedback. In addition, a HealthStream module (a web based system used for mandatory training of YNHH employees) discussing the pneumococcal vaccine, its use, importance, target population, patient barriers, and tools to help overcome these barriers will be created, which will be mandatory for all health-care providers to complete. There will also be questions at the end of the module to assess their understanding of the material. Patient education materials available in both English and Spanish which address the specific reasons patients decline the vaccine may include the use of pamphlets, videos, and/or education via website. Training and intervention development will occur in spring 2013.

In phase III, implementation of the CE modules, HealthStream, education materials, and videos will occur, as well as the measurement of impact these interventions have on the pneumococcal vaccination rates. The same procedure of capturing patient refusal and identifying patient barriers based on the one-on-one interview will be conducted, however a more direct and effective response will be provided utilizing the formalized strategies and resources. After the response, patient's acceptance or refusal to get vaccinated will be documented. The collected data will be analyzed and

compared to the vaccination rates in phase I to measure the efficacy of the above interventions. This phase will occur in the summer 2013 to Winter2014.

During phase IV, the program will be expanded to ACPE-accredited continuing education modules and enduring CE opportunities for other pharmacists and health systems to widen the exposure of the developed program. The programs will be recorded and located on University of Connecticut website and incorporated in the Immunization Training for Pharmacists Certificate Activity for current pharmacists and UConn students. Additionally our study of the interventions will be submitted to a peer review journal for national and international audiences. Phase IV will begin in spring 2014.

Deliverables Schedule

Time Frame	Event
Oct – Dec 2012	Develop and validate standard questionnaire
Jan 2013 – Mar 2013	Collect data on patient reasons for refusal
Mar – April 2013	Analyze data to identify common reasons for patient refusal
April – June 2013	Create: <ul style="list-style-type: none"> • CE • HealthStream • Patient educational handouts • Patient education video* * If patient channels are implemented at the hospital
June – Oct 2013	Implementation of the CE, HealthStream, and patient education video
Oct 2013 – Mar 2014	Utilize tools and strategies and collect data on pneumococcal vaccination refusal rates post intervention
March – April 2014	Analyze data to determine effectiveness of intervention
April – Nov 2014	Expand and share tools and strategies to other health systems: <ul style="list-style-type: none"> • CE to other pharmacists and health systems • Online Immunization Training for Pharmacists Certificate Activity for current pharmacists and UConn students • Recording broadcasts to pharmacists across the US • Publish findings in pharmacist journals (i.e. JAPhA)