Overall Aim and Objectives

The aim of this initiative is to increase smoking cessation rates in a region of the United States with a high incidence of tobacco usage.

To achieve this aim, the following key objectives have been defined:

- Collaborate with Giant Eagle, a large regional supermarket chain with 4.6 Million customers in states with high tobacco usage, to offer smoking cessation counseling in their in-store pharmacies
- Assess current smoking cessation efforts among Giant Eagle pharmacists
- Train Giant Eagle Pharmacists in the proven Ask-Advise-Refer smoking cessation counseling methodology via multiple live and on-demand interventions
- Measure the impact of the initiative on cessation efforts

The intended impact of the initiative is as follows:

- Train at least 450 Giant Eagle Pharmacists in Ask-Advise-Refer smoking cessation counseling
- A similar community pharmacy initiative[1] resulted in pharmacists performing counseling with 50 patients each over a 3.5 month period suggesting that potential annual impact is at least 150 patients per year per pharmacist
- Total potential patients impacted in the first year of this initiative, therefore, is 67,500 in the states of West Virginia, Ohio, Maryland and Pennsylvania.

Current Assessment of Need in Target Area

Giant Eagle is a regional, 229 store supermarket chain serving portions of Western Pennsylvania, Ohio, West Virginia and Maryland which equates to 4.6 million customers annually. Despite the fact that tobacco use is the leading known preventable risk factor for mortality in the United States, nearly 440,000 average annual deaths in this country

[1] Hoch MA, Hudmon KS, Lee L, Cupp R, Aragon L, Tyree RA, Corelli RL., "Pharmacists' perceptions of participation in a community pharmacy-based nicotine replacement therapy distribution program." J Community Health. 2012 Aug;37(4):848-54.

are attributable to cigarette smoking.[2] West Virginia (2nd), Ohio (13th) and Pennsylvania (16th), three of the four states where Giant Eagle has stores, are among the top 1/3rd of states with the highest percentage of their population being regular smokers.[3] According to HealthyPeople 2020, only 62.4% of office-based ambulatory care setting visits, among patients aged 18 years and older, include tobacco screening.[4] In addition, research indicates that up to 87% of physicians and other medical professionals receive less than 5 hours of training on tobacco dependence and less than 6% knew AHRQ treatment guidelines for tobacco dependence.[5] Among Giant Eagle's 36,000 employees are 900 PharmDs who work in the pharmacies embedded in a large percentage of their supermarkets. Based on the smoking incidence data cited above, Giant Eagle PharmDs regularly interact with a relatively heavy-smoking customer base. As the data indicates, these PharmDs are likely to not ask their customers if they smoke, and are not adequately trained to screen and offer cessation advice. Giant Eagle has an ongoing, employee-focused smoking cessation effort with a full time employee smoking cessation expert (PharmD) on staff. The PharmD has been conducting cessation group sessions as well as providing individual counseling as needed. Three pilot programs have been conducted to date with 181 total employees participating. The program consists of 1 private intake call (15-20 min) and then 4 group class sessions (in person, 1 hour every week, same day/time each week). To date, quit rates are 70%-85% two to four weeks after the final group class. The rates have been tapering off to 45%-55% 3 months post intervention. This PharmD-driven success, and the similar demographic profile of Giant Eagle's employee and customer populations, has encouraged Giant Eagle to expand their smoking cessation effort to their customers. This project will also build upon existing work of the CS2day initiative by leveraging resources, relationships, and experiences from ongoing CS2day projects (www.ceasesmoking2day.com).

Technical Approach, Intervention Design and Methods

Several published reports have advocated the use of community pharmacies for both identifying tobacco users and offering cessation counseling.[6] Recently, this idea was put into practical action with positive outcomes. In 2009, the Los Angeles County Department of Public Health (LACDPH) and Los Angeles Care Health Plan in collaboration with Ralphs Grocery Company Pharmacies developed and implemented a community pharmacy-based distribution program of 30,000 starter courses of nicotine

[2] CDC. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 1997-2001. MMWR 2005;54(25): 625-628

[3] http://www.smokefree.gov/map.aspx

[4] HealthyPeople.gov – Tobacco Use Objectives

[5] 2008 CHEST Annual Conference, Reichert, V et al, http://www.chestnet.org/accp/article/physicians-lack-smoking-cessation-training

[6] Hudmon, K. S., Hemberger, K. K., Corelli, R. L., Kroon, L. A., & 469 Prokhorov, A. V. (2003). The pharmacist's role in smoking cessation counseling: perceptions of users of nonprescription 471 nicotine replacement therapy. Journal of the American Pharmacists Association, 43(5), 573–582.

patches and gum. [7] A majority of participating pharmacists felt that cessation efforts could be integrated into the pharmacy work flow, that the community pharmacy was a viable location to offer cessation counseling, and that the pharmacy profession should be more active in providing cessation counseling. Because pharmacists have historically cited "lack of time" as a key barrier to providing cessation counseling[8], it is significant that Ralphs pharmacists reported being able to complete cessation counseling in 7 minutes or less (median – 5 minutes). The proposed Giant Eagle initiative intends to leverage the positive outcomes from the Ralphs/LACDPH program by incorporating some of its proven interventions and evaluation tactics.

This project will employ a "Train the Trainer" strategy in order to make smoking cessation counseling a competency of Giant Eagle PharmDs. A mixture of live meetings and enduring activities, delivered in a variety of formats and media, will be employed to train the PharmDs in "Ask. Advise. Refer" cessation counseling methodology.

- **Ask-Advise-Refer**

"Ask-Advise-Refer" is the American Dental Hygienists Association (ADHA's) national Tobacco Intervention Initiative designed to promote cessation intervention by dental hygienists. The approach, developed in 2003, integrates the "5 A's" (Ask, Advise, Assess, Assist, Arrange) into an abbreviated intervention (3 minutes in length) that remains consistent with recommended smoking cessation guidelines. This protocol was then adapted and refined by the Rx for Change program specifically for use with pharmacists. Rx for Change has been used to train over 100,000 clinicians throughout the US and abroad in smoking cessation counseling.[9] Over the last ten years, tens of thousands of pharmacists have been trained to successfully use this counseling protocol. The concise nature of the counseling is intended to remove the barrier of time constraints cited by so many healthcare practitioners. The Giant Eagle PharmD will be trained to first ask all patients about tobacco use. Patients who self-identify will then be advised to quit. The bulk of the "Train the Trainer" effort is spent on teaching this aspect of the counseling. The final portion of the counseling, "Refer" will result in Giant Eagle PharmDs referring their patient/client to quitlines as well as to web-based and local cessation programs. Quitlines are telephone-based tobacco cessation services that have been around since the late 1980's. Most are accessed through a toll-free number and provide callers with a myriad of services including educational materials, referral to formal cessation programs, and individualized telephone counseling. Evidence has revealed that quit lines are convenient, effective and preferred by smokers.

[7] Hoch MA, Hudmon KS, Lee L, Cupp R, Aragon L, Tyree RA, Corelli RL., "Pharmacists' perceptions of participation in a community pharmacy-based nicotine replacement therapy distribution program." J Community Health. 2012 Aug;37(4):848-54.
[8] Dent, L. A., Harris, K. J., & Noonan, C. W. (2010). Tobacco treatment practices of pharmacists in Montana. Journal of the American Pharmacists Association, 50(5), 575–579.
[9] http://rxforchange.ucsf.edu/

The initiative will offer Giant Eagle Pharmacists a variety of educational interventions which, individually and collectively, will provide training in how to conduct Ask-Advise-Refer cessation counseling. Interventions include:

- **Live, in-person training**

In-person training will be conducted by our PI at 15-20 locations with 50-75 Giant Eagle PharmDs at each meeting. The training will combine didactic lecture, Q&A, video modeling of counseling sessions, and role play. It will be based on extensive trainings with pharmacists through the Rx for Change program and various CS2Day projects conducted over the last twelve years by project primary investigator, Frank Vitale (see page 11).

- **Live webinars**

For those Giant Eagle Pharmacists that cannot attend a live training session but value in-person Q&A and discussion, 5 separate live webinars will be conducted by our PI. These webinars will likely be scheduled during the evening hours to maximize potential participation.

- **Web-based enduring material and Toolkit**

An interactive, online version of the Ask-Advise-Refer training session, conducted by our PI, will be made available 24/7 as an on-demand resource. The online activity will be housed within a web site featuring a collection of related tools and resources that the Giant Eagle PharmDs can access on-demand.

The combination of interactive live training with supporting online resources is reinforced by the following proven adult learning strategies: multiple exposures to education are more effective than a single exposure; multi-media interventions are more effective than a single medium intervention; multiple instructional techniques (e.g., live meeting & interactive online) are preferred over a single technique; sequential interventions have a greater impact on behavior by allowing for a period of practical application using a "learn-work-learn" model.[10] [11] Both the live meetings and enduring material activity will carry CPE credit.

Evaluation Design

In order to assess the impact of this initiative, we will utilize a validated survey instrument that has been deployed in similar pharmacist-targeted Ask-Advise-Refer cessation training efforts as part of the ongoing Rx for Change effort. The survey

[10] Marinopoulos SS, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, Miller RG, Thomas PA, Prokopowicz GP, Qayyum R, Bass EB. Effectiveness of Continuing Medical Education. Evidence Report/Technology Assessment No. 149 (Prepared by the Johns Hopkins Evidence-based Practice Center, under Contract No. 290-02-0018.) AHRQ Publication No. 07-E006. Rockville, MD: Agency for Healthcare Research and Quality. January 2007.

[11] Mazmanian PE, Davis DA, Galbraith R; American College of Chest Physicians Health and Science Policy Committee. Continuing medical education effect on clinical outcomes: effectiveness of continuing medical education: American College of Chest Physicians Evidence-Based Educational Guidelines. Chest. 2009 Mar;135(3 Suppl):49S-55S.

instrument, a representative sample of which is included below this description, includes assessment of the following areas:

- Past training for tobacco cessation including familiarity with local quitlines
- Tobacco cessation counseling
- Confidence-based cessation counseling questions
- Attitudinal questions about cessation counseling

The survey will allow us to assess Giant Eagle PharmD cessation activities and perceptions about pharmacy's role in tobacco control including:

- Self-reported familiarity with the state quitline
- Past-month activities for how many patients they:
    - Asked whether they smoked or used tobacco?
    - Advised to quit?
    - Provided smoking cessation counseling?
    - Referred to a quitline
- Importance of perceived barriers to (a) tobacco cessation counseling and (b) provision of referrals to tobacco quitlines
- Perceptions associated with adoptability of the Ask-Advise-Refer protocol including:
    - Compatibility for integration into routine community pharmacy practice
    - Appropriateness of the protocol for use in their community pharmacy
    - Confidence in the respondent's individual ability to implement the protocol

The data collected in the survey align with HealthyPeople 2020 objectives for tobacco use such as TU-9.1, Increase tobacco screening in office-based ambulatory care settings - target of 68.6% of patients being screened. It also aligns with the NCQA's Tobacco Cessation – Advising Smokers to Quit, described as the number of patients receiving advice to quit smoking from a doctor or other health provider during the measurement year.

We will utilize the survey instrument (a slightly modified version of the example included below) to establish a pre-intervention baseline and a post-intervention initiative impact analysis. Because the intention is to attempt to provide training for all Giant Eagle PharmDs, there will not be a non-intervention control group. Participants will complete the surveys themselves and the data will be collected and analyzed by an outcomes group made up of members of the participating organizations. A three month follow-up survey will also be conducted to determine the sustainability of the training. The CE-certified activities, including the enduring material and live meetings, will also generate Moore's Level 1-3b outcomes which will be reported separately. We will also attempt to work with the state agencies involved with managing the quitlines to gauge volume of call activity related to this initiative.

When the funding expires, the web-based training module and related tools and resources website will still be available for on-demand access. Interested Giant Eagle PharmDs from outside the test regions can access the materials anytime. By creating the on-demand web resources, we feel that the program materials can be disseminated to interested parties in an efficient and cost-effective manner. The PI will seek to present the outcomes to other pharmacy chains in an attempt to encourage similar cessation training among their employees. There is also the possibility, if the outcomes are positive, to submit the findings for publication in relevant journals.

Sample Data Collection Form

YOUR BACKGROUND and PHARMACY WORK SETTING	
1 What degree(s)/training have you attained? **MARK ALL THAT APPLY.**	⊙1 **B.S. Pharmacy** ⊙2 **Pharm.D.** ⊙3 **Masters degree** ⊙4 **Residency training** ⊙5 **Fellowship training** ⊙6 **Other: _____**
2 How long have you worked as a pharmacist?	**years** **months**
3 How long have you worked in your current pharmacy location?	**years** **months**
4 How many **paid** hours per week do you work in your primary pharmacy site?	. **hours per week**
YOUR PAST TRAINING for TOBACCO CESSATION	
5 Have you ever received formal comprehensive training (e.g., behavioral and medication counseling skills) for tobacco cessation counseling? **MARK ALL THAT APPLY.**	⊙1 **No** ⊙2 **Yes, in pharmacy school** ⊙3 **Yes, after I graduated from pharmacy school** ⊙A **I attended a live CE program** ⊙B **I completed a written CE program** ⊙C **I completed a web-based CE program** ⊙D **Other: _____**
6 How familiar are you with the services provided by your State's tobacco quitline?	⊙1 **Not at all familiar** ⊙2 **Somewhat familiar** ⊙3 **Very familiar**
TOBACCO CESSATION COUNSELING	
7 About what percentage of all prescription patients in your pharmacy are asked whether they use tobacco (by you, or someone else at the pharmacy counter)? **PLEASE ESTIMATE, TO THE BEST OF YOUR ABILITY, A PERCENTAGE BETWEEN 0 AND 100.**	%
8 In the **<u>past month</u>**, how many patients in your pharmacy did **<u>you</u>** … **PLEASE RESPOND FOR YOURSELF ONLY (I.E., NOT FOR OTHERS IN THE PHARMACY).**	
a. Ask whether they smoke?	**e. Provide a quitline card or brochure?**
b. Advise to quit smoking?	**f. Offer to send a "Fax Referral" form to the tobacco quitline for a patient?**
c. Provide smoking cessation counseling?	**g. Submit a "Fax Referral" form to the tobacco quitline for a patient?**
d. Discuss the toll-free tobacco quitline?	**h. Help, in any way, with quitting smoking?**

9 In the **past month**, how many patients did **you** provide counseling for the use of…

a. A non-prescription nicotine product? (nicotine gum, lozenge, or patch)

b. Varenicline (Chantix)?

c. Bupropion SR (Zyban or generic)?

d. Nicotine nasal spray or inhaler (Nicotrol)?

10 This set of questions is designed to help us get a better understanding of the difficult aspects of providing smoking cessation assistance in community pharmacies. Please rate how certain you are that you can do each of the things described below, by marking your response.

PLEASE RATE YOUR DEGREE OF CONFIDENCE BY MARKING A NUMBER FROM 1 TO 10, WHERE:

1 = CANNOT DO AT ALL, 5 = MODERATELY CAN DO, 10 = HIGHLY CERTAIN CAN DO

		Cannot do at all				Moderately can do					Highly certain can do
a.	Routinely ask patients whether they smoke	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
b.	Explain to patients why it is important for the pharmacy to ask about tobacco use	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
c.	Advise patients who smoke to quit	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
d.	Demonstrate genuine concern about the impact of smoking on health	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
e.	Provide counseling for **nonprescription** medications for smoking cessation? (nicotine patch, gum, lozenge)	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
f.	Provide counseling for **prescription** medications for smoking cessation (Chantix, Zyban/bupropion SR, Nicotrol nasal spray, Nicotrol inhaler)	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
g.	Provide behavioral counseling for smoking cessation	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
h.	**Encourage patients who are not ready to quit to think about quitting in the near future**	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
i.	**Discuss and provide patients who smoke with materials for calling the tobacco quitline (e.g., cards or brochures)**	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
j.	**Provide smoking cessation counseling (medication or behavioral) when the pharmacy is busy**	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10
k.	**Providing smoking cessation counseling (medication or behavioral) when the pharmacy is slow**	⊙1	⊙2	⊙3	⊙4	⊙5	⊙6	⊙7	⊙8	⊙9	⊙10

OPINIONS about COUNSELING PATIENTS to QUIT SMOKING

11 Please rate the extent to which you agree with the following statements.

DARKEN ONE CIRCLE FOR EACH ITEM.	STRONGLY DISAGREE	DISAGREE	NOT SURE	AGREE	STRONGLY AGREE
a. Asking patients about smoking increases the likelihood that they will quit.	⊙1	⊙2	⊙3	⊙4	⊙5
b. It is difficult for me to get people to quit smoking.	⊙1	⊙2	⊙3	⊙4	⊙5
c. Counseling patients about quitting is not an efficient use of my time.	⊙1	⊙2	⊙3	⊙4	⊙5
d. Patients appreciate it when I provide advice about quitting smoking.	⊙1	⊙2	⊙3	⊙4	⊙5
e. Discussing smoking cessation improves my relationship with patients.	⊙1	⊙2	⊙3	⊙4	⊙5
f. I feel uncomfortable asking patients whether they smoke.	⊙1	⊙2	⊙3	⊙4	⊙5

g. As a pharmacist, I can play an important role in helping patients quit.	⊙1	⊙2	⊙3	⊙4	⊙5
h. I need more training to help patients quit smoking.	⊙1	⊙2	⊙3	⊙4	⊙5
i. I have insufficient time to counsel patients about quitting smoking.	⊙1	⊙2	⊙3	⊙4	⊙5
j. I should take a more active role in helping patients to quit smoking.	⊙1	⊙2	⊙3	⊙4	⊙5
k. Patients will be offended if I inquire about their smoking status.	⊙1	⊙2	⊙3	⊙4	⊙5

OPINIONS about COUNSELING PATIENTS to QUIT SMOKING, continued					
DARKEN ONE CIRCLE FOR EACH ITEM.	STRONGLY DISAGREE	DISAGREE	NOT SURE	AGREE	STRONGLY AGREE
l. Providing tobacco cessation counseling is important to our pharmacy even if only a few patients quit.	⊙1	⊙2	⊙3	⊙4	⊙5
m. I have an obligation to advise patients on the health risks associated with tobacco use.	⊙1	⊙2	⊙3	⊙4	⊙5
n. I lack support from corporate/owner to provide cessation services.	⊙1	⊙2	⊙3	⊙4	⊙5
o. If there was an effective way to provide brief advice (<1 minute) about quitting, I would be more likely to do this routinely with patients.	⊙1	⊙2	⊙3	⊙4	⊙5

12 How would you rate your **overall ability** to assist patients with quitting? **MARK ONE RESPONSE.** ⊙1 **Poor** ⊙2 **Fair** ⊙3 **Good** ⊙4 **Very good** ⊙5 **Excellent**

13 Please describe <u>your</u> intention to <u>routinely</u> implement the following tobacco cessation activities.

DARKEN ONE CIRCLE FOR EACH ITEM.	I AM **NOT** CONSIDERING DOING THIS	I AM CONSIDERING DOING THIS IN THE **NEXT FEW MONTHS**	I AM CONSIDERING DOING THIS IN THE **NEXT FEW WEEKS**	I **ALREADY** DO THIS
a. Asking almost all (or all) patients whether they use tobacco	⊙1	⊙2	⊙3	⊙4
b. Advising almost all (or all) patients (whom you are aware use tobacco) to quit	⊙1	⊙2	⊙3	⊙4
c. **Discussing and providing patients who smoke with materials for calling the tobacco quitline (e.g., cards or brochures)**	⊙1	⊙2	⊙3	⊙4
d. **Discussing with patients who smoke the option of completing a "Fax Referral" form that the pharmacy will fax to the quitline, after which the quitline will contact the patient directly to provide cessation counseling**	⊙1	⊙2	⊙3	⊙4

E. Detailed Work Plan and Deliverables Schedule

	Q4 2012	Q1 2013	Q2 2013	Q3 2013	Q4 2013	Q1 2014	Q2 2014
Funding Received	X						
Initiative Kick-Off Call	X						
Enduring Material/Web Resource Planning Call	X						
Enduring Material - Draft Content Outline		X					
Enduring Material - Primary Investigator (PI) to Review and Revise Content Outline		X					
Enduring Material - Website and Publicity Build and Review		X					
Enduring Material - Content Development, Draft Slides, Practice Tools		X					
Enduring Material - PI Call to Discuss Draft Slides and Additional Materials		X					
Enduring Material - Content Development and Revisions		X					
Enduring Material - Internal Accuracy Review		X					
Enduring Material - CD/Faculty Review		X					
Enduring Material - CE Review/Accreditation		X					
Enduring Material and Web Resource - Ready for Launch		X					
Live Training/Webinar Planning Call			X				
Live Training/Webinar Content Development			X				
Preparation of Evaluation/Assessment Materials/Forms			X				
Live Training/Webinar Materials Finalized			X				
Live Training/Webinar Dates Scheduled			X				
Kick-Off of Initiative with Giant Eagle Pharmacists				X			
Baseline Data Collection at Giant Eagle Pharmacies				X			
Outcomes Reporting - Provide Baseline Data to Supporter and Giant Eagle					X		
Launch Enduring Material and Web Resource					X		
Live Training Conducted (15-20 sites)					X	X	
Webinars Conducted					X	X	
Post Intervention Outcomes Data Collection at Giant Eagle Pharmacies						X	X
Outcomes Analysis							X
Outcomes Reporting - Final Outcomes Report to Supporter and Giant Eagle							X

The work plan for this initiative is outlined above. The timeline for roll-out among Giant Eagle PharmDs has been pushed back since the submission of the original LOI. Giant Eagle has experienced delays with implementing a new pharmacy reporting/prescription system and don't want this smoking cessation initiative to get lost in that effort. Per the original LOI, we will commence development of the training materials upon receipt of the grant in Q4 2012 and finalize those materials and data collection instruments between Q4 2012 and the end of Q2 2013. Rather than kick the project off with Giant Eagle PharmDs in Q1 2013, we will roll-out the initiative in Q3 2013 – a shift of approximately 6 months. As the timeline chart indicates, baseline data collection will take place in Q3 2013 and the training sessions, both live and onDemand, will be conducted between Q4 2013 and Q1 2014. Post-intervention data collection will commence at the end of Q1 2014 with final data analysis and outcomes reporting taking place in Q2 2014. We apologize for the unplanned delay but think it is vital to ensure optimal outcomes.