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Title:

Evaluation of Pharmacist-Led Telehealth Smoking Cessation Services in a Primary Care Setting

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Introduction

Cigarette smoking is still the leading cause of preventable disease, disability, and death in the United States as it accounts for more than 480,000 deaths per year, and greater than 16 million Americans have at least one smoking-related disease.¹ Some of these smoking-related diseases include heart disease, stroke, chronic obstructive pulmonary disease (COPD), and lung cancer. It is estimated that \$300 billion is spent each year in the United States on costs directed to smoking-related illnesses.^{2,3}

Quitting smoking helps lower the risk for smoking-related illness and can add years to patients' lives.^{1,4} Evidence shows that smoking cessation reduces the risk for heart attack and stroke.⁴ It is predicted that the risk for heart disease is reduced within 1 to 2 years of quitting, while the risk of stroke may reduce to that of a nonsmoker within 2-5 years of quitting.⁴ It is also known that ten years after quitting smoking, the risk of dying from lung cancer decreases by half.⁴

The use of counseling or medications can assist with smoking cessation. Counseling can come from various sources including healthcare providers such as primary care providers (PCP), pharmacists, or behavioral health specialists as well as smoking quit line programs, which are usually funded by departments of health. Medications utilized for smoking cessation include nicotine replacement therapy (NRT), bupropion (Wellbutrin®/Zyban®), and varenicline (Chantix®).⁵ The most effective strategy in treating smoking dependence is using the combination of counseling and medications, rather than using either one alone.⁵ This is where the pharmacist plays a vital role due to their motivational interviewing skills and medication knowledge.

PrimaryOne Health (P1H) is a federally qualified health center with the goal of improving access to comprehensive, quality health care services. As a part of the primary care team, pharmacists at P1H work with patients and providers to design therapeutic treatment plans for the management of many chronic disease states, including tobacco use disorder. P1H clinical pharmacists have been providing smoking cessation services since 2011 and manage patients under collaborative practice agreements (CPA). Typically, these services would consist of at least one face to face visit followed by a face to face or telephonic follow up visit. Due to the COVID-19 pandemic, pharmacists at P1H switched to offering the service exclusively through telehealth for a period of time. The smoking cessation services include individual patient appointments for education, behavioral counseling, and medication management. The purpose of this study is to evaluate the effectiveness and patient satisfaction with pharmacist provided services received for smoking cessation.

A recent evaluation of three systematic review articles on pharmacist-led smoking cessation services determined that pharmacist interventions may lead to higher smoking cessation rates or no difference in rates compared to usual care.⁶ The authors concluded that the low quality of evidence made it difficult to determine the overall effectiveness of pharmacist-led interventions.⁶ This review concluded that further well-conducted randomized control trials comparing pharmacist-led smoking cessation interventions with the standard of care or no intervention may help to reduce uncertainty.⁶ A 2019 Cochrane Systematic Review on community

pharmacy smoking cessation interventions displayed similar results; as it concluded that community pharmacists can offer effective support in smoking cessation, but the quality of evidence was low.⁷ Some of the limitations to the evidence were possible risks of bias and low numbers of patients who quit smoking.⁷ Another limitation identified in these reviews was the diversity of outcome measures, with some studies using biochemical verification and others using self-reported changes in smoking behavior.⁷ The authors concluded that further studies should record pharmacotherapy that participants received and whether this made a difference in the study arms to show a true difference.⁷ While studies have been completed on the impact of the pharmacist in smoking cessation, more studies are needed to increase the quality of evidence. It is also unclear if culturally diverse, underserved patient populations in the United States were represented in any of these studies.^{6,7} Lastly, this study will focus on pharmacist provided telehealth smoking cessation services, offering a unique perspective to already established literature.

For the first time in 30 years, the Surgeon General released a report on smoking cessation.⁸ The report highlighted the role of pharmacists in assisting in the management of smoking cessation and noted that authorizing pharmacists to prescribe smoking cessation therapies and bill for interventions made could increase the success of the services.⁸ According to the National Alliance of State Pharmacy Associations, there are currently 12 states with statutes or regulations in which pharmacists can prescribe smoking cessation products utilizing a statewide standing order.⁹ In the state of Ohio, under current law, pharmacists can prescribe smoking cessation products under a CPA with physicians and mid-level providers.¹⁰ The data from this project could help in expanding these services and support reimbursement. The proposed study will aim to fill the identified gaps in the literature by measuring a standardized smoking cessation outcome recommended by experts¹¹ to a comparator group and include a patient sample from a culturally diverse and underserved patient population. This study will also fill a gap by tracking the pharmacotherapy patients received to determine if there is a difference in the care received by a pharmacist. Additionally, there is limited evidence related to patient satisfaction with pharmacist-provided smoking cessation services¹² and this study will address that gap, as well.

Objectives

The primary objective of this study is to assess the number/rate of patients with a 30-day point prevalence abstinence and to assess patient satisfaction of smoking cessation services. The secondary objectives are to assess the number of encounters and amount of time of counseling received, and to assess the number of prescriptions for nicotine replacement therapy (NRT), varenicline (Chantix®), and bupropion (Wellbutrin®/Zyban®) prescribed at each visit.

Methods

This is a prospective cohort survey study performed at PIH in collaboration with The Ohio State University College of Pharmacy and was approved by its institutional review board.

Setting

PIH is located in central Ohio and is recognized as a level 3 patient-centered medical home by the National Committee for Quality Assurance (NCQA). Across 11 health center sites, PIH provides care for over 48,000 unique individuals in culturally and socioeconomically diverse communities of Franklin and Pickaway counties.

Participants

Patients of PIH who were 18 years of age or older and had a type of tobacco use disorder, and new quit attempt between March 30, 2020 and August 31, 2020 were included in the study. A new quit attempt is defined as not seeing a healthcare provider for smoking cessation counseling in the previous 6 months. A patient who had a new quit attempt smoking cessation visit with the pharmacist during this time period was included in the pharmacist group. A patient who had a new quit attempt smoking cessation visit with PCP was included in the PCP group. A visit for smoking cessation was identified if a CPT code for smoking

cessation counseling was attached to the visit (e.g., 99406/99407), since this is standard practice for documenting for both pharmacists and PCPs at PIH. Patients with tobacco use disorder and only use other forms of tobacco besides cigarettes or who speak a language other than English were excluded. Patients who are deceased were also excluded from the study.

Data Collection

At the time of IRB approval, a report was run to identify the study population using the criteria outlined above. This report identified whether patients were seeing the pharmacist or PCP for smoking cessation and if English was their primary language. All patients identified for the pharmacist group were included in the study sample. A matched sample (1:2) from the PCP group was created based on the following factors, as appropriate: age, gender, race, ethnicity, insurance type, history of COPD, and history of ASCVD.

The REDCap¹³ survey, written by the study authors, was sent out to patients in the two study arms at least seven months following the initial smoking cessation visit. The survey was sent out using a mixed methods approach including email, phone, and mail. Previous studies have indicated that mail surveys have the highest response rates when compared to phone and web, but using a mixed combination of mail, phone, and web can increase response rates.¹⁴ The survey was pilot tested by patients not eligible for the study and was developed based on previously published surveys.¹² Based on guidance from the National American Quitline Consortium (NAQC), a patient reported 30-day point prevalence abstinence was assessed.¹¹ Survey questions determined if healthcare providers educated patients on why they should quit smoking and medication options used for smoking cessation. Survey questions also assessed if patients felt their healthcare provider addressed their concerns about quitting smoking, modifying behaviors, and obtained overall patient satisfaction on how they felt the healthcare provider assisted them with smoking cessation. For all patients in the sample for each given month (April, May, June, July, and August), the survey was administered as seen in Figure 1. Data from the survey was collected and evaluated by the study investigators.



Figure 1. Survey mixed methods communication approach.

Study investigators conducted chart reviews for patients who responded to the survey. The following data was collected for each visit that smoking cessation was addressed from March 30, 2020 – February 28, 2021: demographics (age, gender, ethnicity, insurance type), diagnosis of COPD, past ASCVD event, medication(s) prescribed, and time spent counseling (<3 minutes, 3-10 minutes, >10 minutes). During the study period, pharmacists could only enter into CPAs with physicians by Ohio law.

Statistical Analysis

Descriptive statistics were used to analyze how satisfied patients are with smoking cessation services provided by pharmacists and PCPs. Briefly, discrete data was presented as count (n) and frequency (%); continuous data was summarized as mean/standard deviation (SD) or median/interquartile range (IQR). Groupwise comparisons were conducted using χ^2 tests or Fisher's exact tests (for categorical variables) or Student's t tests or Mann-Wilcoxon-Whitney rank tests (for continuous variables normally distributed or not normally distributed, respectively) where appropriate. Matching and statistical tests in this study were

conducted using R3.4 software (The R Project for Statistical Computing, <http://www.r-project.org>). All statistical tests were two-sided, and the significance level was $\alpha = 0.05$.

Results

Across the pharmacist and PCP groups, 133 patients were invited to participate in the study (44 and 89, respectively), with 4 individuals being excluded, see Figure 2. The majority of participants in both groups completed the survey via phone. The total response rate was 37.5%, with a response rate of 40.9% in the pharmacist group and 35.9% in the PCP group. Baseline characteristics were comparable between the two groups (Table 1).

For the primary outcome of a 30-day point prevalence abstinence, 22.2% (n=4) in the pharmacist group and 9.4% (n=3) in the PCP group reached this goal (p=0.23), Figure 3.

Data around patient satisfaction with smoking cessation services showed some similarities in both the pharmacist and PCP groups, however, patient satisfaction was significantly higher in the pharmacist group when it came to discussion around medications used to quit smoking (100% vs 65.6%, p=0.0041), understanding how to properly use the medications (100% vs 62.5%, p=0.0020), identifying behavioral changes that could be incorporated to assist with quitting (94.4% vs 65.6%, p=0.036) and frequent follow up visits to discuss progress of quitting (83.3% vs 46.9%, p=0.016), Table 2.

When asking participants in the PCP group if their provider offered them an appointment to speak with the pharmacist to discuss quitting smoking, it was found that the majority (66.0%) of patients may not have been given the opportunity. All participants in the pharmacist group had referrals placed by their PCP and 11 individuals in the PCP only group may have been offered the opportunity to speak with a pharmacist about quitting smoking but declined.

Of the 50 participants who completed the survey across both groups, there were a total of 46 encounters for the 18 patients in the pharmacist group compared to 48 encounters for the 31 patients in the PCP group, Table 3. Patient data for 1 individual was missing from analysis. The majority of pharmacist visits included greater than 10 minutes of counseling whereas the majority of PCP visits included less than 3 minutes of counseling, and on average, patients in the pharmacist group had one additional visit for smoking cessation as compared to the PCP group, Table 3.

Across the individual pharmacist and PCP visits there was a statistically significant difference in pharmacotherapy between the two groups, with pharmacists being more likely to prescribe dual NRT and medications other than NRT alone, Table 3.

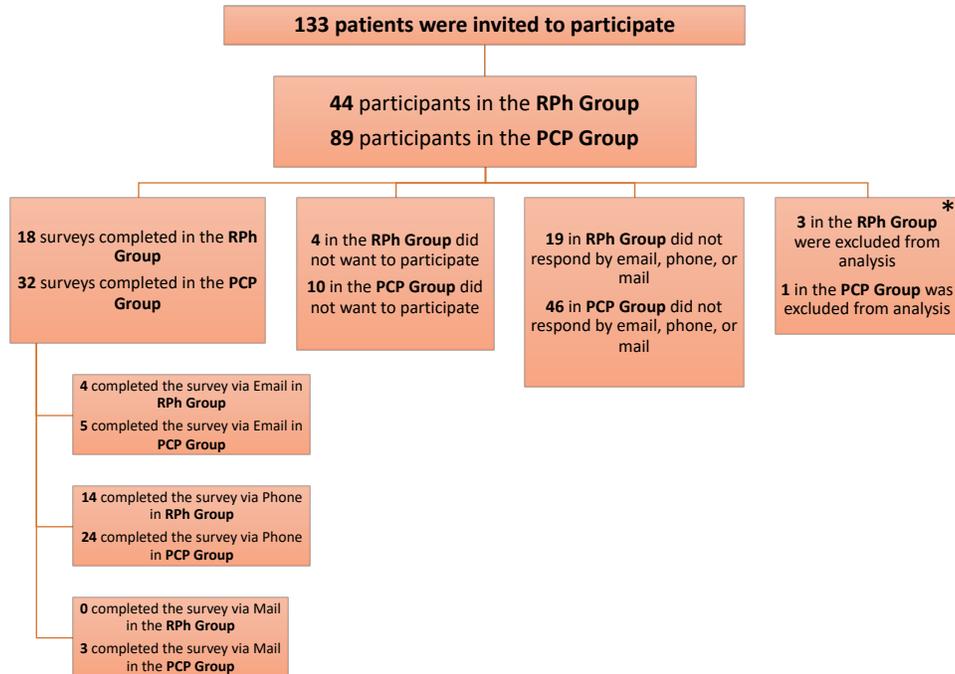


Figure 2. Patient algorithm.

*3 patients in the RPh group and 1 patient in the PCP group were excluded from analysis because it was found they had a visit for smoking cessation within the 6-month timeframe.

Table 1. Patient Demographics

| Characteristics | RPH group (n = 18) | PCP group (n = 32) | P value* |
|--------------------------------|-----------------------|-----------------------|-------------------|
| Age group, years, n (%) | | | 0.40 ^a |
| 21-30 | 1 (5.6%) | 3 (9.4%) | |
| 31-40 | 4 (22.2%) | 4 (12.5%) | |
| 41-50 | 2 (11.1%) | 7 (21.9%) | |
| 51-60 | 6 (33.3%) | 15 (46.9%) | |
| 61-70 | 4 (22.2%) | 3 (9.4%) | |
| 71-80 | 1 (5.6%) | 0 (0%) | |
| Sex, n (%) | | | 0.50 ^a |
| Male | 3 (16.7%) | 9 (28.1%) | |
| Female | 15 (83.3%) | 23 (71.9%) | |
| Race, n (%) | | | 0.54 ^a |
| Black/ African American | 9 (50%) | 13 (40.6%) | |
| White | 9 (50%) | 16 (50%) | |
| Other | 0 (0%) | 3 (9.4%) | |
| Ethnicity, n (%) | | | 0.61 ^a |
| Hispanic | 2 (11.1%) | 2 (6.3%) | |
| Not Hispanic | 16 (88.9%) | 30 (93.7%) | |
| Insurance status, n (%) | | | 0.85 ^a |
| Medicaid | 13 (72.2%) | 19 (59.4%) | |
| Medicare | 1 (5.6%) | 4 (12.5%) | |
| Commercial | 3 (16.7%) | 5 (15.6%) | |

| | | | |
|--------------------------------|------------|------------|-------------------|
| Uninsured | 1 (5.6%) | 4 (12.5%) | |
| History of COPD, n (%) | | | 0.73 ^a |
| Yes | 5 (27.8%) | 7 (21.9%) | |
| No | 13 (72.2%) | 25 (78.1%) | |
| History of ASCVD, n (%) | | | 0.49 ^a |
| Yes | 5 (27.8%) | 6 (18.8%) | |
| No | 13 (72.2%) | 26 (81.2%) | |

*All statistical tests were two-sided, and the significance level was 0.05.

^aFisher's exact test was used.

30-day Point Prevalence Abstinence:

Have you smoked any cigarettes or tobacco/nicotine products (including e-cigarettes, vaping pen, etc.), even a puff, in the last 30 days?

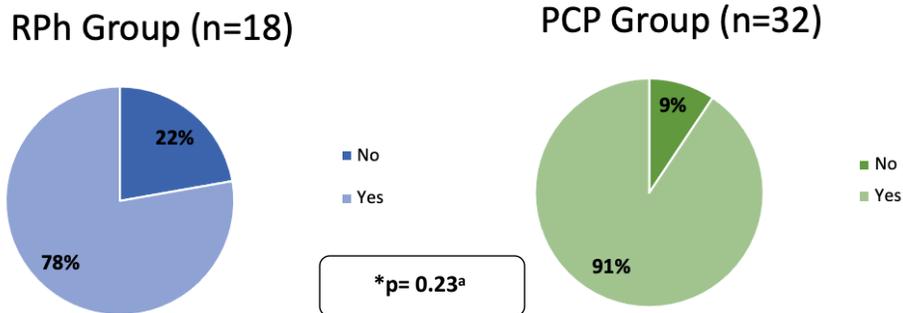


Figure 3. Assessment of 30-day point prevalence abstinence

*All statistical tests were two-sided, and the significance level was 0.05.

^aFisher's exact test was used where appropriate.

Table 2. Patient satisfaction of smoking cessation services

| Patient Satisfaction of Smoking Cessation Services | | | | |
|--|----------------------------------|------------------------------------|---|---------------------|
| My provider ... | Group (RPh n=18 vs. PCP n=32) | Strongly Agree & Agree n (%) | Strongly Disagree & Disagree n (%) | P value* |
| Educated me on why I should quit smoking | RPh | 17 (94.4%) | 1 (5.6%) | 0.23 ^a |
| | PCP | 25 (78.1%) | 7 (21.9%) | |
| Talked with me about why I want to quit smoking | RPh | 16 (88.9%) | 2 (11.1%) | 0.098 ^a |
| | PCP | 21 (65.6%) | 11 (34.4%) | |
| Addressed my concerns about quitting smoking | RPh | 17 (94.4%) | 1 (5.6%) | 0.073 ^a |
| | PCP | 23 (71.9%) | 9 (28.1%) | |
| Helped me to understand how medications could work to help with quitting | RPh | 18 (100%) | 0 (0%) | 0.0041 ^a |
| | PCP | 21 (65.6%) | 11 (34.4%) | |
| Helped me to understand how to properly use medications to help with quitting | RPh | 18 (100%) | 0 (0%) | 0.0020 ^a |
| | PCP | 20 (62.5%) | 12 (37.5%) | |
| Helped me to identify changes to my behaviors to help with quitting | RPh | 17 (94.4%) | 1 (5.6%) | 0.036 ^a |
| | PCP | 21 (65.6%) | 11 (34.4%) | |
| Followed up with me frequently to talk about my progress with quitting smoking | RPh | 15 (83.3%) | 3 (16.7%) | 0.016 ^a |
| | PCP | 15 (46.9%) | 17 (53.1%) | |
| I would recommend my provider to a family member or friend who wants to quit smoking | RPh | 18 (100%) | 0 (0%) | 0.28 ^a |
| | PCP | 28 (87.5%) | 4 (12.5%) | |

*All statistical tests were two-sided, and the significance level was 0.05.

^aFisher's exact test or χ^2 test was used where appropriate.

Table 3. Comparison of number of visits, time spent, and medications prescribed per visit of RPh and PCP groups

| Characteristics | RPH group (46 visits) | PCP group (48 visits) | P value* |
|------------------------------------|--------------------------|--------------------------|---------------------|
| Medication prescribed | | | 0.045 ^a |
| None | 27 | 34 | |
| NRT Patch | 2 | 4 | |
| NRT Gum | 1 | 2 | |
| NRT Lozenge | 2 | 5 | |
| NRT dual therapy (Patch + Lozenge) | 7 | 1 | |
| NRT dual therapy (Patch + Gum) | 2 | 1 | |
| Bupropion | 1 | 0 | |
| Varenicline | 4 | 0 | |
| Time spent at visit | | | <0.001 ^a |
| <3 minutes | 0 | 46 | |
| 3-10 minutes | 7 | 1 | |
| >10 minutes | 39 | 0 | |
| Total number of visits | | | 0.089 ^b |
| Mean (sd) | 2.56 (2.38) | 1.52 (0.81) | |
| Median (IQR) | 1 (1, 4.25) | 1 (1, 2) | |
| Sample size | 18 | 31 | |

minutes; sd, standard deviation; IQR, interquartile range, from 1st to 3rd quartile.

*All statistical tests were two-sided, and the significance level was 0.05. Missing data were not included in statistical tests.

^aFisher's exact test was used.

^bUnpaired Student's t test was used.

^cUnpaired U rank sum test was used.

Discussion

Most patients did not reach a 30-day point prevalence abstinence; however, more individuals reached the goal in the pharmacist group (4/18, 22.2%) as opposed to the PCP group (3/32, 9.8%). According to the Centers for Disease Control and Prevention (CDC), fewer than one in ten adult cigarette smokers succeed in quitting each year.¹⁵ Based on a similar study looking at cessation rates of individuals undergoing elective surgery, the percentage of patients who reached a 30-day point prevalence abstinence at 6 months was 20.0% (n=120) in the group who was referred to a pharmacist compared to 7.0% (n=104) in the group who was not.¹⁶ NAQC recommends using caution when comparing quit rate programs due to the fact that services offered may differ in a variety of ways, however, in both studies patients who were seen by a pharmacist surpassed the national average considered by the CDC.^{11,15} This study was conducted during the COVID-19 pandemic. According to an article in the Wall Street Journal, the decade long decline in U.S. cigarette sales halted in 2020 as many people used tobacco products more frequently due to the stress around the pandemic and spending more time at home.¹⁷ This is an important take away, as it likely influenced cessation rates, leading to a lower percentage of patients reaching this goal in the study.

The results demonstrate that the majority of patients are satisfied with the services that they are receiving from their providers regarding smoking cessation. Patients perceived that pharmacists addressed how smoking cessation medications work, how to properly use the medications, and behavior changes significantly more than PCPs. This could be due to the pharmacists' expertise in medication therapy management and motivational interviewing. It is also important to note that pharmacists are not under the same time constraints as PCPs which may have also contributed to these findings. Based on the study findings, pharmacists also follow up more frequently to discuss progress with quitting smoking in comparison to PCPs.

Pharmacists spend more time counseling patients on smoking cessation compared to PCPs. Although the total number of visits when comparing pharmacists to PCPs was not statistically significant, there is clinical significance, as the pharmacists group has a lower sample size and higher average rate of visits, Table 3. Spending more time counseling may lead to higher rates of smoking cessation, as seen in the pharmacist group. These results are consistent with findings from previous literature which found that more intensive programs that provided structured care and behavioral support where patients had consistent follow-up likely had better cessation rates compared to less intensive programs which typically comprised of a few minutes of advice on how to quit.⁷

In addition to their capacity to spend more time and follow up more frequently with patients, pharmacists, the medication experts on the interprofessional team, are uniquely positioned to provide smoking cessation medication management. Pharmacists are well trained to collect and assess the many independent patient variables that should be considered when choosing therapy such as screening for contraindications, drug interactions, and potential adverse drug reactions. Pharmacists are also well-versed in providing evidence-based recommendations. In this study, pharmacists were more likely to prescribe dual NRT which is an important finding considering that a randomized controlled trial has shown that dual NRT is more effective than NRT monotherapy at 22 weeks.^{18 19} Pharmacists were also more likely to prescribe medications other than NRT which is a key finding, as studies show that bupropion is just as effective as NRT monotherapy and varenicline is shown to be more effective than monotherapy NRT or bupropion.²⁰ These findings support pharmacists' involvement in more intensive, evidence-based medication management for smoking cessation. They also validate the need for pharmacists to prescribe smoking cessation medications and bill for interventions via standing order/CPAs to increase the success of services, as proposed by the Surgeon General.

In 2019, 88.8% of adults at PIH were screened for tobacco use and received cessation interventions.²¹ The results of this study indicate that some patients from the PCP group do not recall being offered an appointment with a pharmacist. This may be due to the patients not being interested in quitting

or providers needing to be re-educated on the service and the referral process. The PCP's assessment of the patient's interest in quitting may also play a factor in their decision to offer a pharmacist referral. Further investigation is likely needed to determine the factors that influence PCP's choices around referrals to pharmacists or other smoking cessation services. As an internal next step, the clinical pharmacy team at P1H will take a closer look at the referrals being placed around smoking cessation.

The small sample size and the low incidence of 30-day point prevalence abstinence makes it difficult to detect a statistically significant difference between the two groups. A larger sample size may have allowed for differences between the groups to be detected. The study was originally designed to reach patients via text messaging as a first step prior to the steps outlined in Figure 1. At the last minute this feature was unable to be utilized due to external factors outside of the researchers' control. The inability to use the text messaging feature through REDCap limited an opportunity in reaching patients for a higher response rate. However, our mixed methods approach utilizing email, phone, and mail likely diversified the patient sample responding to the survey and enhanced response rates. Excluding non-English speaking patients is also a potential limitation, as 35.1% of patients served by P1H in 2019 were best served in a language other than English.²¹ Unfortunately, this exclusion was necessary in order for patients to be able to understand and engage in the study survey. There is also the potential for recall bias, as patients were asked to think back over the past year. In addition, non-responder bias is also a limitation, as there is a potential that the results of the respondents could differ in a meaningful way from nonrespondents. Lastly, the use of self-reported measures of smoking cessation abstinence may limit the reliability of the evidence although this is a best practice recommendation.^{11,22}

This study highlights the impact of pharmacist driven services on culturally diverse, underserved patient populations, illustrating the satisfaction provided to individuals who typically may not be able to participate in these services. This study supports the expansion of pharmacist services and reimbursement proposed by the Surgeon General. These changes would expand patient access to obtain better success with tackling this significant public health problem. Future research may be needed to survey PCPs on determining their comfort with prescribing non-NRT monotherapy options and should seek to include larger sample sizes so that differences in smoking cessation abstinence can potentially be detected.

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