



# **Increasing Vaccination Rates with an Appointment-Based Pharmacy Model**

*Submitted to Pfizer by  
University of Cincinnati  
James L. Winkle College of Pharmacy  
Heidi Luder, PharmD  
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## **I. MAIN SECTION OF THE PROPOSAL**

### **1. Overall Goal and Objectives**

The overall goal of this project is to increase vaccination rates by systematically assessing vaccination status, administering necessary vaccinations at the pharmacy through an appointment-based pharmacy model, and accessing and reporting vaccination history in a statewide vaccination database. Specifically, the objectives of the research are to increase vaccination rates for influenza, pneumococcal, shingles, hepatitis, and tetanus vaccinations for older adults, determine the acceptance rate of vaccinations offered at the pharmacy, increase patient satisfaction with receiving vaccinations at the pharmacy, and assess the feasibility of pharmacy access to a state immunization registry. These objectives address the need for increased vaccination rates by overcoming multiple barriers to immunization such as patient accessibility to immunizers, patient knowledge of recommended vaccinations, and incomplete and inaccurate vaccination histories.

### **2. Technical Approach**

#### **a. Current Assessment of need in target area**

In 2011, the Centers for Disease Control Behavioral Risk Factor Surveillance System reported that, in Ohio, 38.6 percent of individuals greater than 65 years of age did not receive the yearly influenza vaccine. Additionally, about one in three patients greater than age 65 have not received the pneumococcal vaccine.<sup>1</sup> Furthermore, statewide vaccination data is not available for high risk patients less than 65 years of age who are eligible for additional vaccinations, such as patients with diabetes. Anecdotal observations at the pharmacy, however, suggest that these high risk patients are particularly underserved with regard to vaccinations. Therefore, there remains a need to increase vaccination rates for older adults and other high risk individuals in Ohio.

Community pharmacists have a significant role in administering vaccinations and a simple recommendation by a pharmacist to receive a vaccination can increase vaccination rates.<sup>2</sup> There are several opportunities for pharmacists to reach out to patients to promote vaccinations. However, in the current pharmacy workflow, there is not a standardized system for promoting vaccines at the pharmacy counter. Especially for refills, patients often receive prescriptions without speaking with the pharmacist. Since a barrier to immunizations is a lack of patient understanding of which vaccines are necessary, increased pharmacist engagement with patients at the pharmacy would increase vaccination rates. We will utilize a system change which will promote patient counseling and encourage pharmacists to assess patients' vaccination history, and offer vaccinations while patients are at the pharmacy to pick up prescriptions.

Patient-report is the current method of assessing vaccination history at the community pharmacy; however patients are not always aware of their vaccination histories and may be inaccurate historians. A statewide vaccination reporting system is available in Ohio, yet pharmacies are not currently accessing the database for vaccination information and are not reporting administered vaccinations in this system. This information disconnect creates a serious problem as pharmacists are not able to effectively and objectively assess vaccination histories and physicians may not have an accurate record of vaccinations administered at the

pharmacy. Not entering these vaccinations in the database creates a communication barrier between the pharmacy and the physician offices which could potentially result in the duplication of vaccinations. For this project, pharmacists will receive access to the statewide immunization database and will be required to review the database prior to the administration of vaccines; and then enter vaccinations into the database following administration at the pharmacy. Additionally, the dispensing system will be upgraded to include a vaccination history section which the pharmacist or pharmacy technician will be required to update during the appointment from the vaccination history gathered by both patient report and from the immunization database. Providing pharmacy access with the vaccination database will improve communication of vaccine information between pharmacists and physician offices and will also allow pharmacists to access the database to assess vaccination needs as patient-report may not be accurate or complete.

For this study, patients aged 60 or older with greater than five medications and/or high risk disease states such as diabetes and asthma/COPD, will be targeted for the intervention. However, all patients who receive multiple prescriptions from the pharmacy may opt into the project. In addition to increasing vaccination rates, this project will have two important secondary benefits. Targeting patients with high risk disease states will ensure high risk patients are approached to offer appropriate vaccinations. Targeting patients with several medications will allow for the synchronization of refills to prevent excessive visits to the pharmacy and decrease the complexity and timing issues associated with refilling medications. We anticipate that this benefit, in particular, will be a strong motivator for patients to opt into project participation.

#### **b. Intervention Design and Methods**

In order to increase vaccination rates, a system change will be utilized to facilitate the assessment and administration of vaccinations by pharmacists. The system change will include a medication synchronization project, which utilizes an appointment-based pharmacy model (ABM). For this synchronization project, medication refills that are due at differing times in the month will be synchronized to a date of the patient's choice and as covered by the insurance company.

Additionally, a process change will be implemented which will require pharmacists to access vaccination history from *Ohio Impact SIIIS*, the state immunization tracker. This will allow pharmacists to objectively assess patient's vaccination history. Furthermore, pharmacists will be required to update vaccination information in *Ohio Impact SIIIS* after pharmacists assess vaccination history at the pharmacy. All vaccinations administered at the pharmacy will be documented in the database. Over time, as *Ohio Impact SIIIS* is utilized more globally, reported vaccination rates will increase. The current pharmacy dispensing system does not monitor vaccination histories; therefore, a technology update will be implemented to allow pharmacists to document the gathered vaccination history in the dispensing system for reference during follow-up patient ABM visits.

A pharmacy technician at an off-site call center will recruit and identify eligible patients who normally fill prescriptions at the intervention pharmacies for the medication synchronization portion of project. The technician will enroll patients in the appointment-based refill program and schedule an appointment in the existing clinical services scheduler at the

pharmacy to notify pharmacists of the appointment. Upon enrollment into the ABM program, the pharmacy technician will discuss a preferred pick-up date with the patient and will discuss which maintenance medications the patient would like to pick up during the appointment. The dispensing system will automatically refill all selected medications on the pre-determined date. After the medications refills are synchronized to a single monthly date, patients will receive a telephone call to remind them of their appointment to pick up prescriptions. The pharmacy technician will troubleshoot problems as necessary, including scheduling refills after new prescriptions are prescribed and calling insurance companies for overrides.

The pharmacist appointments will be scheduled for 15 minute increments to allow for adequate integration into the existing pharmacy workflow. To maintain patient privacy, all appointments will be conducted in private counseling areas in the pharmacy. Pharmacists will be able to access a list of all patient appointments for the day in the clinical services scheduler, allowing the pharmacist to prepare for the patients' appointments. During an appointment, the pharmacist will perform a variety of services for the patient including medication therapy management, patient counseling, and assessment of the patient's vaccination status. Pharmacists will be instructed that for the purposes of this project, vaccinations will be the main focus of the appointment. The pharmacist will review the *Ohio Impact SIIIS* data and reconcile this with the patient-reported vaccination history. If the pharmacist determines there is an unmet vaccination need, the pharmacist will offer to provide the appropriate vaccinations at that appointment. Administering vaccines at the time the need is identified will increase the convenience for patients and will prevent patients from prolonging the receipt of the vaccine after a gap in therapy is identified. For vaccinations, such as the shingles vaccine, which require a prescription from the physician in Ohio, the pharmacist will request a prescription from the physician and following receipt of a prescription, administer the vaccine at the next follow-up appointment. While the time for each patient appointment is relatively short, the scheduled monthly appointment with the pharmacist will allow a relationship to be formed between the pharmacist and the patient, which will allow for enhanced medication and vaccination management.

Pharmacy personnel, including the pharmacists and the technicians, will receive training on the study protocol and all system and process changes. All Kroger pharmacists are currently trained and required to administer vaccinations at the pharmacy, therefore training regarding vaccinations and vaccination technique will not be necessary. Additionally, pharmacists are already incorporating Medication Therapy Management services into the pharmacy workflow. By providing these advanced counseling and medication management services, pharmacists have already begun engaging with patients and forming relationships. While pharmacists have a strong desire to counsel patients, the current workflow does not support in-depth counseling. This model will give pharmacists additional face to face counseling time.

This project will have a significant impact because there is a large number of older adults who need to receive additional vaccinations. In the Cincinnati area, the percentage of patients greater than age 65 is 10.8 percent, or just over 32,000 patients.<sup>3</sup> The sample population of patients that Kroger Pharmacies serve is also large, as Kroger Pharmacies capture 30 percent of the pharmacy market share in the area.

### c. Evaluation Design

The evaluation design will focus on both formative and summative aspects of this program. A mixed methods strategy that includes the collection of both quantitative and qualitative data will assess the impact on interventions on vaccination rates for older, at-risk adults as well as improved adherence to medications. These are the primary patient outcomes for this study. They will be assessed in a pre-post design that includes a matched control group. Internal pharmacy data will be used to determine the number of vaccines administered in the year prior to the intervention, compared to the number of vaccines administered during and following the intervention. We will also examine on-time prescription refills for the same period. The appointment-based model will be piloted in 26 Kroger Pharmacies. For a control group, 26 Kroger Pharmacies with similar patient demographics, pharmacy volume, and baseline immunization rates to the intervention pharmacies will not initiate the ABM.

To assess patient engagement with this project, we will administer a patient satisfaction survey which will assess perceived satisfaction, benefits, and convenience with the ABM intervention. Additionally, we will monitor the acceptance rate of patients who are offered to enroll in the ABM. From patients who choose not to participate in the ABM, we will gather information regarding their refusal. Finally, we will monitor the individual patient acceptance rates of immunizations recommended by the pharmacist, and document reasons why patients refused vaccinations.

To assess the usability of the *Ohio Impact SIIIS* database, pharmacists will monitor the accuracy of the vaccination data compared to patient-report of vaccination history. Additionally, a satisfaction survey will be distributed to pharmacists at the completion of the study to assess the pharmacist's perceived importance, accessibility, and convenience with obtaining and reporting information into the system. Project staff will also document technological and other issues related to accessing and using the *Ohio Impact SIIIS* database.

We expect to enroll approximately 100 patients at each pharmacy location (an average of five percent of the total pharmacy population) for approximately 2,600 total patients. Based on current local immunization rates, we conservatively estimate that each patient will receive two additional vaccines compared with statistics from our baseline period. This represents a 10 % increase in vaccinations over the project period. The quantitative data from this project will be analyzed using Student t-tests, Analysis of Variance, and paired comparison tests. These statistical tests will compare the data from the intervention group to that of the control group and include comparisons from the baseline period to the project period data. Survey data will be initially presented as percentages and means. Additional multivariate analyses will be conducted to assess relationships among response variables. Final results of the project will be submitted to peer-reviewed journals. Final reports will be sent to several state agencies in Ohio (including the Ohio Department of Health, state pharmacy associations, and relevant state legislative committees). Additionally, the authors will disseminate the information through posters or presentations at national conferences. This project is highly generalizable to community pharmacy practice across the country, as many pharmacy chains are providing immunizations and are searching for sustainable models to systematically administer vaccinations and increase vaccination rates.

### 3. Detailed Workplan and Deliverables Schedule

The project will be completed over a two year period, starting January 2014. The first phase is project development, which will last approximately five months. During this phase, four important activities will occur to prepare for the intervention: 1) Kroger will pilot the ABM in the 26 pharmacies to streamline the medication synchronization process and troubleshoot problems; 2) the Kroger pharmacy dispensing system will receive an upgrade which will create a section for documenting and maintaining vaccination histories, since updating this field will be required in the intervention stores; 3) Kroger will register with the *Ohio Impact SIIIS* database to gain access to the statewide vaccination tracker; and 4) patient and pharmacist satisfaction surveys will be constructed and validated.

Starting May 2014, pharmacy staff will receive training, which will last approximately two months. The pharmacy staff will be trained on the study protocol by the principal investigator. Pharmacists will receive training on the *Ohio Impact SIIIS* database and appropriate methods for ascertaining vaccination histories. The principal investigator will offer multiple training sessions at each pharmacy in order to train all pharmacy staff. After the initial training session, the principal investigator will maintain regular contact with the study pharmacies to ensure continued compliance with study procedures.

We expect the study period to begin in August 2014. After the initial pilot phase, the vaccination-focused ABM model will be implemented in pharmacies. The existing ABM will continue, but pharmacists will be instructed to focus the appointment on obtaining complete and accurate vaccination histories and administering vaccinations during the visit. Baseline vaccination data will be pulled from 2013 vaccination dispensing records for a comparison. The study period will last one year, with at least two preliminary data analysis points during the one year period to present at two national pharmacy meetings, the Association of Health-System Pharmacists (ASHP) and the American Pharmacist Association (APhA). Since vaccination rates fluctuate naturally throughout the year, each data point will be compared to the same time the previous year.

After the year-long study period, complete data analysis will begin. The investigators will analyze the data compared to the previous year and to the control group, as described above in the Evaluation Design section. Additionally, patient and pharmacist satisfaction surveys will be distributed and analyzed during this period. After data analysis, a manuscript will be constructed for publication in a high impact medical-related journal.

**Table 1. Detailed Workplan and Deliverable Schedule**

Activity	Project Month	Responsible Person(s)	Anticipated Outcomes
Create and submit IRB protocol	1	Luder Heaton Speer	IRB approval
Pilot ABM in pharmacies to synchronize medication refills	2-5	Frede Kroger administrative assistant Luder	Troubleshoot and resolve issues, successfully implement medication synchronization

Update dispensing system to include vaccination records	2-5	Frede Kroger administrative assistant Kroger technology personnel	Dispensing system updated to document vaccine history
Register pharmacy for Ohio Impact SIIIS	2-5	Frede Luder	Registered for Ohio Impact SIIIS
Construct and validate patient satisfaction surveys	2-5	Luder Heaton Frede Kroger administrative assistant	Patient satisfaction surveys validated
Construct and validate pharmacist surveys	2-5	Luder Heaton Frede Kroger administrative assistant	Pharmacist surveys validated
Training on vaccine-specific ABM and study protocol in 26 pharmacies	6-8	Luder Frede Kroger administrative assistant	Pharmacy staff trained and ready to complete project according to protocol
Training on Ohio Impact SIIIS	6-8	Luder Frede Kroger administrative assistant	Pharmacy staff trained and able to access and document in Ohio Impact SIIIS
Continue ABM and incorporate vaccine-focused appointments in pharmacies	9-21	Luder Frede Kroger administrative assistant	Vaccine-focused ABM implemented in 26 pharmacies
Extract baseline vaccination data		Frede Kroger administrative assistant	Data extraction completed
Supervise pharmacies and monitor compliance with study protocol	9-21	Luder Frede Kroger administrative assistant	Pharmacies compliant with study protocol and engaged with project
Provide ongoing communication with stores regarding project progress	9-21	Luder Frede Kroger administrative assistant	Pharmacies informed of study progress
Troubleshooting vaccine documentation in dispensing system	9-21	Kroger technology personnel	Vaccine documentation accurate and complete in study pharmacies
Extract preliminary vaccine data	11	Frede Kroger administrative assistant	Data extraction completed



Analyze preliminary vaccines data	11	Luder Heaton	Data successfully analyzed
Send patient satisfaction surveys	11	Kroger administrative assistant	Patients enrolled in study receive and complete satisfaction survey
Construct abstract and poster presentation for ASHP	12	Luder Heaton Frede	Abstract accepted for presentation
Present poster at ASHP	12	Luder	Poster presented and information disseminated
Extract preliminary vaccine data #2	14	Frede Kroger administrative assistant	Data extraction completed
Analyze preliminary vaccine data #2	14	Luder Heaton	Data successfully analyzed
Send patient satisfaction surveys #2	14	Kroger administrative assistant	Patients enrolled in study receive and complete satisfaction survey
Construct abstract and poster presentation for APhA	15	Luder Heaton Frede	Abstract accepted for presentation
Present poster at APhA	15	Luder	Poster presented and information disseminated
Extract final vaccine data	22	Frede Kroger administrative assistant	Data extraction completed
Send final patient satisfaction surveys	22	Kroger administrative assistant	Patients enrolled in study receive and complete satisfaction survey
Administer pharmacist satisfaction surveys	22	Kroger administrative assistant	Pharmacists receive and complete satisfaction survey
Analyze and perform statistical analyses of final data	22-23	Luder Heaton	Data successfully analyzed
Interpret results	22-23	Luder Heaton	Data interpreted accurately
Generate manuscript and final project report	24	Luder Heaton Frede	Manuscript created and submitted for publication

Communicate results to pharmacies and upper-level Kroger management	24	Frede Luder	Upper-level management informed of study results and project expanded
Coordinate project budget and contact with grantor	1-24	Speer	Budget managed at University of Cincinnati and communication with grantor maintained

## II. ORGANIZATIONAL DETAIL

### 1. Leadership and Organizational Capacity

The University of Cincinnati (UC) James L. Winkle College of Pharmacy and Kroger Pharmacy will partner to develop, implement, and evaluate this project. Kroger pharmacy, located in the Cincinnati-Dayton area is comprised of 102 pharmacies and 30 patient care centers. Kroger pharmacists provide a variety of community patient care services including medication therapy management; vaccinations; healthcare screenings; food, weight and nutrition counseling; smoking cessation; and American Diabetes Association recognized diabetes self-management education programs (DSME). Kroger Pharmacy's most robust services include diabetes and hypertension coaching programs for City of Cincinnati employees and retirees, modeled after successful coaching program such as The Asheville Project and The Diabetes 10-City Challenge.<sup>4</sup> Through these clinical programs, Kroger pharmacists establish and maintain strong relationships with patients. These relationships are maintained through the regular basis in which patients present to the pharmacy and/or grocery store. Kroger Pharmacy's Leadership team includes a Clinical Coordinator whose role is specifically designed to expand the pharmacy's clinical services. The Clinical Coordinator provides oversight to all clinical programs implemented in the pharmacy and plays an important administrative role to ensure projects meet the goals and objectives to increase the delivery of services in the community pharmacy setting and expand the role of a pharmacist.

The UC James L. Winkle College of Pharmacy maintains a strong relationship with Kroger Pharmacy. In addition to a shared faculty position and community pharmacy fellowship program, they have jointly offered a community pharmacy residency program for nine years and have trained 20 residents. Throughout this partnership, UC and Kroger have collaborated on several published research projects<sup>5-7</sup> including a project which received the American Pharmacist Association Clinical Research Award in 2012.<sup>8</sup> As a research-intensive academic institution, faculty at the University of Cincinnati have high expectations for conducting research and are well-trained researchers capable of designing, implementing, and evaluating successful research projects.

### 2. Staff Capacity

The primary investigator on this project is Dr. Heidi Luder. Dr. Luder is responsible for and will lead all aspects of this project including the design, implementation, evaluation, and dissemination. **Heidi Luder, PharmD, MS, BCACP** is an Assistant Professor of Pharmacy Practice

at University of Cincinnati with a practice site at Kroger Pharmacy. Dr. Luder's responsibilities at Kroger Pharmacy as a shared faculty member are to provide patient care services and expand existing clinical services. Dr. Luder is expected to serve as a project manager for new clinical service programs and is available to perform these activities. As the project manager for several other projects, Dr. Luder has established a rapport with Kroger Pharmacists and is able to provide training and follow-up to ensure project implementation. Prior to her faculty role, from 2011-2013, she was the first Community Pharmacy Outcomes Fellow working jointly with The University of Cincinnati and Kroger Pharmacy. Dr. Luder completed coursework for a Master's of Science in Health Outcomes Research in 2013. She has worked on several research projects, including a Transition of Care project which received grant funding from the Community Pharmacy Foundation. For the Transition of Care project, Dr. Luder designed, implemented, and evaluated the entire project and is capable of carrying out these roles in similar projects. In the last year, two manuscripts were accepted for publication in the Journal of The American Pharmacist Association and an additional three manuscripts are pending publication in various peer-reviewed journals. Dr. Luder is well-trained in community pharmacy and completed a First Year Residency in Community Pharmacy at Froedtert Hospital in Milwaukee, Wisconsin.

**Pamela Heaton, PhD** is a co-investigator for this project. She will provide consultation on the design of the study and will assist Dr. Luder in the evaluation and dissemination of the information. Dr. Heaton is the Chair and Associate Professor of Pharmacy Practice and Administrative Sciences at the University Of Cincinnati College Of Pharmacy. Dr. Heaton has a long-standing history of successful research with over 32 publications, over 60 national poster presentations, and over one million dollars in external funding from such organizations as the State of Ohio, Agency for Healthcare Research and Quality, and the Clinical and Transitional Science Award (CTSA grant). As a leader in the College of Pharmacy, she will also provide administrative support and leadership for the management of the grant at the University of Cincinnati.

**Stacey Frede, PharmD, CDE**, the Clinical Coordinator for Kroger Pharmacy in the Cincinnati-Dayton area, will oversee the operations of this project. Dr. Frede will assist with developing the study protocol, oversee all research activities, and provide administrative support for Kroger personnel. Dr. Frede has knowledge and experience with research and publication and has collaborated with the University of Cincinnati on multiple research projects. As the Kroger Pharmacy residency director, Dr. Frede assists residents with the yearly writing of American Pharmacist Association (APhA) Incentive Grants and encourages publication of residency research projects. Additionally, Kroger Pharmacy was selected as one of 25 participants for the APhA Foundation *Project Impact: Diabetes* grant.

### **III. DETAILED BUDGET**

A total of **\$374,819** is requested for this project. The grant money is requested for the following expenses: principal investigator and co-investigator salary support, travel, materials and supplies, indirect facilities and administration costs, and a subcontract to Kroger to support the technology functionality changes, advertising costs, and administrative support necessary for project implementation. Please note that all salaries are listed at the FY14 rate; a small increase has been allowed for FY15 in all calculations.

Heidi Luder, the principal investigator will provide 15 percent effort for overseeing the project, training pharmacy staff, data analysis, and information dissemination through the presentation of posters and a publication of a manuscript, at a salary of \$98,500 plus \$11,041, the standardized rate set by the University of Cincinnati for fringe benefits. Therefore a total of \$40,887 is requested for salary relief and benefits for Dr. Luder. Pamela Heaton, a co-investigator will oversee the design of the study and participate in the data analysis of the project which will account for 10 percent of her time at a salary of \$165,202 with an additional \$12,346 allocated for fringe benefits, totaling \$45,717.

These grants are processed and managed by the Center for Continuous Professional Development (CCPD) office at the University of Cincinnati. The CCPD office will provide support through an interprofessional collaboration committee, and will provide management of the funds and communication with the funding agency. Barb Speer in the CCPD office will receive salary and fringe benefit support for her work at 2% effort and a salary of \$47,940, totaling \$2,768.

\$5,454 is requested for travel to the American Society of Health-System Pharmacy and American Pharmacist Association Annual Meetings. The funding will help support registration fees and travel expenses. \$4,040 is requested for miscellaneous materials and supplies which may include office materials for the pharmacists to create patient education handouts and training materials. Indirect costs will be limited to 28% as indicated in the request for proposal, totaling \$81,992.

Kroger will be subcontracted with the University of Cincinnati to receive \$193,961. A portion of this money will be used to support technology developments necessary to add functionality to the existing dispensing system in order to create a vaccination history section. A technology support person will develop this modification and provide technical support at 25% effort and a salary of \$100,000, plus fringe benefit, totaling, \$72,183.

Additionally, co-investigator Stacey Frede will receive salary support at 15% effort and a salary of \$167,000, including fringe benefits, totaling \$72,327. Dr. Frede will be responsible for providing leadership support to the project during the implementation phase. To assist with management of the project in such a large number of stores, administrative support staff will be needed to provide secretarial and organizational support to the project at 12% effort and a salary of \$85,000, including fringe benefits, totaling \$29,451.

Advertising through fliers, billboards, mailers, and other promotional material will be utilized to assist in the enrollment of patients into the ABM. \$20,000 will be allocated to advertising efforts.

**Table 2: Itemized Budget**

Direct Costs	US \$	Description	Notes
Direct Labor Costs			Deliverables/Justification
Create and submit IRB protocol	\$1,918	Luder (0.2%) Heaton (0.2%)	IRB approval
Pilot ABM in pharmacies to synchronize medication refills	\$8,639	Frede (1.0%) Kroger administrative assistant (1.0%)	Troubleshoot and resolve issues, successfully implement medication synchronization

		Luder (0.5%)	
Update dispensing system to include vaccination records	\$63,793	Frede (1.0%) Kroger administrative assistant (0.5%) Kroger technology personnel (20%)	Dispensing system updated to document vaccine history
Register pharmacy for Ohio Impact SIIS	\$2,473	Frede (0.4%) Luder (0.2%)	Registered for Ohio Impact SIIS
Construct and validate patient satisfaction surveys	\$3,645	Luder (0.4%) Heaton (0.4%) Frede (0.1%) Kroger administrative assistant (0.1%)	Patient satisfaction surveys validated
Construct and validate pharmacist surveys	\$2,918	Luder (0.3%) Heaton (0.3%) Frede (0.1%) Kroger administrative assistant (0.1%)	Pharmacist surveys validated
Training on vaccine-specific ABM and study protocol in 26 pharmacies	\$11,007	Luder (2.0%) Frede (1%) Kroger administrative assistant (0.3%)	Pharmacy staff trained and ready to complete project according to protocol
Training on Ohio Impact SIIS	\$3,066	Luder (0.5%) Frede (0.2%) Kroger administrative assistant (0.3%)	Pharmacy staff trained and able to access and document in Ohio Impact SIIS
Continue ABM and incorporate vaccine-focused appointments in pharmacies	\$2,783	Luder (0.4%) Frede (0.3%) Kroger administrative assistant (0.1%)	Vaccine-focused ABM implemented in 26 pharmacies
Extract baseline vaccination data	\$1,701	Frede (0.2%) Kroger administrative assistant (0.3%)	Data extraction completed
Supervise pharmacies and monitor compliance with study protocol	\$17,057	Frede (3%) Luder (0.5%) Kroger administrative assistant (0.5%)	Pharmacies compliant with study protocol and engaged with project
Provide ongoing communication with stores	\$9,824	Frede (1.5%) Luder (0.5%)	Pharmacies informed of study progress

regarding project progress		Kroger administrative assistant (0.5%)	
Troubleshooting vaccine documentation in dispensing system	\$14,436	Kroger technology personnel (5%)	Vaccine documentation accurate and complete in study pharmacies
Extract preliminary vaccine data	\$3,419	Frede (0.2%) Kroger administrative assistant (1.0%)	Data extraction completed
Analyze preliminary vaccines data	\$7,298	Luder (1.0%) Heaton (1.0%)	Data successfully analyzed
Send patient satisfaction surveys	\$2,454	Kroger administrative assistant (1.0%)	Patients enrolled in study receive and complete satisfaction survey
Construct abstract and poster presentation for ASHP	\$9,709	Luder (1.0%) Heaton (1.0%) Frede (0.5%)	Abstract accepted for presentation
Present poster at ASHP	\$546	Luder (0.2%)	Poster presented and information disseminated
Extract preliminary vaccine data #2	\$3,419	Frede (0.2%) Kroger administrative assistant (1.0%)	Data extraction completed
Analyze preliminary vaccine data #2	\$7,298	Luder (1.0%) Heaton (1.0%)	Data successfully analyzed
Send patient satisfaction surveys #2	\$2,454	Kroger administrative assistant (1.0%)	Patients enrolled in study receive and complete satisfaction survey
Construct abstract and poster presentation for APhA	\$9,709	Luder (1.0%) Heaton (1.0%) Frede (0.5%)	Abstract accepted for presentation
Present poster at APhA	\$546	Luder (0.2%)	Poster presented and information disseminated
Extract final vaccine data	\$3,665	Frede (0.2%) Kroger administrative assistant (1.1%)	Data extraction completed
Send final patient satisfaction surveys	\$3,926	Kroger administrative assistant (1.6%)	Patients enrolled in study receive and complete satisfaction survey
Administer pharmacist satisfaction surveys	\$3,926	Kroger administrative assistant (1.6%)	Pharmacists receive and complete satisfaction survey
Analyze and perform statistical analyses of final data	\$7,297	Luder (1.0%) Heaton (1.0%)	Data successfully analyzed
Interpret results	\$7,297	Luder (1.0%)	Data interpreted accurately

		Heaton (1.0%)	
Generate manuscript and final project report	\$29,604	Luder (3.0%) Heaton (3.0%) Frede (1.6%)	Manuscript created and submitted for publication
Communicate results to pharmacies and upper-level Kroger management	\$14,738	Frede (3.0%) Luder (0.1%)	Upper-level management informed of study results and project expanded
Coordinate project budget and contact with grantor	\$2,768	Speer (2%)	Budget managed at University of Cincinnati and communication with grantor maintained
<b>Subtotal</b>	\$226,333.00		
<b>Direct Initiative Costs</b>			<b>Deliverables/Justification</b>
Kroger Advertising	\$20,000	Advertising for promotion of ABM, including fliers, signs, etc.	Adequate enrollment in ABM and study
Travel to ASHP and APhA	\$5,454	For registration fees and travel expenses	Information disseminated at multiple national pharmacy meetings
Training materials and supplies	\$4,040	Printing and office supplies such as binders ,etc.	Adequate references for pharmacy personnel regarding study protocol
<b>Subtotal</b>	\$ 29,494.00		
<b>Subtotal</b>	\$292,827.00		
<b>Institutional Overhead/Indirect</b>			
University Overhead, including taxes, utilities, IT, printing, etc.	\$81,992	28% per RFP allowances	
<b>Subtotal</b>	\$81,992		
<b>Total Initiative Budget</b>	\$374,819		
<b>Total Amount Requested</b>	<b>\$374,819</b>		

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7. Fuller L, Conrad WF, Heaton P, Panos R, Eschenbacher W, Frede S. A Pharmacist-Managed Chronic Obstructive Pulmonary Disease Screening in a Community Setting. *J Am Pharm Assoc*. In Press.
8. Rosser S, Frede, S.M., Conrad WF, Heaton PC. Development, Implementation, and Evaluation of a Pharmacist-Conducted Screening Program for Depression. *J Am Pharm Asso*. In Press.
9. Winfrey C, Wortman S, Frede S, Kunze N, Conrad WF, Heaton PC. Pharmacist-initiated peripheral arterial disease screening program in a community pharmacy setting. *Journal of the American Pharmacists Association : JAPhA*. May-Jun 2011;51(3):373-377.



**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Heidi R. Luder		POSITION TITLE Assistant Professor of Pharmacy Practice	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Drake University, Des Moines, IA	PharmD	2010	Pharmacy
University of Cincinnati, Cincinnati, OH	MS	2013	Pharmacy

**A. Personal Statement**

The overall goal of this project is to increase vaccination rates by systematically assessing vaccination status, administering necessary vaccinations at the pharmacy through an appointment-based pharmacy model, and accessing and reporting vaccination history in a statewide vaccination database. I will be the principal investigator for this project and will be responsible for the design, implementation, and evaluation of this study. I have extensive experience in the community pharmacy setting and completed a community pharmacy residency at Froedtert Hospital in Milwaukee, WI. Additionally, as a shared faculty, I currently practice in the community pharmacy setting at Kroger Pharmacy and am familiar with pharmacy practice in the community and specifically at Kroger. Furthermore, I have completed a community pharmacy outcomes fellowship and received a Masters of Science in Health Outcomes Research and am confident in implementing and evaluating practice-based research projects. I have developed and implemented several research projects in collaboration with Kroger Pharmacy and the University of Cincinnati, including a transition of care project and a patient-centered medical home project with multiple hospitals and health-systems in the Cincinnati area.

**B. Positions and Honors****Positions and Employment**

2013-Present      Assistant Professor of Pharmacy Practice, University of Cincinnati/Kroger Pharmacy, Cincinnati, OH  
 2011-2013        Community Pharmacy Outcomes Fellow and Clinical Pharmacist, University of Cincinnati/Kroger Pharmacy, Cincinnati, OH  
 2010-2011        PGY-1 Community Pharmacy Resident, Froedtert Hospital, Milwaukee, WI

**Honors**

American Association of Colleges of Pharmacy Walmart Scholars Program, 2012

Mylan Pharmaceuticals Excellence in Pharmacy Award, 2010

Lambda Kappa Sigma Ethel Health Key Award, 2010

**Professional Memberships**

Ohio Pharmacists Association, 2011-Present

Principal Investigator/Program Director (Last, First, Middle): Luder, Heidi R.

American Association of Colleges of Pharmacy, 2011-Present

American Pharmacists Association, 2010-Present

Leadership: Transitions Newsletter Editorial Advisory Board, 2011-2013

American Society of Health-System Pharmacists, 2009-2011, 2012- Present

### **C. Selected Peer-reviewed Publications (in chronological order).**

#### **Most relevant to the current application**

Hui-Callahan B, **Luder HR**, Frede SM. The Impact of a Pay-for-Performance-for-Patients (P4P4P) Model for Diabetes in a Grocery Store Setting. Journal of the American Pharmacists Association, In Press.

#### **Additional publications (in chronological order)**

**Luder HR**, Gillard D. Pharmacist Intervention to Increase Medication Adherence by Promoting the use of Pillbox Organizers in Patients Followed in the DITTO Clinic. Journal of the Pharmacy Society of Wisconsin. March/April 2012.

Heaton PC, Patel A, **Luder HR**, Tundia NL. Noncompliance in U.S. Emergency Departments: Trends and Predictors of Visits Resulting from Poor Medication Compliance, 2005-2007. Journal of the American Pharmacists Association, 2013 Sept/Oct; 53(5), 513-519.

### **D. Research Support**

#### **Ongoing Research Support**

Title: "Community Pharmacist Collaboration with a Patient Centered Medical Home: Establishment of a Patient-Centered Medical Neighborhood and Payment Model"

Principal Investigator: Heidi Luder

Agency: Community Pharmacy Foundation

Period: Dec 2013-Dec 2014

Amount: \$43,069

#### **Completed Research Support During the Past Three Years**

Title: "Impact of a Community Pharmacy Post-Discharge Medication Therapy Management Program on Hospital Readmission Rate"

Principal Investigator: Heidi Luder

Agency: Community Pharmacy Foundation

Period: May 2012-June 2013

Amount: \$50,000

Principal Investigator/Program Director (Last, First, Middle): Luder, Heidi R.

Title: Utilizing Quality Measures in a Community Pharmacy to Improve Patient Care

PI: Andrea Santoro

Agency: American Pharmacists Association Foundation

Period: 2012-2013

Role: Co- Investigator

Amount: \$1,000

Title: Utilizing a Medical and Community-Based Approach to Increase Enrollment in a Smoking Cessation Program

PI: Taylor Garber

Agency: American Pharmacists Association Foundation

Period: 2012-2013

Role: Co- Investigator

Amount: \$1,000

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Pamela C. Heaton		POSITION TITLE Associate Professor of Pharmacy Practice	
eRA COMMONS USER NAME Heatonp			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Cincinnati	BSP Pharm	1985	Pharmacy
University of Cincinnati	MS	1998	Social and Administrative Pharmacy
University of Cincinnati	PhD	2003	Social and Administrative Pharmacy

**A. Personal Statement**

The goal of this study goal of this project is to increase vaccination rates by systematically assessing vaccination status, administering necessary vaccinations at the pharmacy through an appointment-based pharmacy model, and accessing and reporting vaccination history in a statewide vaccination database. Dr. Heaton will work closely with Dr. Luder to assume responsibility for deliverables from the University of Cincinnati. She will assume an active role in the data analysis portion of the grant. She will work with the data collected by the clinical pharmacists to measure the success of the project. She has extensive experience working with large datasets and quality measures. She will also assume responsibility for completion of a final manuscript.

**B. Positions and Honors****Positions and Employment**

1985-1987 Peace Corps Volunteer, Central African Republic  
 1987-1989 Staff Pharmacist, Hook-Superx, Inc.  
 1989-1991 District Pharmacy Manager, Hook-Superx, Inc.  
 1991-1994 Corporate Manager of Pharmacy Computer Systems, Hook-Superx, Inc.  
 1994-1998 Staff Pharmacist, University Hospital  
 1998-2003 Clinical Coordinator of the Drug Utilization Program for Ohio Medicaid  
 2003-2009 Assistant Professor, College of Pharmacy, University of Cincinnati  
 2009- Associate Professor, College of Pharmacy, University of Cincinnati  
 2010 Chair, Division of Pharmacy Practice and Administrative Sciences.

**Honors**

1996 Ohio Society of Health System Pharmacists' Ciba-Geneva Humanitarian Award  
 1998 Member, Rho Chi Honorary Society  
 2005 Best Paper Award from the Journal of Pharmacoepidemiology and Drug Safety  
 2006 Award of Excellence for Best Paper from the Journal of Managed Care Pharmacy

### **Professional Memberships**

American Association of Colleges of Pharmacy, 2003-present  
Chair-Elect of Ethics Special Interest Group, 2007  
American College of Clinical Pharmacy, 2003-present  
Secretary/Treasurer Outcomes and Economics PRN, 2005  
Grants and Fellowship Selection Committee, 2004-2007  
American Society of Health System Pharmacists, 2004-2007  
American Pharmacists Association, 2004-present  
International Society of Pharmacoeconomics and Outcomes Research, 2004-present

### **C. Selected Peer-reviewed Publications (in chronological order).**

#### **Most relevant to the current application**

Rosser S, Frede S, Conrad WF, Heaton PC. Development, Implementation, and Evaluation of a Pharmacist-Conducted Screening Program for Depression. *J Am Pharm Assoc* (2003). 2013 Jan-Feb;53(1):22-9

Fuller L, Conrad WF, Heaton PC, Panos R, Eschenbacher W, Frede SM. A Pharmacist-Managed Chronic Obstructive Pulmonary Disease Screening in a Community Setting. *J Am Pharm Asso.* (2003). 2012 Sep-Oct;52(5):e59-66.

Winfrey C, Wortman S, Frede S, Kunze N, Conrad WF, Heaton PC. Pharmacist-Initiated Peripheral Arterial Disease Screening Program in a Community Pharmacy Setting, *J Am Pharm Asso.* 2011. May-Jun;51(3):373-7.

*Note: This article was selected to win the 2012 Clinical Research Paper Award from the American Pharmacists Association.*

Berry EA, Kelton CM, Guo JJ, Heaton PC. Adaption and Application of the Agency for Healthcare Research and Quality's Asthma Admission Rate Pediatric Quality Indicator to Ohio Medicaid Claims Data. *Research in Social & Administrative Pharmacy.* 2012. June 12 (epub ahead of print).

Knight DE, Draeger RW, Heaton PC. Pharmacist Screening for Depression among Patients with Diabetes in an Urban Primary Care Setting. *J Am Pharm Assoc.* 2008 Jul-Aug;48(4):518-21.

#### **Additional publications (in chronological order)**

Heaton PC, Schuchter J, Lannon CM, Kemper AR. Impact of Drug Label Changes on Propofol Use in Pediatrics for Moderate Conscious Sedation. *Clin Ther.* 2011; 33 (7):886-895. PMID: 21703686.

Berry EA, Kelton CM, Heaton PC. National Estimates of the Inpatient Burden of Pediatric Bipolar Disorder in the United States. *J Ment Health Policy Econ.* 2011 Sep;14(3):115-23.

Tundia M, Heaton PC, Kelton CML. The National Burden of E-Code-Identified Adverse Drug Events among Hospitalized children using a National Discharge Database. *Pharmacoepidemiol Drug Saf.* 2011 Aug;20(8):866-78. PMID: 21574209.

Heaton PC, Tundia NL, Schmidt N, Wigle PR, Kelton CM. The National Burden of Pediatric Hospitalizations for Inflammatory Bowel Disease: Results from the 2006 Kids' Inpatient Database. *J Pediatr Gastroenterol Nutr.* 2012;Apr;54(4):477-85. PMID: 22027564.

Czosek RJ, Meganathan K, Anderson JB, Knilans TK, Marino BS, Heaton PC. Cardiac Rhythm Devices in the Pediatric Population: Utilization and Complications. *Heart Rhythm.* 2012;Feb 9(2): 199-208. PMID: 21907171

*Note This article was selected to receive an accompanying editorial.*

Desai VC, Heaton PC, Kelton CML. Impact of the Food and Drug Administration's Antipsychotic Black Box Warning on Psychotropic Drug Prescribing in Elderly Patients with Dementia in Outpatient and Office-based Settings. *Alzheimers Dement*. 2012 Jan 26 (Epub ahead of print).

Desai CA, Cavanaugh TM, Kelton CML, Guo JJ, Heaton PC. Trends in the Utilization of, Spending On, and Prices for Outpatient Antifungal Agents in US Medicaid Programs: 1991-2009. *Clin Ther*. 2012 Oct;34(10):2118-2131.

Tundia NL, Kelton CML, Cavanaugh TM, Guo JJ, Hanseman DJ, Heaton PC. The Effect of Electronic Medical Record System Sophistication on Preventive Healthcare for Women. *J Am Med Inform Assoc*. 2013 Mar-Apr;20(2):268-76.

Anderson JB, Czosek RJ, Knilians TK, Meganathan K, Heaton PC. Post-operative heart block in children with common forms of congenital heart disease: results from the KID database. . J Cardiovasc Electrophysiol. 2012 Jun 26. Epub ahead of print.

Czosek RJ, Anderson JB, Heaton PC, Cassedy A, Schnell B, Cnota JF. Staged Palliation of Hypoplastic Left Heart Syndrome: Trends in Mortality and Length of Stay Utilizing a National Database from 2000-2009. *Am J Cardiol*. 2013 Jun 15;111(12):1792-9.

## **D. Research Support**

### **Ongoing Research Support**

"TransitionRx: Impact of a Community Pharmacy Post-Discharge Medication Therapy Management Program on Hospital Readmission Rate"

PI: Heidi Luder

Agency: Community Pharmacy Foundation.

Period: March 1, 2012 to October 30, 2013

Role: Faculty Mentor

*The goal of this study is to document that community pharmacist-provided discharge MTM services reduce 30-day readmission rates.*

"The Impact of Clinical Pharmacists on Health Outcomes"

PI: Pam Heaton

Agency: The Kroger Company

Period: September 1, 2009 to August 31, 2015

The goal of this project is to measure the impact of services provided by clinical pharmacists on the health outcomes of patients.

Role: PI

"Medicaid Retrospective Drug Utilization Review and Health Services Research Program for Ohio"

PI: Pamela C. Heaton, PhD

Agency: Ohio Department of Human Services and Ohio Board of Regents Medicaid Technical Assistance and Policy Program

Period: March 28, 2008 to June 30, 2014

This funding allows for the administration of the state's DUR program and an additional six research projects concerning medication use and safety.

Role: PI

Principal Investigator/Program Director (Last, First, Middle): Heaton, Pamela C.

“Clinical Translational Science Award”

PI: Joel Tsevat

Agency: National Institute of Health

Period: September 1, 2009 to August 30, 2014

Role: Investigator

The goal of this project is to increase training pathways for PharmD students such as through a joint PharmD/PhD program.

**Completed Research Support During the Past Three Years**

“Impact of the Use of Sulfonylureas on Diabetes-Related Hospital Readmissions”

PI: Pam Heaton

Agency: Merck

Period: Nov 1, 2012 to April 30, 2013

Role: PI

*The goal of the study is to determine the diabetes-related hospital re-admission rate in patients with diabetes treated with sulfonylureas.*

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Stacey M. Frede, PharmD, BCACP, CDE		POSITION TITLE Clinical Coordinator Residency Program Director	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Dayton, Dayton, Ohio	BS	2000	Biochemistry
University of Cincinnati, Cincinnati, Ohio	PharmD	2004	Pharmacy
University of Cincinnati/Kroger Cincinnati, Ohio		2004-2005	PGY1 Residency

**A. Personal Statement**

The goal of the proposed research is to increase vaccination rates for adult immunizations through a systematic approach to patient assessment, education, and provision of vaccinations by the community pharmacist. In addition, the communication of vaccine status to the primary care physician through the use of the state immunization registry is being investigated. As the Clinical Coordinator for the Cincinnati Kroger Marketing Area, I am serving as the co-investigator on this project. My role will include oversight in the design and implementation of the pharmacist provided services, participation in training, program management, and quality assurance. Kroger Pharmacy in Cincinnati is well recognized for the innovative services provided and our vision for continuing to advance community pharmacy. Kroger pharmacy is well established in this area as a provider of vaccinations and is a partner in the community focused on increasing appropriate vaccination rates. As a preceptor of residents a community pharmacy fellow, I have extensive experience in design and implementation of research and quality improvement projects in the community pharmacy setting. I was part of the team that designed and implemented the Cincinnati Pharmacy Coaching Programs that began in 2008 and have an established record of success and improved patient outcomes. I was key to the selection of our site in both the American Pharmacists Association Foundation's Project IMPACT: Diabetes and DOTxMED study, and to the implementation of these projects in our pharmacies. I am passionate about the need for continued research in the community pharmacy setting in order to provide evidence of the pharmacist's value as an integral member of the health care team. This proposal has the resources needed to have a large impact on immunization rates in our community and to serve as a model for future programs.

**B. Positions and Honors****Positions and Employment**

2004-2008	Adjunct Assistant Professor of Pharmacy Practice, University of Cincinnati
2005-2006	Patient Care Pharmacist, Residency Preceptor; Kroger Pharmacy 014355 Cincinnati KMA
2006-2011	Clinical Pharmacist, Residency Site Coordinator, Kroger Pharmacy, Cincinnati KMA
2008-present	Adjunct Assistant Professor of Pharmacy Practice with voting privileges, University of Cincinnati
2011-2013	District Clinical Coordinator, Residency Director, Kroger Pharmacy, Cincinnati KMA
2013-present	Division Clinical Coordinator, Residency Director, Kroger Pharmacy, Cincinnati KMA



## **Professional Memberships**

- 2004- present American Pharmacists Association, member  
Expert Panel Member ASHP/APhA Transitions of Care Project, 2012
- 2004- present American Society of Health System Pharmacists, member  
Pharmacy Residency Accreditation Guest Surveyor, 2012-present
- 2004- present Ohio Pharmacists Association, member  
Disease State Management Task Force, 2013

## **Honors**

- 2004 Daniel A. Herbert Incentive Grant for Innovation, American Pharmacists Association Foundation
- 2008 Featured Pharmacist in *Pharmacy Today* May issue
- 2010 Spirit in Excellence Award, The Kroger Co.
- 2010 DOTxMED Study Participant, American Pharmacists Association
- 2011 Project ImPACT: Diabetes Community Participant, American Pharmacists Association Foundation
- 2012 Clinical Research Paper Award, American Pharmacists Association

## **C. Selected Peer-reviewed Publications (in chronological order).**

### **Most relevant to the current application**

Heaton PC and **Frede SM** Patients Need More Counseling on Diet, Exercise and Smoking Cessation: Results from the National Ambulatory Medical Care Survey. *J Am Pharm Assoc.* 2006 May June; 46(3), 364-369.

Winfrey C, Wortman S, **Frede SM**, Kunze, N, Conrad WF, Heaton PC. Pharmacist-initiated peripheral arterial disease screening program in a community pharmacy setting. *J Am Pharm Assoc.* 2011 May- Jun;51(3):373-7

Fuller L, Conrad WF, Heaton PC, Panos R, Eschenbacher W, **Frede SM**. A Pharmacist-Managed Chronic Obstructive Pulmonary Disease Screening in a Community Setting. *J Am Pharm Assoc.* 2012 Sep-Oct;52(5):59-66

Rosser S, **Frede SM**, Heaton PC, Conrad WF. Development, Implementation, and Evaluation of a Pharmacist-Conducted Screening Program for Depression. *J Am Pharm Assoc.* 2013 Jan-Feb;53:22-29

### **Additional publications**

Hui-Callahan B, Luder HR, **Frede SM**. The Impact of a Pay-for-Performance-for-Patients (P4P4P) Model for Diabetes in a Grocery Store Setting. Publication accepted and pending. *Journal of the American Pharmacists Association*, 2013.

## **D. Research Support**

### **Ongoing Research Support**

Title: Community Pharmacist Collaboration with a Patient Centered Medical Home: Establishment of a Referral and Payment Model

PI: Heidi Luder

Frede, Stacey M.

Co-Investigator (Last, First, Middle): Frede, Stacey, M

Agency: Community Pharmacy Foundation

Period: 2013-2014

Role: Co- Investigator

This project is designed to build a sustainable model of partnership between a community pharmacy and patient centered medical home.

### **Completed Research Support During the Past Three Years**

Title: TransitionRX: Impact of a Community Pharmacy Post-Discharge Medication Therapy Management Program on Hospital Readmission Rate

PI: Heidi Luder

Agency: Community Pharmacy Foundation

Period: 2012 - 2013

Role: Co-Investigator

This project was a proof of concept study evaluating community pharmacist impact on hospital readmission rates.

Title: Utilizing Quality Measures in a Community Pharmacy to Improve Patient Care

PI: Andrea Santoro

Agency: American Pharmacists Association Foundation

Period: 2012-2013

Role: Co- Investigator

This project evaluated baseline data and intervention strategies designed to improve pharmacy metrics based on PQA measures.

Title: Utilizing a Medical and Community-Based Approach to Increase Enrollment in a Smoking Cessation Program

PI: Taylor Garber

Agency: American Pharmacists Association Foundation

Period: 2012-2013

Role: Co- Investigator

This project evaluated partnering with community organizations and physicians to increase the rate of participation in smoking cessation.

Title: Development and Implementation of a Chronic Obstructive Pulmonary Disease Management Program in a Large Community Chain Pharmacy

PI: Kim Arvin

Agency: American Pharmacists Association Foundation

Period: 2011-2012

Role: Co- Investigator

This project implemented and evaluated a new service for patients with COPD.



**The James L. Winkle  
College of Pharmacy**

**Office of the Dean**  
3225 Eden Avenue  
University of Cincinnati Medical Center  
PO Box 670004  
Cincinnati OH 45267-0004

Phone (513) 558-3784  
Fax (513) 558-4372

October 17, 2013

Heidi Luder, PharmD, MS  
Assistant Professor  
College of Pharmacy, University of Cincinnati  
Cincinnati, OH 45267-0004

Dear Dr. <sup>Heidi</sup>Luder,

The College of Pharmacy at the University of Cincinnati is very supportive of the request for funding submitted by you to Pfizer for the project titled "Increasing Vaccination Rates with an Appointment-Based Pharmacy Model." The College has a long longstanding relationship with Kroger Pharmacy. We have successfully partnered to provide a community pharmacy residency and fellowship. I know that you and Dr. Heaton are committed to the project.

The College of Pharmacy is dedicated to advancing research that seeks to improve quality of care that patients receive. In particular, research which showcases the impact of pharmacist-provided care is especially exciting. I am pleased to support this project and will make sure that adequate resources are available to you to complete the work in a timely and professional manner.

I am confident that your study will greatly impact our community with increased vaccination rates.

Sincerely,

A handwritten signature in black ink, appearing to read 'Neil J MacKinnon', written over a large, sweeping flourish.

Dr Neil J MacKinnon, Dean and Professor  
James L Winkle College of Pharmacy  
University of Cincinnati



## KROGER FOOD STORES

P.O. Box 46234, Cincinnati, OH 45246

10/17/2013

Dr. Heidi Luder  
College of Pharmacy  
3225 Eden Avenue  
136 Health Professions Building  
Cincinnati, Ohio 45267

Dear Dr. Luder,

Thank you for the opportunity to collaborate with The University of Cincinnati for the proposed research project titled, "Increasing Vaccination Rates with an Appointment-Based Pharmacy Model." This project represents an exciting opportunity to utilize an innovative pharmacy dispensing model to expand opportunities for community pharmacists to meet with patients individually and assess for and administer appropriate vaccinations.

As the Pharmacy Merchandiser for Kroger Pharmacy in the Cincinnati-Dayton Marketing Area, I am pleased to provide administrative and technical support for this immunization project. I will ensure that adequate resources and personnel are available to complete this project. I believe this project will have a significant impact on community pharmacy practice as it will provide a sustainable model to deliver vaccinations, improve patient satisfaction, and ensure appropriate documentation and communication of administered vaccines.

I offer my fullest support and commitment to the immunization project as proposed by the University of Cincinnati. I believe this novel project will make a positive impact to the community pharmacy and will significantly increase vaccination rates.

Sincerely,

A handwritten signature in black ink, appearing to read "Bhavin Patel".

Bhavin Patel, RPh.  
Pharmacy Merchandiser  
The Kroger Co.  
Cincinnati-Dayton KMA



## KROGER FOOD STORES

P.O. Box 46234, Cincinnati, OH 45246

10/17/2013

Mary Ucci  
Director, Grant Administration  
Sponsored Research Services  
University of Cincinnati  
PO Box 210222  
Cincinnati, Ohio 45211

Dear Ms. Ucci,

Please consider this, Kroger's letter of intent to collaborate with The University of Cincinnati on Pfizer's request for proposal. Dr. Heidi Luder of the James Winkle College of Pharmacy will be the Principal Investigator for the University of Cincinnati and will be submitting the application titled, "Increasing Vaccination Rates with an Appointment-Based Pharmacy Model"

The appropriate programmatic and administrative personnel of Kroger involved in this grant are aware of Pfizer's subcontract policies and are prepared to establish the necessary subaward agreement(s) consistent with those policies.

By signing this letter of support, Kroger provides the University of Cincinnati the same assurances, certifications, and agreements that it would to Pfizer if this proposal were originating from our institution.

If you have any questions please contact

We appreciate your consideration of this proposal and look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bhavin Patel".

Bhavin Patel, RPh  
Pharmacy Merchandiser  
The Kroger Co.  
Cincinnati-Dayton KMA

## **A. Increasing Vaccination Rates with an Appointment-Based Pharmacy Model**

**B. Goal:** The goal of this project is to increase vaccination rates by systematically assessing vaccination status and administering necessary vaccinations at the pharmacy through the establishment of an appointment-based pharmacy model.

**C. Objectives:** To increase vaccination rates for influenza, pneumococcal, shingles, hepatitis, and tetanus vaccinations for older adults, determine the acceptance rate of vaccinations offered at the pharmacy, increase patient satisfaction with receiving vaccinations at the pharmacy, and assess the feasibility of pharmacy access to a state immunization registry.

**D. Assessment of Need for the Intervention:** In 2011, the Centers for Disease Control Behavioral Risk Factor Surveillance System reported that, in Ohio, 38.6 percent of individuals greater than 65 years of age did not receive the yearly influenza vaccine. Additionally, about one in three patients greater than age 65 have not received the pneumococcal vaccine.<sup>1</sup> While these numbers have improved in recent years, there remains a need to increase vaccination rates for older adults in Ohio.

Community pharmacists have a significant role in administering vaccinations and a simple recommendation by a pharmacist to receive a vaccination can increase vaccination rates.<sup>2</sup> There are several opportunities for the pharmacist to reach out to patients to promote vaccinations. However, in the current pharmacy workflow, there is not a standardized system for promoting vaccines at the pharmacy counter. Especially for refills, patients often receive prescriptions without speaking with the pharmacist. Since a barrier to immunizations is a lack of patient understanding of which vaccines are necessary, increased pharmacist engagement with patients at the pharmacy would increase vaccination rates. We are proposing a system change which will promote patient counseling and encourage pharmacists to ask patients for their vaccination history, and offer vaccinations while patients are at the pharmacy to pick up prescriptions.

For this study, all patients who receive multiple prescriptions from the pharmacy may opt into the project. However, patients with greater than five medications and/or high risk disease states such as diabetes and asthma/COPD, will be targeted for the intervention. In addition to increasing vaccination rates, this project will have two important secondary benefits. Targeting patients with high risk disease states will ensure high risk patients are approached to offer appropriate vaccinations. Targeting patients with several medications will allow for the synchronization of refills to prevent excessive visits to the pharmacy and decrease the complexity and timing issues associated with refilling medications. We anticipate that this benefit, in particular, will be a strong motivator for patients to opt in to project participation.

**E. Intervention Design and Methods:** In order to increase vaccination rates, a system change will be implemented to facilitate the assessment and administration of vaccinations by pharmacists. The system change will include a medication synchronization project. For this synchronization project, medication refills that are due at differing times in the month will be synchronized to a date of the patient's choice. After the medications refills are synchronized to a single monthly date, patients will receive a telephone call to establish an appointment to pick

up the medications. During this appointment, the pharmacist will perform a variety of services for the patient including medication therapy management, patient counseling, and assessment of the patient's vaccination status. If the pharmacist determines there is an unmet vaccination need, the pharmacist will offer to provide the appropriate vaccinations at that appointment. Administering vaccines at the time the need is identified will increase the convenience for patients and will prevent patients from prolonging the receipt of the vaccine after a gap in therapy is identified.

Secondarily, as part of the project, Kroger Pharmacies will report vaccinations administered at the pharmacy in Ohio IMPACT, the state immunization tracker. Currently, the pharmacy dispensing system does not interface with Ohio IMPACT and vaccines that are administered at the pharmacy do not automatically populate in this system. In order for pharmacists to report vaccinations in IMPACT, the pharmacy staff must manually enter the information into the database, which is not feasible in the pharmacy workflow. Therefore, a system change to automatically upload this information from the pharmacy dispensing system is necessary to ensure complete communication of the information. Not entering these vaccinations in the database creates a communication barrier between the pharmacy and the physician offices which could potentially result in the duplication of vaccinations. Providing pharmacy access with the Ohio IMPACT database will improve communication and will also allow pharmacists to access the database to assess vaccination needs as patient-report may not be accurate or complete.

The overall population size of older adults who may need to receive additional vaccinations is large. In the Cincinnati area, the percentage of patients greater than age 65 is 10.8 percent or approximately 32,037 patients.<sup>3</sup> The sample population of patients that Kroger Pharmacies serve is also large as Kroger Pharmacies capture 30 percent of the pharmacy market share in the area.

**F. Innovation:** The appointment-based pharmacy model (ABM) is a pharmacy workflow model which was previously implemented in a pilot program through the Alliance for Patient Medication Safety (APMS).<sup>4</sup> However, current literature focuses on the impact of the program on patient adherence, which is likely the result of the actual medication synchronization component of the program. The impact of the individualized appointment and the additional interaction between the patient and the pharmacist is not previously studied and there is currently no literature which assesses the impact of the appointment-based model on vaccination rates. Furthermore, there is no current literature which describes the utility of community pharmacy access to state immunization registries on the assessment of vaccination history at the pharmacy and the impact of pharmacy reporting in the state registry for additional communication about vaccinations.

Not only does this project build upon the ABM pilot programs in existing literature, this project also builds upon existing work to increase vaccinations within Kroger Pharmacies. Kroger Pharmacies have conducted several projects to increase vaccination rates, including increasing promotional materials and advertising at the pharmacy. Pharmacists are encouraged to promote vaccinations at the pharmacy counter using promotional materials; however this intervention has not been widely successful as there is no structured time for the pharmacists to complete these activities. Additionally, in Northern Kentucky, Kroger Pharmacy is currently

partnering with a primary care physician office to promote and refer patients to the pharmacy to receive vaccinations. However, our proposed project is the first large-scale project that focuses on system changes to increase vaccination promotion at the pharmacy counter when patients pick up prescriptions. We expect that targeting patients individually will make a greater impact than broad marketing tactics or partnering with a single physician office.

**G. Design of Outcomes Evaluation:** Internal pharmacy data will be used to determine the number of vaccines administered in the year prior to the intervention compared to the number of vaccines administered during the intervention. The appointment-based model will be piloted in two Kroger Pharmacies initially. Two Kroger Pharmacies with similar patient demographics, pharmacy volume, and baseline immunization rates to the intervention pharmacies will not initiate the ABM, to serve as a control group. To assess patient engagement with this project, we will administer a patient satisfaction survey which will assess perceived satisfaction, benefits, and convenience with the ABM intervention. Additionally, we will monitor the acceptance rate of patients who are offered to enroll in the ABM. Finally, we will monitor the individual patient acceptance rates of recommended immunizations and document reasons why patients refused vaccinations.

We expect to enroll approximately 30 percent of pharmacy patients into the ABM and conservatively estimate that each patient will receive one additional vaccine that they would not have otherwise received. Therefore, we expect to see a 30 percent increase in vaccination sales as part of this project. Final results of the project will be published in a high impact peer-reviewed journal. Additionally, the authors will disseminate the information through posters or presentations at national conferences.

**H. Project Timeline:**

Jan 2014 - May 2014	June 2014	June 2014 - May 2015	June 2015	July 2015
Develop technology and system changes for the ABM	Begin ABM in pharmacies	Data Collection Period	Analyze data	Prepare manuscripts for dissemination

**I. Requested Budget:** An estimated budget of **\$375,000** is requested for the project which includes compensation for the investigators and technology development costs to integrate the appointment-based model and Ohio IMPACT vaccination database into the existing pharmacy system.



## Organizational Detail:

**The University of Cincinnati (UC) James L. Winkle College of Pharmacy** and **Kroger Pharmacy** will partner to develop, implement, and evaluate this project. Kroger Pharmacy, located in the Cincinnati-Dayton area is comprised of 102 pharmacies and 30 patient care centers. Kroger pharmacists provide a variety of patient care services including medication therapy management; vaccinations; healthcare screenings; food, weight and nutrition counseling; smoking cessation; and American Diabetes Association recognized diabetes self-management education programs (DSME). Kroger Pharmacy's most robust services include diabetes and hypertension coaching programs for City of Cincinnati employees and retirees, modeled after successful coaching program such as The Asheville Project and The Diabetes 10-City Challenge.<sup>5</sup>

The UC James L. Winkle College of Pharmacy maintains a strong relationship with Kroger Pharmacy. In addition to a shared faculty position and community pharmacy fellowship program, they have jointly offered a community pharmacy residency program for nine years and have trained 20 residents. Throughout this partnership, UC and Kroger have collaborated on several published research projects<sup>6-8</sup> including a project which received the American Pharmacist Association Clinical Research Award in 2012.<sup>9</sup>

The primary investigator on this project is Dr. Heidi Luder. **Heidi Luder, PharmD, MS, BCACP** is Assistant Professor of Pharmacy Practice at University of Cincinnati with a practice site at Kroger Pharmacy. Prior to her faculty role, from 2011-2013, she was the first Community Pharmacy Outcomes Fellow working jointly with The University of Cincinnati and Kroger Pharmacy. Dr. Luder completed coursework for a Master's of Science in Health Outcomes Research in 2013. She has worked on several research projects, including a Transition of Care project which received grant funding from the Community Pharmacy Foundation. In the last year, two manuscripts were accepted for publication in the Journal of The American Pharmacist Association and an additional three manuscripts are pending publication in various peer-reviewed journals. Dr. Luder is well-trained in community pharmacy and completed a First Year Residency in Community Pharmacy at Froedtert Hospital in Milwaukee, Wisconsin.

**Pamela Heaton, PhD** is a co-investigator for this project. Dr. Heaton is the Chair and Associate Professor of Pharmacy Practice and Administrative Sciences. Dr. Heaton has over 32 publications, over 60 national poster presentations, and over one million dollars in external funding from such organizations as the State of Ohio, Agency for Healthcare Research and Quality, and the Clinical and Transitional Science Award (CTSA grant).

**Stacey Frede, PharmD, CDE**, the Clinical Coordinator for Kroger Pharmacy in the Cincinnati-Dayton area will oversee the operations of this project. Dr. Frede will assist with developing the study protocol, will oversee all research activities, and will provide administrative support for Kroger personnel. Dr. Frede has knowledge and experience with research and publication and has collaborated with the University of Cincinnati on multiple research projects. As the Kroger Pharmacy residency director, Dr. Frede assists residents with the yearly writing of American Pharmacist Association (APhA) Incentive Grants and encourages publication of residency research projects. Additionally, Kroger Pharmacy was selected as one of 25 participants for the APhA Foundation Project Impact: Diabetes grant.

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