

***Improving Patient Immunization Rates through Optimizing
Pharmacy's Role in Providing Immunization Services***

Shenandoah University
Bernard J Dunn School of Pharmacy
1775 N. Sector Court
Winchester, VA 22601

RealCME
545 West 45th Street
Suite 11-D
New York, NY 10036

RxAlly
201 Loudoun Street, SE
Suite 300
Leesburg, Virginia 20175

I. Overall Goal and Objectives

Overall Goal: To promote and increase pneumococcal vaccinations among adults over age 65 and high-risk patients aged 2-64 with comorbid conditions at a regional community pharmacy chain in North Carolina through an educational initiative that will utilize an experienced team of pharmacy educators and American Pharmacists Association (APhA) immunization trainers, an accredited medical education companies, and an outcome analytic company.

The key objectives include:

- 1 Increase pneumococcal immunization rates among high risk populations
- 2 Increase pharmacists' and pharmacy staff's knowledge and ability to identify appropriate candidates for the pneumococcal vaccine
- 3 Increase pharmacists' and pharmacy staff's comfort level in improving immunization awareness of the pneumococcal vaccination through direct patient interaction
- 4 Educate and train targeted pharmacists and pharmacy staff to provide immunization related clinical services

II. Technical Approach

A. Current assessment of need in target area

Healthy people 2020 set target pneumococcal immunization rates at 60% for high-risk adults aged 18-64 years and at 90% for adults > 65 years of age.¹ According to the National Health Interview Survey (NHIS), pneumococcal vaccination coverage for adults ≥ 65 years and high-risk adults age 19-64 in the United States was 59.7% and 18.5% respectively in 2010.² Specifically within the state of North Carolina, the CDC's Behavioral Risk Factor Surveillance System (BRFSS) indicate that less than one third (30.2%) of the 10,205 patients surveyed received the pneumococcal vaccine.³ This data indicates a gap in pneumococcal vaccinations at both the national and state level.

Pharmacists are uniquely positioned, due to both accessibility and their expanding role in patient care, to serve as vaccine advocates. Since the advent of the American Pharmacists Association's National Certificate Training Program on Pharmacy-Based Immunization Delivery, over 150,000 pharmacists and future pharmacists are trained to administer vaccinations.⁴ Many states now authorize pharmacists to administer multiple vaccinations, expanding patient access to vaccines within the community. Due to these advancements, many pharmacies have further developed their services to include extensive immunization programs.

Kerr Drug, an affiliate of RxAlly, is a regional community pharmacy chain located in North Carolina that provides comprehensive health and wellness offerings, including a robust immunization program. The company consists of 76 stores statewide and employs approximately 200 pharmacists and 400 pharmacy staff members. A typical staff includes a range of 2-8 members based on the volume and hours of the individual stores. Immunization initiatives at Kerr Drug have historically provided between 25,000 and 55,000 influenza vaccinations annually.

The regional community pharmacy chain is responsible for 239,907 patients of which 22% or 52,834 patients are over 65 years of age. Additionally, 1,140 patients will be turning 65 years old by 12/31/2012. Furthermore, there are 8,105 patients within the chain's population that should receive the pneumococcal vaccination due to a comorbid condition of diabetes mellitus or a respiratory disease as identified by prescription claims data. This increases a target population for pneumococcal vaccinations to approximately 62,000 patients within this regional community pharmacy chain alone.

There is a large gap, however, in the number of patients being immunized in this population at a store level. Despite the ability of pharmacists in North Carolina to administer pneumococcal vaccinations in addition to those for influenza and herpes zoster, only a small percentage of the target population received the vaccine from their Kerr Drug pharmacist. In 2010, barely 30% of the 76 pharmacy locations (23 stores) were active in vaccinating for pneumococcal disease, administering only 220 total pneumococcal vaccinations. This number increased to 41 pharmacy locations administering 317 vaccinations in 2011. Despite an increase from 2010 to 2011 of 97 vaccinations, these numbers represent only 0.5% of the target population at the regional community pharmacy chain.

Since the pneumococcal vaccination is not a yearly vaccination, the number of patients that could be targeted on an annual basis would diminish as more patient receive the vaccine. It is also possible that many patients are receiving this vaccination at their primary care physician's office. However, there is still a large gap in coverage as reported by the CDC for this state and the country.

If 60% of those patients over 65 years old, have indeed receive the pneumococcal vaccine previously, this gap in care leaves an estimated 24,000 patients at this regional community pharmacy chain that are still potentially at risk and have not been vaccinated. For that population, the current rate of administration for pneumococcal vaccinations at the regional community pharmacy chain in 2011 is about 1.3% (an increase from 0.89% in 2010). While this company has been committed to providing clinical immunization services to their community, it

is clear that their current endeavors are not meeting the goals set forth by Healthy People 2020. This community pharmacy chain is not alone.

There are numerous barriers to achieving higher immunizations including lack of awareness of the disease by patients or the availability of the vaccine. Some healthcare providers also fail to assume responsibility for vaccination.⁵ While Kerr Drug is ready to rise to the challenge of closing the gap in care concerning pneumococcal immunizations, their current initiatives have not facilitated this increase. Currently the regional community pharmacy chain takes a passive approach in advocating for increased immunization rates. While pharmacists are given guidelines to ask **all** patients about immunizations, there is a lack of focus on identifying at risk patients for the pneumococcal vaccination and a lack of education and support to empower pharmacists to increase awareness of this disease and vaccine. To fill the educational void, the program described in this proposal will provide a variety of educational, screening and marketing tools at a set of test stores within the regional community pharmacy chain.

The proposed intervention will consist of a multi-module education program delivered to pharmacists and pharmacy staff, targeted marketing for the regional community pharmacy chain, and screening tools to identify and track targeted high risk patients. Several parties will directly benefit from the interventions. First and foremost, the high-risk patients who will receive the pneumococcal vaccination will have a decreased risk of disease and mortality. The community as a whole would also benefit from a decrease in disease and potential related health care costs. Pharmacists and pharmacy staff will receive continuing education credits needed for re-certification and licensure as well as a potential increase in knowledge coupled with an increase in comfort identifying and communicating with patients concerning the pneumococcal vaccination. Finally, the regional community pharmacy chain will benefit by increased reimbursement for immunization services provided at their stores.

References:

1. US Department of Health and Human Services. Healthy People 2020 objectives. Available at <http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/immunization.pdf>. Accessed October 8, 2012.
2. Centers for Disease Control and Prevention (CDC). Adult Vaccination Coverage-United States, 2010. MMWR. 2012;61:66-72.
3. 2011 BRFSS Survey Results: North Carolina accessed at <http://www.schs.state.nc.us/schs/brfss/2011/nc/risk/PNEUVAC3.html>
4. American Pharmacists Association. Pharmacy-Based Immunization Delivery: A Certificate Program for Pharmacists 12th edition. Washington, DC:2011.
5. Rehm SJ, File TM, Metersky M, et al. Identifying barriers to adult pneumococcal vaccination: an NFID task force meeting. Postgrad Med. 2012;124:71-79

B. Intervention Design and Methods

Stage A: Development of Educational Programming, Screening Tools, and Marketing Materials

During the first quarter of 2013, all pharmacists and pharmacy staff employed and working at the store level of the regional community pharmacy chain will take a pre-test to evaluate current knowledge of the indications for pneumococcal vaccinations, ability to screen for patients in need of pneumococcal vaccination and comfort in improving awareness of the pneumococcal vaccination. The **Self Assessment Program (SAP)** will evaluate current mastery and performance levels pharmacists and pharmacy staffs of the participating regional chain pharmacies regarding pneumococcal screening and vaccination. This SAP will be offered prior to the online educational curriculum activities and the data will be used by the immunizing faculty at Shenandoah University to refine the online educational curriculum content.

Preparation for the intervention will also include the creation of a screening tool and in-store marketing materials to be utilized within the test stores. Of the 76 stores, 50 stores will be in the test group and 26 stores will be in the control group determined by randomization in a 2:1 ratio. Randomization will also be completed by matching stores with similar immunization rates and patient populations.

The proposal will be submitted to the IRB at Shenandoah University for approval during this time frame.

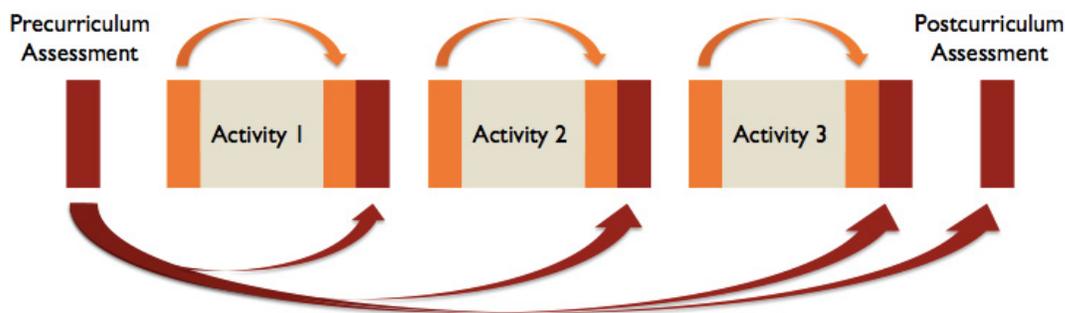
Stage B: Delivery of Online Educational Modules

At the completion of Stage A, three online education modules will be created to be delivered to pharmacists and pharmacy staff at the stores within the test group. These modules will be delivered during the 3 month period of June 1, 2013 - August 30, 2013 by RealCME for the purpose of educating, training and empowering pharmacists and pharmacy staff to provide more comprehensive immunization services. The modules will use a variety of educational strategies including didactic learning, case based methodologies and patient interaction simulations. Kerr Drug is committed to the engagement of their pharmacists and pharmacy staff in this initiative and will strongly recommend that all employees from test stores participate in the educational modules and screening process. To show Kerr's commitment, a stipend will be provided to participating employees.

The first of the online educational activities, the **Virtual Grand Rounds** activity, will emphasize to the topic of immunization and focus on indications for pneumococcal vaccinations, identification and characteristics of high-risk patients, utilizing immunization schedules, and related immunization topics. This module will build upon the knowledge obtained previously

by pharmacists during the American Pharmacists Association Pharmacy Based Immunization Delivery, a National Certificate Program for Pharmacists. It will also focus on knowledge deficits identified in the baseline assessment of pharmacists and pharmacy staff during Stage A. The second module, the **PharmacyConsult** activity, will then introduce and train participants on the use of screening tools to identify at risk patients through a case-based approach. The final module in the series, the **DecisionPoints** activity, will allow pharmacists to interact with various high-risk patient types in simulated patient interactions to improve their ability to motivate individuals to seek immunization. All of the modules will also remain available to the pharmacists and the pharmacy staff for reference and re-education as needed during the targeted screening and immunization period.

At the conclusion of the three online modules within a 6-8 week time frame, pharmacists and pharmacy staff will participate in a post-test to evaluate changes in comfort and knowledge levels. The **Post Curriculum Assessment (PCA)** will measure learners' retention across all domains. The PCA includes the RealIndex® and a selection of questions previously presented in the curriculum, which cover all learning objectives and question types. The RealIndex® is a composite score based on a multidimensional question that addresses the learning objectives identified in the curriculum. Participants will be presented with a real-life clinical scenario, followed by a series of statements to be assessed as either consistent with or inconsistent with evidence-based best practice and with actions they would take in their own practice. The RealIndex® is administered prior to the first activity of the curriculum (baseline), after the completion of each activity, and finally in a post-curriculum follow-up assessment (PCA).



Stage C: Targeted Patient Screening and Immunizations

Prior to this time period, the regional community pharmacy chain will provide current immunization rates, cumulatively and by store, to serve as an additional baseline reference. Beginning September 1, 2013, marketing to increase awareness of the pneumococcal disease and vaccination will be placed in all stores of the test group. Multi-media in-store marketing

within test stores will be comprised of prescription bag label advertisements, signage located throughout the store, label buttons, and audio advertisements.

Additionally, individual pharmacy locations within the test group will begin to use the developed screening tool to identify the target population for screening related to the pneumococcal vaccination. Both pharmacists and pharmacy staff will identify those patients over age 65 and those patients age 2-64 who have a comorbid condition of diabetes mellitus or a respiratory disease (COPD or asthma) during the prescription filling process. When identified as a patient who has an indication for the vaccination, a screening tool will be attached to the patient's prescription bag. At pick-up, the pharmacist or pharmacy staff member will approach the patient about the pneumococcal vaccination. The pharmacist or pharmacy staff member will use the skills developed during the online educational modules to provide the patient with brief education on the benefits of the pneumococcal vaccination. At this time, the pharmacist or pharmacy staff member will also gather information about the patient's previous vaccination history and record the outcome of the interaction (vaccination received or vaccination denied and reason). Any patient who requests a pneumococcal vaccination from the pharmacy without being identified through the prescription filling workflow, will also need to have a screening tool completed and identify the reason for the pneumococcal vaccination request (i.e. marketing materials, referral from physician, etc.). All screening tools will be collected at each store and sent to Shenandoah University for cataloging and analysis.

The project manager and content experts at Shenandoah University will provide educational and procedural support during this time period. District Management of the regional community pharmacy retail chain will also provide guidance and facilitate successful implementation of the initiative.

Stage D: Data Collection and Analysis

At the completion of a one-year period (September 1, 2013 - August 30, 2014), analysis of the outcomes will be completed for dissemination to the regional community pharmacy chain as well as to the national pharmacy community. The regional community pharmacy chain, through RxAlly, will report immunization rates of pneumococcal and influenza cumulatively and by store for the one-year period. Additionally, the data from the screening tools will be analyzed and reported, including number of patients screened, number of patients who previously received pneumococcal vaccination and the reasons for denial of vaccination at the community pharmacy.

RealCME will report outcomes from their RealMeasure platform on specific learner domains: knowledge, competence, confidence, and practice strategy. Additionally, learning objectives and subject areas identified in the needs assessment will be assigned to specific questions. All questions presented to the learner in the Pre-Test of an activity are paired with the identical

question in the Post-Test and follow-up (PCA). Changes in learner domains will be evaluated cumulatively across a curriculum, as well as by activity. This data will be shared with Shenandoah University for comparative analysis.

C. Evaluation Design

To address the gap in pneumococcal immunization rates, immunization rates after the one-year period (Stage C) for the pneumococcal vaccine will be compared between the two groups. Additionally, immunization rates for the influenza vaccine will be analyzed in the same fashion to see if targeted screening, patient interactions and marketing for the pneumococcal vaccine also impacted overall clinical immunization services. These rates will be generated by prescription claims data from the regional community pharmacy chain.

Screening rates, from the analysis of the returned screening tools, will be reported using descriptive statistics including the number of high risk patients that were identified, the number of patients who were already vaccinated and those who refused vaccination. These values will be compared to those who actually received the vaccination as confirmed by prescription claims.

The ReallIndex® system, as defined above, will produce composite learner scores and is designed to provide meaningful insight into the effect of the curriculum on a learner's clinical practice. Participation rates from the activities of the online education curriculum, as well as, performance analysis will be provided by RealCME and sent to Shenandoah University for analysis. Performance analysis will include the measurement of change in the ReallIndex® from baseline to the final intervention. It will also measure the impact of participation in multiple activities, of different types of activities, and the cumulative effect of each additional activity on the change in ReallIndex® from baseline.

Analysis of the primary endpoint will compare immunization rates between the test store group and control group, using the Student's t-test and SPSS software. Factors that could influence the overall rates of pneumococcal immunization including educational module participation rates, performance analysis, baseline immunization rates, store location, percentage of store population over age 65, percentage of store population aged 2-64 with comorbid conditions, and screening rates will also be analyzed using the Student's t-test.

Given the increase in pneumococcal immunization rates at this regional community pharmacy chain was less than 0.5% from 2010 to 2011, the interventions at test stores are expected to produce a pneumococcal immunization rate that is at least double that of baseline from 2011. This would mean an additional 600 pneumococcal vaccinations would be provided by this regional community pharmacy chain. While this may not bring the immunization rate to that

proposed by Healthy People 2020, this would provide evidence that educational initiatives and direct pharmacist-patient interaction in combination with targeted screening can increase the overall level of pneumococcal vaccinations in the community. The successful interventions could then be expanded to other pharmacies within the RxAlly network, increasing pneumococcal immunization rates across the country.

At the completion of the data analysis, all outcomes will be shared with the management of the regional community pharmacy chain for further use in their immunization initiatives.

Additionally, an abstract(s) will be submitted for a poster presentation at a national pharmacy meeting allowing the data to be shared with other community pharmacists and community pharmacy companies. Additionally, a manuscript will be written and submitted to a pharmacy journal to help other community pharmacies increase pneumococcal immunization rates at their sites.

III. Detailed Work Plan and Deliverables Schedule

A three-month period from January 1, 2013 - March 31, 2013 will be used for Stage A: Development of Educational Programming, Screening Tools, and Marketing Materials. Baseline immunization rates from the regional community pharmacy chain will be reported and pharmacists and pharmacy staff for the organization will participate in the SAP. During this period, online education programs will also be developed for both pharmacists and pharmacy staff. Other interventional materials, including perforated screening tools and marketing displays will be created for dissemination to pharmacy locations participating in the study.

At the completion of Stage A, the online education modules will be developed and disseminated to pharmacists and pharmacy technicians at test store locations. Completion of the modules and a PCA will need to occur within a 3-month window of June 1, 2013 - August 30, 2013. During this time, all screening and promotional materials will be disbursed to test store locations.

Starting September 1, 2013, pharmacies will commence screening of targeted patients during the prescription filling process and provide pneumococcal vaccinations for a one-year period. At the end of the one-year period (August 30, 2014) claims data from the pharmacy computer system will be tabulated to determine immunization rates. Screening tools will be cataloged and evaluated. Comparison of immunization rates between the test and control groups as well as to baseline will be analyzed.

Dissemination of the results will be provided to the regional community pharmacy chain and all interested parties by December 31, 2014. Proposed abstract(s) will be submitted to national

pharmacy organizational meetings by this time as well. A manuscript for publication will be drafted and expected submission will occur by April 30, 2015.

Key Deliverables	Planning	2013				2014				2015
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Obtain immunization faculty and project management	X									
Obtain commitment from partners	X									
Prepare and submit IRB proposal to Shenandoah University		X								
Creation of Self Assessment Program		X								
Creation of screening tool		X								
Development of in-store marketing		X								
Delivery of SAP to Kerr pharmacists and pharmacy staff		X								
Obtain Continuing Education Accreditation from ACPE through SU for online modules		X								
Data tracking/report generation			X							
Development of Virtual Grand Rounds		X	X							
Development of PharmacyConsult		X	X							
Development of DecisionPoints		X	X							
Delivery of online educational modules			X	X						
Post Curriculum Assessment and analysis				X						
Dissemination of in-store marketing				X						
Dissemination of screening tool				X						
Screening and Immunizations				X	X	X	X	X		
Oversight of program implementation at test stores				X	X	X	X	X		
Data tracking/report generation								X		
Catalog and analysis of screening tool									X	
Statistical analysis of immunization rates									X	
Preparation and submission of abstract(s)									X	
Preparation and submission of manuscript										X
Presentation at national pharmacy meeting(s)										X