Tobacco Interventions Delivered by Pharmacists: A Summary and Systematic Review

Larry A. Dent, Pharm.D., Kari Jo Harris, Ph.D., M.P.H., and Curtis W. Noonan, Ph.D.

**Background.** As one of the most accessible health care professionals, pharmacists are in an ideal position to provide tobacco-cessation and prevention services. Although there is growing interest in expanding the pharmacist's role in tobacco treatment, few published studies have assessed the efficacy or effectiveness of tobacco-cessation services delivered by pharmacists in the United States.

**Objective.** To summarize and critique studies that examined pharmacist-delivered tobacco-cessation services.

**Methods.** Articles written in English that appeared in peer-reviewed journals were identified from a systematic review of literature published from 1980–2006. Publications were selected for review if the interventions were delivered by pharmacists, if the intervention included United States Food and Drug Administration–approved drugs (if drug therapy was used), and if smoking-cessation rates could be calculated.

**Results.** Fifteen studies met inclusion criteria. Fourteen of the studies targeted smoking, and one targeted spit (chewing) tobacco. Five studies were controlled, and 10 were uncontrolled. One of the controlled studies (chewing tobacco) and eight of the uncontrolled studies were conducted in the United States. Findings of the uncontrolled U.S. studies suggest that pharmacists can deliver smoking-cessation services. Three of the controlled studies found statistically significant differences between the pharmacist-based intervention and the control group, and the trend in the other two studies was toward the effectiveness of the pharmacist-delivered intervention. Only six of the 15 studies reviewed used biochemical measures to verify self-reported cessation.

**Conclusion.** The uncontrolled and controlled studies reviewed demonstrate that pharmacists can deliver tobacco-cessation interventions, and the evidence strongly suggests that they are effective in helping smokers to quit. Future studies conducted in the United States that are well controlled and include biochemical verification of smoking status are needed to provide definitive confirmation that pharmacist-delivered interventions are effective for smoking cessation. With the availability and expanded training of pharmacists, this is an opportune time for testing and disseminating evidence-based research evaluating the effectiveness of pharmacist-delivered tobacco-cessation services.

**Key Words:** pharmacy, pharmacist's role, tobacco, smoking, cessation interventions.

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Tobacco use produces substantial health-related economic costs to society and is the single most common cause of preventable death and disease in the United States. Although in the
United States more than 47 million adults smoke, an estimated 70% want to quit. Cigarette smoking results in more than $100 billion in direct and indirect costs annually. Even minimal (<3 min) tobacco interventions delivered by clinicians increase the proportion of smokers who quit from 7.9% to 10.2% (odds ratio 1.3, 95% confidence interval 1.1–1.6). Such small changes applied over a large population have a large public health impact and are the basis for the U.S. Clinical Practice Guideline recommendation that all clinicians (e.g., physicians, nurses, dentists, pharmacists) should provide every tobacco user with at least minimal tobacco intervention.

Pharmacists are in an ideal position to provide tobacco-cessation services on-site, in the pharmacy, where tobacco-cessation drugs are obtained. Tobacco companies have commonly used point-of-purchase strategies, such as instant price reductions, to promote existing and new products. Public health interventions have also begun to adopt strategies of delivering interventions at the point of purchase, and these have been effective in promoting healthy behaviors, such as increasing physical activity and healthier eating.

Further, pharmacists are the most accessible health professionals in the U.S. health care system. More than 200,000 pharmacists are employed in various practice environments across the United States, and the number of pharmacists is expected to grow to 250,000 by 2020. Pharmacists are particularly accessible health care providers in rural areas where the number of pharmacists/100,000-population was 71.2 in 2000 and is expected to increase to 76.7 in 2020.

Pharmacists are receiving training in tobacco-cessation approaches and are interested in providing tobacco-cessation services. Using a train-the-trainer model, pharmacist educators are disseminating curricula to pharmacy schools to enhance tobacco-cessation training of pharmacy students. This approach has led to increasing pharmacists’ interest and confidence in providing tobacco services. In a recent survey, 71% of pharmacists thought that tobacco-cessation counseling is an important activity, and 45% were interested in providing such counseling.

Automation technology and certification of technicians are freeing pharmacists from traditional dispensing responsibilities. Updated pharmacy practice laws that allow collaborative practice agreements with physicians are empowering pharmacists to initiate and modify drug therapy for patients. Pharmacists in a wide variety of settings have begun to provide direct patient care, including smoking cessation. For example, in the Delaware project more than 100 pharmacists were trained and provided counseling to 4000 patients. Participating pharmacists received reimbursement for smoking-cessation counseling, which consisted of an initial session and two follow-up sessions. Further, with an approved protocol, pharmacists in New Mexico can prescribe bupropion and nicotine replacement therapy (NRT). In addition, pending final legislature approval, Medicaid will pay pharmacists in New Mexico for their services.

Although there is growing interest in expanding the pharmacist’s role in treating tobacco use, we were able to locate only two published reviews of studies testing pharmacist-delivered interventions. One systematic review conducted by the Cochrane Collaboration was limited to studies of smoked tobacco that used randomized designs with control groups. The other review included only a 10-year period, was limited to studies conducted in community pharmacies, and did not identify all of the published reports testing pharmacist-delivered tobacco interventions. We reviewed a broader range of studies and provide readers with a summary of each study.

Methods

PubMed was searched for English-language articles published in peer-reviewed journals from 1980–2006 that described pharmacist-delivered tobacco-cessation interventions. Keywords for the search were pharmacy or pharmacist and tobacco or smoking. The lower limit of 1980 was chosen because the first U.S. Food and Drug Administration (FDA)–approved tobacco-cessation drugs were available in the early 1980s. For a study to be included in the review, it had to have evaluated interventions delivered by a pharmacist and, if drugs were used, included only drugs that were FDA-approved for smoking.

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cessation. The article also had to provide quit rates or sufficient data from which quit rates could be calculated. When quit rates were not presented with use of intent-to-treat (ITT) procedures, we recalculated quit rates by using the data presented (when possible). The presentation of ITT quit rates facilitates the reader’s comparison of findings from studies with a wide range of participant dropout rates. Although the use of ITT provides a conservative estimate of quit rates, this and other methods to account for missing data (such as imputation techniques, where values for missing data are calculated from existing data) are standard practice in tobacco control research because loss to follow-up is assumed to be nonrandom and likely due to treatment failure. Both controlled and uncontrolled studies were included.

Point prevalence of abstinence and continuous abstinence are two efficacy measures used in the tobacco-cessation trials. Point prevalence is defined as not smoking (not even a puff) for the specified period leading up to a single point of follow-up. Seven-day and 30-day rates of point prevalence of abstinence are commonly used measures in smoking-cessation trials. Continuous abstinence is defined as not smoking (not even a puff) throughout the specified period of follow-up and is measured at multiple time points. The time periods of abstinence assessed in smoking-cessation trials range widely (e.g., from 1 mo to >12 mo). Because the length of time specified that an individual needs to remain abstinent is generally weeks to months, it is a stringent criterion for abstinence. For similar time periods, continuous abstinence rates are generally lower than the 7-day point prevalence rate of abstinence.

Results

Fifteen studies met selection criteria for our review (Tables 1–4) and are summarized below. The studies were grouped according to controlled versus uncontrolled, verified versus nonverified, and whether it was conducted within or outside the United States. Three of the five controlled studies used biochemical verification to confirm abstinence. Only one of the controlled trials was conducted in the United States, and this study targeted chewing-tobacco cessation. Three of 10 uncontrolled studies used biochemical

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Table 1. Controlled Studies of Pharmacist-Delivered Tobacco-Cessation Interventions

<table>
<thead>
<tr>
<th>Study Objective</th>
<th>Setting or Pharmacists</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled and verified</td>
<td>8 pharmacists from 5 community pharmacies in Palo Alto, CA</td>
<td>410 self-referred chewers randomly assigned to treatment (n=206) or control (n=204)</td>
</tr>
<tr>
<td>To examine the efficacy of a pharmacist-delivered program for chewing-tobacco cessation using NTS vs minimal contact behavioral intervention</td>
<td>100 community pharmacists in Belfast, Northern Ireland, and 24 in London, England</td>
<td>484 self-referred smokers randomly assigned to treatment (n=265) or control (n=219)</td>
</tr>
<tr>
<td>To evaluate a structured community pharmacy–based smoking-cessation program vs ad hoc advice from pharmacists</td>
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</tr>
<tr>
<td>To compare quit rates of participants in a smoking-cessation program started in hospital using NTS and continued in either a community pharmacy or hospital setting with quit rates in a minimal intervention group</td>
<td>Hospital research pharmacist and 9 community pharmacists in Adelaide, South Australia</td>
<td>102 former hospital inpatient smokers randomly assigned to hospital pharmacist treatment (n=35), community pharmacist treatment (n=34), and control (n=33)</td>
</tr>
<tr>
<td>Controlled and nonverified</td>
<td>42 pharmacies in Aarhus, Denmark</td>
<td>522 self-referred smokers stratified by 2 levels of smoking and randomly assigned to treatment (n=235) or control (n=267)</td>
</tr>
<tr>
<td>To compare smoking-cessation rates among individuals using over-the-counter NTS with those using placebo patch</td>
<td>62 pharmacies in Grampian, Scotland</td>
<td>492 self-referred smokers randomly assigned to treatment (n=224) or control (n=268)</td>
</tr>
<tr>
<td>To evaluate a training program for community pharmacy personnel to improve smoking-cessation counseling vs no training</td>
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</tr>
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</table>

NTS = nicotine transdermal system; NRT = nicotine replacement therapy.
verification, and 8 uncontrolled trials were conducted in the United States.

Controlled and Verified

In the United States, one randomized trial used biochemical verification. This study evaluated the effects of a nicotine transdermal system (NTS) versus placebo for chewing-tobacco cessation. In this study, 410 participants from five pharmacies were randomly assigned to receive either NTS or placebo. All participants received behavioral counseling, which included two pharmacy visits, two support calls, and self-help materials. At 6 months, the 7-day point prevalence ITT quit rate was 38% for the treatment group and 34% for the control group, validated by saliva cotinine level. Quit rates were not significantly different between groups. As behavioral counseling was offered to each group, this study evaluated drug treatment rather than pharmacist-delivered counseling. The high quit rate reported among the non-drug treatment placebo group suggests a strong main effect attributed to pharmacist counseling.

Outside the United States, two controlled trials using biochemical verification were reviewed. In the first, from the United Kingdom, 124 pharmacists from 100 pharmacies in Northern Ireland and 24 pharmacies in London randomly assigned 484 smokers to treatment and control groups in order to evaluate the effectiveness of a structured community-based smoking-cessation program compared with ad hoc advice from pharmacists. Participants assigned to the treatment program were offered NRT (patches or gum) if appropriate. For the behavioral component, they received a leaflet and individual counseling with use of the Pharmacists’ Action on Smoking (PAS) program flip-chart. Participants returned to the pharmacy for follow-up advice at weekly intervals for 4 weeks, then monthly for 3 months. The control group received normal pharmaceutical service including provision of NRT by the pharmacist but were not given a leaflet or counseling with the PAS flip-chart, nor were they asked to return for follow-up visits. The NRT was begun in 230 of 265 patients in the treatment group and 183 of 219 smokers in the control group. At 12 months, those who reported not smoking since the intervention at 3, 6, and 12 months were tested for urinary cotinine. At 12 months, the continuous abstinence ITT rate was 14.3% in the treatment group and 2.7% in the control group (p<0.001).

The second controlled trial outside the United States was conducted in Australia. Quit rates of a pharmacist-delivered smoking-cessation program, which was started in a hospital and continued in either the community pharmacy or hospital setting, were compared with quit rates in a minimal intervention group. Of 102 inpatient smokers, 35 were randomly assigned to the hospital arm, 34 to the community arm, and 33 to the hospital minimal intervention arm. All patients assigned to the two intervention arms attended an initial 30–45-minute consultation with the hospital pharmacist, then appointments were made with either the hospital pharmacist or community pharmacist for the following week. The intervention consisted of a maximum of 16 weekly visits. An NTS was dispensed at these visits if required, with appropriate counseling. Nine local pharmacies took part in the study. Continuous and point prevalence abstinence rates were assessed in each arm at 3, 6, and 12 months after enrollment. At 12 months, abstinence was verified with exhaled carbon monoxide test, and the 30-day point prevalence abstinence rate was 38% (22.9% ITT) for the hospital intervention arm, 24% (14.7% ITT) for the community pharmacy arm, and 4.6% (3%
ITT) for the control arm (p=0.031). The continuous abstinence rate was 24% (14.3% ITT) for the hospital arm, 19% (11.8% ITT) for the community pharmacy arm, and 4.6% for the control arm (p=NS).

Controlled and Nonverified

Two controlled studies without biochemical verification were conducted outside the United States. In Denmark, 42 pharmacies randomly assigned 522 smokers in a study to assess the smoking-cessation rates among individuals using over-the-counter NTS compared with a placebo patch. Participants were stratified by two levels of smoking. Those smoking 20 or more cigarettes/day started to use 21-mg/day patches, and participants who smoked less started to use 14-mg/day patches. Patches were provided for a period of 12 weeks. Participants were assessed at 1, 2, 3, and 6 months. At 6 months for light smokers (≥ 10 cigarettes/day), the point prevalence quit rate was 23% for the treatment group and 18% for the placebo group (p=NS). For heavy smokers (≥ 20 cigarettes/day), it was 11% for the treatment group and 4% for the placebo group (p<0.05). At 6 months in

<table>
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<tr>
<th>Study Objective</th>
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<th>Participants</th>
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<tbody>
<tr>
<td>To measure efficacy, safety, and satisfaction outcomes in subjects participating in a community pharmacist-based smoking-cessation program</td>
<td>20 community pharmacies in Sydney area of New South Wales, Australia</td>
<td>127 self-referred smokers</td>
</tr>
<tr>
<td>To assess the efficacy of a pharmacist-delivered program for smoking cessation using bupropion SR</td>
<td>Pharmacist-managed program at a VA medical center in Durham, North Carolina</td>
<td>71 smokers referred by clinic primary provider</td>
</tr>
<tr>
<td>To evaluate effectiveness of a pharmacist-based smoking-cessation program and to measure changes in health-related quality of life</td>
<td>4 pharmacists trained as facilitators using the Cooper-Clayton Program, Lexington, Kentucky</td>
<td>31 self-referred smokers</td>
</tr>
<tr>
<td>To provide pharmacists with smoking-cessation consultation guidelines for patients using NTS and to test effectiveness of consultation services</td>
<td>40,220 patients from 6651 pharmacies in a U.S. national program</td>
<td>1925 of 40,220 self-referred smokers were included, of whom 1704 participants from 1246 pharmacies were eligible for survey at 6 mo</td>
</tr>
<tr>
<td>To evaluate effectiveness of a smoking-cessation program offered by the National Corporation of Swedish Pharmacies</td>
<td>880 National Corporation of Swedish Pharmacies that offered 20 courses</td>
<td>140 self-referred smokers</td>
</tr>
<tr>
<td>To study feasibility of covering NRT and paying for pharmacist-delivered smoking-cessation counseling for low-income Medicaid and state insurance program enrollees</td>
<td>Managed Medicaid Program offered by 2 community health centers and 2 community pharmacies in Seattle, Washington</td>
<td>32 self-referred eligible enrollee smokers</td>
</tr>
<tr>
<td>To assess effectiveness of a smoking-cessation program in chain pharmacies</td>
<td>15 pharmacists from 7 chain pharmacies in Richmond, Virginia</td>
<td>48 smokers, self-referred or referred by primary care provider</td>
</tr>
<tr>
<td>To assess effectiveness of pharmacist-delivered tobacco-cessation program in a Coast Guard clinic</td>
<td>A pharmacist-managed program in a Coast Guard clinic in Alameda, California</td>
<td>50 smokers referred by medical providers</td>
</tr>
<tr>
<td>To assess effectiveness of a pharmacist-delivered tobacco-cessation program in a VA outpatient clinic</td>
<td>Pharmacist-managed program at VA community-based outpatient clinic in Missoula, Montana</td>
<td>148 veteran smokers self-referred or referred by primary care provider</td>
</tr>
<tr>
<td>To assess effectiveness of a pharmacist-delivered smoking-cessation program in a VA medical center, and to determine whether quit rates differed among various smoking-cessation products</td>
<td>Pharmacist-managed program at a VA medical center in Durham, North Carolina</td>
<td>198 veteran smokers referred by primary care provider</td>
</tr>
</tbody>
</table>

NRT = nicotine replacement therapy; SR = sustained release; VA = Veterans Affairs; NTS = nicotine transdermal system; IR = immediate release.
combined analyses, the 4-week point prevalence quit rate was 17% (16.5% ITT) in the intervention group and 11% in the control group by self-report. The continuous abstinence rate was 8% in the intervention group and 5% in the control group by self-report.

In another study, which was conducted in Scotland, 62 pharmacies were recruited and randomized to participate in a study to assess the quit rates of participants who received smoking-cessation counseling from trained pharmacy personnel compared with quit rates for smokers who received only standard pharmacy support. A total of 492 customers who sought advice on stopping smoking or who bought over-the-counter NRT (patches or gum) were enrolled in the study and received either the intervention or control condition. All intervention pharmacists and pharmacy assistants received a 2-hour training program to improve their smoking-cessation counseling based on the stage-of-change model. The stage-of-change model, also known as the Transtheoretical Model of Change, works by facilitating change through a series of five stages: precontemplation, contemplation, preparation, action, and maintenance. Tobacco cessation is a process, not an event, with the patient moving from being uninterested, unaware or unwilling to make a change (precontemplation), to considering a change (contemplation), to deciding and preparing to make a change. Action is then taken, and over time, attempts to maintain the new behavior occur. Training included only instruction on preparation, action, and maintenance stages of change. Motivational interviewing techniques to encourage smokers to move from precontemplation to contemplation were not covered in the training because individuals entering a pharmacy for advice on smoking cessation are already in the contemplation or preparation stage. Smokers in the treatment group received the Pharmacy Support Program, which included registration, counseling, and documentation of the participant’s progress. Smokers in the control group received standard professional support. Participants were assessed at 1, 4, and 9 months. At 9 months, the continuous abstinence rate was 12% (11.6% ITT) for the intervention group and 7.4% (7.1% ITT) for the control group by self-report (p=0.089).

Uncontrolled and Verified

One uncontrolled study using biochemical verification was conducted outside the United States. In Australia, 127 participants from 20 pharmacies were enrolled in a study to assess the effectiveness of a pharmacist-delivered program using an algorithm designed to assist participants with smoking cessation. Participants received NTS and attended 6 weekly sessions over 9 weeks facilitated by pharmacists trained to provide cognitive-behavioral interventions and counseling based on the stage-of-change model. At 6 months, the 3-month point prevalence quit rate was 18.9%, and the continuous abstinence rate was 16.5% (14.2% ITT) by carbon monoxide test.

Two uncontrolled studies using biochemical verification were conducted in the United States.
In one Veterans Affairs (VA) medical center, 71 patients were referred by their primary care provider to participate in a study to assess the efficacy of a pharmacist-delivered program for smoking cessation with use of bupropion sustained-release (SR) tablets. The program consisted of three clinic visits (baseline visit ~ 60 min, 8-wk and 6-mo visits ~ 30 min), and follow-up telephone calls at 1, 2, and 6 weeks after the quit date, and monthly thereafter for 6 months. Participants received behavioral counseling and educational materials on smoking cessation. Those without contraindications also received bupropion SR. At 6 months, the 7-day point prevalence quit rate was 12.7% by carbon monoxide test and 25.4% by self-report, and the continuous abstinence rate was 2.8% by carbon monoxide test and 9.9% by self-report.

In another open-label trial, 31 self-referred patients participated in a study to evaluate the effectiveness of a comprehensive pharmacist-based program. A secondary goal was to measure changes in health-related quality of life. Individuals were offered nicotine patches or gum and received extensive behavioral modification counseling consisting of weekly 1-hour group sessions over 12 weeks. The program was facilitated by four pharmacists trained to administer the Cooper-Clayton Program, a comprehensive behavioral smoking-cessation program that includes education, skills training, and social support. At 6 months, the 7-day point prevalence abstinence rate was 26% by carbon monoxide test and 32% by self-report. The study also showed a trend toward improvement in quality of life.
Uncontrolled and Nonverified

Six uncontrolled and nonverified studies reviewed were conducted in the United States, and one was outside the United States. In one U.S. study, 6651 pharmacies and 40,220 patients participated in the Pharmacists Educating Patients Program (PEPP), which provided pharmacists with smoking-cessation consultation guidelines on NTS and tested their effectiveness in delivering the program. Participants were eligible to receive weekly counseling after enrollment in PEPP. At the time of the survey, 1704 randomly selected patients completing 6 or more months of treatment from 1246 pharmacies were used in the final analysis. At 6 months or more, the 7-day point prevalence abstinence rate was 33% and the continuous abstinence rate was 28% by self-report.

In another study, conducted in Sweden, 140 self-referred smokers from 880 pharmacies were enrolled in a study to assess the effectiveness of a program offered by the National Corporation of Swedish Pharmacies. Nicotine replacement therapy (patches or gum) was offered to participants, along with 6 group meetings over 8 weeks. Each meeting lasted about 1.5 hours. At 12 months, the continuous abstinence rate was 33% by self-report.

In a second U.S. study, 32 self-referred patients participated in a pharmacist-delivered smoking-cessation program at two community health centers and two community pharmacies. This
study explored the feasibility of coverage for NRT (patches or gum) and payment for pharmacist-delivered smoking-cessation counseling at the time of NRT pick-up for low-income, managed Medicaid and Basic Health Plan enrollees. A 2-week supply of NRT was dispensed, and follow-up appointments were scheduled in 2-week intervals. Up to five counseling sessions/enrollee were covered. At 3 months after initial dispensing of NRT, the point prevalence quit rate at time of interview was 12.5% by self-report.

In a third U.S. study, 48 patients were self-referred or referred by their primary care provider to participate in a program to assess the effectiveness of smoking-cessation services delivered by 15 community pharmacists from seven chain pharmacies. Participants met individually with one of the trained pharmacists for up to three visits and received counseling on behavioral modification and smoking-cessation pharmacotherapy. Patients used a variety of smoking-cessation aids during the study, which included bupropion SR, nicotine patch, nicotine nasal spray, combination of patch and bupropion SR, or no drug therapy. Patients were assessed at 1, 3, 6, and 12 months. At 12 months, the continuous abstinence rate was 25% by self-report, and patients reported that they were satisfied with the pharmacist’s care.

In a fourth study in the United States, 50 patients were referred by their primary care provider to participate in a smoking-cessation program offered by a pharmacist at a Coast Guard clinic in California. A survey was conducted to assess the effectiveness of the program. The program consisted primarily of individual counseling once/week for six sessions using information from the American Cancer Society Fresh Start program, professional articles, and health care publications. Only five patients received group counseling. Drugs offered to participants were NRT (patch or gum) or bupropion SR. At 12 months, the point prevalence quit rate at time of interview was 8% by self-report.

In a fifth U.S. study, 148 patients were self-referred or referred by their primary care provider to participate in an on-going pharmacist-delivered program at a VA community-based outpatient clinic over a 4-year period. A survey was conducted to assess the effectiveness of the program. The program consisted of three group sessions over 5 weeks (~6 hrs for all three sessions combined) utilizing behavioral-cognitive strategies and pharmacotherapy with either NRT (patches or gum), bupropion SR, or bupropion immediate-release (IR) once it became available as a generic formulation. At 6 months up to 4 years, the point prevalence quit rate at time of interview was 41.5% (36.5% ITT) by self-report.

In a sixth study in the United States, 198 patients were referred by their primary care provider to participate in a pharmacist-managed cessation program at a VA medical center over a 2-year period. The study evaluated the effectiveness of a pharmacist-delivered program in an outpatient clinic and sought to determine whether smoking quit rates differed among various smoking-cessation products. Patients received pharmacotherapy and six brief counseling sessions by telephone or in-person when possible over 6 months. Pharmacotherapy included nicotine patch, nicotine inhaler, nicotine patch plus inhaler, or bupropion SR. Patients were assessed at 6 weeks, 3 months, and 6 months. At 6 months, the continuous abstinence rate was 10% for participants taking NRT and 3.1% for those receiving bupropion SR by self-report. At 6 months, combined analysis resulted in a 7-day point prevalence quit rate of 5.3% and continuous abstinence rate of less than 0.5% by self-report.

**Discussion**

As this review demonstrates, there are numerous variations in design and methods to measure efficacy of studies assessing pharmacist-led smoking-cessation interventions. These differences make it difficult to formally compare the outcomes of these studies, but a weight-of-evidence approach would indicate that these studies collectively demonstrate the positive impact that pharmacists can have on increasing smoking cessation. Based on our review, several recommendations have been formulated, which include a need for studies conducted within the United States, use of control groups, biochemical verification to validate results, and consistent reporting of outcomes. Future studies that can assess pharmacist-led interventions in various settings will allow for a more quantitative assessment of the effectiveness and, ultimately, an economic analysis that would argue for or against a greater involvement of pharmacists in smoking-cessation activities.

**Need for Controlled Trials Conducted in the United States**

All five controlled studies observed positive benefits from pharmacist-led interventions, and
three of the five demonstrated significant differences between treatment groups. Of the two studies that did not detect significant differences between groups, one tested the effects of NRT compared with placebo patches on chewing-tobacco users in the United States. Tobacco users in both groups received the same pharmacist-delivered behavioral intervention, suggesting that the pharmacist-delivered behavioral intervention may be responsible for the quit rates (~35%) found in both groups. The other controlled study that did not detect significant differences between groups did not meet recruitment goals and thus was under-powered to detect the observed differences between groups.

Among the three controlled studies that found statistically significant differences in quit rates between the intervention and control groups, quit rates in the intervention group ranged from 14–16% using ITT at the longest time point reported (6–12 mo). These quit rates are comparable to those of other controlled trials that showed quit rates ranging from 13.4% with minimal contact to 22% with higher intensity. Findings from two of these studies (those conducted in the United Kingdom) led the Cochrane Review team to conclude that pharmacists may have a positive effective on smoking cessation, but the strength of evidence is limited. Further, the three studies that demonstrated effectiveness of the pharmacist-delivered intervention on tobacco cessation were conducted outside the United States; these countries have distinctive health care policies and delivery systems that are likely to affect study findings. Similarly designed studies conducted in the United States are needed to provide strong evidence of the effectiveness of pharmacist-delivered interventions within the context of the U.S. health care system.

Use of Comparison Groups

The uncontrolled studies falling outside the Cochrane Review criteria contribute additional information on the effectiveness of pharmacist-led smoking-cessation interventions. Ten uncontrolled studies documented quit rates using ITT of about 5–36% among smokers participating in pharmacist-delivered interventions. Five of these studies that were conducted in the United States reported quit rates of more than 20% using ITT at the longest time point reported (6–12 mo). Although these studies did not compare quit rates in the treatment group with a comparison or control group, the findings provide strong evidence that pharmacist-delivered interventions are feasible and very likely effective. These studies demonstrate that pharmacist-delivered interventions can be delivered in a variety of nonresearch environments, are acceptable to patients and pharmacists, and are likely to be effective in a variety of settings (community health centers, community pharmacies, chain pharmacies, VA clinics), using different intervention techniques (various tobacco-cessation drug therapies, brief advice, multiple sessions) and modes of intervention delivery (group, individual).

These uncontrolled studies provide strong evidence that pharmacist-delivered interventions are feasible in the United States, but it is difficult to interpret the effectiveness of these programs because none compared the outcomes of the treatment group with a similar comparison or control group. It is therefore not possible to isolate the pharmacist-based intervention as the independent variable that is solely responsible for the cessation. The strongest design to strengthen internal validity is the randomized controlled trial, wherein participants are randomly assigned to receive treatment or control conditions and the success of the program is determined by measuring the difference in cessation rates between groups.

Longer Duration of Follow-up

A wide range of quit rates were reported for the different follow-up periods. Quit rates reduced dramatically from shorter to longer follow-up periods up to about 6 months. In studies reporting both 6- and 12-month follow-up periods, the results showed less variation. Based on these limited data, a short period of follow-up (e.g., ≤ 3 mo) may not be representative of long-term smoking-cessation success, but 6 months of follow-up after the quit date should be sufficient for assessing future studies of pharmacist-led smoking-cessation interventions and is consistent with recommendations from leading tobacco researchers.

Methods to Account for Loss to Follow-up in Analyses

Studies measured smoking cessation by using point prevalence and continuous abstinence. Point prevalence quit rates were reported for a
variety of end points. Recommendations from a committee of leading tobacco researchers suggest reporting sustained abstinence (no smoking since the quit date, allowing for a short slip early on) and 7-day point prevalence as a secondary measure. Further, the committee suggests reporting results by using survival analysis to describe outcomes more fully.24

Six of the studies reviewed did not account for missing data in their analyses. In smoking-cessation studies that include interpersonal contact with an interventionist (such as a pharmacist), participants may fail to appear for treatment because they are unable to quit smoking. Therefore, it is likely that loss to follow-up is nonrandom. Studies reporting cessation outcomes based on only complete cases will overestimate the study’s success rate. The ITT analysis considers the outcome in all subjects according to their initially assigned treatment (recording those who are lost to follow-up as smokers). The use of ITT or other methods to account for loss to follow-up is necessary in smoking-cessation studies involving contact with interventionists, such as pharmacists.44

Biochemical Verification

Only six of the reviewed studies used biochemical measures to verify self-reported cessation or abstinence. Two of the studies demonstrated the importance of using biomarkers, as cessation rates were higher by self-report compared with carbon monoxide verification at 6 months (25.4% vs 12.7%)31 and 32% vs 26%).32 These studies point to the importance of using biomarkers to confirm smoking status among participants enrolled in future pharmacist-led intervention studies. The use of biomarkers in clinic-based studies is consistent with recent guidelines that further recommend the use of salivary or urinary cotinine levels, the major proximate metabolite of nicotine, to verify self-report of 7-day cessation. Cotinine is highly specific and sensitive for tobacco use and has the advantage of rapid elimination.49

Conclusion

The uncontrolled and controlled studies reviewed demonstrate that pharmacists can deliver tobacco interventions, and the evidence strongly suggests that they are effective in helping smokers in the United States to quit. Future studies conducted in the United States that are well controlled and include biochemical verification of smoking status are needed to provide definitive confirmation that pharmacist-delivered interventions are effective for smoking cessation. With the availability and expanded training of pharmacists, this is an opportune time for testing and disseminating evidence-based research evaluating effectiveness of pharmacist-delivered tobacco-cessation services. Widespread and effective utilization of pharmacists as providers of tobacco-cessation services could significantly reduce the smoking rate across the United States.

References
20. Petty D. Drugs and professional interactions: the modern day pharmacist. Heart 2003;89(suppl 2):i31–2; discussion i35–7.