

ALBANY COLLEGE OF PHARMACY

Use of Pharmacy Practice Faculty and Student Pharmacists to Screen, Educate,
and Provide Pneumococcal Vaccine to Elderly Patients in Vermont

Pfizer Note: No funds were provided for direct acquisition of vaccines

C. Main Section of the proposal (not to exceed 15 pages):

1. Overall Aim & Objectives:

Overall Aim: In 2010, an estimated 39,500 cases of invasive pneumococcal disease occurred in the United States, resulting in 4000 deaths with the majority occurring in patients >50 years of age (Centers for Disease Control and Prevention (CDC) 2011. Active Bacterial Core Surveillance Report, Emerging Infections Program Network, *Streptococcus pneumoniae*, 2010, available at <http://www.cdc.gov/abcs/reports-findings/survreports/spneu10-orig.html>, accessed June 26, 2012). In addition to the invasive disease caused by this organism, pneumococcal pneumonia is, by itself, responsible for 16,000 deaths each year, even though hundreds of thousands of office visits and over two million hospital days are contributed to pneumococcal pneumonia.

The overall aim of this proposal is to prevent pneumococcal disease through vaccination of Vermonters over the age of 65 who reside in skilled nursing facilities, residential care homes and assisted living residencies, with the goal of achieving 90% vaccination rates as stated in Healthy People 2020 (Huang SS, Johnson KM, Ray GT, et al. Healthcare utilization and cost of pneumococcal disease in the United States. Vaccine 2011; 29:3398-3412). This will enlarge the focus of vaccinations in preventative healthcare from the pediatric population to include the susceptible, accessible, and growing elderly population in Vermont in the form of pneumococcal vaccination. This program will be led by the Vermont campus of the Albany College of Pharmacy (ACPHS), the only school of pharmacy in Vermont. In this program, pharmacy students and faculty who are certified immunizers will take responsibility for traveling to skilled nursing and residential daycare facilities throughout the state and providing vaccinations, thus alleviating sub-specialists of the burden of providing them.

Vaccines are in need of a healthcare worker “champion”. Immunizations rates have not improved and in some cases have fallen behind CDC recommendations. In many instances, at routine visits to primary care offices, options proposed for patient vaccination are not offered. (Matzke GR. Health policy 2011: implications for pharmacists. *Ann Pharmacother* 2011; 45:412-3). Pharmacists are medication experts and are recognized as providers in a report approved by the U.S. Surgeon General, Dr. Regina Benjamin. (Giberson S, Yoder S, Lee MP. *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General*, Office of the Chief Pharmacist, U.S. Public Health Service, Dec 2011). Pharmacists have mastered clinical tools surrounding drug therapy in an ambulatory care setting. These tools, which include Medication Therapy Management (MTM), implementing the Medication Appropriateness Index (MAI), and Motivational Interviewing (MI), all have outcomes of increased medication awareness and adherence. Data alluded to in the aforementioned report suggest that as patients become more adherent to their medications, although the cost of drugs may increase, the overall cost of care decreases. It is logical to include vaccinations among therapies that decrease use of medical care, and to facilitate this change with pharmacists, many of whom can vaccinate. Colleges of Pharmacy, such as ACPHS-Vermont, have the unique mission of educating and training student pharmacists who will shape the future of the pharmacy profession, where pharmacists will play a greater role in patient outreach. Through the power of education and service to society, the students and faculty of

ACPHS-Vermont can make a profound mark on decreasing pneumococcal disease and preventing its adverse sequelae.

Objectives: To achieve the overall aim of this project, we plan to pursue the following specific objectives, which will utilize professional student organizations from Albany College of Pharmacy and Health Sciences Vermont Campus as a workforce, in conjunction with American Pharmacist Association-trained faculty members, to reach out with education, supplies and expertise to educate and vaccinate the elderly patients in skilled nursing, assisted living and residential care facilities throughout Vermont using an established model(Dang CJ, Dudley JE, Truong HA, et. al. Planning and implementation of a student-led immunization clinic. *American Journal of Pharmaceutical Education*, 2012; 76(5): Article 78):

1. We will partner with the Vermont Program for Quality in Healthcare (VPQHC) for patient access and identification.
2. Students will ascertain a complete list of all of the physicians involved in the care of each patient as well as obtaining patient medication regimens from interviews conducted using the clinical tool of Medication Therapy Management (MTM). This history may be gleaned from medication bottles, taking a verbal history from the patient and/or medical charts where applicable.
3. Through student-led group discussions, facility staff and residents will be educated regarding the importance of vaccination, and myths surrounding vaccination will be quelled with facts. Patients, families (when appropriate), and healthcare workers will be educated on current adult immunization guidelines (Johnson DR, Nichol KL, Lipczynski K. Barriers to adult immunization. *Am J Med*. 2008; 121[7 Suppl 2]:S28-35).
4. We will provide a detailed medication history report complete with recommendations to be left with the patient and/or facility for sharing with the patient's provider and/or family upon a subsequent visit (in adherence to HIPPA regulations).
5. We will assess the current immunization history of each patient and supplement current general or sub-specialist care with pneumococcal vaccination and medication therapy management. Vaccination claims will be submitted to commercial insurers and to Medicare to ensure that a CPT code is generated, enabling the immunizations to be tracked.
6. We will communicate with identified and current health care practitioners regarding the patient's immunizations. This will include coordination of vaccinations and medications with the patient's current active provider, which is especially critical in a society where both providers and medical plans frequently change.

7. Patients, facilities, and providers will be provided with copies of the vaccination and medication therapy management interactions. These will be placed into the medical chart as applicable.
 8. We will compare pre-vaccination initiative and post-initiative data to measure the success of the project. These data will come from reliable sources from the State of Vermont.
 9. We will create a database as an objective performance evaluation checklist and submit the information to the Vermont Immunization Registry.
2. **Technical Approach:** Describe how this initiative will meet the aim of the specific area of interest for the RFP. For each institution/organization/association, describe the specific role that they will undertake to meet the goals of this initiative.
- a. **Current Assessment of need in target area**
 - i. Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that describes the problem). Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed.

Of the nearly 30 million patients under surveillance in 2010, there were approximately 39,500 cases of invasive pneumococcal disease resulting in roughly 4,000 deaths. Each year, approximately 16,000 total deaths due to pneumococcal pneumonia occur in the population of patients above 50 years-old, with the greatest number occurring in patients who are 65 or older (Centers for Disease Control and Prevention (CDC) 2011. Active Bacterial Core Surveillance Report, Emerging Infections Program Network, *Streptococcus pneumoniae*, 2010. Available at: <http://www.cdc.gov/abcs/reports-findings/survreports/spneu10-orig.html>, accessed June 26, 2012). The number of occurrences of invasive pneumococcal disease per 100,000 patients in this age group is estimated at 37 cases, with a resulting mortality rate of 5.61 per 100,000 cases. Invasive pneumococcal disease is also responsible for hundreds of thousands of hospital visits and millions of clinic visits each year that tax the healthcare system (Huang SS, Johnson KM, Ray GT, et al. Healthcare utilization and cost of pneumococcal disease in the United States. *Vaccine* 2011; 29:3398-3412).

Current recommendations state that Vermonters over the age of 65 should receive one dose of pneumococcal polysaccharide vaccination to prevent pneumonia if they have not received one since turning 65 [CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1997; 46(RR08):1-24]. In 2004, the most recent date for which data are available, 66% of Vermonters over the age of 65 were vaccinated for pneumonia (Vermont Dept of Health and Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System Survey Data, 2004). The Healthy Vermonters 2010

goals for adult immunization are for 90% of Vermonters over the age of 65 to receive yearly influenza vaccinations and for 90% of this group to also have been properly vaccinated against pneumonia (Healthy Vermonters 2010 <http://www.healthyvermonters.info/admin/pubs/hv2010/hv2010.shtml>, accessed 7/20/12).

The data gap for immunizations has recently directed the Vermont legislature to focus on vaccines administered throughout the state. This discussion has largely focused on pediatric school-age patients. Until recently, Vermont state law for vaccination of school-aged children was left to parental discretion, resulting in many children not being vaccinated. This in turn resulted in the manifestation of diseases that are generally well-controlled through immunization. The discussion and subsequent legislative resolution of pediatric vaccinations has placed a large burden of work on the understaffed Vermont Immunization Registry, resulting in its attention currently being focused on pediatric immunizations, and temporarily being turned away from immunizations for the elderly. In this project, we will vaccinate Vermont's elderly population, and will then supply the information to the Vermont Immunization Registry.

Data from Online Survey, Certification and Reporting (OSCAR), a data network maintained by the Centers for Medicare and Medicaid Services (CMS) in cooperation with state long-term care surveying agencies, show the following vaccination rate data for the last four quarters aggregated from skilled nursing facilities throughout Vermont (excluding residential care homes and assisted living residencies):

June 2012: 79.87% influenza; 73.26% pneumococcal
March 2012: 79.25% influenza; 75.66% pneumococcal
December 2011: 78.57% influenza; 79.49% pneumococcal
September 2011: 75.54% influenza; 80.80% pneumococcal

These data demonstrate the current gap between vaccination rates in the elderly and the Healthy People 2020 objective (<http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx>) to increase the percentage of adults vaccinated against pneumococcal disease to the 90% level.

As a significant step toward meeting this goal, our initiative will capture elderly patients for pneumococcal vaccination who are in contact with the roughly 100 skilled nursing, assisted living, and elderly day facilities throughout the state of Vermont that provide care or services to the elderly. It would be significant to link a vaccination initiative with a downward shift in the number of cases of invasive pneumococcal disease and pneumococcal pneumonia in Vermont. Alternatively, we could obtain the number of Medicare antibiotic prescriptions written for macrolide or fluoroquinolone antibiotics for outpatients older than 65 years of age. These data would be even more specific if obtained through our targeted elderly facilities to be completed at the conclusion of the program.

- ii. *Describe the primary audience(s) who will directly utilize or benefit from the project outcomes and how the project outcomes might be broadly disseminated to the primary audience. Describe how you will determine if the target audience was fully engaged in the intervention.*

This outreach initiative, led by Pharmacy Practice faculty and student pharmacists from the ACPHS Vermont campus certified as immunizers through the American Pharmacists Association immunization program, has Vermont senior citizens residing in or frequenting adult care service facilities as its target patient population. This initiative will link students and faculty to provide service to Vermont's aging population who utilize senior day facilities or skilled nursing facilities throughout the state. The project outcomes will be broadly disseminated to audiences including Pfizer, the Vermont Department of Public Health, the immunization registry for Vermont, the Antibiotic Stewardship Committee for the State of Vermont, Medicare and Medicaid of Vermont, as well as to the primary commercial insurers in Vermont (MVP, Blue Cross/Blue Shield, and Cigna). In addition, the Vermont Blueprint for Health team, located in the Department of Vermont Health Access, will be notified of our results with the expectation that they are communicated to physicians and to patient centered community-based medical homes throughout the state, as sanctioned by the Affordable Care Act. Publications resulting from this initiative will also be shared with the healthcare bodies listed above.

This project will take place over two years, and will include 36 sessions per year (1 per month per participating project faculty member) for a total of 72 outreach and vaccination sessions over the two-year life of the grant. Faculty members and student pharmacists will work with facilities identified by the Executive Director for the Vermont Healthcare Association (VHCA) for implementing the process. VHCA represents nursing homes and residential care facilities throughout the entire state. This process will proceed in a planned and publicized manner to achieve maximum attendance and participation for sessions held at the selected facilities.

The programs will involve hosting an immunization clinic, as well as providing education and counseling on the importance of invasive pneumococcal disease prevention in this population. As an added benefit, student pharmacists and their preceptors will provide educational sessions for patients to discuss their current medications and diseases in either a brown-bag format or in a Medication Therapy Management (MTM) format, depending upon the setting. As an effort to promote inclusion of these data in each patient's medical record (written or electronic), immunization and educational activities will be documented and copies provided to each patient's PCP, as well as to all other physicians identified with specific patient encounters. The pneumococcal vaccination outcome will be evaluated using nursing home specific data through the OSCAR system, number of immunizations reported to the registry and commercial as well as Medicare data that is available for Vermont. We will look for decreased numbers of patients aged 65 years or older admitted as inpatients to acute care facilities with invasive pneumococcal disease and pneumococcal pneumonia, as reported to the state through the Vermont Information Technology Leaders (VITL; our state electronic monitoring database), and for decreased macrolide and fluoroquinolone prescriptions used to treat suspected community-acquired pneumonia via Medicare and commercial prescription data for Vermont. As of June

19, 2012, according to the Immunization Action Coalition, the State of Vermont does not mandate pneumococcal or influenza vaccine for residents in long-term care facilities. Facilities are neither required to vaccinate nor to make these vaccinations available to their patients (www.immunize.org/laws/tc.asp, accessed 6/19/12).

Through subsequent grant opportunities or state initiatives supporting pharmacy faculty as members of a patient-centered medical home (PCMH) team through the Department of Vermont Health Access (DVHA) or Vermont's Blueprint for Health, this program will be extended to the remaining facilities that care for elderly as well as to all elderly patients who may come in contact with PCMHs throughout the state.

- b. **Intervention Design and Methods:** Describe the way the intervention planned addresses the established need and produces the desired results. Please provide a rationale showing the desired results are feasible using the intervention being proposed*

Our planned interventions will provide counseling and vaccination at the residences or gathering places of the elderly, thus addressing the need for pneumococcal vaccination in the elderly population. The rationale for this planned intervention is that pharmacists are medication experts and recognized by the U.S. Surgeon General as providers who are well-suited to act as vaccine champions. Through the power of education and service to society, the students and faculty of ACPHS-Vermont can make a profound mark on decreasing pneumococcal disease and preventing its adverse sequelae. Decreasing pneumococcal disease through our program to vaccinate the elderly is feasible because faculty will partner with motivated students and their organizations to schedule nearly continuous outreach programs serving Vermonters throughout the state.

*c. **Evaluation Design***

- i. Describe how you will determine if the practice gap identified in the needs assessment was addressed for the target group in terms of the metrics used for the needs assessment.*

It is our intention to link this vaccination initiative to a negative shift in the number of cases of invasive pneumococcal disease and pneumococcal pneumonia with increased immunization rates in patients greater than 65 years of age. Because prevention of pneumococcal disease through vaccination has typically been targeted toward pediatric populations and is not CDC-reportable, data specific for our elderly target population in Vermont will be gathered from commercial and Medicare sources, as well as from OSCAR. We will obtain the number of Medicare and commercial antibiotic prescriptions written for macrolide or fluoroquinolone antibiotics for patients older than 65 years of age and match these data against the time period of the vaccination initiative.

ii. Identify the sources of data that you anticipate using to make the determination.

Data from the Vermont Department of Health specific to pneumococcal disease in the state will serve as a baseline. In addition, the principal investigator is an active member of the Antibiotic Stewardship Committee for Vermont, and thus has access to all infectious disease-related data reported in the state. We will look at Medicare prescription data for the use of antibiotics targeted against *Streptococcus pneumoniae*, with particular attention to the macrolides and fluoroquinolones. In addition to data reported to the state, we will query VHCA for data targeting the above criteria.

iii. Describe how you expect to collect and analyze the data.

As a result of this intervention, the number of vaccinated patients who reside in or use elder-care facilities is expected to quantitatively increase as a result of the educational and free vaccination clinic components of our outreach efforts. The increase in the number of patients vaccinated will be quantitatively reflected in data from VITL. In addition, faculty will keep records of patients vaccinated and of medication-related interventions. This information will be coordinated by the Principal Investigator. We also expect to observe a quantitative decrease in patient hospitalizations with invasive pneumococcal disease throughout Vermont. We will also analyze data to determine outcomes with respect to the number of antibiotic medications prescribed for Community Acquired Pneumonia in patients aged 65 years or older in an outpatient setting by searching billing codes for this diagnosis. A link between the billing codes used in commercial and Medicare databases and macrolide and fluoroquinolone antibiotic use will be correlated for the pre- and post- immunization periods in an effort to demonstrate change.

Vaccination forms will be completed for the patient and will reside either with the patient or with their residential institution, if a skilled nursing facility. A notification of vaccination letter will be sent to the patient's primary care physician and/or specialists who frequently attend to the patient. In addition, an MTM form containing a comprehensive medication history, as well as physician recommendations pertaining to the patient's medications, will be placed in the patient's chart if the patient resides in a skilled nursing environment, or it will be given directly to the patient for consultation with his or her physician. These data will be entered into a form in Microsoft Excel®, enabling data from all participants in the program to be retrieved as needed.

Identify the method used to control for other factors outside this intervention.

Since there are approximately 100 facilities throughout Vermont providing varied levels of care to the elderly and we are targeting approximately 72 facilities over 2 years, data from facilities not targeted will be used as a control group for this intervention. Data obtained from the year prior to the intervention year will also serve as a control.

3. **Detailed Workplan and Deliverables Schedule:** *Include a narrative (which counts toward the 15-page limit) describing the workplan and outlining how the project will be implemented over the X-year period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable. In the budget, associate each of the deliverables to a specific dollar amount.*

This program will be led by the Vermont campus of the Albany College of Pharmacy and Health Sciences (ACPHS), the only school of pharmacy in the state. In this program, pharmacy will take responsibility for vaccinations, thus alleviating the sub-specialists who often provide them of this burden. Through student-led group discussions, facility staff and residents will be educated regarding the importance of vaccination, and myths surrounding vaccination will be quelled with facts. We will comprehensively assess and document patient vaccine history and provide written documentation to the facility. A written letter to the primary care provider (PCP) will be provided as a follow-up, which the PCP can then enter into electronic or hand-written charts. Students will ascertain a complete list of all physicians actively interacting with each patient from interviews, medical charts and medication bottles if present in the setting. Documentation regarding vaccination will be provided to each physician involved with the patient. To ensure that each patient has a record of what the traveling pharmacy-run clinic has provided, we will use Microsoft Excel® to create an objective performance evaluation checklist guided by patient-specific information. Each of the pharmacy preceptors and student groups will be scheduled to perform a clinic at least one day per month at different locations throughout Vermont for the duration of the grant, ending in September 2014.

1. We will partner with the Vermont Program for Quality in Healthcare (VPQHC) for patient access and identification. VPQHC is the body that oversees all skilled nursing facilities, assisted living and adult day facilities for elderly throughout Vermont. We have already contacted the Executive Director, who has agreed to aid us in guiding our initiative throughout the various facilities. VPQHC also provided data from the OSCAR system regarding vaccination rates of the elderly in the skilled nursing facilities on a quarterly basis and will continue to report these values each quarter as the project is rolled out to assess how close to the 90% goal we are able to achieve.
2. Students will ascertain a complete list of all of the physicians involved in the care of each patient as well as obtaining patient medication regimens from interviews conducted using the clinical tool of Medication Therapy Management (MTM). This history may be gleaned from medication bottles, taking a verbal history from the patient, family members and/or medical charts where applicable. Determining all the physicians who are caring for a patient and providing them a record of vaccination closes a perceived existing gap in the health care team.
3. Through student-led group discussions, facility staff and residents will be educated regarding the importance of vaccination and myths surrounding vaccination will be

quelled with facts. Patients, families (when appropriate or desired), and healthcare workers will be educated by ACPHS students and faculty on current adult immunization guidelines as part of the free services we will be providing at this clinic (Johnson DR, Nichol KL, Lipczynski K. Barriers to adult immunization. *Am J Med.* 2008; 121[7 Suppl 2]:S28-35).

4. Upon a subsequent visit, we will provide a detailed medication history report complete with recommendations to be left with the patient and/or facility (depending upon the facility type) to be shared with the patient's provider and/or family, in adherence to HIPPA regulations (see attached forms M and S).
5. We will assess the current immunization history of each patient and supplement current general or sub-specialist care with pneumococcal vaccination where warranted and provide medication therapy management clinics to identify and address potential adverse events or therapeutic inadequacies secondary to prescribed and over-the-counter medications patients may be taking. Vaccination claims will be submitted to commercial insurers and to Medicare to ensure that a CPT code is generated, enabling the immunizations to be tracked. Billing will be performed by administrative assistant for the project. We are not expected to bill for this grant, however this is the only way that data will be tracked by state, federal and commercial agencies and be useable in our final analysis of the project.
6. We will communicate with identified and current health care practitioners regarding a patient's immunizations. This will include coordination of vaccinations and medications with the patient's current active provider, which is especially critical in a society where both providers and medical plans frequently change. A copy of verification of vaccination will be left in the chart at the facility where warranted and/or given to the patient, in addition to being sent to the patient's primary care physician.
7. Patients, facilities, and providers will be provided with copies of the vaccination and medication therapy management interactions. These will be placed into the medical chart or provided to the patient or family member as applicable to the type of facility where the clinic is being conducted.
8. We will compare pre-vaccination initiative and post-initiative data from OSCAR, the database used by VPQHC to report quarterly vaccination rates, to measure the success of the project. These data will come from OSCAR, Vermont Medicare and commercial insurance companies doing business in Vermont.
9. We will use Microsoft Excel® to create a spreadsheet as an objective performance evaluation checklist and submit the information to the Vermont Immunization Registry to assist them in building their vaccination database of elderly throughout the state.

Deliverables Schedule		
Task	Deliverable	Completion Date
Hire and provide salary and benefits for the project coordinator	Preparation, coordination, and administration of project events.	August 2014
Engage the Vermont Healthcare Association Executive Director to develop a targeted, prioritized list of nursing homes/residential care homes and assisted living residencies	Targeted and prioritized list of nursing homes/residential care homes and assisted living residencies	September 2012
Engage leaders of student organizations (ASHP, APhA, Rho Chi and Phi Lambda Sigma) to organize student teams for outreach programs	Student teams to participate in outreach programs effort one day per month/possible weekends throughout the year	September 2012
Engage faculty to insure uniform conduct of medication histories, MTM, patient education, and vaccination preparation	Faculty preceptors to function as outreach program leaders	September 2013
Obtain supplies for traveling vaccination/MTM clinic	Completely outfitted traveling vaccination/MTM clinic, with all necessary supplies and forms for documentation to patients and providers	August 2014
Preparation and production of promotional and educational materials for traveling clinic and media.	Educational materials for patients and for presentations to elderly groups, and promotional material highlighting this partnership between ACPHS and Pfizer	September 2014
Four faculty and cadres of students traveling to and conducting clinics	Vaccinations, MTM, medication history, education with patients and facility staff	September 2014
Report project results to Pfizer	Interim report to Pfizer regarding project achievements	September 2013

Task	Deliverable	Completion Date
Prepare poster with preliminary results from the first year of data collection.	Poster presentation, involving collaboration with and mentoring of pharmacy students, at the American Society of Health System Pharmacists Midyear Clinical Meeting of first-year vaccination data	December 2013
Prepare poster on MTM and educational data from the traveling clinic	Poster presentation of MTM and educational impact of initiative, involving collaboration with and mentoring of pharmacy students, at American Association of Colleges of Pharmacy meeting	July 2014
Prepare manuscript of entire project for publication in a peer-reviewed journal by PI, faculty and students, and preparation of a presentation of data	Manuscript describing project and outcomes, submitted for publication and poster presentation of project data at a national meeting TBD, involving collaboration with and mentoring of pharmacy students	Winter/Spring 2014