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RESEARCH

Outcomes of a randomized trial evaluating two approaches for promoting pharmacy-based referrals to the tobacco quitline

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ABSTRACT

Objectives: To evaluate the long-term impact of 2 promising intervention approaches to engage pharmacy personnel (pharmacists, technicians) in referring patients who want to quit smoking to the tobacco quitline.

Design: Randomized trial.

Setting: Community pharmacies in Connecticut (n = 32) and Washington (n = 32).

Intervention: Two intervention approaches were evaluated: academic detailing (AD), which involved on-site training for pharmacy staff about the quitline, versus mailed quitline materials (MM).

Main outcome measures: Changes in the overall percentage of quitline registrants who reported hearing about the quitline from any pharmacy during the 6-month baseline monitoring period versus the 12-month intervention period, and between-group comparisons of a) the number of quitline registrants who reported hearing about the quitline from one of the study pharmacies during the 12-month intervention period, and b) the number of quitline cards and brochures distributed to patients during the first 6 months of the intervention period.

Results: The percentage of quitline callers who reported having heard about the quitline from a pharmacy increased significantly, from 2.2% during the baseline monitoring period to 3.8% during the 12-month intervention ($P < 0.0001$). In addition, comparisons controlled for seasonal effects also revealed significant increases in referrals. Across all 64 pharmacies, 10,013 quitline cards and 4755 brochures were distributed. The number of quitline cards distributed and the number registrants who reported hearing about the quitline from a pharmacy did not differ by intervention approach (AD vs. MM), although AD pharmacies distributed more quitline brochures ($P = 0.022$).

Conclusion: Brief cessation interventions are feasible in community pharmacies, and the 2 approaches evaluated for engaging pharmacy personnel were similarly effective and collectively led to meaningful increases in the number and proportion of all patients who called the quitline. Involvement of community pharmacy personnel in tobacco cessation presents a significant opportunity to promote quitline services by connecting patients with an effective publicly available resource.

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Given the proven negative effects of tobacco use, the U.S. Public Health Service recommends that all patients be screened for tobacco use at every clinical encounter.¹ However,

routine comprehensive cessation counseling is rarely integrated into practice owing to insufficient time or expertise. Asking patients about tobacco use, advising patients who use tobacco to quit, and referring patients to other resources (“Ask-Advise-Refer”) for additional assistance is less time and resource intensive and therefore likely more conducive to implementation in busy practice settings.² Pharmacy staff can make referrals to any evidence-based cessation program based on patient preference, such as group programs, web-based programs, or counseling programs provided by a tobacco quitline. Publicly funded quitlines are accessible at no cost to callers, and counseling from a quitline is significantly more

Disclosure: At the time of the study, S. Zbikowski and L. Miles worked for Alere Wellbeing, the quitline service provider. All of the other authors report no conflicts of interest.

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Key Points**Background:**

- The role of the pharmacy profession in promoting tobacco cessation has expanded in recent years.
- Although numerous studies have explored the feasibility of community pharmacies in assisting patients with quitting, none has estimated the extent to which pharmacies generate patient referrals to the tobacco quitline.
- In a randomized trial conducted with 64 pharmacies in 2 states (CT and WA), we evaluated the impact of 2 promising intervention approaches (on-site academic detailing about the quitline vs. mailed quitline materials) to engage pharmacy personnel in providing brief interventions to refer patients who want to quit smoking to the tobacco quitline.
- This study builds on previous literature by conducting long-term follow-up (12 months) and using incoming call data from the tobacco quitlines in 2 states over a period of 18 months.

Findings:

- The percentage of all quitline callers who reported having heard about the quitline from a pharmacy increased significantly from baseline over the 12-month intervention period.
- The 2 approaches evaluated were similarly effective. Collectively, they lead to meaningful and significant increases in the number and proportion of all patients who call the quitline.
- Brief cessation interventions are both feasible and effective for implementation in the community pharmacy setting.

effective than less intensive interventions (pooled risk ratio, 1.38; 95% confidence interval, 1.28–1.49).³

It is well established that pharmacists express high levels of interest in assisting their patients with quitting,⁴ yet time constraints limit their capacity to address tobacco use with patients.^{4–9} As such, pharmacies might serve as an ideal setting for brief interventions and referrals to the tobacco quitline. There is a growing body of research providing evidence of feasibility for integrating brief cessation interventions into busy practice settings. Emerging data suggest that the community pharmacy is a logical venue for implementing the Ask-Advise-Refer approach for tobacco cessation.^{10–12} In addition, pharmacy staff members are uniquely positioned to intervene with patients who use tobacco, because they serve all segments of the population, including the medically uninsured and underinsured.

A promising strategy to advance clinicians' awareness of tobacco quitlines is "academic detailing," which entails having an individual (e.g., a licensed health care provider or other representative) visit clinicians in their practice settings to discuss and facilitate integration of evidence-based tobacco cessation interventions.^{13,14} For decades, the pharmaceutical

industry has effectively applied a drug detailing approach to promote the use of therapeutic agents, and in a systematic review it was determined that these efforts effectively alter the prescribing practices of physicians.¹⁵ Although not commonly used in pharmacy practice settings, evidence suggests that academic detailing interventions increase a) clinician-delivered cessation counseling,^{16–19} b) use of medications for cessation,^{16,17,19,20} and c) referrals to tobacco quitlines.^{17,19,21–23} To guide efforts toward enhancing the role of the pharmacy profession in tobacco cessation, investigators worked in tandem with quitline personnel to define and evaluate the impacts of what were perceived to be 2 viable disseminable intervention approaches (academic detailing [AD] vs. mailed materials [MM]) on generating referrals to tobacco quitlines.

Methods*Overview of study design*

Pharmacies from 2 states, Connecticut (CT; n = 32) and Washington (WA; n = 32), were selected from comprehensive listings of all licensed pharmacies in each state. They were recruited and randomized to receive either on-site AD describing the quitline or printed materials by mail about the quitline and brief information on how to refer patients. To ensure selection of pharmacies from geographic areas with minority populations, we stratified the listing based on racial and ethnic categories, defined a priori with the use of zip code–based census data for the patient populations served. After stratifying by pharmacy type (chain or independent), we conducted a 2-stage selection process. We first selected zip codes at random from within each category, and then randomly selected 1 pharmacy within each zip code. If a pharmacy did not agree to participate, another pharmacy within the same zip code was randomly selected for recruitment. If no pharmacies in the chosen zip code consented to participate, an alternate zip code was randomly selected as a replacement. This process continued until all strata were saturated.²⁴

After a decision to participate was made and consent forms from pharmacists and technicians were received, the pharmacies were randomized to the 2 intervention arms (Figure 1). Below, we provide a brief description of the interventions, study measures, and statistical analyses relevant to quitline call outcomes and group comparisons. More detailed aspects of the study are reported elsewhere, including a) pharmacy sampling, recruitment approaches, and associated recruitment outcomes,²⁴ and b) study procedures, measures, and baseline findings, including characteristics of the pharmacies and participating staff members as well as baseline quitline call data.²⁵ Study procedures were approved by the Purdue University Human Research Protection Program.

Intervention components

Quitline representatives from the 2 participating states a) provided access to existing materials used to promote their quitline, b) allowed the researchers to include additional questions for callers during the quitline enrollment, thereby

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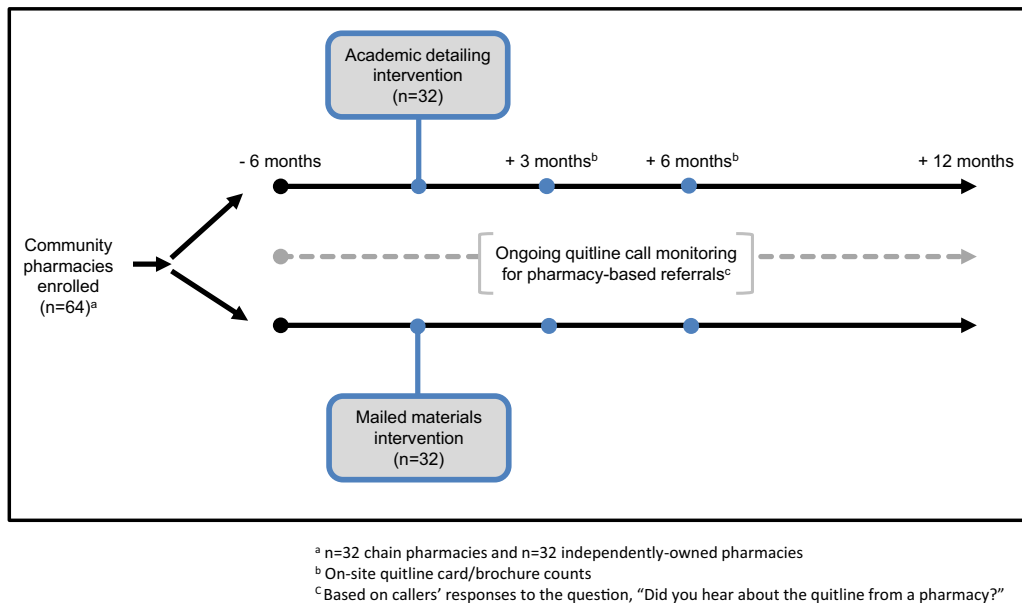


Figure 1. Prospective study design, with randomization to intervention group.

capturing information about pharmacy-based referrals, and c) granted approval to use their quitline enrollment data for key outcome measures (e.g., call volume and deidentified participant demographic data). To supplement the existing quitline materials, pharmacies in both intervention arms received pharmacy-specific materials, including posters, buttons for pharmacy jackets, and stickers for pharmacy bags that were used before Independence (from tobacco) Day in July, the Great American Smokeout in November, and New Year's Day. Quitline cards and brochures used for distribution to patients were printed with pharmacy-specific ID numbers to facilitate linking quitline callers with the individual study pharmacies during the 12-month intervention period. A description of all components is in Table 1, and differences between intervention arms are described below.

Academic detailing intervention group

For the 32 pharmacies randomized to the AD group, a member of the research team who was a licensed pharmacist made 1 visit to each. This included a 30-minute training about the Ask-Advise-Refer process and the tobacco quitline services. The detailer attempted to meet with each participating staff member, either individually or in small groups, to discuss the Ask-Advise-Refer model of care and elicit feedback on how to best integrate the model into routine pharmacy practice. Pharmacy technicians were trained to participate in the overall process by asking about tobacco use at intake, advising patients who use tobacco to quit, and referring patients who were interested in quitting to the pharmacist and/or the tobacco quitline for counseling. The study team provided each pharmacy with published articles describing the effectiveness of the quitline²⁶⁻²⁸ and a CD-ROM with videos demonstrating the Ask-Advise-Refer process. The overall training for this intervention group addressed 2 referral approaches: a) providing a quitline brochure or card to a patient and b)

directly enrolling a patient in quitline services via the state's fax referral form and process. In the latter case, a referral form is faxed directly to the quitline, and the quitline then contacts the patient for enrollment. Finally, the detailer provides additional assistance by placing quitline cards and brochures in key locations and hanging quitline posters in prominent areas of the pharmacies.

Mailed materials intervention group

Participating personnel at the 32 pharmacies randomized to the non-AD intervention group received all quitline materials by mail. As described previously,²⁵ this group differed from the academic detailing group in that they did not receive the CD-ROM with videos demonstrating the Ask-Advise-Refer process nor the published articles describing effectiveness of the quitline. In addition, this minimal intervention group was not provided the ability to submit faxed referrals to the quitline.

Study measures

Pharmacy-based referrals to the CT and WA quitlines were monitored for approximately 6 months before the launch of the interventions (in November and December 2009) and continued for 12 months after the intervention (Figure 1). Specifically, on contacting the quitline during the baseline and intervention period, a registration intake specialist asked each caller a series of intake questions, which included, "Did you hear about the quitline from a pharmacy?" After the pharmacies received the intervention (AD or MM), callers who responded "yes" to this query were asked a series of additional questions. The purpose of these questions was to a) capture the specific pharmacy location, e.g., to determine whether it was one of the 64 participating pharmacies, b) assess whether the caller had seen or obtained any of the quitline materials

Table 1
Key intervention components

Quitline cards (with pharmacy ID number for future linking)
Quitline trifold brochures (with pharmacy ID number for future linking)
“Ready to Quit? I can help” buttons (worn on the lapel of pharmacy coats)
Quitline stickers (placed on prescription bags) ^a
Quitline posters (placed in salient locations)
<i>Pharmacologic Product Guide</i> and <i>Drug Interactions with Smoking</i> resource materials (laminated; for use by pharmacists)
<i>How to Implement Ask-Advise-Refer</i> resource, describing step-by-step process (laminated; for use by pharmacists and technicians)
Quitline fax referral forms ^b
CD-ROM with video vignettes of the Ask-Advise-Refer counseling approach ^b
Relevant published literature, supporting the concept of the quitline ^b

^a Provided to pharmacies for New Year’s Day, Independence Day, and the Great American Smokeout.

^b Provided in academic detailing arm only.

while in the pharmacy, and c) characterize whether the patient or a pharmacy staff member had initiated the discussion about tobacco. A member of the research team also conducted on-site assessments at 3 and 6 months, conducting hand-counts of remaining quitline cards and brochures to estimate overall distribution of materials from each site.

Study outcomes

When calling the quitline, participants were asked a series of intake questions. Callers were classified as being “referred” to the state quitline if they indicated that they heard about the quitline from a pharmacy. The primary study outcomes include a) changes in the overall percentage of quitline registrants who reported hearing about the quitline from any pharmacy during the baseline monitoring period versus the intervention period, and b) between-group comparisons of the numbers of quitline registrants who reported hearing about the quitline from one of the study pharmacies during the 12-month intervention period. Secondary outcomes reported here include the number of quitline cards and brochures distributed to patients and the extent of utilization of the various promotional quitline materials (quit cards and brochures) at the 3- and 6-month visits.

Statistical analysis

Summary statistics were used to characterize the participating pharmacies and the utilization and distribution of quitline materials. Because the intervention materials were not distributed until after the baseline monitoring period, the incoming quitline calls were not linkable to individual pharmacies during this period. Therefore, the change in the percentage of quitline registrants who reported hearing about the quitline at a pharmacy between the baseline monitoring period versus the 12-month intervention period were analyzed in aggregate as overall percentages and tested for statistical significance with the use of chi-square tests of independence. To aid interpretation, monthly percentages also were graphically presented across the baseline and follow-up periods and stratified by state.

Differences in outcomes between the AD and MM pharmacies during the 12-month intervention period were analyzed at the pharmacy level. The outcomes included the number of smokers who registered for cessation counseling, the total number of quitline cards and brochures distributed, and the number of calls per 100 cards and brochures

distributed at each pharmacy. Comparisons between study conditions were made with the use of linear regression and negative binomial regression models, with the outcome regressed on the study condition variable, state (CT or WA), and pharmacy type (chain or independent). Analyses, which were also repeated after stratifying by state, were conducted in SPSS version 24.²⁹

Results

Participating community pharmacies and pharmacy personnel

Overall, 50% of contacted pharmacies agreed to participate in the study (49% of independently owned pharmacies and 51% of retail chain pharmacies).²⁴ Of the 32 retail chain pharmacies (16 in CT and 16 in WA), 21 were traditional stand-alone pharmacies, 8 were grocery-store pharmacies, and 3 were mass-merchant pharmacies. From these locations, a total of 124 pharmacists and 127 pharmacy technicians participated in the randomized trial,²⁵ representing 73% of all pharmacists and 59% of all technicians employed at the 64 pharmacies at the time of enrollment.²⁴

Quitline callers referred by pharmacies

The percentage of all quitline callers (CT and WA combined) who reported having heard about the quitline from a pharmacy increased significantly from 2.2% (126 of 5675 callers) during the baseline monitoring period to 3.8% (641 of 16,873 callers; $P < 0.0001$; Figure 2a) during the 12-month intervention period. Increases for the individual states were also significant, with CT increasing from 1.3% (22 of 1721 callers) to 2.2% (108 of 4890; $P < 0.022$; Figure 2b) and WA increasing from 2.6% (104 of 3954 callers) to 4.4% (533 of 11,983 callers; $P < 0.0001$; Figure 2c).

To control for the potential effects of seasonality, the baseline monitoring period was compared with a parallel time period during the intervention 1 year later. In this analysis, the percentage of all callers who heard about the quitline from a pharmacy increased from 2.1% to 4.3% (400 of 9361 callers; $P < 0.0001$). The percentage of CT callers who heard about the quitline from a pharmacy significantly increased from 1.3% to 2.3% (65 of 2833 callers; $P < 0.021$), and the percentage of WA callers who heard about the quitline from a pharmacy significantly increased from 2.6% to 5.1% (335 of 6528 callers; $P < 0.0001$).

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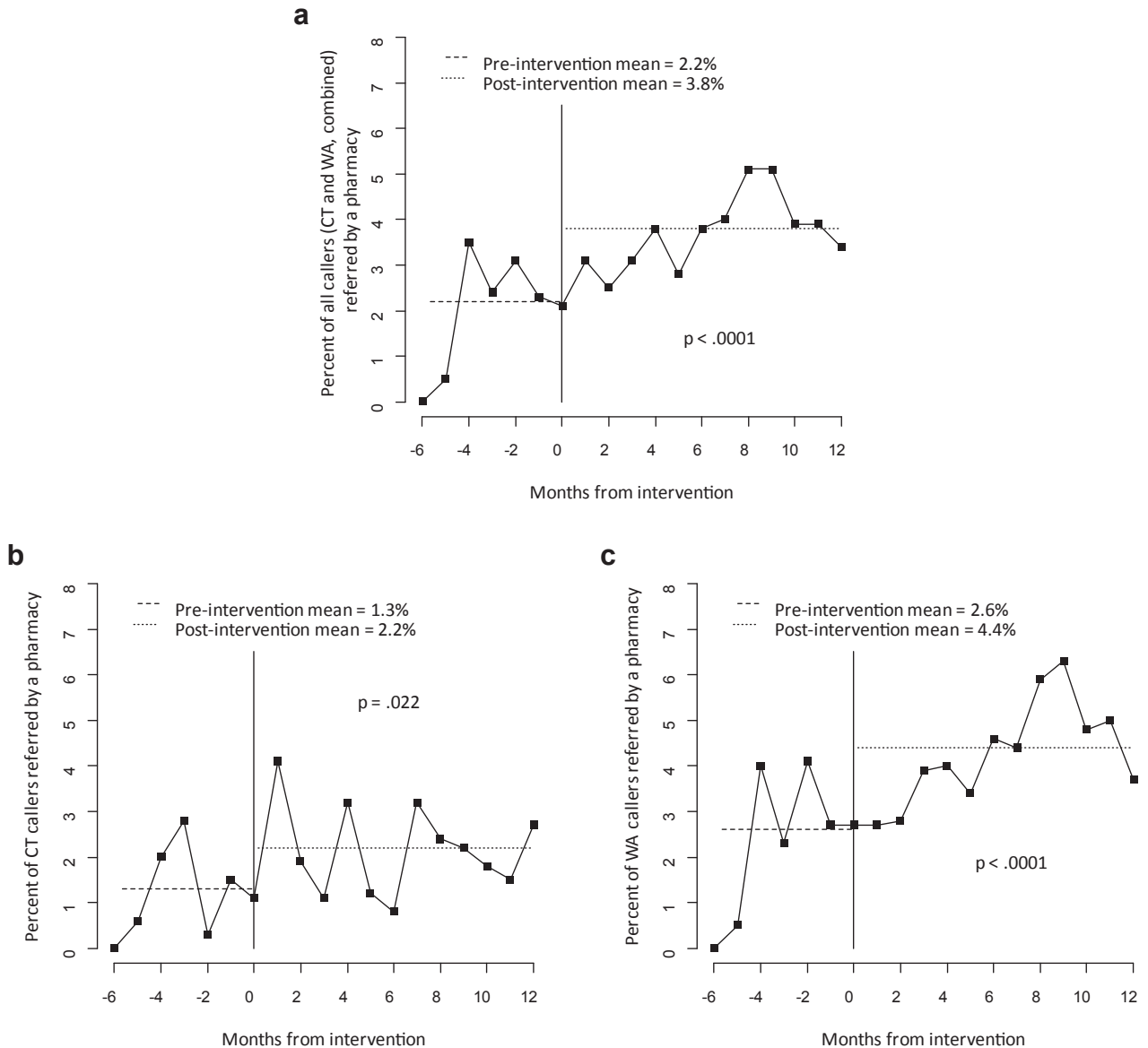


Figure 2. (a) Percent of all callers referred by a pharmacy. (b) Percent of CT callers referred by a pharmacy. (c) Percent of WA callers referred by a pharmacy.

After adjusting for state and pharmacy type, there were no statistically significant differences found between the AD and MM groups in the mean numbers of quitline registrants who reported hearing about the quitline from a study pharmacy (AD, 2.8 ± 3.6 ; MM, 2.4 ± 3.1 ; $P = 0.547$). The total number of faxed referrals received during the study period was 23.

Of all callers who reported hearing about the quitline at one of the 64 participating pharmacies, 42% recalled seeing or receiving a quitline card and 38% recalled seeing or receiving a brochure. In addition, callers reported seeing the following: countertop display with quitline materials (17%), quitline sticker on their prescription bag (10%), quitline poster (7%), and a pharmacy staff member wearing a "Ready to quit? I can help" button (5%). Overall, 37% ($n = 60$) indicated that they spoke with a staff member about the quitline.

Quitline materials distribution: academic detailing versus mailed materials groups

Across all 64 pharmacy locations, a total of 10,013 quitline cards (mean per pharmacy, 156.5 ± 102.1 ; range, 0 to 464) and 4755 brochures (mean per pharmacy, 74.3 ± 67.2 ; range, 0 to 300) were distributed from study pharmacies during the 6-month post-intervention period. After adjusting for state and pharmacy type, there were no statistically significant differences found between the AD and MM groups in the total number of quitline cards distributed per pharmacy (AD, 150.1 ± 93.4 ; MM, 162.8 ± 111.3 ; $P = 0.622$), the number of calls per 100 cards dispensed at each pharmacy (AD, 2.6 ± 3.6 ; MM, 1.9 ± 2.7 ; $P = 0.304$), or the number of calls per 100 brochures dispensed at each pharmacy (AD, 10.0 ± 28.4 ; MM, 11.0 ± 33.9 ; $P = 0.898$). Similar results were found for these outcomes when the analyses were stratified by state.

A statistically significant difference was found between the AD and MM groups for the mean number of quitline brochures distributed per pharmacy (93.4 ± 73.4 vs. 55.5 ± 55.2 ; $P = 0.022$). Stratification by state showed that the difference between the AD and MM groups in the mean number of quitline brochures distributed per pharmacy was significantly different in CT (130.2 ± 80.1 vs. 67.2 ± 65.6 ; $P = 0.021$) but not in WA (56.6 ± 42.6 vs. 43.3 ± 41.1 ; $P = 0.375$).

Discussion

In recent years, the pharmacist's role in tobacco cessation has evolved substantially owing to systematic integration of tobacco cessation education into pharmacy school curricula and the passing of legislation in several states enabling pharmacists to provide cessation medications without a written order from a prescriber. Results of the present study suggest that brief tobacco cessation interventions are feasible in the community pharmacy setting, and that the 2 approaches evaluated for engaging pharmacists (AD and MM) are similarly effective and collectively lead to meaningful increases in the number and proportion of all patients who call the quitline.

Advancing previous research,^{5,9} this study integrated the pharmacy technician as a key team member in the overall intervention process. Working at the point of first contact and through the intake of prescriptions, technicians are strategically positioned to ask about tobacco use, advise individuals to quit, and refer those interested in quitting either to the pharmacist for more counseling or directly to the tobacco quitline. Although previous research³⁰ has demonstrated that through training, technicians achieve improved knowledge, attitudes, and self-confidence for helping tobacco users to quit, pharmacy-based cessation initiatives have not yet fully explored or tapped the technician's potential for this expanded role. In other initiatives, technicians have been effectively integrated into the screening process to identify patients eligible for immunizations³¹ and naloxone distribution for treatment of opioid overdose.³²

Key strengths of the present study include the overall number of pharmacies ($n = 64$) within 2 states, 50% pharmacy recruitment rate, high level of staff participation within each pharmacy, a 12-month intervention period, and a randomized design that included a baseline monitoring period and the ability to control for seasonality. Furthermore, partnerships with the state quitlines enabled tracking the number of pharmacy-based referrals to the quitlines rather than methods used in previous studies which relied on the self-reported number of patients referred by pharmacy personnel.^{5,10,11}

Because nearly 70% of individuals who smoke want to quit³³ but most will not be ready to quit at the time of the clinical encounter at the pharmacy, an important outcome measure for the present study was the number of quitline materials (cards, brochures) distributed at the study sites. Overall, 10,013 cards and 4755 brochures were distributed during the first 6 months of the intervention period. The number of quitline cards distributed and the number of registrants who reported hearing about the quitline from a pharmacy did not differ by intervention approach (AD vs. MM), although AD pharmacies distributed significantly more quitline brochures. On-site visits by study staff ensured

accuracy of counts of remaining materials, although this did not eliminate the possibility that materials were misplaced within the pharmacy or accidentally or intentionally removed before staff visits. This was the first pharmacy-based cessation study that enabled linkage to quitline cards and brochures and to individual participating pharmacies; through a detailed procedure, the quitline was able to capture this information from callers. However, only 167 of 641 individuals (26%) who indicated that they heard about the quitline from a pharmacy were directly linkable to one of the study sites. This suggests that individuals were unable to recall the location of the pharmacy where they received the quitline advice, the methods used during the registration process to link callers with the referring sites was not sufficiently effective, or callers heard about the quitline from nonstudy pharmacies. Although we attempted to control for the latter in our design through comparisons with the baseline monitoring period and between-state comparisons, we cannot rule out external confounders. The quitline, however, was not actively implementing interventions with pharmacies in either CT or WA during the study period. Furthermore, we observed very similar patterns in call fluctuation between states, suggesting that the changes were a result of the study interventions.

It is notable that the fax referral option in the AD group was not heavily used, perhaps because a) most patients are not ready to quit at the time of the initial discussion, b) patients are not ready to commit to the quitline as their cessation provider, or c) pharmacy staff inconsistently offered the quitline fax referral as an option. Other methods of referral might be considered, such as a web-based portal that directly connects patients to the quitline, which has been shown to be effective in family practice clinics.³⁴

Because the effectiveness of telephone quitlines is well established,³ it was not the purpose of this study to track actual quit attempts or cessation outcomes; the goal was to change practice behavior, and as such, pharmacy personnel, not the patients, were the study subjects. Although they are important, patient perspectives of the pharmacy-based interventions were not characterized. It is also possible that participants who directly called privately sponsored quitlines were not captured in the caller registration data provided by the CT or WA state quitlines. In addition, the study design did not enable tracking of patients who quit as a result of a conversation at a pharmacy but chose not to call the quitline. Finally, patients might have told others (family, friends, co-workers) about the quitline, and this, too, was not captured. As such, the full ramifications of pharmacy-based cessation counseling are not limited to the numbers reported here and are likely more significant than reported, given the large numbers of materials (nearly 15,000 quitline cards and brochures) that were distributed to patients over a period of 6 months at the 64 study sites.

Engaging community pharmacy personnel in tobacco cessation presents a significant opportunity to promote quitline services and to connect patients with an effective publicly available cessation resource. The results of this study suggest that both the AD and MM approaches yield positive impact, providing states with options for programmatic planning based on staffing and budgetary constraints. Extrapolating the number of individuals who reported hearing about the

quitline from one of the 64 participating pharmacies during the study period to the 1678 community pharmacies in CT and WA, one would anticipate meaningful increases in the total number of quitline calls deriving from pharmacy-based referrals each year.

Conclusion

This study advances earlier research by applying novel outcome measures and long-term follow-up in a large number of pharmacies to demonstrate that brief tobacco cessation interventions are both effective and feasible for implementation in the community pharmacy setting. Improvements in the training of pharmacists over the past 2 decades³⁵⁻³⁷ and recent legislation³⁸ further support this expanded role and enable pharmacists to practice at the top of their license by (in some states) prescribing all FDA-approved medications for smoking cessation. Pharmacy technicians also play a key role in the overall process by asking about tobacco use, advising patients to quit, and referring patients who are ready to quit for counseling to be provided by the pharmacist or the tobacco quitline. Future studies should examine the impact of system-wide routine integration of Ask-Advise-Refer with management support of cessation activities, reimbursement models for provision of this cognitive service, and the impact of pharmacy-based interventions on cessation outcomes.

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