

## REVIEW ARTICLE

# Outpatient Interventions for Smoking Cessation: the Pharmacist's Role as an Extender

Brianne L. Porter, PharmD,<sup>1</sup> Sarah Adkins, PharmD, BCACP,<sup>2</sup> & Jay H. Shubrook, DO, FACOFP, FAAFP, BC-ADM<sup>3</sup>

<sup>1</sup>The Ohio State University - College of Pharmacy

<sup>2</sup>The Ohio State University - College of Pharmacy

<sup>3</sup>Touro University California - College of Osteopathic Medicine

## KEYWORDS:

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As the number of patients who have cardiovascular and metabolic disease grows, tobacco cessation should be a prime target for risk reduction. Physicians, already rushed during chronic care visits, often do not have the time to thoroughly address or follow up with smoking cessation efforts. As there is a move toward an interprofessional team-based approach and patient-centered care, physicians may consider utilizing extenders of the team, such as pharmacists, to help manage chronic diseases as well as aid patients on the journey to ending tobacco use. Pharmacists continue to be highly rated on Gallup's Poll of Most Trusted Professionals and are one of the most accessible healthcare providers. This manuscript will review the current evidence for pharmacist-based smoking cessation interventions. Fourteen studies were reviewed. These studies report positive outcomes in both the clinic setting as well as the community setting, indicating that pharmacists may serve two beneficial roles: to alleviate the physician's workload through extension of care and to follow a patient throughout the process of smoking cessation. Team-based approach to chronic care and behavior change can have a positive impact on patients and should be explored further and implemented more routinely in chronic care.

## INTRODUCTION

Human use of tobacco dates as early as the late 1400s when first introduced in Europe.<sup>1</sup> While early tobacco practice was frequently deemed spiritual or medicinal, the first recorded history describes both belief and skepticism of health and financial benefits. After becoming popular throughout Europe in the 1500s, it was not until one hundred years later the first commercial crop was grown in the United States in Virginia.<sup>2</sup> Although some evidence still supported tobacco usage, evidence against it began to grow. In 1689, The Medical School of Paris released an official statement that smoking shortens life. In the mid-1800s, British Parliament passed a bill requiring several railway cars to be smoke-free while the United States was beginning to manufacture cigarettes for the first time.<sup>1</sup> Data supporting the dangers of tobacco through cigarette smoking began surfacing during the early to mid-1900s. Finally in 1964, evidence from more than 7,000 articles in the United States literature elicited the Surgeon General to place a warning on the use of cigarettes.<sup>3-6</sup>

According to the Centers for Disease Control and Prevention (CDC), 1 of every 5 American adults smoked cigarettes in 2013. Moreover, smoking is the leading cause of preventable death and is linked to 1 in 5 deaths each year (Figure 1). Contributing risk factors include living in poverty and having a lower education level, as well as a disability.<sup>5,7</sup> Since the official warning set forth by the Surgeon General in 1964, cigarette smoking has been linked to an increased risk of reproductive complications, cardiovascular

disease, and cancer.<sup>8,9</sup> Additionally, smoking has been linked to an increased risk of type 2 diabetes mellitus and insulin resistance as well as a general decrease in overall health.<sup>10</sup> While addressing the nicotine component is important, it would be remiss not to mention cigarettes contain a number of carcinogens leading to the dangers of smoking.<sup>11</sup>

Despite the universal awareness surrounding the health risks associated with smoking, attempts at quitting often fail. Notable factors contributing to the challenge of cessation include physical addiction to nicotine, accelerated delivery of nicotine to the brain through inhalation, and emotional and behavioral associations connected to the act of smoking.<sup>12</sup> Consequently, support is required for successful cessation. Organizations, such as the American Cancer Society and the American Lung Association, offer support focused on how to quit while also addressing the three components of addiction: physical, psychological, and behavioral.<sup>13</sup> Additionally, successful smoking cessation programs have been designed to assist with these components as well.<sup>14</sup> While healthcare providers frequently treat the physical component by recommending appropriate pharmacologic therapy, they should also address the psychological and behavioral components. Providers can utilize the 5 A's of Intervention (Ask, Advise, Assess, Assist, and Arrange) to open up conversation, identify triggers, and enable the patient to determine a plan of action by use of motivational interviewing.

It is well-recognized that episodic, uncoordinated care by a single provider or a small group of providers does not assist in effective change for chronic behavior or disease. The journey to smoking cessation is no exception. Chronic patient-centered care, including work with behavior and lifestyle changes, requires a

## CORRESPONDENCE:

Brianne L. Porter, PharmD | [porter.618@osu.edu](mailto:porter.618@osu.edu)

**FIGURE 1:**

Percentage of smokers by state in 2013 according to the CDC

STATE	YEAR	PERCENTAGE OF SMOKERS
Arizona	2013	16.3
Arkansas	2013	25.9
California	2013	12.5
Colorado	2013	17.7
Connecticut	2013	15.5
Delaware	2013	19.6
District of Columbia	2013	18.8
Florida	2013	16.8
Georgia	2013	18.8
Hawaii	2013	13.3
Idaho	2013	17.2
Illinois	2013	18.0
Indiana	2013	21.9
Iowa	2013	19.5
Kansas	2013	20.0
Kentucky	2013	26.5
Louisiana	2013	23.5
Maine	2013	20.2
Maryland	2013	16.4
Massachusetts	2013	16.6
Michigan	2013	21.4
Minnesota	2013	18.0
Mississippi	2013	24.8
Missouri	2013	22.1
Montana	2013	19.0
Nebraska	2013	18.5
Nevada	2013	19.4
New Hampshire	2013	16.2
New Jersey	2013	15.7
New Mexico	2013	19.1

STATE	YEAR	PERCENTAGE OF SMOKERS
New York	2013	16.6
North Carolina	2013	20.3
North Dakota	2013	21.2
Ohio	2013	23.4
Oklahoma	2013	23.7
Oregon	2013	17.3
Pennsylvania	2013	21.0
Rhode Island	2013	17.4
South Carolina	2013	22.0
South Dakota	2013	19.6
Tennessee	2013	24.3
Texas	2013	15.9
Utah	2013	10.3
Vermont	2013	16.6
Virginia	2013	19.0
Washington	2013	16.1
West Virginia	2013	27.3
Wisconsin	2013	18.7
Wyoming	2013	20.6

coordinated team-approach. An interprofessional team, with complementary skill sets and an open platform of communication, can provide the best outcomes for patients. This team may include direct care providers such as physicians, physician assistants, and nurse practitioners, but additionally we must consider what extenders, such as nurses, medical assistants, educators, mental health practitioners, pharmacists, social workers, and nutritionalists can bring to the table.

Acknowledging the heterogeneity of the United States health care system, the interprofessional team may look different in varying healthcare settings depending on the health care location, availability of each specialist, and reimbursement issues. Pharmacists can participate in many of these settings. Commonly considered in the commercial (community) role only, pharmacists are now routinely embedded in hospital-based clinical teams, patient centered medical homes (PCMHs), and chronic disease clinics in settings such as academic medical centers, federally qualified health centers (FQHCs), and Veterans Affairs (VA) clinics. These placements provide a change in focus from dispensing medication to direct patient care and counseling. For example, pharmacists may enter

collaborative practice agreements to manage chronic diseases, such as diabetes, hypertension, and heart failure. Involvement of pharmacists in these settings has been helpful, as each member of the team can assume a smaller, more specific role in care and population management.

In the community setting, pharmacists are often considered the “most accessible healthcare professional to the public,”<sup>15</sup> and they are stepping out from behind the counter to counsel patients, conduct medication therapy management (MTM) interventions, and immunizations (Table 1). As extenders to providers, with at least 4-6 times as many touches a year and the trust of the public according to the annual Gallup Poll relating to public perceptions of honest and ethical standards,<sup>16</sup> pharmacists are perfectly suited to provide smoking cessation services. This is especially important as primary care providers continue to trend toward a projected shortage. Pharmacists can address the physical component

through recommendation of therapy and may counsel patients on proper use of medication while utilizing motivational interviewing to encourage patients to identify triggers and determine plans of action. During monthly visits, a pharmacist is uniquely positioned to maintain regular follow up throughout the process. This manuscript explores two roles the pharmacist may play to assist in smoking cessation efforts.

## METHODS

Materials for this review were obtained by a PubMed search. Articles considered for inclusion were of original research between 2000 and 2014, using combinations of keywords such as pharmacist, smoking cessation, tobacco cessation, pharmacy, community, outpatient, and intervention; English language; clinical trials; published in a peer-reviewed journal; and focused on evaluations of

**TABLE 1:**

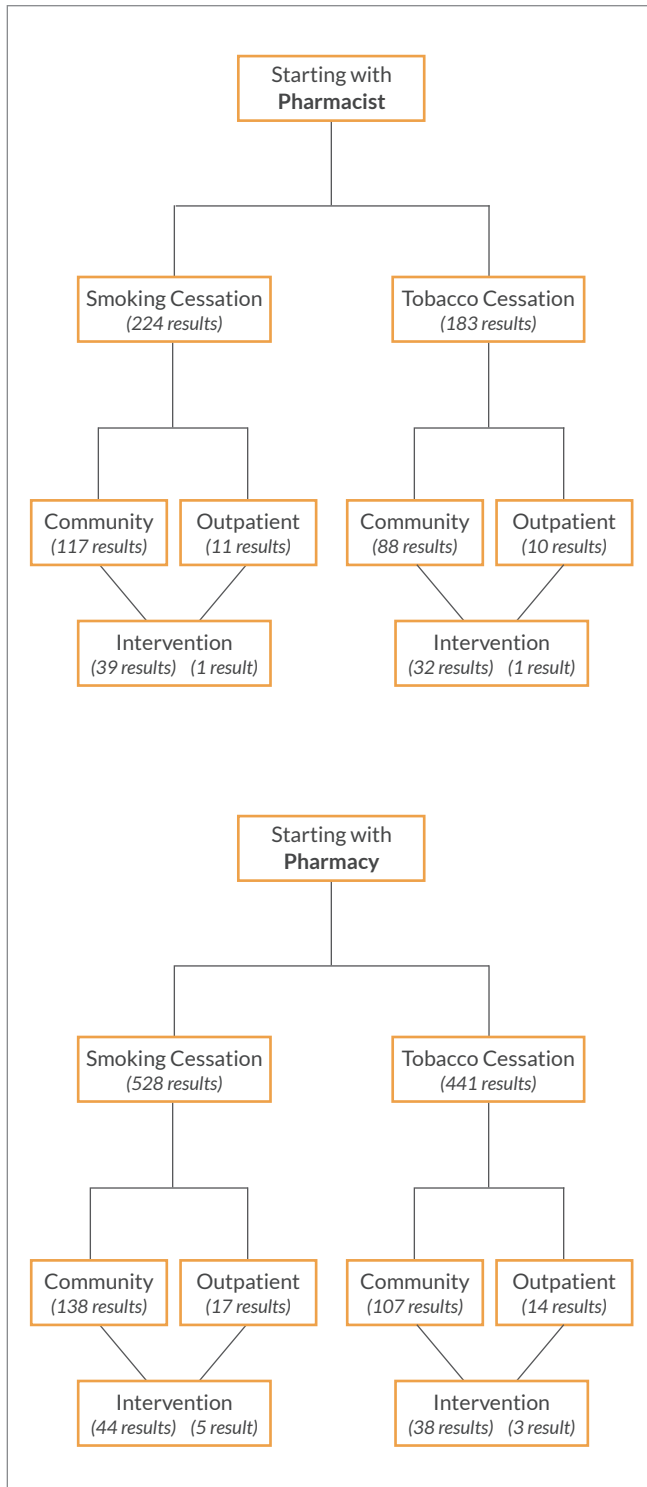
Description and distribution of pharmacist roles in various settings according to the American Association of Colleges of Pharmacy (AACP) Alumni Survey in the 2014 national report.

PHARMACY SETTING	DESCRIPTION	DISTRIBUTION (% of pharmacists employed)
Chain Community Pharmacy	Traditional roles of dispensing medications and educating patients.	31.3 %
Independent Community Pharmacy	Dispense medications and educate patients. Not affiliated with a chain or publicly traded company.	7.4 %
Hospital / Inpatient	Fill medication orders, screen for allergies and adverse drug reactions, serve as a medication experts to hospital staff.	32.1 %
Clinic-Based Pharmacy / Ambulatory Care	Direct patient care and medication management in an outpatient setting.	6.9 %
Consultant	Provides expert advice on medication use and pharmacy services.	1.4 %
Home Care	Provides a range of medications, including IVs, for patient home administration.	0.7 %
Nursing Home / Long Term Care	Manage dosing, interactions, therapy regimens tailored to this specific patient population.	2.0 %
Academia	Disciplines within academic pharmacy include administration, biological sciences, clinical science, continuing education, experiential education, drug discovery, medicinal/natural products, and pharmacology.	5.6 %
Association Management	Hold nation and state positions in pharmacy associations with administrative roles.	0.1 %
Pharmaceutical Industry	Marketing, research and product development, quality control, sales, and administration.	1.8 %
Managed Care	May work for health plans or pharmacy benefit management companies to provide the highest quality drug therapy management.	2.4 %
Government or Regulatory Agency	Direct patient care with affiliation to national services and or armed forces.	2.9 %
Other		3.8 %
Not applicable		1.5 %

smoking cessation programs implemented in outpatient clinics or community pharmacies. Articles were excluded if they were published before 2000, compared pharmacologic therapy as the main objective, were not original research, or evaluated smoking cessation services provided by a non-pharmacist healthcare provider. Advanced keyword combination searches in PubMed yielded many results and were narrowed down by including additional keywords (Figure 2). Articles were selected from the unique searches according to inclusion criteria. Additionally, references from selected articles were explored to include articles not indexed in PubMed. Twelve articles that met the inclusion criteria were selected for review.

**FIGURE 2:**

Schematic of search results



## ROLE OF THE PHARMACIST

While pharmacists have provided intermittent smoking cessation services for over 20 years, there has been a movement over the last 15 toward developing sustainable programs. Despite having differing responsibilities in each role, smoking cessation services have been provided in inpatient and outpatient settings. This review will examine the smoking cessation services provided by the pharmacist in the outpatient setting as part of an interprofessional team in clinic or in community practice.

## CLINIC SETTING

Selected studies in the clinic setting primarily focus on the successful implementation of pharmacist-managed programs and the comparison of an intervention group to routine care. These studies provide valuable insight to the potential influence of a pharmacist-managed smoking cessation clinic on successful quit attempts.

Three studies reported on the impact on quit attempts in patients participating in pharmacist-managed smoking cessation clinics.<sup>17-19</sup> In the first study (N=21), successful quit attempts were demonstrated at 3 months (47.6%) and 6 months (52.4%) in a program consisting of 6 counseling sessions over 8 weeks with intention to treat follow up. Patients could be referred by a provider, pharmacist, or self-referred and were recommended appropriate pharmacotherapy based on choice and appropriateness. Notably, quitters found the counseling sessions and discussion regarding medication options to be helpful, although not statistically significant compared to non-quitters.<sup>17</sup>

The second study (N=31) demonstrated successful quit rates in a similar pharmacist-managed program. In this program, participants attended once weekly group sessions for one hour. Sessions lasted 12 weeks with an additional 12 weeks for relapse prevention. Trained pharmacists provided behavior modification counseling alongside nicotine replacement therapy (NRT) as patches or gum. Self-reported abstinence data was collected weekly at the group sessions and confirmed by carbon monoxide (CO) detected in the breath at 3 and 6 months. Tests of less than 10 parts per million of CO confirmed abstinence. About half (16) of the original participants completed 3 months, and 10 participants completed the full 6 month program. At 3 months, 13/16 participants were abstinent while 8/10 were abstinent at 6 months.<sup>18</sup>

The third study (N=198) focused on a physician-referred, pharmacist-managed smoking cessation clinic at a VA Center and found that abstinence rates fell quickly between 6 and 12 weeks. The authors concluded either regular follow up is necessary during the first 6 weeks of a quit attempt, or a longer timeframe for follow up is needed to improve quit rates.<sup>19</sup>

When comparing outcomes of pharmacist-based services to routine care, a study in a VA clinic (N=100) showed higher success rates in the treatment group, who received 6 hours of group counseling in 3 sessions spread over 5 weeks. Routine care was described as one 5-10 minute counseling session similar to the 1-800-QUIT-NOW line. Higher success rates in the treatment group were observed at the 7-day point prevalence cotinine-confirmed ( $p=0.041$ ), 30-day point prevalence ( $p=0.014$ ), and 6 month abstinence ( $p<0.041$ ). All patients were offered either bupropion IR or nicotine patches. Following intention to treat, all patients lost to follow up were assumed to be smokers.<sup>20</sup>

A retrospective analysis (N=1006) at a different VA clinic compared patients receiving pharmacist-managed telephone counseling and medication to routine care, defined as those patients receiving pharmacologic therapy alone. This study identified cessation trends and abstinence as documented in Tobacco Cessation Clinic Reminders, a section of the electronic health record. Patients were offered NRT or bupropion SR. There were significantly more patient-reported abstinences at 1, 3, and 6 months ( $p<0.0001$  for all time periods) in the treatment group (N=503). While smoking history was not different between groups, the routine care group had fewer quit attempts ( $p<0.001$ ) and were more likely to use NRT alone rather than bupropion or a combination ( $p<0.001$ ). It is important to note this data may not be generalizable due to the specific patient population in this study. Additionally, data was collected retrospectively, so it is possible the standard of care group was misrepresented if abstinence was not properly documented.<sup>21</sup>

## COMMUNITY

Selected community-based studies have demonstrated the role of pharmacists providing smoking cessation services. Of the studies chosen to review, three main themes were identified: assessing tobacco users' perception of counseling in the community setting, assessing feasibility of implementing these services, and identifying intervention outcomes.

Tobacco users' perceptions of pharmacist services have been positive overall. A toll-free number provided to patients who purchased NRT in one study (N=103) invited patients to participate in a survey assessing methods for quitting, the patient's perception of community pharmacy-based interventions, and the types of interventions patients find to be helpful. The responses were analyzed descriptively. Overall, patients found pharmacist assistance to be appealing with over 60% of patients surveyed reporting they would either probably or definitely quit as a result of pharmacist intervention. Additionally, 46% of patients were either very likely or extremely likely to work one-on-one with a pharmacist for a co-pay while 68% of patients would meet if there was no charge. Preferred types of interventions varied suggesting they should be tailored to the individual's needs.<sup>22</sup>

A second study (N=24), also utilizing the interview method, assessed patients' perceived appropriateness of an Ask-Advise-Refer (AAR) intervention as part of a larger study. Sixty-three percent (63%) of respondents reported pharmacists conducting smoking cessation counseling in the community setting as being appropriate. Additionally, patients reported they would prefer to initiate the conversation and that advertising the AAR service would prompt them to do so.<sup>23</sup> These studies lend to the theory patients are willing to work with the pharmacist.

Feasibility of implementation was considered in chain pharmacies from a previous study. Participating pharmacies (N=16) were blindly randomized to either a control group (offered 1-800-QUIT-NOW cards and/or enrolled in the Fax to Quit (FTQ) program) or the experimental group (FTQ plus training for AAR, suggestions for integration into workflow, and advertisements). Pharmacists (N=32) and technicians (N=48) were asked to record data on a day-to-day basis. The experimental group asked, advised, and enrolled more patients to quit ( $p < 0.001$ ,  $p < 0.001$ ,  $p < 0.001$ ) and gave out more quit cards ( $p < 0.05$ ) than the control group, while no baseline differences existed between pharmacies. While quit rates were not assessed and data was analyzed using a regression model, feasibility of one model of implementation was demonstrated.<sup>24</sup>

In a second feasibility study, pharmacists (N=192) were surveyed during a conference regarding their likelihood to address the US Clinical Practice Guideline 5 A's, in addition to their interest in and the feasibility of implementing smoking cessation services. They were given the opportunity to provide information regarding any barriers to this process. Eighteen percent of state-licensed pharmacists were in attendance, and of those over half (54%) reported they were most likely to advise a patient to quit smoking, the same number would advise on proper use of prescription (54%), and 62% would advise on nonprescription medication. Barriers to implementation included lack of time (52%), lack of reimbursement (26%), and lack of training (19%).<sup>25</sup> This is consistent across professions. While physicians reported that they were comfortable with providing smoking cessation counseling, 38% felt that it took too much time.<sup>26</sup> Overall, pharmacists are confident in addressing the issue (76%) and feel it is feasible to provide these services (56%).<sup>25</sup>

In a third feasibility study, a group of community pharmacists (N=9) utilizing the AAR model were asked to place a value with the service. They ranked counseling as the most expensive service they provide compared to discussing cessation, enrolling patients in the quit line, and contacting a patient's provider.<sup>27</sup> Overall, the studies above demonstrate that it is likely feasible to implement the AAR model in a community pharmacy with a trained and willing team.

Outcomes of smoking cessation programs have shown potential as well. When comparing smokers referred to the quit line (N=100) to those counseled using a tailored electronic counseling aid, Exper\_Quit, either with (N=100) or without (N=100) nicotine patches, those being counseled were more likely to make a quit attempt ( $p < 0.02$ ) and demonstrated higher 7-day point prevalence abstinence than the observation group ( $p < 0.01$ ). Those receiving patches were twice as likely to quit as those only receiving counseling ( $p < 0.01$ ).<sup>28</sup> Similarly, pharmacists in another study (N=6987) providing either one or three counseling sessions found that patients who completed three counseling sessions were more likely to quit ( $p < 0.001$ ).<sup>29</sup> A third study (N=346), focused on a pharmacist-managed smoking cessation service with follow up at 1, 3, and 6 months, found that 40-50% of patients were likely to respond to follow up calls at all three intervals, and abstinence rate held steady around 25% at each follow up session. Of those participants, 50% were initially confident that they could quit, and the most commonly prescribed medication was nicotine patches at 30% compared to other NRT, varenicline (Chantix), and bupropion SR (Zyban).<sup>30</sup>

Generally, these community studies recognize that tobacco users' accept pharmacists as a tool for intervention, the feasibility of one particular implementation model of a smoking cessation service in the community setting has been described, and pharmacists in the community setting are uniquely situated to support patients during the quitting process. Each study, with certain limitations, provides evidence that pharmacy-managed smoking cessation services in the community should be further explored.

## CONCLUSION

Smoking is the single biggest lifestyle behavior leading to premature mortality. It is widely known that there are no health benefits from smoking, yet 18% of adults and 23.3% of children smoke.<sup>9</sup>

Providing patient education about smoking cessation is a responsible public health action and is cost effective. Unfortunately, the time allotted for family physician office visits is not long enough to address current lifestyle-based, chronic conditions. As we move from episodic care to a patient centered, shared decision making care model in the PCMH, the skill set for physicians and the health care team must adapt. It is unreasonable to expect that a single individual with less than a handful of visits per patient per year will successfully navigate every behavioral change needed for chronic disease.

Behavioral change requires a different skill set than other medically related encounters. When a patient develops an infection, a diagnosis, as well as effective and safe treatment options, is desired. This is also true of behavioral change; however, unlike an infection, chronic health care and behavioral-related conditions are largely self-managed. The health care team is not present during times of typical problem solving.<sup>31</sup> Quit-lines have been useful in providing access to experts during times of need; however, many smokers still remain reluctant to call and discuss a subject as intimate as cessation with someone they do not know.

There is not enough provider time per week to complete all preventive and chronic care necessary. It is estimated that if a physician is going to meet the USPSTF recommendations, it would take 1,773 hours per year or 7.4 hours per day to provide all preventive services.<sup>32</sup> Further, this research team took the ten most common chronic conditions and applied them to a family physician's panel of 2,500 patients. To provide high quality chronic disease care to the practice, it would require 3.5 hours per day for a controlled disease and up to 11 hours per day for uncontrolled diseases.<sup>33</sup> Clearly, the treatment team must adjust to meet these challenges.

Utilizing the interprofessional health care team, including extenders into the community, will likely provide timely interventions and enough "touch points" to enable patients make difficult behavioral changes and maintain healthy lifestyle habits.

One of the most challenging behavioral changes is tobacco cessation. Pharmacists have demonstrated success in aiding this process in the clinic and community settings. Further expanding the treatment team to include pharmacists will increase accessibility to health advice for patients and potentially improve adherence. Using this evidence-based approach, patients may be more likely to stop deleterious behavior and physicians can focus on other aspects of the visit, while patients have access to the expanded health care team.

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