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Quitting patterns and success rates of a tobacco cessation program led by New Mexico Pharmaceutical Care Foundation

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Quitting Patterns and Success Rates of a Tobacco Cessation Program Led by New Mexico Pharmaceutical Care Foundation

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ABSTRACT

The objective of the present study was to assess the effectiveness of a pharmacists-assisted tobacco cessation program led by New Mexico Pharmaceutical Care Foundation (NMPCF) and to characterize participants' quitting patterns during the study period.

Data from the program from 2004 to 2011 consisting of 1486 participants were combined for analysis. Point prevalence quit rates were calculated and survival analysis was performed to evaluate program effectiveness. A qualitative case study with participating pharmacists was conducted to explore intervention elements that could impact participants' likelihood of successfully quitting tobacco. Four quitting patterns were defined including immediate quitters, delayed quitters, once quitters, or never quitters. Multinomial logistic regression was performed to identify patient characteristics associated with quitting patterns.

The average point prevalence quit rate at 6 months was 18.7%. The average abstinent time was 76.8 days (standard error = 3.59 days). The

probability of a patient being continuously abstinent for 7 days was 89.1%, while the likelihood of being abstinent for 30 days and 180 days were 46.0% and 16.5%, respectively. Patients who were under 18 years old, less educated, less dependent on nicotine, and had higher confidence to quit were more likely to be immediate quitters rather than never quitters.

Pharmacists are capable of delivering tobacco cessation services. Patients' likelihood of quitting tobacco depends both on themselves and the intervention they receive. Intensive counseling and close follow-up are important elements of an effective tobacco cessation intervention. Different quitting patterns exist among patients. Patients with different quitting patterns have distinctive characteristics in terms of level of nicotine dependence, pharmacotherapy used, motivational factors and demographic factors. Interventions need to be tailored for patients with different quitting patterns.

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Chapter 1 Introduction

Background and problem statement

Tobacco use is a known cause of multiple cancers, heart disease, stroke, complications of pregnancy, and chronic obstructive pulmonary disease (COPD).[1] It remains the chief avoidable cause of death in the United States, accounting for more than 435,000 deaths each year.[2] Furthermore, smoking results in approximately $100 billion in health care costs and another $97 billion in lost productivity in the United States every year.[3] Despite the well acknowledged harms of smoking and its economic burden, the 2006 National Health Interview Survey (NHIS) suggested that the prevalence of cigarette smoking among the U.S. adults was approximately 21%.[4] Smokers are aware of the health dangers of tobacco use and struggles to quit the habit. Around 70% of the smokers who participated in 2000 NHIS reported that they wanted to quit, and 41% had tried to quit during the preceding year.[5] Another study showed that almost two thirds of smokers who did not successfully quit were interested in trying to quit again within 30 days.[6]

However, quitting using tobacco is a difficult task with multiple barriers. Weight gain, craving for smoking, loss of pleasure, stress and depression after quitting as well as being around smokers, have been reported as the most common reasons for relapse.[7, 8 9, 10] Overcoming these barriers without health professionals intervention and pharmaceutical aid is challenging. There has been evidence showing that patients who received advice and assistance for quitting

tobacco during their physician visits had better satisfaction about their care[11] and smokers take physicians' advice as an important motivator for attempting to quit.[12] A meta-analysis from Cochrane showed that success rates of self-help interventions ranged from 2% to 10%, which were slightly higher than that of no intervention (pooled relative risk=1.21; 95% C.I. 1.05-1.39). [13] Another meta-analysis indicated that behavioral interventions delivered by health care providers were more effective compared to interventions where no health professional was involved. More importantly, the success of interventions did not differ by type of clinician. Physicians (estimated quit rate= 19.9%; 95% C.I. 13.7%–26.2%) and other clinicians (estimated quit rate=15.8%; 95% C.I. 12.8%–18.8%) were almost equally successful in helping smokers quit.[14]

Strategies of interventions have been designed to assist clinicians with counseling both smokers who are ready to quit and smokers who are reluctant to quit. The 2008 Clinical Practice Guideline for Treating Tobacco Use and Dependence recommends a brief clinician led intervention to be offered to all tobacco users using the "5 A's" strategy (Ask, Advice, Assess, Assist, Arrange). For patients who are unwilling to quit, a clinician should provide a motivational intervention, consisting of five major components ("5 R's", relevant, risk, rewards, roadblocks, repetition). In addition to brief counseling, the guideline also recommends tobacco cessation products be offered to all smokers attempting to quit except when contraindicated and for specific populations among whom the effectiveness of the products is unclear. A combination of counseling and

pharmacotherapy is more effective than counseling alone or pharmacotherapy alone. [14] First-line agents, including bupropion sustained-release (bupropion SR), nicotine replacement therapy (NRT), and varenicline, are effective in a broad range of populations.[15, 16]

Despite the potential contributions that clinicians could make to tobacco cessation and the availability of well-developed interventions, counseling on tobacco cessation does not take place in day-to-day health care settings. According to the National Committee for Quality Assurance's (NCQA) 2007 State of Health Care Quality Report, 73.8% commercially insured smokers and 68.2% Medicaid smokers received advice to quit in 2006. Counseling about quitting only happened to 43.2% commercially insured smokers and 36.7% Medicaid smokers.[17] Physician counseling occurred in 21% of smokers' visits in 2003[18] and lack of time was reported as a central barrier to counseling by physicians.[19] Compared to physicians and other clinicians, pharmacists are relatively more accessible to patients.[20] Their unique position in the health care system allows them to identify smokers who are willing to quit and assist them throughout the quitting process. Pharmacists in New Mexico have been granted more authority and might play even a greater role in tobacco cessation than their peers in other states. With an approved protocol, they could prescribe tobacco cessation products, which makes it possible for them to help tobacco users quit more directly.[21] More importantly, pharmacists are also interested in providing tobacco cessation services and see it as an important activity of their profession.[22, 23] In

order to strengthen pharmacist's capability of counseling tobacco use, efforts such as the Rx for Change program have been established to expand tobacco cessation training among pharmacy students as well as licensed pharmacists.[24] The Rx for Change curriculum has been disseminated to pharmacy schools throughout the U.S. and has already obtained acceptance and positive feedback.[25]

Studies have been conducted to demonstrate the effectiveness of pharmacists-led tobacco cessation interventions. A Cochrane review identified two randomized controlled trials of pharmacists-assisted tobacco cessation programs in U.K., which showed a continuous abstinent rate of 18.5% at 6 month and 12.0% at 9 month, respectively. [26] Observational studies with varying designs of intervention have also demonstrated the effectiveness of pharmacists-delivered services.[27] A successful quit depends on the smoker as well as the intervention received. While characteristics of successful quitters have been extensively studied in various populations, the impact of intervention elements on one's likelihood of success remains understudied. A few studies compared interventions using quantitative approaches. Elements including intensity of counseling, format of counseling and number of counseling formats adopted, combination of counseling and medication, and intervention setting have been shown to be associated with success rates. [14, 28, 29] Nevertheless, research on intra-intervention level, aiming to understand within-study difference, is rare. We have very limited knowledge on the reasons why some clinicians are more

successful in helping smokers quit than others in the same cessation program and their perception of their success.

While quit rates of various interventions have been reported previously, the process of quitting remains understudied. Few studies have presented a comprehensive picture of how patients' post-intervention smoking behaviors changed over time or how the final point prevalence quit rate was reached.[30] The transtheoretical model of change (TTM) is the most widely known theory of health behavior change and has been applied to guide tobacco cessation. It proposes that tobacco users move through 5 stages before they successfully achieve abstinence.[31] The stages are "precontemplation" (not thinking about quitting), "contemplation" (thinking about quitting), "preparation" (planning to quit in the next 30 days), "action" (quitting successfully for up to six months), and "maintenance" (no tobacco use for more than six months). The process of quitting tobacco is complicated, during which patients might return from advanced stages like "action" to earlier stages such as "preparation". Moreover, patients in the "preparation", "action", or "maintenance" stage of quitting would require different types of support from those in "precontemplation" or contemplation". Therefore, quitting tobacco is a process that requires interventions tailored to patients' stage of quitting and it also takes repeated efforts to reinforce treatment effects. Point prevalence quit rate does not represent such a continued and complex process. In order to better understand the process of quitting and improve future interventions, quitting patterns and

smokers' transitions in smoking behaviors that emerge during the quitting process need to be evaluated in more details. Predicting tobacco users' quitting pattern and transitions will also provide clinicians with more information about how patients move between the stages after/during intervention, which in turn, will help them better assist patients in quitting tobacco.

Study question, specific aims and hypotheses

The primary objective of the present study was to assess the effectiveness of a pharmacists-assisted tobacco use cessation program led by New Mexico Pharmaceutical Care Foundation (NMPCF) and to characterize participants' quitting patterns during the study period. We proposed four specific aims to be accomplished by this study.

Aim 1: To calculate 1 month, 3 months, and 6 months point prevalence quit rates of the NMPCF tobacco cessation program.

Aim 2: To study participants' probability of being continuously abstinent and their quitting experience over time.

Hypothesis 1: Participants' likelihood of being continuous abstinent was associated with patient characteristics including age, gender, ethnicity, education level, tobacco use, past quitting attempt, pharmacotherapy use, nicotine dependence, confidence to quit, and importance to quit.

Aim 3: To identify quitting patterns among participants and compare participants of different quitting patterns with respect to pharmacotherapy use and other baseline characteristics.

Hypothesis 2: Participants' quitting patterns were related to patient characteristics including age, gender, ethnicity, education level, tobacco use, past quitting attempt, pharmacotherapy use, nicotine dependence, confidence to quit, and importance to quit.

Aim 4: To assess the variation in success rates among pharmacy stores, and to explore elements of effective tobacco cessation services.

Hypothesis 3: Pharmacy stores had varying point prevalence quit rates at 1 month, 3 months, and 6 months.

Hypothesis 4: Quit rates were affected by intervention elements such as intensity of intervention sessions, frequency of follow-ups, and format of counseling.

Chapter 2 Literature review

Three systematic Medline reviews, with respective focus on effectiveness of pharmacists-assisted tobacco cessation interventions, quitting patterns, and significant predictors of successful abstinence, were performed. The search strategies and the existing literature were summarized for each topic.

Effectiveness of pharmacists-assisted tobacco cessation programs

The literature search was performed up to January, 2012, restricting to English and human literature. The MeSH term “pharmacists” was combined with the MeSH term “tobacco use cessation” in the search. Original studies on pharmacists-assisted tobacco cessation programs with data analysis of quit rate(s) were eligible. We also added studies from reference lists of reviews. Interventions in which pharmacists did not take an active role were excluded. Editorials and perspective articles were excluded. The search produced 69 citations, among which 6 original studies and 2 reviews were identified. Another three original studies were identified from the reviews. Included studies were summarized by intervention, outcome and sample size (Table 1). Compared to the other programs, the one offered by Missoula Veteran Affair Veteran Health Administration outpatient clinic in Missoula, Montana achieved extremely high long-term abstinence rate.[32] The program was administered by a pharmacy specialist and offered about 4 to 5 times per year depending on the number of referred patients. One hundred and thirty veterans participated in the program during 2001-2003. At the follow-up telephone surveys completed in June and December of 2001, 2002, and 2003, 41.5% of them continued to be abstinent after the end of the program with 54 for 6 months, 42 for 1 year, 27 for 2 years, 20 for 3 years, and 4 for 4 years. The success was related to the proper design and delivery of the program. Before admitting veterans into the group class sessions, an initial assessment of their motivation to quit was conducted and a one-to-one motivational counseling using 5“Rs” was delivered if the veteran was

in precontemplation and unwilling to quit. Moreover, the 3 group class sessions were designed based on the Transtheoretical Model of Change with specific focus on preparing smokers to quit, assisting smokers to take action, and helping them to maintain abstinence. Pharmaceutical aids were also offered to participants without any charges in conjunction with the group counseling sessions. This was a perfect example proving that pharmacists could deliver effective tobacco cessation services given the intervention was well planned and designed based on evidence.

Table 1 Summary of Pharmacists-assisted Tobacco Cessation Programs from Literature

Reference	Number of participants	Intervention	Outcome
Zillich et al (Pharmacothepray 2002)	31 self-referred	Weekly group session for 12 weeks led by pharmacist(s); nicotine replacement therapy (NRT) paid by participants; follow-up via phone	*Verified abstinence at 3 and 6 months: 42% and 26%
Roth et al (Pharmacotherapy 2001)	71 referred by physician	Counseling with clinical pharmacist; educational booklet; bupropion SR; phone follow-up; 3 clinic visits	Self-reported continuous abstinence at 8 weeks and 6 months: 15.5% and 9.9%
Kennedy et al (J Am Pharm Assoc 2002)	48 identified by community pharmacist or referred by physician	Counseling with community pharmacist; pharmacotherapy paid by participants; face-to-face visits/phone follow-up	Self-reported continuous abstinence at 12 months: 25%
Smith et al (Am Pharm 1995)	2,001 participated in the Pharmacists Educating Patients Program	Counseling with pharmacist; NRT (transdermal)	Self-reported abstinence at 10 months: 33%
Bauld et al (Nicotine & Tob Res 2011)	1374 invited by letter	One-to-one counseling with pharmacist for 12 weeks; pharmacotherapy;	*Verified continuous abstinence at 52 weeks: 3.6%
Costello et al (Cancer Causes Control 2011)	3588	3 sessions of pharmacists-led behavioral intervention; 5 weeks NRT	Self-reported point prevalence abstinence rate at 7 day: 27.7%
Maguire et al (Addition 2001)	484 enrolled by pharmacists	Booklet and a one-to-one counseling with pharmacist at baseline; weekly follow-up for 4 weeks and then monthly for 3 months with pharmacist	*Verified continuous abstinence at 12 months: 14.3%
Roth et al (Pharmacotherpy 2005)	198 referred by physician	Tailored behavioral counseling with pharmacist; educational materials; pharmacotherapy; follow-up via phone/visit	Self-reported continuous abstinence rate for NRT and bupropion SR: 22.9% and 7.7%
Dent et al (J Am Pharm Assoc 2004)	130 veteran self-referred or referred by physician	3 session counseling using the Transtheoretical Model of Change with pharmacist; pharmacotherapy	Self-reported continued abstinence (6 months-4 year): 41.5%

*Verified by exhaled carbon monoxide test or continine

Comparing the interventions and outcomes of these 9 studies, group sessions and intensive interventions appeared to be more effective than interventions conducted individually or without close follow-up. However, the observed difference could also be associated with differences in study samples. The success rate of the program reported by Zillich et al[33] was more than 5 times higher than that of the program reported by Bauld et al[34]. However, the participants in the program Zillich et al described seemed to be more motivated to quit compared to the participants in the other program. On average they had tried to quit 3.2 times and paid for pharmacotherapy by themselves. None of the 9 studies analyzed time to relapse or presented quit rate on a longitudinal basis.

Quitting patterns

The literature search was conducted up to January, 2012, restricting to English and human literature. The MeSH term “tobacco use cessation” was combined with the keywords “pattern*” and “quit”. We were interested in studies assessing quitting patterns or relapse patterns during or after a tobacco cessation intervention. Studies concentrating on smoking patterns or usage patterns of medications, services or programs were excluded. The search gave 296 citations and abstracts were reviewed to determine the eligibility of each article. We identified 4 studies evaluating quitting or relapse patterns and 1 study assessing reduction pattern.

Gonzales et al pooled data from two identically designed clinical trials of varenicline versus bupropion sustained-release and placebo, and described two types of successful quitters, which were immediate quitters (IQ) and delayed quitters (DQ).[30] In both trials, participants received 12-week treatment and were followed up for 52 weeks. The primary end-point of the trials was continuous abstinence for weeks 9-12 and the target quit date (TQD) was day 8 followed the first week treatment. IQ achieved initial abstinence immediately on the day 8 TQD and remained continuously abstinent for weeks 2–12. QD were those who quit later than the TQD or those who experienced lapses between TQD and week 9, but were then able to achieve continuous abstinence for weeks 9–12. They found that the proportion of DQ among successful quitters was similar across treatments and DQ were less likely to remain abstinent at 52 weeks

compared to IQ. Hajek et al analyzed data from a clinical trial of 12-week extended treatment of varienicline and showed that DQ were more likely to benefit from the extended treatment compared to IQ.[35] They randomized a total of 1208 IQ and DQ who were abstinent at least for the last week of a 12-week varenicline treatment to either 3 months continued treatment with varenicline or placebo. The extended course of varienicline was effective in preventing DQ from relapse at 52-week (odds ratio (OR)=1.7, 95% confidence interval (95% C.I.): 1.2-2.4), but such effect was not seen among IQ (OR=1.1, 95% C.I.: 0.8-1.5). In addition, they also found smokers who initially delayed to achieve abstinence to be more likely to relapse at 52-week after adjusting baseline characteristics as Gonzales et al described. The results of above two studies indicate that DQ need prolonged treatment to reinforce treatment effects. This information is valuable for tailoring individualized interventions and improving effectiveness as well as efficiency of future programs. Both of the studies were restricted to pharmacotherapy and the generalizability of these findings to other tobacco cessation interventions was not clear.

There also have been studies evaluating patterns of smoking reduction, lapses during quitting attempts, and resumption after relapse. Estabrooks et al concluded that initial successful reduction was associated with final success.[9] Conklin et al identified 4 patterns of smoking resumption after relapse including low-lever users, moderate users, slow returners, and quick returners. [36] Ussher et al found that patients using 16 hour nicotine patches were more likely to lapse

during afternoons and evenings than in mornings ($p<.0001$).[37] Of the 5 studies identified, only Gonzales et al presented the baseline characteristics of IQ, DQ, and all sample, but no extensive analysis was done to characterize the two patterns they defined.

Significant predictors of successful abstinence

The literature search was conducted up to January, 2012, restricting to English and human literature. The MeSH term “tobacco use cessation” was combined with the keyword “predictors”, “reasons”, or “characteristics”. We limited the search to studies that evaluated characteristics of successful quitters or elements of effective interventions. The search yielded 595 citations and the abstract of each article was reviewed to determine the eligibility of articles. We excluded studies on smoking behaviors, characteristics of smokers, effectiveness or utilization of interventions, services or pharmacotherapies, and reasons, intention, motivation, or attempts to quit. In order to increase relevance of the review to the present proposal, studies focused on a particular population such as cancer patients or pregnant women were further excluded as well as studies whose sample consisted of smokers who did not attempt to quit. Ninety-one studies met the above inclusion criteria. With exception of two studies evaluating intervention elements, almost all the studies focused on identifying characteristics of successful quitters. Eight domains of predictors were identified from the literature. Non-significant predictors were not included in the following discussion.

1) Use of pharmacotherapy

   Tobacco cessation products approved by the Food and Drug Administration (FDA) include NRT, bupropion sustained release (Zyban®, Wellbutrin®), and varenicline tartrate(Chantix®).[38] Other than clinical trials specifically designed to study efficacy of tobacco cessation products[39-42],

prior evaluations of tobacco cessation programs also demonstrated that use of pharmacotherapy was effective and independently predicted successful cessation. Results from a behavioral intervention among elderly smokers showed that smokers who used NRT were 4.36 more likely to quit than those who did not receive NRT.[43] Adherence was low among smokers who were using NRT to quit, but adherence to NRT was found to be predictive of successful cessation.[44] A retrospective analysis of abstinence outcomes of enrollees of a quitline service showed that smokers who used varenicline tartrate were 1.85 times more likely to quit at 3 month follow-up compared to smokers who used NRT after controlling for age, gender, previous amount of tobacco use, and number of counseling calls.[45] In a study of 285 patients who attended a tobacco cessation clinic, patients in the bupropion sustained release (SR) group had 2.89 times increased odds of being continuously abstinent at 6 month compared to those in the placebo group.[46] Other studies also found use of bupropion SR independently predictive of tobacco cessation.[46-49]

2) Nicotine dependence

A couple of variables have been used as measures of nicotine dependence including score of Fagerstrom Test of Nicotine Dependence (FTND) , age when first started smoking, average number of cigarettes per day, and time to first cigarette after waking. FTND is a validated questionnaire used to measure smokers' level of nicotine dependence,

which consists of six items (see Appendix A for the full questionnaire).[50] Scoring per item is either a two or four level response with values 0, 1, 2, or 3. Items are summed and the possible scores range from 0 to 10. Previous studies categorized FTND differently, but it has been consistently found to be independently predictive of successful quits in various studies.[51-54] In a non-randomized clinical trial, participants who with FTND score greater than 8 were 1.63 times more unlikely to succeed in quitting smoking at 1 year compared to those with FTND score less than 4.[53] Number of cigarettes consumed per day and time to first cigarette after waking are two components of FTND. Both of them have been shown to be indicative of likelihood of successfully quitting tobacco use.[46, 55-61] An analysis of a behavioral intervention in Italy found that smokers who initiated smoking after 18 years old were 1.65 times more likely to quit at 1 year than other after adjusting for previous attempts, number of cigarettes, education level, and age.[57] Another study in Finland found starting at a late age to be a significant predictor in male smokers, but not in female smokers.[56]

3) Health perception and comorbidities

Health has been cited as the most predominant reason for wanting to quit in surveys.[62-64] A survey among German industrial employees was conducted to study reasons of attempting to quit. Of 360 employees who were in contemplation or preparation stage, 94% of them stated health

risks as the reason for quitting, which predominated financial (27%) or image-related (14%) reasons.[64] A study conducted among an elderly, low-income population Lebanon showed that having at least one chronic illness and having a functional disability significantly increased the odds of smoking cessation.[65] Experiencing a health-related problem might change patients' smoking behavior. In a group of smokers who were newly diagnosed with head and neck cancer in Florida, 62% of them planned to quit smoking in the next 3 months [66], which is 20% higher than the national percentage.[5] A study of 717 smokers treated at an emergency department (ED) revealed that having a smoking-related event, such as a diagnosis of respiratory diseases, predicted 7-day abstinence within one month after controlling for nicotine dependence, self-efficacy, and other smoking-related variables, while presence of a smoking-related disease was not a significant predictor.[67] Another study even found having a smoking-related disease was inversely related to abstinence at 7-week[51], although diagnosis of smoking-related diseases has been identified as a strong trigger of smoking cessation.[68]

The role, which depressive symptoms or history of depression plays in quitting process, is in dispute. Several studies have demonstrated that smokers having depressive symptoms or a history of major depressive disorders were less likely to quit smoking than others[47, 49, 69], while a meta-analysis, which included 15 studies, showed that a lifetime history of major

depression was not related to failure in smoking cessation treatment.[70] Interaction between a tobacco cessation program, targeting rural teenage smokers, and depression was suggested.[71]

4) Psychological factors

Previous studies have demonstrated that self-efficacy of smokers, and their confidence and degree of motivation to quit are predictive of smoking cessation. Typically, smokers' self-efficacy is defined as confidence in ability to refrain from smoking in negative affect situations such as being with a smoker, and in habitual or craving situations.[72-74] In a study of low-educated women who received a brief cessation intervention, 1 point increase on a 4-point scale of self-efficacy was associated with doubling odds of smoking cessation at one week.[75] In some studies confidence to quit at this time was used as a measure of self-efficacy and found to be predictive of quitting as well.[44, 76, 77] A study using a French measure of motivation (Q-MAT) indicated that smokers with a score greater than 17 were 1.63 times more likely to quit than others.[51] A qualitative study that followed 15 adolescent smokers over 3 months found that reasons of quitting were not equally motivating and successful quitters usually had greater motivation.[78]

5) Previous attempts

A study of a 5-week group behavioral intervention found that attempting to quit in the past was associated with 1.49 times increased odds of being abstinent at 6 month post-intervention.[57] Duration of past attempts has also been found to be associated with current success after adjusting for nicotine dependence, use of pharmacotherapy and demographic characteristics, with longer previous attempt being indicative of success of current attempt.[51, 59, 69, 79]

6) Social influence

A study of 1,335 adolescent smokers from six European countries assessed the impact of social influence, measured by three scales representing influences from family, friends, and others in the same school, on smoking behaviors. [80] Each scale included 3 domains: a) social norm, which assessed adolescents' perceptions of whether it was important what others thought (that they definitely should smoke or should not smoke); 2) social pressure, which measured how often direct pressure to smoke was perceived by adolescents; 3) perceived smoking behavior of others (how many of social acquaintances smoked). The study showed that depending on the country, social influences from family, friends and others in the same school were related to adolescent smokers' perception of smoking, intention to quit, and successful quitting at 6 month. Other studies also found that those with a social network discouraging smoking were more

likely to quit.[81, 82] Lack of social support has been identified as a trigger of relapse.[83] A study of 1790 nurses using an online tobacco cessation service showed that quitters were more likely to report support from colleagues, working at a smoking-free facility, and having cessation services at workplace.[84] Not only smokers' work environment, but also their environment at home affects the likelihood of quitting. The presence of a non-smoking partner or a partner who quits smoking significantly predicts a smoker's quitting behavior.[39, 73, 85-87] Moreover, adoption of smoking ban at home was also suggested to be effective in assisting smokers to quit and preventing relapse.[82, 88-90]

7) Demographic factors

Previous studies also showed that smokers' demographic and socioeconomic characteristics were associated to chance of success. A large number of studies included age in analysis and consistently found that smokers with older age were more likely to quit than others. [45, 47, 61, 69, 79, 81, 88, 91-94] Being married was also consistently found to be associated with cessation.[51] Studies on gender difference in likelihood of quitting had discrepant findings with the majority of the studies indicating that males were more likely to quit[92, 43, 57, 69, 94, 95]. The literature also suggests smokers with higher education level, income and social class are more likely to quit. [44, 56, 59, 73, 93]

8) Intervention elements

We only identified two studies that evaluated the impact of intervention characteristics on effectiveness of tobacco use cessation services. Both studies assessed the smoking cessation services provided under the National Health Service in UK, but with different analytic approaches. Brose et al pooled the data from 126, 890 treatment episodes in the English network of stop-smoking services (SSSs) and each treatment episode was a unit of analysis.[29] The characteristics examined included setting, medication, and type of support. After adjustment for smokers' characteristics, they found substantial variation in success rate across service characteristics. Single NRT was associated with higher success rates than no medication (OR 1.75, 95% CI 1.39 to 2.22). Combination of NRT and varenicline was more effective than single NRT. Group support was linked to higher success rates than one-to-one support (OR 1.43, 95% CI 1.16 to 1.76). Primary care settings were less successful than specialist clinics (OR 0.80, 95% CI 0.66 to 0.99). In contrast to Brose et al, the investigators of the other study assessed the association between service characteristics and quit rates on a service-level instead of a treatment episode level. A survey was sent out to 133 service coordinators to obtain information on service characteristics, areas where services were offered, and outcomes of services measured by number of smokers reached and cessation rate.[28] The final analysis included 76 services and considerable variation in cessation rates was found across services. They used

ordinary least squares regression to characterize the relationships between outcomes and area and service characteristics. Services in health action zones, which were located in areas of high deprivation, reached on average 140% more smokers than those in other parts of the country. Services with strong relationship with local primary care organizations reached more smokers. Number of intervention sessions, group intervention, and strong relationship with local primary care organizations were positively related to cessation rate, while services operating in deprived areas achieved a lower cessation rate.

Summary of literature reviews

The purpose of the literature reviews was to inform variable selection for the statistical analyses of patients' continuous abstinence and quitting patterns, and to assist the design of the case study for exploring elements of effective intervention. In summary, previous research in pharmacists-assisted tobacco cessation programs indicates variations in intervention design as well as intervention outcomes measured by quit rates. The majority of the existing literature on predictors of successful tobacco abstinence focuses on patient characteristics. Seven domains of individual characteristics were identified from the literature review including pharmacotherapy use, level of nicotine dependence, health perceptions and comorbidities, psychological factors (e.g. confidence to quit), previous attempts, social influences from family and friends, and demographic factors (e.g. age, gender). Patient characteristics from intake questionnaire, if related to these factors, were included in the survival analysis as well as the pattern analysis. Findings about elements of effective tobacco cessation interventions from the two UK studies (e.g. type of pharmacy, format of counseling, frequency and intensity of intervention) were incorporated into developing survey questions for the case study with the pharmacists.

Chapter 3 Methods

This study was a retrospective and longitudinal cohort of the patients participated in the NMPCF tobacco cessation program with data collected over 7 years. The study consisted of four parts, including quit rates calculation, survival analysis, pattern analysis, and case study with participating pharmacists. Point prevalence quit rates and patients' continuous abstinence analyzed by survival analysis were intended to evaluate the effectiveness of the tobacco cessation program. The case study was adopted to explore variation in quit rates across pharmacies and constituents of an effective intervention. The pattern analysis was aimed to investigate the potentially existing quitting patterns among patients. The study methods, results, and discussion were organized around these four essential parts of the study.

Data source

The data was from a pharmacists-assisted tobacco cessation program led by New Mexico Pharmaceutical Care Foundation (NMPCF). NMPCF initiated the program in 2004 and offered it every year until 2011 when the program ended due to suspension of funding by New Mexico Department of Health. By 2011, 23 pharmacy stores across New Mexico had participated in the program for at least 1 year and 1486 smokers had received the service. Patients were either self-referred, or approached and invited to participate the program by pharmacists. The program provided patients with pharmacotherapy up to the value of $137.50 and/or free counseling sessions with pharmacists. No financial compensation was given to patients for their participation. Participating pharmacists were reimbursed for providing the service and the program received funding from New Mexico Tobacco Use Prevention and Control Program (TUPAC). Intake and follow-up questionnaires developed by TUPAC were adopted and administered by pharmacists. The intake questionnaire was administered to each patient at recruitment to obtain baseline information on tobacco use, previous quit attempts, working and home environment, confidence to quit, importance to quit, and other demographic characteristics. Three follow-ups at 1 month, 3 months, and 6 months were scheduled to follow up with patients' tobacco use status. The follow-ups were either conducted face-to-face in pharmacy or via telephone. Participants who responded to at least one of the 4 questionnaires (1 intake and 3 follow-ups) were included for analysis.

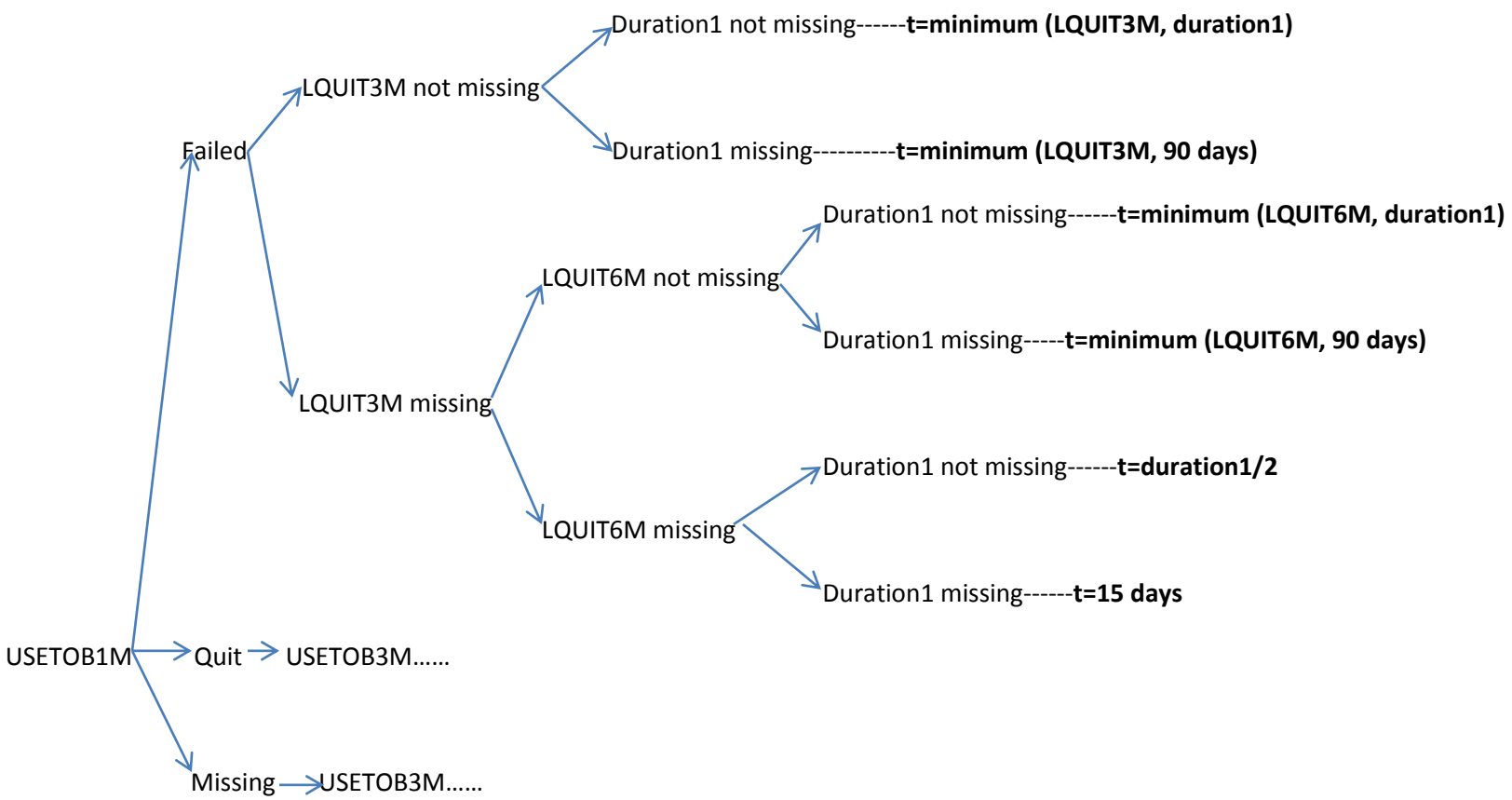
Quit rates

For each follow-up, an overall point prevalence quit rate as well as point prevalence quit rates by year and by pharmacy store were calculated. The question “do you currently use tobacco products?” was used to determine participants’ tobacco use status. This question only measured patients’ tobacco use status at the moment of the follow-up. “Intention to treat” was adopted for calculating quit rates. Specifically, missing at follow-ups was assumed to be failures and included in the quit rate calculation.

Survival Analysis

In addition to calculating point prevalence quit rates, Kaplan-Meier survival curves were used to present the probability of a participant remaining continuously abstinent over time until the final follow-up. Cox proportional hazard model was used as the multivariate analysis to assess what patient characteristics were associated with relapse. The question “have you used tobacco even once since your quit date?” was asked at each follow-up and it was used to determine patients’ continuous abstinence status. At the 3 months and 6 months follow-up, a question “how long did you remain quit” was asked if patients reported that they had used tobacco since quit date. Together with the intake and follow-up dates, these two questions were used to determine how long a participant remained abstinent after their quit date. Figure 1 demonstrates how the time of abstinence was assigned to each individual.

Figure 1 Schematic for Assigning Time of Abstinence

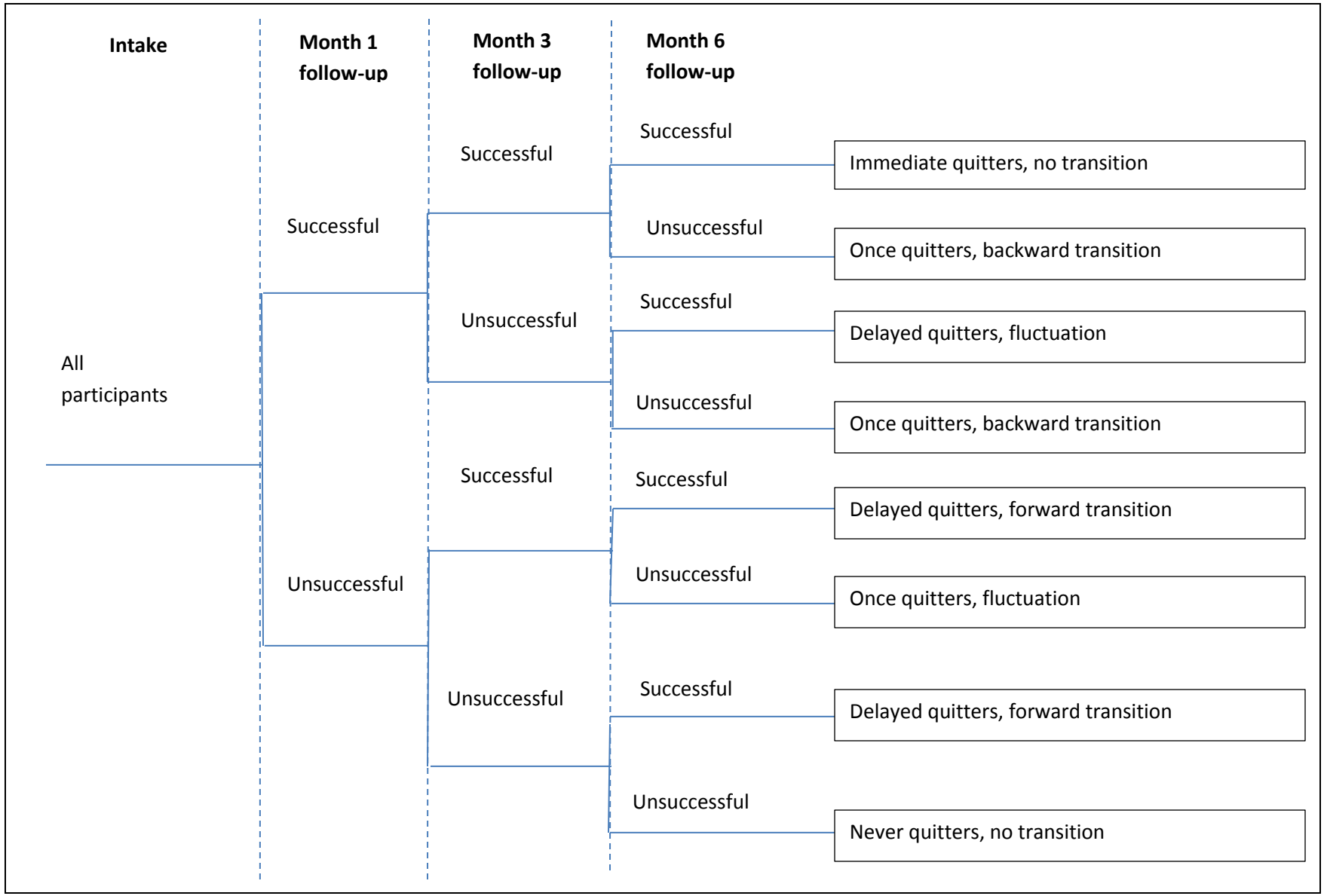


*USETOB1M: patients' response to ever used tobacco since quit date at 1 month follow-up
USETOB3M: patients' response to ever used tobacco since quit date at 3 months follow-up
LQUIT3M/LQUIT6M: if reported failure to quit at 3 months follow-up, how long the patient remained quit
Duration1: time period between intake and 1 month follow-up
t: assigned time of abstinence

Quitting patterns and transitions

One of the primary goals of the study was to characterize patients with quitting patterns. We defined 4 distinctive quitting patterns, which made quitting pattern a polytomous outcome. Therefore, multinomial logistic regression model was used to identify patients' characteristics for each quitting pattern. Patients were categorized in two ways. In both categorizations, we only considered patients' abstinent status at the point of follow-up, determined by the question "do you currently use tobacco?" Missing at any follow-up was considered as failure to quit. Patients were first categorized into 4 groups: immediate quitters (IQ), delayed quitters (DQ), once quitters (OQ), and never quitters (NQ). IQ were those who achieved initial abstinence immediately at 1 month and remained abstinent at the other two follow-ups. DQ were those who did not successfully quit using tobacco at 1 month or both 1 month and 3 months, but eventually succeeded at 6 months. The term OQ was used to characterize those who quit smoking at 1 month or 3 months, but did not achieve final success at 6 months. NQ were those who failed to be abstinent at any of the 3 follow-ups. The patients were also categorized by their transition of tobacco use behaviors. Their transitions could be classified as no transition, forward transition, backward transition, or fluctuation. Staying abstinence or using tobacco across 3 follow-ups was defined as no transition. Moving from smoking to abstinence only once during 3 follow-ups was forward transition while the opposite was backward transition. Transiting between abstinence and smoking twice was considered as fluctuation (Figure 2).

Figure 2 Categorization of Patients Based on Quitting Pattern and Transition



From our literature review, we did not find any studies that assessed the relationships between quitting patterns and smokers' characteristics. Nevertheless, there has been abundant literature discussing predictors of successful quitters. The defined quitting patterns could be seen as a further categorization of successfully quitters and non-quitters. Those who succeeded at 6 months were further classified as IQ and DQ, whereas those who failed in the end were categorized into OQ and NQ. Therefore, the literature on predictors of successful quitters should be, to some extent, relevant to patients' quitting patterns. We decided to fit the predictors of successful quitters identified from the literature into our multinomial logistic regression model of quitting patterns.

Elements of an effective tobacco cessation program

In order to understand what makes an effective tobacco cessation program and how a program impacts patients' quitting behaviors, we conducted a case study with pharmacists who participated in providing the program. Pharmacists who provided the tobacco cessation service to at least 25 patients were contacted and invited to participate in a 20 minutes interview. The interview was administered face-to-face or over phone by one of the investigators. All the responses were collected anonymously.

As suggested by the literature, settings where interventions are delivered are associated with intervention effectiveness. Therefore, we asked 3 questions regarding the size and type of the pharmacy. The rest of the questions were related to the service, containing 3 dimensions with respective focus on following up with patients, counseling, and pharmacists' perception about the program. We integrated aspects of contents, duration, frequency, and format into the questions about follow-ups and counseling. Four questions about pharmacists' perceptions of the tobacco cessation service they provided in the end of the survey (Appendix B). Pharmacists' responses were summarized and assessed in a qualitative manner. We were particularly interested in the reasons why some pharmacists were more successful than others and how their practice differed.

Data cleaning and re-categorization

Often, the follow-ups did not take place exactly at 1 month, 3 months, and 6 months. We set a time range that we believed was plausible for each follow-up. Dates of follow-ups outside the time range were considered erroneous and were changed to missing. For 1 month follow-up, a visit occurred between 10 days to 90 days after intake was believed to be reasonable. The range for 3 months and 6 months follow-up were set as 30-270 days and 60-540 days, respectively. When patients' response to their continuous abstinence status ("have you used tobacco even once since your quit date?") at later follow-ups contradicted with their response at earlier follow-ups, we assumed the earlier response to be more accurate and used it to calculate length of abstinence.

We re-categorized age, education, number of cigarettes consumed per day, tobacco use in the past 30 days, pharmacotherapy use, importance to quit, confidence to quit, and number of class sessions attended based on percentile distribution. Both confidence to quit and importance to quit were measured on a scale of 1 to 5 with 5 being the most confident/important. Confidence to quit was divided into score less than 3, equal to 3, equal to 4, and equal to 5. Importance to quit was divided into score equal to 3 or less, equal to 4, and equal to 5. Age was categorized into less than 18 years, 18 to 34 years, 35 to 44 years, 45 to 54 years, 55 to 64 years, and 65 years or older. Education was re-classified as eighth grade or less, some high school or high school, some college or above. Tobacco use in the past 30 days consisted of 3 groups: "only cigarettes",

“cigarettes, bidis, chew/dip”, and “other combinations”. Use of pharmacotherapy was classified as none, only NRT, only varenicline, and other combinations. Number of class sessions attended was classified into one session, two sessions, and three sessions or more. We incorporated questions about whether a patient attempted to quit in the past year and how long the patient remained quit at that attempt into one variable, namely “quit attempt in the past year”. It consisted of 5 groups: “didn’t try at all”, “tried and stayed quit for 1 week or less”, “tried and stayed quit for 1 week-1 month”, “tried and stayed quit for 1 month-6 months”, and “tried and stayed quit for more than 6 months”. For the rest of the variables, we kept the original categorization from the intake questionnaire. Whether used alternative method to quit, and gender were binary. Workplace ban of smoking had 3 options: “yes”, “no”, and “I don’t work”. Home ban of smoking contained 4 groups, which were “yes, anywhere”, “only in certain rooms & outdoors”, “only outdoors”, and “no, not allowed at all”. Presence of other tobacco users in the household had 3 groups including “no other tobacco users”, “someone smokes”, and “someone uses smokeless tobacco”. A likert scale was used to measure patients’ satisfaction about the program including options “very satisfied”, “satisfied”, “somewhat satisfied”, and “not satisfied”.

Although Fagerstrom Test for Nicotine Dependence (FTND) was not given to patients, the baseline questionnaire adopted two questions from FTND. One was “how many cigarettes/day do you smoke?”, and the other one was “how soon after you wake up do you smoke your first cigarette?”. Number of cigarettes per

day was divided into 4 groups: half pack per day or less, half pack to 1 pack, 1 pack to 1.5 packs, and more than 1.5 packs. Time to first use of tobacco after waking also had 4 groups including “within 5 minutes”, “6-30 minutes”, “31-60 minutes”, and “after 60 minutes”. A modified FTND was created using these 2 pieces of information, with possible scores ranging from 0 to 6. The same scoring scheme from FTND was used and the 2 individual item scores were summed up to obtain a total modified FTND score for each patient in the sample. Patients were grouped based on their modified FTND score (groups: score 0-2, score 3, score 4, and score 5-6). Higher score indicated higher nicotine dependence.

Statistical analyses

Statistical analyses performed are summarized in Table 2. An alpha level of 0.05 was adopted for all the statistical analyses in this study. SAS 9.2 was used to conduct all the statistical analyses.

1) Quit rates

   Chi-square tests were used to compare the quit rates by year and by pharmacy store.

2) Survival analysis

   Kaplan Meier survival function is provided below. To apply it to our case, it is a product of the proportion of patients who remain quit at t_1, t_2, … , t_i, where n_i is the number of people at risk of relapse (excluding those who were already censored or relapsed) just prior to t_i and d_i is the number of people who relapse during t_i and t_{i+1}. Patients who stayed quit throughout the program period were censored. Their length of continuous abstinence was defined as the duration between the day of the last follow-up and the day of intake. We also censored those who were lost to follow-up but did not relapse during the period when they were under observation. Log rank test was used for univariate analysis to compare abstinence experience between patients with different baseline characteristics.

$$\hat{S}(t) = \prod_{t_i<t} \frac{n_i - d_i}{n_i}.$$

Table 2 Statistical Tests Performed

Objective/analysis	Univariate statistical tests	Multivariate statistical tests	Multivariate model building
Compare quit rates across pharmacies and years	Chi-square test	NA	NA
Survival analysis	Log-rank test	Cox proportional hazard model	1) Enter any variable with p-value<0.05 in the univariate analysis; 2)Backward elimination using LR test
Pattern analysis	Multinomial logistic regression	Multinomial logistic regression	

Variables with p-value less than 0.05 from log-rank test were included in the Cox proportional hazard model. The hazard function is also provided. It measures the hazard of relapsing at time t given a specified set of patient characteristics X. Hazard ratio (HR), which compares the hazard of relapse between two groups with different characteristics, is calculated by dividing the hazard of one group by the other. However, the assumption of proportionality needs to be met in order for Cox proportional hazard model to yield unbiased estimates of HR. The model assumes that the relative hazard of relapse is independent of time. In other words, the relative hazard of one group relapsing compared to another group needs to be constant over time, otherwise the estimated HR would be biased. A hazard rate that is increasing over time tends to overestimate the impact of the independent variable, whereas a hazard rate that is decreasing over time tends to bias the HR to zero.[96]

$h(t)=h_0(t)\ \exp(\beta_1 x_1+ \beta_2 x_2+ \ldots + \beta_i x_i)$

Hazard Ratio= $h(t)_p/h(t)_q$

Use of pharmacotherapy, tobacco use, number of cigarettes consumed per day, time to first use of tobacco after waking, quit attempt in the past year and duration of abstinence, confidence to quit, importance to quit, home ban of smoking, presence of other smokers in household, workplace ban of smoking, age, gender, and education were considered as potential

factors that could impact patients' abstinence and were included in the analyses.

3) Quitting patterns

Multinomial logistic regression was performed as both univariate and multivariate analysis for characterizing quitting patterns. Based on the findings from the literature review on predictors of successful quitting, baseline characteristics obtained from the intake questionnaire including use of pharmacotherapy, quit attempt in the past year and duration of abstinence, confidence to quit, importance to quit, home ban of smoking, presence of other smokers in household, workplace ban of smoking, age, gender, and education were examined in the multinomial logistic regression model. The modified FTND score was also included. Although tobacco use was not identified as a predictor of successful quitting in the existing literature, we believed that it might also be related to one's risk of relapse and quitting pattern and decided to include it in the analyses.

All the variables were examined separately in univariate analysis first. Any variable with a global p value less than 0.05 was included in multivariate analysis. Backward elimination strategy was adopted for multivariate analysis. Variables that were not significant were tested individually in descending order of p value for their importance to the model. The likelihood ratio (LR) test was used to compare the full model (with the

variable being tested) and the reduced model (without the variable being tested). If LR test was significant, it meant that the variable was important in terms of explaining the variation in quitting patterns observed among patients. Therefore, the decision to keep a variable in the model was made based on whether the LR test was significant. Information on income, ban of smoking at workplace, alternative method to quit, number of class sessions attended, and satisfaction about the program were only collected for year 2004-2007. In order to maintain more sample size and therefore statistical power, we decided not to include these four variables in the multivariate analysis.

Informed consent

The existing database was already de-identified. The pharmacists who participated in the interview were consented. The study was approved by the Human Research Protection Office at the University of New Mexico.

Chapter 4 Results

After excluding patients who failed to respond to any of the four interviews, 1486 patients were included for analysis. Table 3 shows the baseline characteristics of the study sample. About 90% of them were between 18 to 64 years old at the time of recruitment. There were fewer male patients than female patients (44.5% vs. 55.5%), among whom 15 (2%) of them were pregnant at baseline. The majority of them were white (70.6%). Almost 47% had at least some college education and 63.7% of them reported they did not have health insurance. Regarding tobacco use in the past 30 days, except that 53.7% of the patients only smoked cigarettes, a large proportion of them (37.4%) reported using cigarettes, pipes, and chew/dips (all three of them). Among those who smoked cigarettes, more than 20% of them consumed more than 1 pack of cigarettes per day. From the reimbursement invoices obtained from NMPCF, we found that 18.9% of the patients attempted to quit without aid of pharmacotherapy, 41.5% only used NRT, and 34.5% only used varenicline. The patients seemed to have a high level of nicotine dependence with 44.3% of them reporting having their first cigarette within 5 minutes after wake up. Almost 20% of the patients had a modified FTND score of 5 or 6, indicating a relatively high level of nicotine dependence. More than 70% of the patients had tried to quit in the preceding year. Nearly half of them reported no workplace ban of tobacco use and 46.3% of them were allowed to smoke anywhere at home. A little more than half of the patients did not have anyone else who was tobacco user in their household at the time of baseline interview. Most the patients indicated the importance for

them to quit (81.3% scored 5 on the scale), but almost half of the patients' reported their confidence to quit was 3 or less on a scale of 5. More than 70% of the patients reported that they had attempted to quit in the past year. For the years in which use of alternative methods to quit, number of sessions attended, and participants' satisfaction were collected, 80.7% patients did not use any alternative method to help themselves to quit, the majority attended at least one session or class, and more than half of them were very satisfied with the service at 1 month.

Table 3 Characteristics of Included Participants from NMPCF Tobacco Cessation Program

Characteristics	N (%)
Age	
<18 years	49 (3.6%)
18-34 years	312 (22.6%)
35-44 years	295 (21.4%)
45-54 years	374 (27.1%)
55-64 years	263 (19.0%)
>=65 years	89 (6.4%)
Gender	
Male	606 (44.5%)
Female	755 (55.5%)
Pregnant	15 (2%)
Ethnicity	
White	961 (70.6%)
Hispanic	324 (23.8%)
Other	77 (5.6%)
Education level	
Eighth grade or less	58 (4.3%)
Some high school or high school	652 (48.7%)
Some college or college or college above	628 (46.9%)
Annual household income*	
Less than $10,000	81 (18.0%)
$10,000---$19,999	90 (20.0%)
$20,000---$49,999	212 (47.0%)
$50,000—$74,999	46 (10.2%)
$75,000 or more	22 (4.9%)
Health insurance	
Yes	454 (36.3%)
No	797 (63.7%)
Use tobacco everyday	
Yes	1325 (96.4%)
No	50 (3.6%)

Table 3 cont.

Characteristics	N (%)
Tobacco use pattern in the past 30 days	
Only cigarettes	741 (53.7%)
Only one type of tobacco (not cigarettes)	25 (1.8%)
Cigarettes and pipes	21 (1.5%)
Cigarettes and chew/dips	27 (2.0%)
Cigarettes, pipes, and chew/dips	516 (37.4%)
Cigarettes, pipes, and bidis	21 (1.5%)
Other combinations	29(2.1%)
# of cigarettes consumed per day	
<=half pack	338 (27.1%)
>half pack, but <=1 pack	631 (50.5%)
>1 pack, but <=1.5 packs	185 (14.8%)
>1.5 packs	95 (7.6%)
Time to first use of tobacco after wake up	
Within 5 minutes	606 (44.3%)
6 to 30 minutes	473 (34.6%)
31-60 minutes	188 (13.7%)
After 60 minutes	102 (7.5%)
Modified Fagerstrom score (maximum possible=6)	
0-2	339 (27.4%)
3	358 (28.9%)
4	347 (28.1%)
5-6	193 (15.6%)
Pharmacotherapy used	
None	256 (18.9%)
Only NRT	561 (41.5%)
Only varenicline	467 (34.5%)
Only bupropion	38 (2.8%)
NRT and bupropion	26 (1.9%)
Other combinations	5 (0.4%)
Ban of tobacco use at workplace/school*	
Yes	295 (29.7%)
No	496 (49.9%)
I don’t know	30 (3.0%)
I don’t work	173 (17.4%)

Table 3 cont.

Characteristics	N (%)
Quit attempt in the past year	
Didn't try at all	366 (28.4%)
Tried and stayed quit for <=1 week	100 (7.8%)
Tried and stayed quit for >1 week, but<= 1 month	378 (29.3%)
Tried and stayed quit for > 1 month, but <=6 months	203 (15.8%)
Tried and stayed quit for > 6 months	242 (18.8%)
Allowing smoking at home	
Yes, anywhere	633 (46.3%)
Only in certain rooms & outdoors	175 (12.8%)
Outdoors only	389 (28.4%)
No, not allowed at all	171 (12.5%)
Others use tobacco in the household	
Yes, someone who smokes	586 (42.9%)
Yes, someone who uses smokeless tobacco	36 (2.6%)
No	744 (54.5%)
Confidence to quit (scale 1-5)	
<3	223 (16.3%)
3	357 (26.0%)
4	367 (26.8%)
5	425 (31.0%)
Importance to quit (scale 1-5)	
<=3	53 (5.5%)
4	181 (13.1%)
5	1120 (81.3%)
Used alternate method (eg. acupuncture)*	
Yes	113 (19.3%)
No	472 (80.7%)
# of sessions attended*	
0	53 (9.5%)
1	275 (49.5%)
2	100(18.0%)
>=3	128(23.0%)

Table 3 cont.

Characteristics	N (%)
Satisfaction about the program at 1 month*	
Not at all satisfied	4 (0.7%)
Somewhat satisfied	40 (7.0%)
Satisfied	205 (35.9%)
Very satisfied	322 (56.4%)

*information only collected from 2004 to 2007

Quit rates

The overall point prevalence quit rate was 30.2%, 20.3%, and 18.7% at 1 month, 3 months, and 6 months, respectively. Point prevalence quit rates by year and by pharmacy were calculated and presented in Figures 3 and 4. The chi-square tests showed that the quit rates were significantly different both across years and across pharmacies at all three follow-ups ($p<0.0001$). Year 2009 had the highest 6-month quit rate (28.5%). Year 2004 and 2010 achieved a 6-month quit rate greater than 20%. The quit rate varied more dramatically by pharmacy with pharmacy 8 having the highest 6-month quit rate of 59.4%.

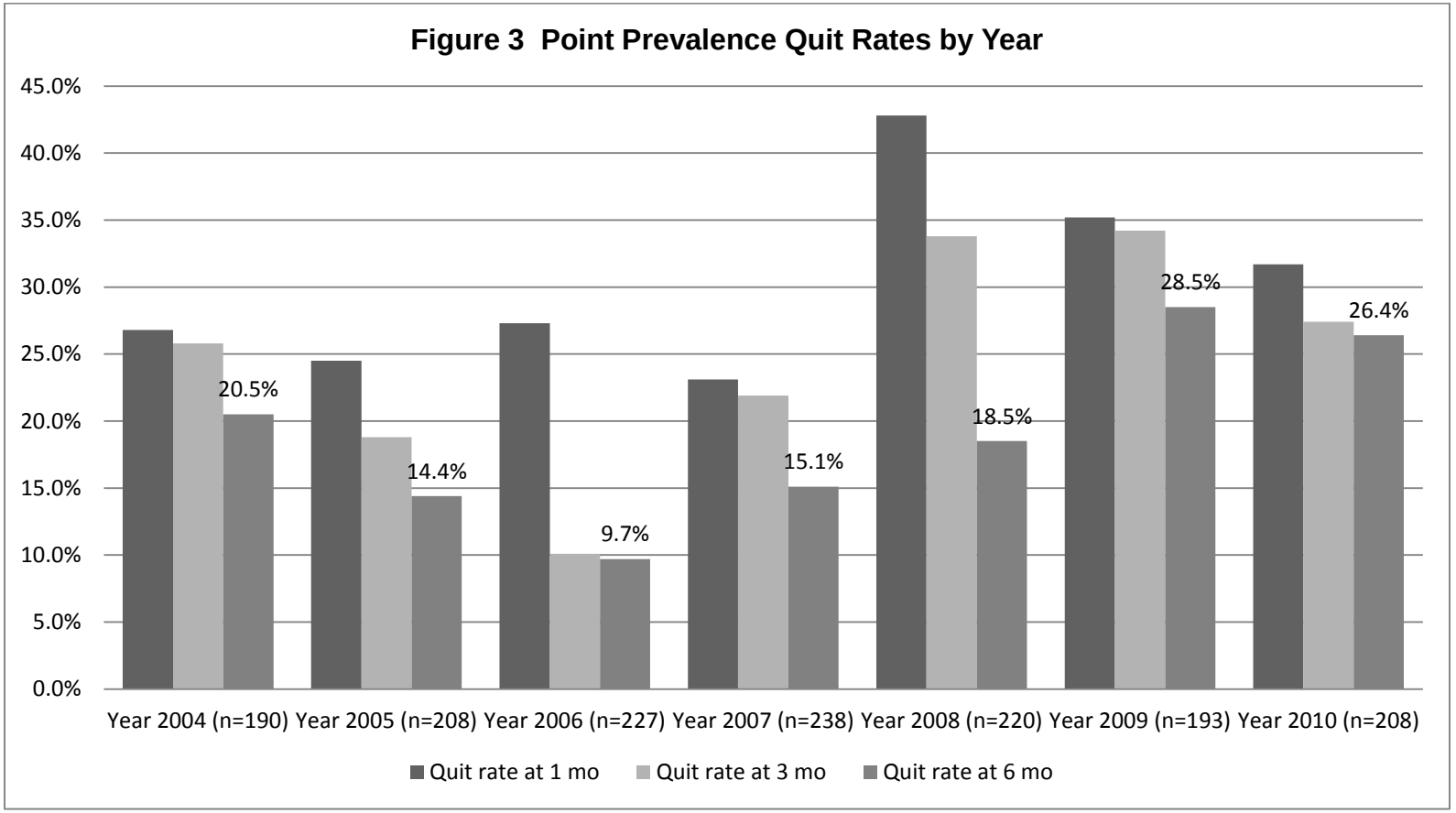
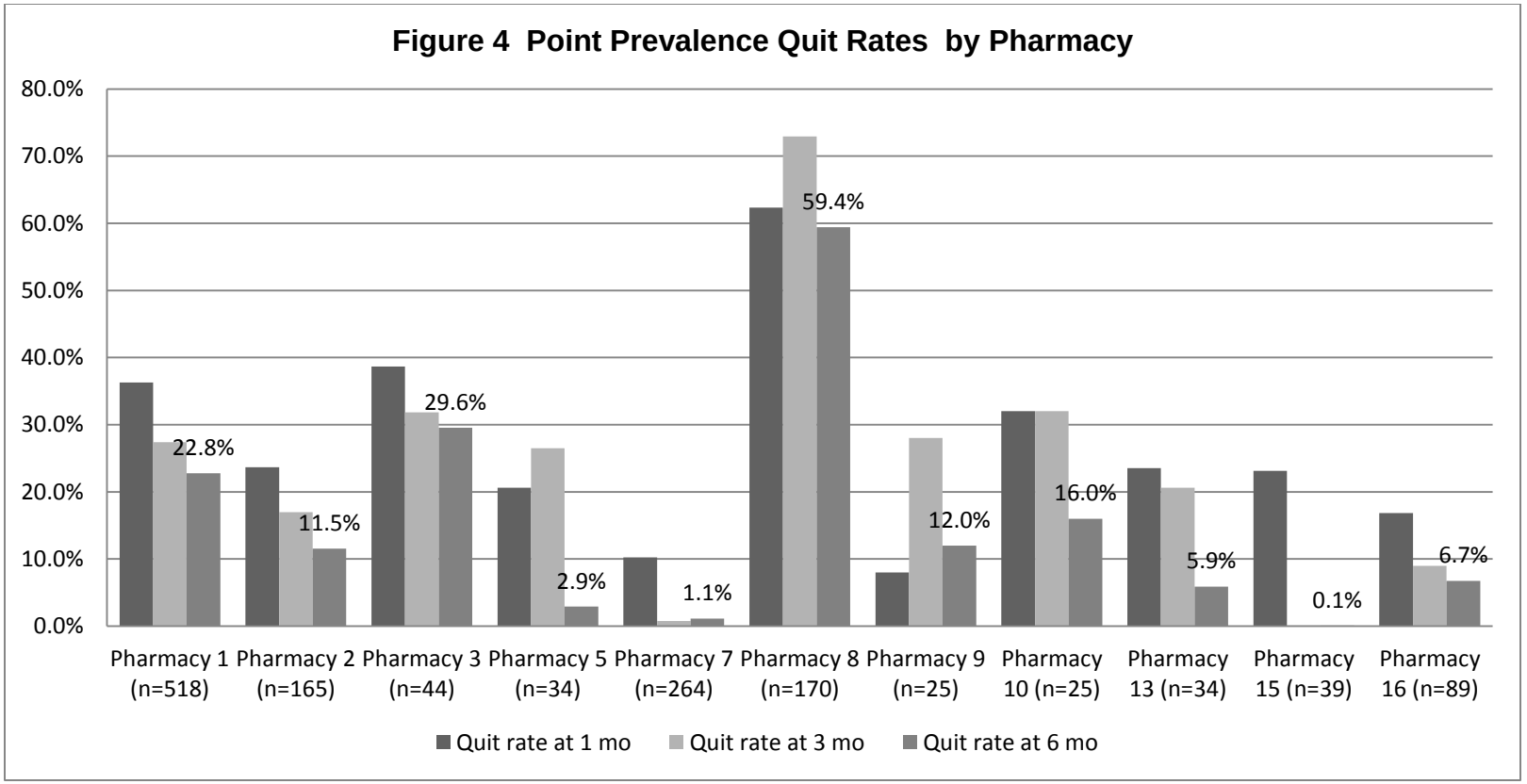


Figure 3 Point Prevalence Quit Rates by Year
45.0%
40.0%
35.0%
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
20.5%
14.4%
9.7%
15.1%
18.5%
28.5%
26.4%
Year 2004 (n=190)
Year 2005 (n=208)
Year 2006 (n=227)
Year 2007 (n=238)
Year 2008 (n=220)
Year 2009 (n=193)
Year 2010 (n=208)
Quit rate at 1 mo
Quit rate at 3 mo
Quit rate at 6 mo



*Only pharmacies with n≥25 are displayed; mo: month(s)

Survival analysis

Among the 1486 patients included in the survival analysis, 684 of them were censored. The majority of them (branch 54, n=456) were censored at the beginning of observation and we assigned zero day to them as their time of abstinence (Table 4). The rest (802 patients) relapsed during observation. The probability of a patient being continuously abstinent for 7 days was 89.1%, while the likelihood of being abstinent for 30 days and 180 days was 46.0% and 16.5%, respectively. A dramatic decrease in probability of remaining quit occurred in the first two weeks, dropping to 77.3%. The mean abstinent time of the study sample was 76.81 days (standard error= 3.59 days). This mean time is likely to be an underestimate due to the fact that a large number of patients were censored. The Kaplan-Meier survival curve of the study sample is displayed in Figure 5.

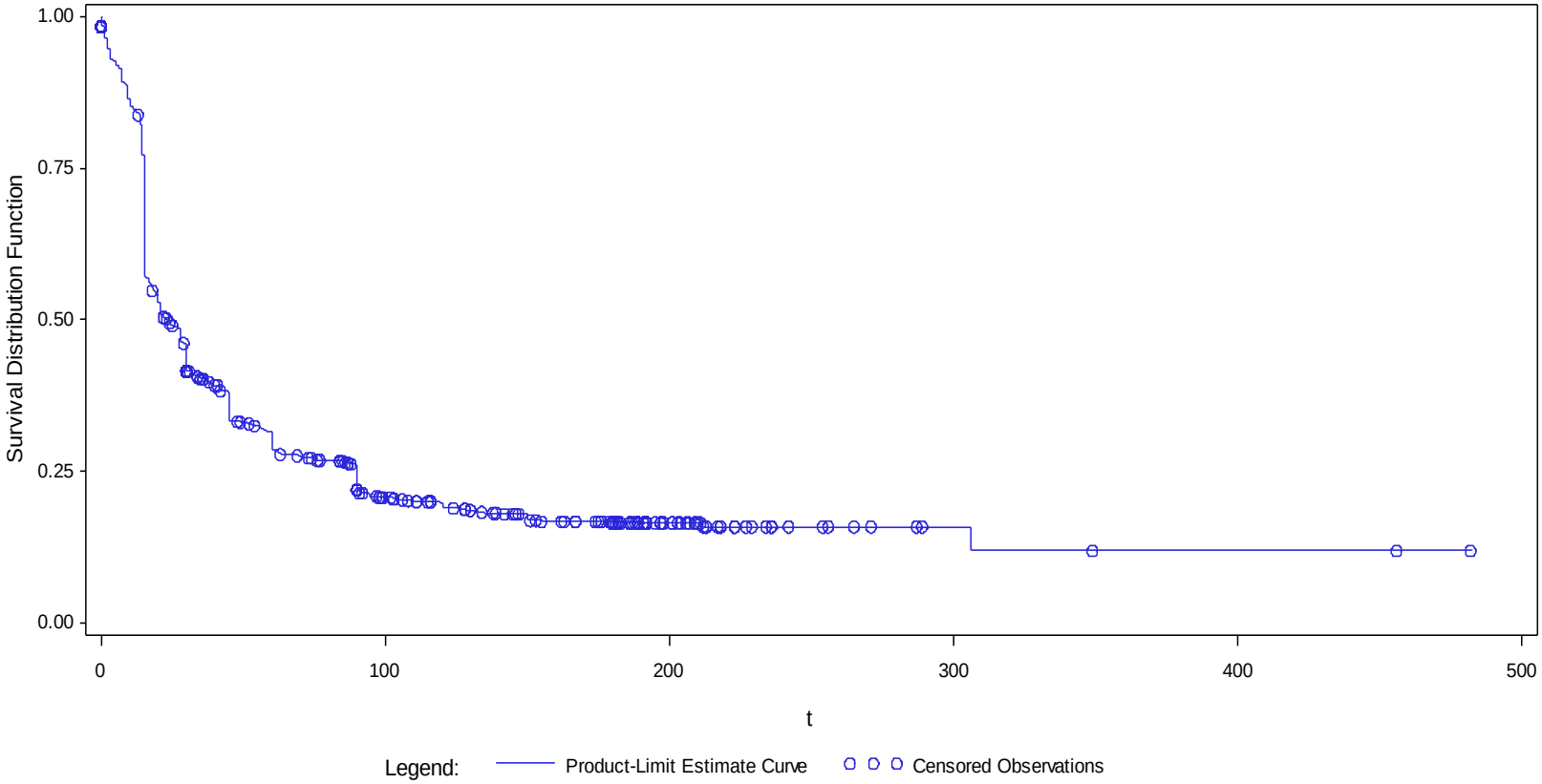
Table 4 Assignment of Time of Abstinence

Branch	Inference of t	t	N (%)
USETOB1M=fail			**585 (39.4%)**
1	LQUIT3M not missing, d1 not missing	Min(LQUIT3M, d1)	105 (7.1%)
2	LQUIT3M not missing, d1 missing	Min(LQUIT3M, 90)	92 (6.2%)
3	LQUIT3M missing, LQUIT6M not missing, d1 not missing	Min(LQUIT6M, d1)	16 (1.1%)
4	LQUIT3M missing, LQUIT6M not missing, d1 missing	Min(LQUIT6M, 90)	16 (1.1%)
5	LQUIT3M missing, LQUIT6M missing, d1 not missing	d1/2	155 (10.4%)
6	LQUIT3M missing, LQUIT6M missing, d1 missing	15 days	201 (13.5%)
USETOB1M=quit, USETOB3M=failed			**75 (5.0%)**
7	LQUIT3M not missing, d1>=LQUIT3M	d1	9 (0.6%)
8	LQUIT3M not missing, d1<LQUIT3M, d2 not missing	Min(LQUIT3M, d2)	36 (2.4%)
9	LQUIT3M not missing, d1<LQUIT3M, d2 missing	Min(LQUIT3M, 270)	2 (0.1%)
10	LQUIT3M missing, LQUIT6M not missing, d1>=LQUIT6M	d1	2 (0.1%)
11	LQUIT3M missing, LQUIT6M not missing, d1<LQUIT6M, d2 not missing	Min(LQUIT6M, d2)	2 (0.1%)
12	LQUIT3M missing, LQUIT6M not missing, d1<LQUIT6M, d2 missing	Min(LQUIT6M, 270)	0 (0.0%)
13	LQUIT3M missing, LQUIT6M missing, d2 not missing	d2/2	0 (0.0%)
14	LQUIT3M missing, LQUIT6M missing, d2 missing	45 days	24 (1.6%)
USETOB1M=quit, USETOB3M=quit, USETOB6M=failed			**14 (0.9%)**
15	LQUIT6M not missing, d2>=LQUIT6M	d2	0 (0.0%)
16	LQUIT6M not missing, d2<LQUIT6M, d3 not missing	Min(LQUIT6M, d3)	5 (0.3%)
17	LQUIT6M not missing, d2<LQUIT6M, d3 missing	Min(LQUIT6M, 540)	0 (0.0%)
18	LQUIT6M missing, d3 not missing	d3/2	9 (0.6%)
19	LQUIT6M missing, d3 missing	90 days	0 (0.0%)
USETOB1M=quit, USETOB3M=quit, USETOB6M=quit (censored)			**70 (4.7%)**
20	d3 not missing	d3	61 (4.1%)
21	d3 missing	180 days	9 (0.6%)
USETOB1M=quit, USETOB3M=quit, USETOB6M=missing (censored)			**38 (2.6%)**
22	d2 not missing	d2	35 (2.4%)
23	d2 missing	90 days	3 (0.2%)
USETOB1M=quit, USETOB3M=missing, USETOB6M=failed			**14 (0.9%)**
24	LQUIT6M not missing, d1>=LQUIT6M	d1	2 (0.1%)
25	LQUIT6M not missing, d1<LQUIT6M, d3 not missing	Min(LQUIT6M, d3)	5 (0.3%)
26	LQUIT6M not missing, d1<LQUIT6M, d3 missing	Min(LQUIT6M, 540)	0 (0.0%)
27	LQUIT6M missing, d3 not missing	d3/2	6 (0.4%)
28	LQUIT6M missing, d3 missing	90 days	1 (0.1%)

USETOB1M=quit, USETOB3M=missing, USETOB6M=quit (censored)			**10 (0.7%)**
29	d3 not missing	d3	9 (0.6%)
30	d3 missing	180 days	1 (0.1%)
USETOB1M=quit, USETOB3M=missing, USETOB6M=missing (censored)			**78 (5.3%)**
31	d1 not missing	d1	22 (1.5%)
32	d1 missing	30 days	56 (3.8%)
USETOB1M=missing, USETOB3M=failed			**73 (4.9%)**
33	LQUIT3M not missing, d2 not missing	Min(LQUIT3M, d2)	37 (2.5%)
34	LQUIT3M not missing, d2 missing	Min(LQUIT3M, 270)	9 (0.6%)
35	LQUIT3M missing, LQUIT6M not missing, d2 not missing	Min(LQUIT6M, d2)	4 (0.3%)
36	LQUIT3M missing, LQUIT6M not missing, d2 missing	Min(LQUIT6M,270)	0 (0.0%)
37	LQUIT3M missing, LQUIT6M missing, d2 not missing	d2/2	13 (0.9%)
38	LQUIT3M missing, LQUIT6M missing, d2 missing	45 days	10 (0.7%)
USETOB1M=missing, USETOB3M=quit, USETOB6M=failed			**5 (0.4%)**
39	LQUIT6M not missing, d2>=LQUIT6M	d2	0 (0.0%)
40	LQUIT6M not missing, d2<LQUIT6M, d3 not missing	Min(LQUIT6M, d3)	0 (0.0%)
41	LQUIT6M not missing, d2<LQUIT6M, d3 missing	Min(LQUIT6M, 540)	0 (0.0%)
42	LQUIT6M missing, d3 not missing	d3/2	4 (0.3%)
43	LQUIT6M missing, d3 missing	90 days	1 (0.1%)
USETOB1M=missing, USETOB3M=quit, USETOB6M=quit (censored)			**4 (0.3%)**
44	d3 not missing	d3	4 (0.3%)
45	d3 missing	180 days	0 (0.0%)
USETOB1M=missing, USETOB3M=quit, USETOB6M=missing (censored)			**12 (0.8%)**
46	d2 not missing	d2	9 (0.6%)
47	d2 missing	90 days	3 (0.2%)
USETOB1M=missing, USETOB3M=missing, USETOB6M=failed			**36 (2.4%)**
48	LQUIT6M not missing, d3 not missing	Min(LQUIT6M, d3)	18 (1.2%)
49	LQUIT6M not missing, d3 missing	Min(LQUIT6M, 540)	10(0.7%)
50	LQUIT6M missing, d3 not missing	d3/2	6 (0.4%)
51	LQUIT6M missing, d3 missing	90 days	2 (0.1%)
USETOB1M=missing, USETOB3M=missing, USETOB6M=quit (censored)			16 (1.0%)
52	d3 not missing	d3	11 (0.7%)
53	d3 missing	180 days	5 (0.3%)
USETOB1M=missing, USETOB3M=missing, USETOB6M=missing (censored)			**456 (30.7%)**
54	All	0 day	456 (30.7%)

*USETOB: ever used tobacco since quit date; LQUIT: reported time of abstinence, d: duration between follow-ups and intake; Min: minimum

Figure 5 Kaplan-Meier Survival Curve----All Patients (n=1486)



Log rank test was performed to determine patient characteristics that influenced patients' probability of remaining quit and their abstinence experience. Except income, work environment, alternative method used to quit, class sessions attended, and satisfaction about the program, all the other baseline characteristics listed in table 1 were analyzed individually. The results of log rank tests are presented in Table 5. Age, pharmacotherapy, and tobacco use in the past 30 days were found to be significantly associated with patients' likelihood of remaining continuously abstinent. Patients under 18 years old had a better chance of keeping themselves from using tobacco again compared to all the other age groups (Figure 6). The p-value for the log rank test was 0.03. Their likelihood of staying abstinent for 120 days was 32.4%. Figure 7 shows the survival curve for each pharmacotherapy group. Log rank test indicated that the quitting experiences by pharmacotherapy groups were significantly different (p=0.02). Patients who only used varenicline had the best quitting experience in the whole time. Their likelihood of quitting continuously for 120 days was 22.9%. Patients who only used NRT had higher likelihood of remaining quit than those who did not use pharmacotherapy and those who tried several types of pharmacotherapy in the first 4 months. Patients who only used NRT had a probability of 18.3% to be continuously abstinence for 120 days and the probability for 180 days was 14.7%. The likelihood of continuous abstinence for the first 30 days was similar among patients with different tobacco use patterns with a rate around 40%. Starting from 30 days, patients who used cigarettes, pipes, and chew/dip in the past 30 days had better quitting experience than

others. Their probability of remaining quit at day 120 was 21.4%, whereas the probability for those who only smoked cigarettes in the past month was 16.6% (Figure 8).

Table 5 Kaplan-Meier Survival Analysis---Results of Log Rank Tests

Variable	**p-value of log-rank test**
Age	**0.03**
Gender	0.83
Ethnicity	0.69
Education level	0.06
Health plan coverage	0.08
Use tobacco everyday	0.14
Tobacco use pattern in the past 30 days	**0.03**
# of cigarettes per day	0.27
Time to first use of tobacco after wake up	0.36
Pharmacotherapy used	**0.02**
Quit attempt in the past year	0.06
Allowing smoking at home	0.59
Presence of other tobacco user in the household	0.88
Confidence to quit	0.41
Importance to quit	0.19

Figure 6 Kaplan-Meier Survival Curve by Age Group (n=1382)

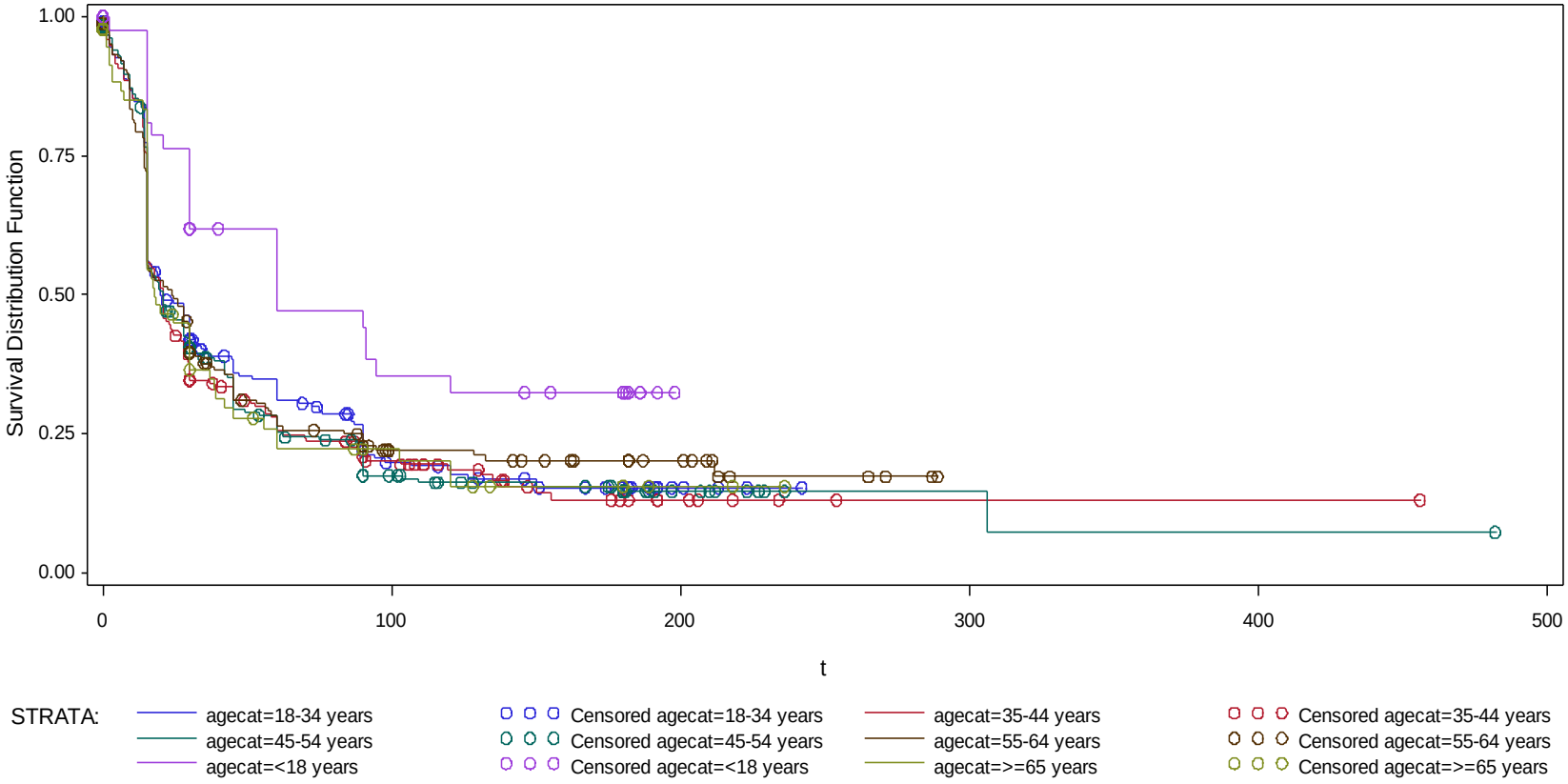


Figure 7 Kaplan-Meier Survival Curve by Pharmacotherapy (n=1353)

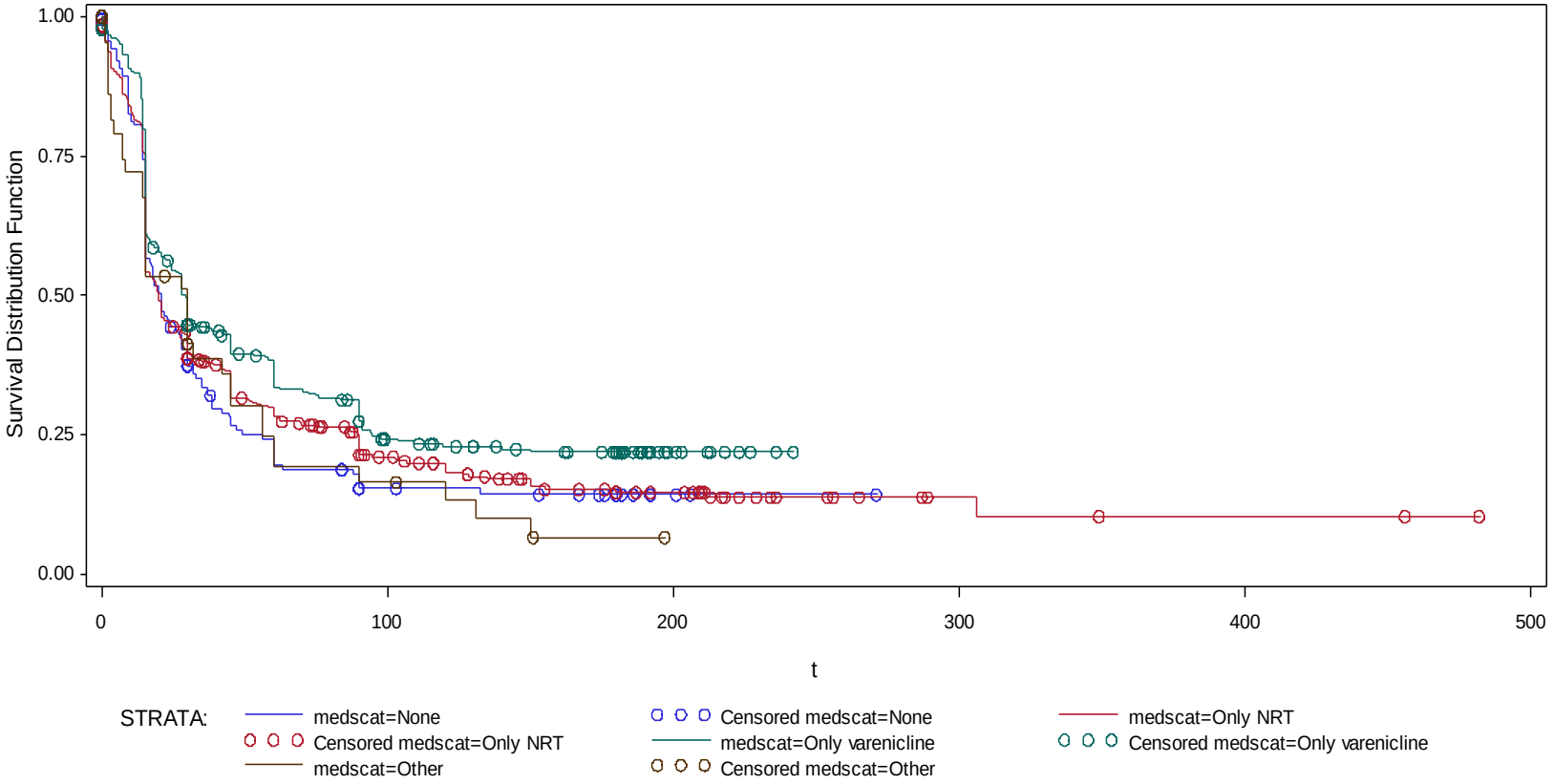
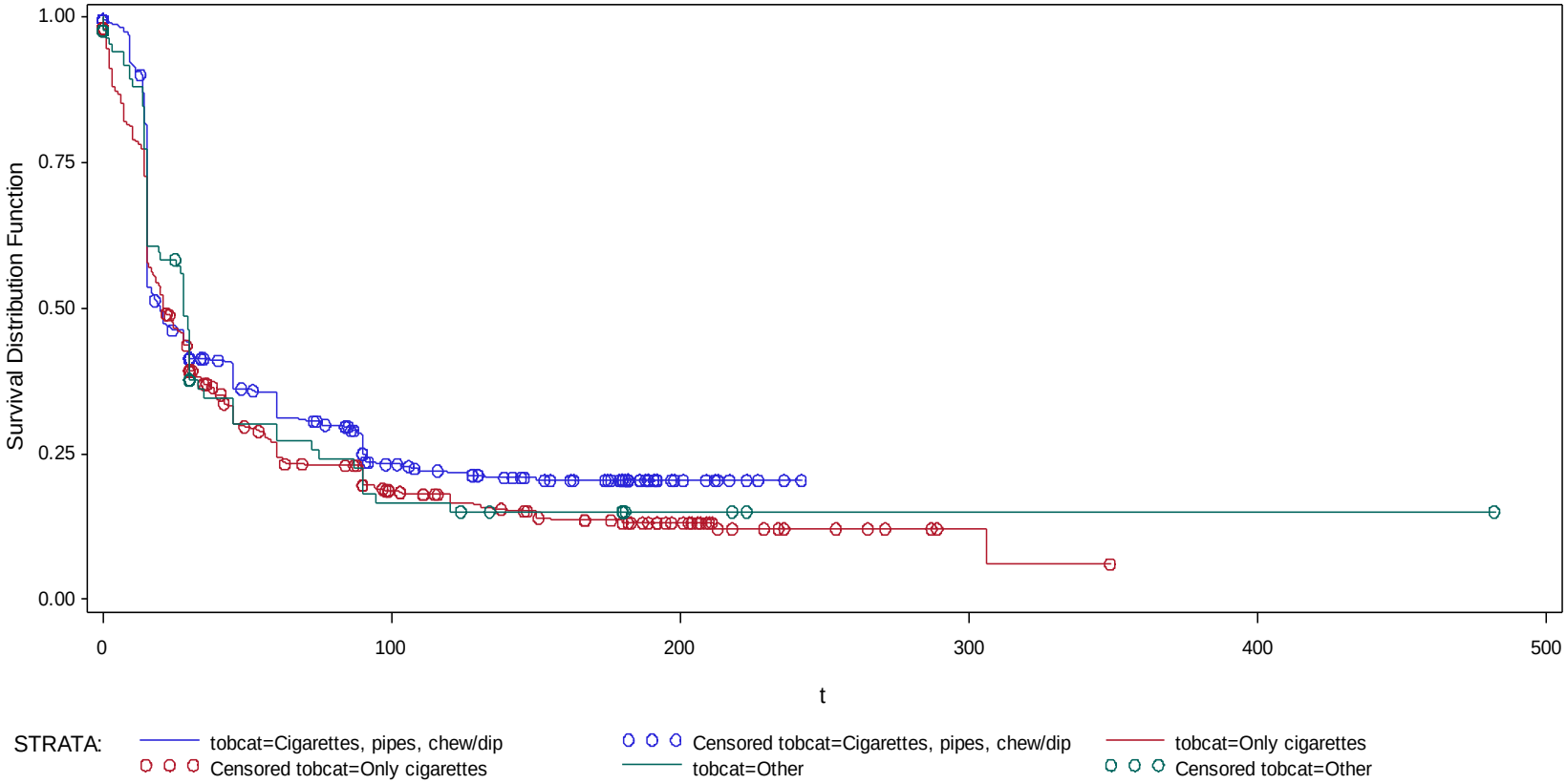


Figure 8 Kaplan-Meier Survival Curve by Tobacco Use in the Past 30 Days (n=1380)



When we entered the covariates that were significant in the Kaplan-Meier survival analysis into the Cox proportional hazard model, we found that the HRs for the covariates were dependent on time. Since the assumption of proportionality was violated, we decided not to use the Cox proportional hazard model and kept the analysis in the univariate level. For the sake of demonstrating the violation, we presented the results of Cox proportional hazard model in Table 6 and Table 7. The interactions between time of abstinence and age group, tobacco use in the past 30 days, and pharmacotherapy used were significant (Table 7). The coefficients of the interactions were negative, which indicated that the hazard rate decreased over time. Also, the overall test of proportionality was also significant with a p-value less than 0.0001. This indicated the dependence of hazard ratios on time. When excluding the interactions with time of abstinence, the hazard ratios were biased toward the null, which was exactly as Menard et al described [96] (Table 6). Due to the violation of the assumption of proportionality, the HR estimates in Table 6 were biased and should not be used.

Table 6 Multivariate Analysis----Results of Cox Proportional Hazard Model (excluding interactions with time)

Independent variable	Hazard ratio	p-value
Age		
<18 years	0.59	0.02
18-34 years	referent	---------
35-44 years	1.07	0.58
45-54 years	1.06	0.58
55-64 years	1.02	0.89
>=65 years	1.04	0.83
Tobacco use pattern in the past 30 days		
Only cigarettes	1.03	0.86
Cigarettes, pipes, and chew/dips	0.94	0.65
Other	referent	----------
Pharmacotherapy used		
None	referent	----------
Only NRT	0.98	0.88
Only varenicline	0.84	0.13
Other	1.06	0.76

*The hazard ratios in Table 6 are biased and should not be used.

Table 7 Multivariate Analysis----Results of Cox Proportional Hazard Model (including interactions with time)

Independent variable	coefficient	Hazard ratio	p-value
Age			
<18 years	2.41	11.16	0.002
18-34 years	referent	---------	---------
35-44 years	2.01	7.44	---------
45-54 years	2.02	7.54	<0.0001
55-64 years	1.99	7.29	<0.0001
>=65 years	2.30	9.94	<0.0001
<18 years*log(t)	-0.75	0.47	0.0003
35-44 years*log(t)	-0.57	0.57	<0.0001
45-54 years*log(t)	-0.60	0.55	<0.0001
55-64 years*log(t)	-0.54	0.58	<0.0001
>=65 years*log(t)	-0.71	0.49	<0.0001
Tobacco use pattern in the past 30 days			
Other	referent	---------	---------
Only cigarettes	11.52	101004.20	<0.0001
Cigarettes, pipes, and chew/dips	11.10	66027.93	<0.0001
Only cigarettes*log(t)	-3.11	0.04	<0.0001
Cigarettes, pipes, and chew/dips*log(t)	-3.00	0.05	<0.0001
Pharmacotherapy used			
None	referent	----------	----------
Only NRT	4.13	61.91	<0.0001
Only varenicline	4.58	97.13	<0.0001
Other	0.73	2.08	0.11
Only NRT*log(t)	-1.32	0.27	<0.0001
Only varenicline*log(t)	-1.46	0.23	<0.0001
Other*log(t)	-0.22	0.80	0.14

Quitting pattern analysis

Based on our definition of quitting patterns, the study sample consisted of 162 (10.9%) immediate quitters, 112 (7.8%) delayed quitters, 312 (21%) once quitters, and 896 (60.3%) never quitters. As for their transitions of tobacco use behaviors during the program period, 89 (6.0%) moved forward from using tobacco to abstinence, 259 (17.4%) had a backward transition, 80 (5.4%) patients' abstinence status fluctuated, and 1058 (71.2%) patients had the same status, staying quit or using tobacco, at all three follow-ups (Table 8).

Table 8 Quitting Patterns and Transitions of Included Participants from NMPCF Tobacco Cessation Program

Quitting patterns	
Immediate quitters	162 (10.9%)
Delayed quitters	116 (7.81%)
Once quitters	312 (21.00%)
Never quitters	896 (60.30%)
Quitting transitions	
Forward transition	89 (5.99%)
Backward transition	259 (17.43%)
Fluctuation	80 (5.38%)
No transition	1058 (71.20%)
Patterns & transitions	
Immediate quitters, no transition	162 (10.90%)
Delayed quitters, forward transition	89 (5.99%)
Delayed quitters, fluctuation	27 (1.82%)
Once quitters, fluctuation	53 (3.57%)
Once quitters, backward transition	259 (17.43%)
Never quitters, no transition	896 (60.30%)

The results of the univariate multinomial logistic regressions are presented in Table 9. Compared to patients with age between 18 to 34, patient under 18 years old were 5.27 time more likely to be IQ and 3.21 times more likely to be OQ. Males were 1.65 times more likely to be DQ than females. Hispanics were more likely to be IQ compared to others (OR=1.68, 95% CI:1.15-2.45). Education was inversely related to one's probability of quitting. Patients who used tobacco everyday were less likely to be DQ and OQ compared to non-daily tobacco users. Patients who used cigarettes, pipes, and chew/dip in the past 30 days were more likely to quit than those who only smoked cigarettes. Patients with a modified FTND score of 4, indicating greater nicotine dependence, were less likely to be DQ than those with a score between 0 to 2 (OR=0.50, 95% CI: 0.27-0.93). Compared with those quitting without aid of pharmacotherapy, patients who only used NRT were more likely to be OQ and patients who only used varenicline were more likely to be IQ and OQ. It was unexpected that patients who attempted to quit in the past year were less likely to be successful at the current attempt than those who did not make attempt to quit in the past year. Ban of tobacco use at work (referent: ban; OR=2.33, 95% CI: 1.37-3.95) and home ban of smoking (referent: no ban; OR=0.41, 95% CI: 0.21-0.79) decreased the probability of quitting immediately. Confidence to quit was associated the likelihood of being IQ. Using alternative method to quit and attending more class sessions also helped patients quit. The less the patients were satisfied with the program, the less likely they were IQ and OQ.

Table 9 Univariate Analysis---Characteristics of Immediate Quitters, Delayed Quitters, and Once Quitters compared to Never Quitters

	Immediate quitters vs. Never quitters	Delayed quitters vs. Never quitters	Once quitters vs. Never quitters
Age			
<18 years	**5.27 (2.42, 11.42)**	1.91 (0.51, 7.18)	**2.31 (1.06, 5.03)**
18-34 years	1	1	1
35-44 years	0.65 (0.38, 1.11)	1.23 (0.65, 2.32)	0.79 (0.53, 1.17)
45-54 years	0.88 (0.54, 1.41)	1.13 (0.61, 2.09)	0.83 (0.57, 1.20)
55-64 years	0.64 (0.37, 1.12)	1.49 (0.80, 2.80)	0.72 (0.47, 1.09)
>=65 years	0.65 (0.29, 1.47)	1.34 (0.56, 3.22)	0.70 (0.38, 1.29)
Gender			
Female	1	1	1
Male	0.97 (0.69, 1.37)	**1.65 (1.09, 2.49)**	0.88 (0.67, 1.16)
Ethnicity			
White	1	1	1
Hispanic	**1.68 (1.15, 2.45)**	1.37 (0.85, 2.20)	1.23 (0.89, 1.70)
Other	0.97 (0.43, 2.22)	1.88 (0.88, 4.03)	1.33 (0.75, 2.36)
Education level			
Eighth grade or less	**2.95 (1.40, 6.20)**	**2.47 (1.01, 6.07)**	1.87 (0.96, 3.64)
Some high school or high school	1	1	1
Some college or college or college above	1.07 (0.75, 1.53)	0.98 (0.64, 1.50)	0.80 (0.60, 1.06)
Health insurance			
No	1	1	1
Yes	0.96 (0.67, 1.39)	1.14 (0.74, 1.75)	1.08 (0.81, 1.45)
Use tobacco every day			
No	1	1	1
yes	1.33 (0.39, 4.50)	**0.32 (0.14, 0.74)**	**0.38 (0.20, 0.73)**
Tobacco use pattern in the past 30 days			
Only cigarettes	1	1	1
Cigarettes, pipes, and chew/dips	**2.36 (1.64, 3.40)**	**3.00 (1.94, 4.63)**	**2.22 (1.66, 2.96)**
Other	**1.97 (1.09, 3.56)**	1.96 (0.94, 4.11)	**1.81 (1.12, 2.91)**
Modified Fagerstrom score			
0-2 low dependence	1	1	1
3	0.80 (0.51, 1.28)	0.92 (0.54, 1.56)	0.75 (0.51, 1.10)
4	0.67 (0.42, 1.09)	**0.50 (0.27, 0.93)**	0.89 (0.61, 1.29)
5-6	0.58 (0.32, 1.05)	0.52 (0.25, 1.06)	0.68 (0.43, 1.07)

Table 9 Cont.

	Immediate quitters vs. Never quitters	Delayed quitters vs. Never quitters	Once quitters vs. Never quitters
Quit attempt in the past year			
Didn't try at all	1	1	1
Tried and stayed quit for <=1 week	**0.29 (0.12, 0.71)**	0.62 (0.25, 1.55)	0.83 (0.48, 1.44)
Tried and stayed quit for >1 week, but<= 1 month	**0.56 (0.36, 0.87)**	1.04 (0.62, 1.76)	0.70 (0.48, 1.02)
Tried and stayed quit for > 1 month, but <=6 months	0.61 (0.36, 1.03)	0.95 (0.50, 1.80)	0.84 (0.54, 1.30)
Tried and stayed quit for > 6 months	**0.40 (0.23, 0.70)**	0.62 (0.32, 1.22)	0.91 (0.61, 1.37)
Ban of tobacco use at workplace/school			
Yes	1	1	1
No	**2.33 (1.37, 3.95)**	1.05 (0.55, 1.98)	1.33 (0.91, 1.94)
I don't work	1.64 (0.83, 3.25)	1.13 (0.50, 2.56)	1.44 (0.90, 2.33)
Allowing smoking at home			
Yes, anywhere	1	1	1
Only in certain rooms & outdoors	**0.34 (0.17, 0.68)**	1.04 (0.56, 1.94)	0.70 (0.46, 1.09)
Outdoors only	0.81 (0.55, 1.19)	1.02 (0.63, 1.67)	0.77 (0.55, 1.06)
No, not allowed at all	**0.41 (0.21, 0.79)**	1.27 (0.70, 2.30)	0.78 (0.51, 1.20)
Presence of other tobacco users in the household			
Yes, someone who smokes	1	1	1
Yes, someone who uses smokeless tobacco	0.85 (0.29, 2.50)	1.38 (0.46, 4.16)	**0.10 (0.01, 0.74)**
No	1.18 (0.83, 1.68)	1.34 (0.87, 2.05)	0.92 (0.70, 1.21)
Confidence to quit (scale 1-5)			
<3 low	1	1	1
3	**2.41 (1.33, 4.37)**	0.75 (0.40, 1.42)	1.03 (0.69, 1.54)
4	**3.19 (1.78, 5.71)**	1.25 (0.70, 2.23)	1.44 (0.98, 2.12)
5	**3.62 (2.04, 6.43)**	**2.19 (1.30, 3.71)**	**2.09 (1.45, 3.01)**
Importance to quit (scale 1-5)			
<=3 low	1	1	1
4	1.59 (0.80, 3.16)	0.66 (0.28, 1.54)	**0.50 (0.29, 0.87)**
5	1.33 (0.75, 2.36)	1.09 (0.60, 1.97)	0.87 (0.60, 1.26)

Table 9 Cont.

	Immediate quitters vs. Never quitters	**Delayed quitters vs. Never quitters**	**Once quitters vs. Never quitters**
Used alternate method (eg. acupuncture)*			
No	1	1	1
Yes	**4.44 (2.54, 7.79)**	2.00 (0.87, 4.62)	1.68 (0.99, 2.88)
# of sessions attended*			
0	1	1	1
1	1.62 (0.58, 4.55)	1.70 (0.55, 5.28)	1.82 (0.93, 3.55)
2	2.31 (0.78, 6.89)	0.91 (0.24, 3.52)	1.10 (0.51, 2.38)
>=3	**6.89 (2.43, 19.52)**	1.08 (0.28, 4.18)	1.57 (0.73, 3.38)
Satisfaction about the program at 1 month*			
Very satisfied	1	1	1
Satisfied	**0.23 (0.13, 0.39)**	0.66 (0.33, 1.31)	**0.31 (0.20, 0.48)**
Somewhat satisfied	**0.03 (0.004, 0.25)**	0.51 (0.16, 1.62)	**0.10 (0.04, 0.26)**
Not at all satisfied	0.34 (0.03, 3.31)	----	----

Other than ethnicity, income, health plan coverage, work ban of tobacco use, whether using alternative methods to quit, class sessions attended, and satisfaction about the program, all the other characteristics were entered into the multivariate model. We first built a model without including pharmacy store as an independent variable and the results of the model are presented in Table 10.

Controlling for all the other variables in the model, age was statistically associated with quitting pattern. Compared to patients who were 18-34 years old, patients under 18 were more likely to be IQ (OR=5.71, 95% CI: 1.84-17.69), while patients with an age between 45 and 54 years (OR=0.58, 95% CI: 0.36-0.93) or between 55 to 64 years (OR=0.58, 95% CI: 0.34-0.98) were less likely to be OQ. Patients with an education level of eighth grade or less were more likely to be IQ and OQ than those who had high school education. Patients who used cigarettes, pipes, and chew/dips in the past 30 days were more likely to be OQ compared to cigarettes smokers (OR=1.93, 95% CI: 1.31-2.85). Nicotine dependence was significantly associated with one's likelihood of being IQ. Compared to those who scored 0-2 on the modified FTND, patients who had a score of 4 were more likely to be IQ and DQ. Pharmacotherapy only helped to a certain extent. Patients who used NRT (OR=2.27, 95% CI: 1.36-3.80) or varenicline (OR=2.41, 95% CI: 1.42-4.10) were more likely to be OQ than those who did not use any form of pharmacotherapy. Home ban of smoking was still inversely related to the likelihood of successful quitting after adjustment for other variables. Patients with higher confidence were more likely to quit, while patients

reported greater importance to quit were less likely to be successful. Although gender, education level, whether using tobacco daily, time to first use of tobacco upon wake up, quit attempt in the past year, and presence of other tobacco users in the household were not significantly associated with quitting pattern, they played important roles in the model. The LR test was significant for each of them. Therefore, we decided to keep all of them in the model. The R square of the model was 0.20.

Table 10 Multivariate Analysis---Characteristics of Immediate Quitters, Delayed Quitters, and Once Quitters compared to Never Quitters (pharmacy stores excluded)

	Immediate quitters vs. Never quitters	Delayed quitters vs. Never quitters	Once quitters vs. Never quitters
Age			
<18 years	**5.71 (1.84, 17.69)**	2.46 (0.44, 13.89)	2.75 (0.95, 7.96)
18-34 years	1	1	1
35-44 years	0.63 (0.32, 1.21)	1.62 (0.74, 3.51)	0.75 (0.46, 1.21)
45-54 years	1.15 (0.64, 2.07)	1.88 (0.90, 3.94)	**0.58 (0.36, 0.93)**
55-64 years	0.52 (0.25, 1.08)	2.01 (0.93, 4.33)	**0.58 (0.34, 0.98)**
>=65 years	0.45 (0.15, 1.37)	1.05 (0.30, 3.63)	0.45 (0.20, 1.01)
Gender			
Female	1	1	1
Male	0.85 (0.54, 1.32)	1.58 (0.97, 2.58)	0.87 (0.62, 1.23)
Education level			
Eighth grade or less	**4.47 (1.56, 12.84)**	1.61 (0.47, 5.52)	**2.61 (1.11, 6.14)**
Some high school or high school	1	1	1
Some college or college or college above	1.25 (0.79, 2.00)	0.93 (0.56, 1.55)	0.87 (0.61, 1.23)
Use tobacco every day			
No	1	1	1
Yes	0.71 (0.14, 3.46)	0.35 (0.11, 1.13)	0.48 (0.19, 1.24)
Tobacco use pattern in the past 30 days			
Only cigarettes	1	1	1
Cigarettes, pipes, and chew/dips	1.45 (0.87, 2.42)	2.02 (1.17, 3.50)	**1.93 (1.31, 2.85)**
Other	0.74 (0.28, 1.95)	1.14 (0.39, 3.33)	1.64 (0.84, 3.20)
Modified fagerstrom score			
0-2 low dependence	1	1	1
3	0.64 (0.37, 1.11)	0.79 (0.43, 1.44)	0.68 (0.44, 1.06)
4	**0.49 (0.27, 0.89)**	**0.43 (0.21, 0.87)**	0.80 (0.51, 1.26)
5-6	0.64 (0.32, 1.28)	0.54 (0.24, 1.19)	0.74 (0.43, 1.29)
Pharmacotherapy used			
None	1	1	1
Only NRT	0.77 (0.41, 1.45)	1.57 (0.76, 3.23)	**2.27 (1.36, 3.80)**
Only varenicline	1.73 (0.94, 3.18)	1.46 (0.68, 3.10)	**2.41 (1.42, 4.10)**
Other	1.55 (0.58, 4.13)	1.39 (0.40, 4.84)	1.59 (0.61, 4.15)

Table 10 Cont.

	Immediate quitters vs. Never quitters	Delayed quitters vs. Never quitters	Once quitters vs. Never quitters
Quit attempt in the past year			
Didn't try at all	1	1	1
Tried and stayed quit for <=1 week	0.35 (0.11, 1.11)	0.89 (0.30, 2.67)	1.44 (0.72, 2.86)
Tried and stayed quit for >1 week, but<= 1 month	0.84 (0.48, 1.47)	1.29 (0.68, 2.42)	0.76 (0.47, 1.20)
Tried and stayed quit for > 1 month, but <=6 months	1.03 (0.52, 2.04)	1.04 (0.47, 2.29)	1.24 (0.73, 2.12)
Tried and stayed quit for > 6 months	0.54 (0.26, 1.10)	0.68 (0.30, 1.52)	1.27 (0.77, 2.08)
Allowing smoking at home			
Yes, anywhere	1	1	1
Only in certain rooms & outdoors	**0.21 (0.09, 0.53)**	0.92 (0.45, 1.87)	0.62 (0.37, 1.05)
Outdoors only	**0.58 (0.35, 0.99)**	0.66 (0.36, 1.22)	**0.54 (0.35, 0.83)**
No, not allowed at all	**0.28 (0.12, 0.66)**	0.60 (0.26, 1.38)	0.58 (0.33, 1.02)
Presence of other tobacco users in the household			
Yes, someone who smokes	1	1	1
Yes, someone who uses smokeless tobacco	2.18 (0.61, 7.78)	2.08 (0.52, 8.30)	0.20 (0.03, 1.64)
No	1.39 (0.88, 2.20)	1.11 (0.66, 1.85)	1.16 (0.82, 1.65)
Confidence to quit (scale 1-5)			
<3 low	1	1	1
3	2.06 (0.94, 4.55)	0.92 (0.40, 2.13)	0.98 (0.56, 1.72)
4	**2.68 (1.22, 5.89)**	1.51 (0.68, 3.34)	1.60 (0.92, 2.77)
5	**3.03 (1.36, 6.77)**	1.99 (0.92, 4.33)	**1.79 (1.04, 3.09)**
Importance to quit (scale 1-5)			
<=3 low	1	1	1
4	0.54 (0.21, 1.39)	0.83 (0.20, 3.52)	**0.31 (0.13, 0.73)**
5	**0.35 (0.15, 0.82)**	1.00 (0.28, 3.60)	**0.48 (0.24, 0.96)**

The variation in quit rates across pharmacies might partly due to differences in patients recruited at each site. In order to rule out patient selection as an explanation for the varying quit rate among pharmacies, we built another multivariate multinomial logistic regression model to examine whether the effect of pharmacy on the probability of quitting would persist after controlling for patient characteristics. Pharmacies that provided the service to less than 25 patients were excluded from the analysis, namely pharmacy 4, 6, 11, 12, 14, and 18-23. Pharmacy 5, 7, and 15 were further excluded due to its extremely low quit rates. Low quit rates made the number of IQ and DQ very small, which would invalidate statistical analysis. The results of the model are presented in Table 11. Using pharmacy 1 as the reference, pharmacy 8 was more successful in terms of having more IQ, DQ, and OQ and pharmacy 2 and 16 were less successful. Patients from pharmacy 8 were 18.25 times more likely to be IQ than patients from pharmacy 1. After adding pharmacy into the model, R square increased to 0.36, meaning that pharmacy together with other variables in the model explained 36% of the variance in quitting patterns among patients. Quit attempts in the past year and presence of household smokers became significant, but confidence and importance to quit, pharmacotherapy use, modified FTND score were no longer significant. Adding pharmacy did not change the overall effects of age, education level, tobacco use in the past 30 days, and home ban of smoking.

Table 11 Multivariate Analysis---Characteristics of Immediate Quitters, Delayed Quitters, and Once Quitters compared to Never Quitters (pharmacy stores included)

	Immediate quitters vs. Never quitters	Delayed quitters vs. Never quitters	Once quitters vs. Never quitters
Pharmacy store			
1	1	1	1
2	**0.15 (0.04, 0.52)**	**0.17 (0.06, 0.46)**	**0.37 (0.20, 0.69)**
3	2.47 (0.78, 7.84)	0.17 (0.02, 1.42)	0.51 (0.15, 1.69)
8	**20.45 (8.70, 48.06)**	**9.40 (3.74, 23.62)**	**2.22 (1.03, 4.76)**
9	0.26 (0.03, 2.35)	0.49 (0.09, 2.53)	0.94 (0.26, 3.37)
13	---	1.26 (0.12, 13.30)	0.97 (0.19, 4.95)
16	**0.23 (0.07, 0.77)**	**0.06 (0.01, 0.46)**	**0.19 (0.08, 0.44)**
Age			
<18 years	**7.04 (1.01, 49.3)**	4.12 (0.40, 42.51)	**7.01 (1.18, 41.59)**
18-34 years	1	1	1
35-44 years	0.38 (0.17, 0.84)	1.25 (0.54, 2.88)	0.64 (0.37, 1.11)
45-54 years	1.09 (0.55, 2.19)	1.96 (0.88, 4.37)	0.60 (0.34, 1.06)
55-64 years	0.51 (0.22, 1.20)	1.95 (0.81, 4.68)	0.57 (0.30, 1.08)
>=65 years	0.84 (0.22, 3.15)	1.92 (0.48, 7.75)	0.47 (0.18, 1.24)
Gender			
Female	1	1	1
Male	0.93 (0.55, 1.60)	1.67 (0.96, 2.92)	0.86 (0.57, 1.29)
Education level			
Eighth grade or less	3.95 (0.92, 17.00)	2.05 (0.43, 9.73)	**3.55 (1.21, 10.42)**
Some high school or high school	1	1	1
Some college or college or college above	1.67 (0.94, 2.97)	1.51 (0.84, 2.70)	0.95 (0.62, 1.46)
Use tobacco every day			
No	1	1	1
Yes	0.90 (0.16, 5.05)	0.42 (0.12, 1.48)	0.46 (0.17, 1.28)
Tobacco use pattern in the past 30 days			
Only cigarettes	1	1	1
Cigarettes, pipes, and chew/dips	1.74 (0.89, 3.40)	1.91 (0.995, 3.68)	**2.54 (1.56, 4.14)**
Other	0.84 (0.28, 2.55)	0.87 (0.27, 2.83)	2.08 (0.97, 4.46)
Modified fagerstrom score			
0-2 low dependence	1	1	1
3	1.20 (0.62, 2.33)	1.18 (0.60, 2.31)	0.93 (0.55, 1.58)
4	0.67 (0.33, 1.37)	0.53 (0.25, 1.14)	0.94 (0.55, 1.60)
5-6	0.97 (0.41, 2.31)	0.66 (0.26, 1.69)	0.90 (0.46, 1.76)

Table 11 Cont.

	Immediate quitters vs. Never quitters	Delayed quitters vs. Never quitters	Once quitters vs. Never quitters
Pharmacotherapy used			
None	1	1	1
Only NRT	1.52 (0.59, 3.88)	2.39 (0.90, 6.30)	1.71 (0.82, 3.57)
Only varenicline	1.97 (0.82, 4.74)	1.62 (0.62, 4.21)	1.83 (0.88, 3.81)
Other	2.23 (0.64, 7.74)	1.39 (0.33, 5.87)	0.98 (0.29, 3.36)
Quit attempt in the past year			
Didn't try at all	1	1	1
Tried and stayed quit for <=1 week	0.60 (0.15, 2.47)	1.58 (0.44, 5.62)	1.81 (0.72, 4.57)
Tried and stayed quit for >1 week, but<= 1 month	1.62 (0.81, 3.23)	2.09 (0.99, 4.42)	1.09 (0.62, 1.89)
Tried and stayed quit for > 1 month, but <=6 months	1.82 (0.77, 4.31)	1.45 (0.57, 3.71)	**1.99 (1.05, 3.76)**
Tried and stayed quit for > 6 months	1.59 (0.66, 3.84)	1.58 (0.62, 4.01)	**1.99 (1.05, 3.75)**
Allowing smoking at home			
Yes, anywhere	1	1	1
Only in certain rooms & outdoors	**0.20 (0.07, 0.56)**	0.93 (0.41, 2.12)	0.67 (0.36, 1.23)
Outdoors only	1.10 (0.55, 2.17)	0.88 (0.43, 1.81)	**0.43 (0.26, 0.73)**
No, not allowed at all	0.70 (0.25, 1.96)	0.94 (0.36, 2.48)	0.66 (0.33, 1.32)
Presence of other tobacco users in the household			
Yes, someone who smokes	1	1	1
Yes, someone who uses smokeless tobacco	**5.03 (1.07, 23.65)**	3.87 (0.73, 20.59)	0.33 (0.03, 3.50)
No	1.46 (0.83, 2.55)	1.05 (0.59, 1.87)	1.31 (0.85, 2.00)
Confidence to quit (scale 1-5)			
<3 low	1	1	1
3	1.68 (0.63, 4.53)	0.86 (0.31, 2.40)	0.96 (0.47, 1.95)
4	1.51 (0.55, 4.12)	1.11 (0.41, 2.99)	1.29 (0.65, 2.59)
5	1.47 (0.53, 4.07)	1.29 (0.50, 3.37)	1.14 (0.57, 2.29)
Importance to quit (scale 1-5)			
<=3 low	1	1	1
4	0.90 (0.28, 2.83)	1.13 (0.24, 5.41)	0.44 (0.16, 1.19)
5	1.08 (0.38, 3.11)	2.49 (0.61, 10.18)	0.84 (0.35, 2.02)

Due to missing information of baseline characteristics from some patients, only 1007 patients were included in the first multivariate model. Since the loss was 32% of the overall sample, we compared the characteristics of the included and the excluded using chi-square test. The results of the comparison are presented in Table 12. Compared to the excluded, more included patients were middle-aged, and a greater proportion of them used tobacco every day, used tobacco cigarettes, pipes, and chew/dip in the past 30 days instead of only cigarettes, tried to quit in the past year, and scored higher on the scale of confidence/importance to quit.

Table 12 Comparison of Excluded Patients Due to Missing Information with Patients Included in Multivariate Analysis

	Included participants (N=1007)	**Excluded participants (N=479)**	**Chi-square test: p-value**
Age			**0.03**
<18 years	34 (3.4%)	15 (4.0%)	
18-34 years	241 (23.9%)	71 (18.9%)	
35-44 years	227 (22.5%)	68 (18.1%)	
45-54 years	261 (25.9%)	113 (30.1%)	
55-64 years	188 (18.7%)	75 (20.0%)	
>=65 years	56 (5.6%)	33 (8.8%)	
Gender			0.96
Female	559 (55.5%)	196 (55.4%)	
Male	448 (44.5%)	158 (44.6%)	
Education level			0.15
Eighth grade or less	39 (3.9%)	19 (5.7%)	
Some high school or high school	503 (50.0%)	149 (45.0%)	
Some college or college or college above	465 (46.2%)	163 (49.2%)	
Use tobacco every day			**0.005**
No	28 (2.8%)	22 (6.0%)	
yes	979 (97.2%)	346 (94.0%)	
Tobacco use pattern in the past 30 days			**<0.0001**
Only cigarettes	542 (53.8%)	199 (53.4%)	
Cigarettes, pipes, and chew/dips	400 (39.7%)	116 (31.1%)	
Other	65 (6.5%)	58 (15.6%)	
Modified fagerstrom score			0.99
0-2 low dependence	275 (27.3%)	64 (27.8%)	
3	291 (28.9%)	67 (29.1%)	
4	282 (28.0%)	65 (28.3%)	
5-6	159 (15.8%)	34 (14.8%)	
Pharmacotherapy used			0.07
None	200 (19.9%)	56 (16.2%)	
Only NRT	397 (39.4%)	164 (47.4%)	
Only varenicline	357 (35.5%)	110 (31.8%)	
Other	53 (5.3%)	16 (4.6%)	

Table 12 Cont.

	Included participants (N=1007)	Excluded participants (N=479)	Chi-square test: p-value
Quit attempt in the past year			**0.01**
Didn't try at all	271 (26.9%)	95 (33.7%)	
Tried and stayed quit for <=1 week	74 (7.4%)	26 (9.2%)	
Tried and stayed quit for >1 week, but<= 1 month	318 (31.6%)	60 (21.3%)	
Tried and stayed quit for > 1 month, but <=6 months	156 (15.5%)	47 (16.7%)	
Tried and stayed quit for > 6 months	188 (18.7%)	54 (19.2%)	
Allowing smoking at home			0.09
Yes, anywhere	456 (45.3%)	177 (49.0%)	
Only in certain rooms & outdoors	135 (13.4%)	40 (11.1%)	
Outdoors only	299 (29.7%)	90 (24.9%)	
No, not allowed at all	117 (11.6%)	54 (15.0%)	
Presence of other tobacco users in the household			0.26
Yes, someone who smokes	441 (43.8%)	145 (40.4%)	
Yes, someone who uses smokeless tobacco	23 (2.3%)	13 (3.6%)	
No	543 (53.9%)	201 (56.0%)	
Confidence to quit (scale 1-5)			**<0.0001**
<3	168 (16.7%)	169 (35.3%)	
3	264 (26.2%)	93 (19.4%)	
4	270 (26.8%)	97 (20.3%)	
5	305 (30.3%)	120 (25.1%)	
Importance to quit (scale 1-5)			**<0.0001**
<=3	60 (6.0%)	125 (26.1%)	
4	127 (12.6%)	54 (11.3%)	
5	820 (81.4%)	300 (62.6%)	

Elements of an effective tobacco cessation intervention

A total of 11 pharmacists provided the service to 25 patients or more, therefore, were selected for the interview. We successfully interviewed 8 selected pharmacists including the pharmacist from pharmacy 8 who achieved a quit rate of 59.4%. Their responses to the interview questions are summarized in Table 13.

Pharmacists in Table 13 were listed in an ascending order of 6 months quit rate. A pattern of quit rate and intervention intensity could be identified. Pharmacists who followed up with patients more frequently and spent more time helping them achieved higher quit rates than others. Pharmacist 8 met with each group weekly in the first 3 months and then every 2 weeks for another 3 months. Most pharmacists reported that they had difficulties in following up with patients. The most frequently reported reason for loss to follow-up was patients' lack of success in quitting tobacco. One pharmacist pointed out that providing free pharmacotherapy would help keep patients in the program. Another pharmacist thought that the patients were not invested enough for them to be successful. Two pharmacists considered inability to provide the full 6-month free pharmacotherapy as a barrier for them to providing the service. Pharmacist 8 did not find following up patients difficult. He stressed that the key was to make sure at the beginning that patients were committed to quit and willing to take time to attend group meetings. Most pharmacists believed that commitment to life style changes rather than the tobacco cessation product was the most important determinant of patients' success. Pharmacist 8 reported care and

encouragement from peers in group as the main thing that helped patients quit. What he did was to put patients of comparable level into same group and have them work together.

All the pharmacists interviewed utilized or at least incorporated part of the TUPAC protocol into their counseling. Except the pharmacist from store 8, all the other pharmacists counseled patients individually and provided some sort of additional resources to patients such as the 1-800-quitline, behavioral modification sheet, and literature from American Cancer Society. Pharmacist 8 adopted group meetings as the format of counseling. In addition to counseling, he also referred patients to the 1-800-Quitline and had group members share their personal phone numbers for mutual support. Time constraints were the barrier reported most frequently by the pharmacists. Except pharmacist 8, all the other pharmacists unanimously agreed that pharmacists had more advantages in providing tobacco cessation services compared with other health professionals. They believed that they were better candidates because they were equipped with knowledge of medications, they were more accessible, and they understood patients' needs and life better than any other health professionals. Pharmacist 8 thought that any health professionals willing to take the time and effort would be a good candidate for providing tobacco cessation services, but he did consider the relative easy accessibility as an advantage on pharmacists' side.

Table 13 Summary of Pharmacists' Responses to the Interview Questions

RPh from Pharmacy # (6 mo quit rate)	Pharmacy type/# of prescriptions filled per day	Initial contact	Follow-ups	Difficulties in following up with patients/ reason of loss to follow up	Major thing that keeps patients quit	Major thing that prevents patients from quitting	Barriers for providing the service	RPh's advantages of proving TC service
P7 (1.1%)	Independent;400 prescriptions	45-min counseling in person	One 15 mins scheduled; two or three informal chats lasted around 5 mins	NA	Life-style changes	Uncommitted to quitting	Time constraints	Accessible; knowledge about medications, and patients' medical history and life
P5 (2.9%)	Chain;80-100 prescriptions	30 mins-1 hour counseling in person	1 mo, 3 mo, 6 mo f/u: 5-10 mins in person; phone call monthly	Difficult when having many patients at the same time; Reasons: time constraints, unsuccessful	Committed to quitting, regular communication with RPh	Lack of motivation, life stress	Time constraints	Knowledge of medication
P16 (6.7%)	Independent; 90 prescriptions	45 mins-1.5 hours counseling	1 mo and 6 mo 20 mins f/u: 80% via phone; additional 10 mins f/u with several patients	Difficult. Reasons: unsuccessful	Motivation; social support	Uncommitted to life-style changes, stress	Time constraints	Accessible; knowledge of medications; ability to communicate with patients
P2 (11.5%)	Clinical; 8 prescriptions	45 mins-1 hour counseling	At least three 5-10 mins phone calls	Sometime difficult. Mobility of the population, unsuccessful	Readiness to quit	Uncommitted to behavioral modifications	Financial, patients not willing to pay out of pocket	Experienced in conveying this type of information to patients; understand patients' needs

Table 13 Cont.

RPh from Pharmacy # (6 mo quit rate)	Pharmacy type/# of prescriptions filled per day	Initial contact	Follow-ups	Difficulties in following up with patients/ reason of loss to follow up	Major thing that keeps patients quit	Major thing that prevents patients from quitting	Barriers for providing the service	RPh's advantages of proving TC service
P1 (22.8%)	Chain;500 prescriptions	45 mins-1 hour counseling in person	Three 15 mins f/u via phone; Additional 15-30 mins meeting with 15% patients	Difficult to have patients come in; Reasons: telephone disconnected, not taking phone calls	Understanding the addiction, how the therapy work, and its side effects	Program not financed to provide the full 6 month therapy	Couldn't provide free therapy; time constraints	Accessible; ability to identify smokers in pharmacy
P3 (29.6%)	Independent; 250 prescriptions	45 mins-1 hour counseling in person	Minimum of 4 times 40 mins in person f/u, mostly monthly	Not difficult. If patients miss an appointment, they are out of the program. Reasons: unmotivated, high nicotine dependence, side effects of therapy	Committed, communication with RPh	Social pressure, presence of other smokers	No barriers	Accessible; knowledge about medication
P8 (59.4%)	Long-term care; 37 prescriptions	30-40 mins counseling in person	1-3 mo: 30-60 mins group meeting every week; 4-6 mo: 40-45 mins group meeting every two weeks; After 6 mo: continue to meet monthly if patients want; All in person	Not difficult. The key is to make sure at the beginning that they are committed to quit. Encouragement from peers in the group also plays a role in keeping patients in the group.	Care and encouragement from peers in the group	Lack of confidence to quit	Time constraints	Accessible

P#: pharmacist from pharmacy #; RPh: pharmacist

In addition to the above findings, we identified a data collection issue that caused the low quit rate of pharmacy 7. During the conversation with the pharmacist from pharmacy 7, we found out that in majority he only followed up with patients once after the initial contact and the only follow-up could happen at 1 month, 3 months, or 6 months, which would cause missing data for two scheduled visits. Because we considered missing as failure when analyzing data, his quit rate was dramatically pulled down due to this issue. Not contacting patients is different than failure to follow up with them. Among the patients who were not contacted at the scheduled follow-up times, there must be a proportion of them who were actually abstinent, so the real quit rates of pharmacy 7 should be higher than what we calculated according to the data collected. There was a similar issue with pharmacy 3. This pharmacist met patients face to face for all follow-ups. He made a rule with patients that he would stop providing the service for them if they missed a single appointment with him. He stopped following up with the patients who broke the rule and then these patients were shown as missing for the later follow-ups in the data. This issue decreased the calculated quit rate for pharmacy 3.

Chapter 5 Discussion and conclusions

Although tobacco use has been recognized as a health hazard since last century, it remains a major public health concern in the United States. Tobacco use is one of the Healthy People 2020 topic areas retained from Healthy People 2010. Healthy People 2020 tobacco use objectives are organized in 3 key goals: reducing prevalence of tobacco use, implementing health care system changes, and enhancing social and environmental changes. New from Healthy People 2010, under health care system changes, two new objectives have been added to Healthy People 2020, specifically increasing tobacco screening in health care settings by 10 percent and increasing tobacco cessation counseling in health care setting by 10 percent.[97] Considering the attributable deaths to tobacco use were almost as many as the attributable deaths to the world's number two killer cerebrovascular diseases, reducing tobacco use has become an imperative task.[98] A pharmacists-assisted tobacco cessation service in UK had a quit rate of 3.6% at 52 weeks. An economic evaluation of the service showed that it was cost-effective regardless of the relatively low quit rate.[34] The reported incremental cost per quality adjusted life years (QALY) for one to one pharmacist counseling is 2,600 euros, which is only one-tenth of the cost-effectiveness threshold set by National Institute for Health and Clinical Excellence (NICE).[99]

Discussion of study results

The study findings on the program effectiveness add information to the literature regarding community pharmacists' capacity of delivering tobacco cessation services. Comparing to the quit rates of previous pharmacists-assisted programs or programs led by other health professionals, the average quit rates achieved by the NMPCF program are not inferior regardless of the conservative calculation approach we took and the data collection issues. Pharmacy 8 achieved a 6-month point prevalence quit rate of 59.4%, which is rarely seen in the literature. The achieved quit rate by the program proves that pharmacists are capable of delivering effective tobacco cessation services.

Although there have been studies of pharmacists-assisted smoking cessation programs, the majority of them focused on demonstrating success rates in a cross-sectional manner. Our findings from the survival analysis present a longitudinal picture of patients' quitting experiences. The dramatic decrease in quit rate occurred in the first two weeks indicates a clinically critical window of relapse and the needs of enhancing intervention in early period of interventions. According to TTM, our results suggests that a large proportion of patients would experience a relapse from "action" stage back to "preparation" or even "contemplation" at the beginning of quitting, and timely support corresponding to this relapse is needed to help patients through this relapse.

Previous studies mainly focused on adults and rarely included adolescents as study subjects. We had 49 teenagers in the study sample. The results of log rank test showed that patients under 18 years old had a better quitting experience and were more likely to be abstinent continuously. It was within our expectation that patients only used NRT or only used varenicline had higher probability of being continuously quit over time compared to patients who quit without any pharmaceutical aid or those who tried several different products. The effectiveness of NRT and varenicline has been demonstrated by clinical trials and many observational studies. Although we had no data to explain why some patients kept changing products, we believed that switching products was an indicator of their lack of success in quitting tobacco. One pharmacist we interviewed pointed out that those patients who blamed products were usually uncommitted to behavioral modifications and unlikely to be successful. We did not find any study from the literature that assessed the relationship between type of tobacco and the risk of relapse. It has been argued that using smokeless tobacco is of less health hazard than cigarettes smoking because it does not expose tobacco users to toxic combustion gases and particles that are responsible for most tobacco induced diseases.[100, 101] Patients who used multiple tobacco products might pay more attention to their health and might be more aware of the health harms of tobacco, therefore more committed to quitting tobacco use. Future studies are needed to verify our finding that patients who used cigarettes, pipes, chew/dips had a higher probability of being continuously quit than those who only smoked cigarettes.

As we stressed in the results, the estimates of hazard ratios from the Cox proportional hazard model presented in Table 6 were biased towards the null due to the violation of the assumption of proportionality. It is actually more realistic that the impact of age, pharmacotherapy, and tobacco use reduces over time considering quitting tobacco is a difficult task. Although our assignment of the time of continuous abstinence could influence the hazard ratios, we do not think it is the cause of the assumption violation because the same assignment schematic was consistently and systematically applied to all patients. We assumed that patients' early responses about their continuous abstinence were more reliable and accurate. We presumed that the period during which patients were continuously abstinent could not be longer that the duration between the intake day and the day they reported that they had used tobacco. We assumed that those who failed to respond to the question "Have you ever used tobacco once since your quit date" at any of the three follow-ups did not quit for even one day and assigned zero day as their time of continuous abstinence. All these three assumptions are fairly conservative and would only underestimate the time of continuous abstinence.

The goal of the pattern analysis was to characterize patients with different quitting patterns, therefore the results from the multivariate model without pharmacy stores included should be used for interpretation. Pharmacy store here is a proxy for the intervention patients received, which is inevitably related to

some patient characteristics such as pharmacotherapy used, importance to quit, and confidence to quit. Enhancing patients' confidence and perceived importance to quit is part of the counseling intervention. Pharmacies that successfully improved patients' confidence and importance to quit would be shown to have relatively more IQ, DQ, and OQ than others. Including pharmacy in the model, a portion of the variance explained by pharmacotherapy used and importance and confidence to quit would be shared by pharmacy and the ORs for these variables would be changed. The main purpose of building a second model with pharmacy included was to demonstrate that the variation in quit rates across pharmacies could not be fully explained by the difference in patients recruited. This point was proved by the results of the second model and verified through the interviews with participating pharmacists. In fact, pharmacy appeared to be the strongest predictor of patients' likelihood of achieving abstinence in terms of magnitude of ORs and consistency of statistical significance across comparisons from IQ to OQ. This confirmed our hypothesis that the tobacco cessation intervention patients receive also impacts their chance of successfully quitting tobacco.

The results of the pattern analysis showed the existence of different quitting patterns among tobacco users. Conceptualizing the findings with TTM, we could infer that participants were at different stages of quitting tobacco when recruited, spreading among "precontemplation", "contemplation" and "preparation". People who achieved immediate success (IQ) were possibly in "preparation" at recruitment and were ready to make a change. Those who were in

“precontemplation” or “contemplation” needed time and help from pharmacists before taking the action to quit, which makes them more likely to be delayed quitters and once quitters. Reviewing the results of the pattern analysis, it is also clear that patients with each quitting pattern have different characteristics. As proposed by health belief model, the likelihood of a tobacco user taking action to quit is determined by 3 factors, namely perceived benefits of quitting, perceived barriers of quitting, and perceived threat of not quitting. These 3 factors are in turn influenced by demographic factors, confidence and importance to quit, nicotine dependence, experiences of past quitting attempts, and availability of pharmacotherapy. More importantly, the results of the second model, with pharmacy being the strongest predictor of success, suggest that patients’ perception of benefits and barriers of quitting and threats of continuing smoking can be changed by pharmacists’ intervention. By changing patients’ perceived benefits, barriers and threats, pharmacists helped patients move along the stages from “precontemplation”, “contemplation”, and “preparation” to “action” and get ready to quit.

In general, our findings in the predictors of quitting patterns fit health belief model well.[102] For instance, patients with higher education are likely to have a deeper perception regarding the threats and health dangers of tobacco use, therefore are more likely to quit. Nevertheless, we have some results that cannot be understood intuitively and are discussed below. Although the existing literature cannot explain why the association between age under 18 and being IQ was still

present and strong after adjusting for level of nicotine dependence, pharmacotherapy used, type of tobacco, confidence to quit and other patient characteristics, we believed that it was plausible. Adolescent smokers were more likely to respond to increased price of cigarettes. [103] Income, an important factor that would affect adolescents' ability to purchase tobacco, was not included in the model due to substantial missing data for this variable. Our findings on home ban of smoking and importance to quit in the pattern analysis contradict with the existing literature, but we do not find them entirely implausible. Patients who were not allowed to smoke at home or only allowed to smoke in certain rooms were less likely to be IQ than those who were allowed to smoke anywhere at home. Social support is important for someone to be successful in quitting tobacco. Being able to smoke at home might be an indicator of harmonious domestic relationship and family support. Most of the pharmacists we interviewed stressed that personal commitment to quitting is the most important determinant of successful abstinence. Another potential explanation is that those patients are more determined to quit. Their decision to quit comes from themselves rather than family members. Importance to quit might not be necessarily related to how committed a patient is. The patients scored high importance might have health conditions that forced them to quit, but it does not mean that they were ready to quit. Unfortunately, we were unable to examine the effects of health related factors due to lack of such information.

We compared those who had missing data at 6 months follow-up with those who were followed up successfully by pharmacists and reported that they failed to quit in terms of baseline characteristics. We performed chi-square tests and found that they were similar in all the baseline characteristics except for pharmacotherapy ($p<0.0001$) and home ban of smoking ($p=0.01$). A greater proportion of the patients who were missing did not use any pharmacotherapy aid to help them quit compared to those who self-reported themselves being unsuccessful (21.9% vs. 9.6%). Also, a greater percentage of them were allowed to smoke anywhere at home (14.6% vs. 6.7%). When compared to patients who were abstinent at 6 months follow-up, the lost to follow-ups differed in many aspects, including age, education level, tobacco use in the past 30 days, quit attempts in the past year, confidence to quit, and number of cigarettes smoked per day. The similarity in patient characteristics between the lost to follow-ups and the ones who were self-reported being unsuccessful supports our assumption that lost to follow-ups were most likely to be continued tobacco users at the 3 scheduled follow-ups.

The interviews with pharmacists further demonstrated the importance of the tobacco cessation service. Although we could not perform statistical analyses on the pharmacists' responses due to the limited number of interviews conducted, a pattern between high quit rates and intensive interventions and frequent follow-ups can be inferred. Pharmacist 8 met with patients in groups as often as once a week in the first 3 months of the program. This finding is not only consistent with

the current literature, but also supports our point regarding the necessity of reinforcing treatment effects in early period of an intervention. Pharmacist 8 was the only one who adopted group meetings as the format of counseling among all the pharmacists interviewed. As the existing literature suggests, his success might also be related to the format of group counseling. In fact, pharmacist 8 considers group support and encouragement as the major factor that helps patients quit.

It is obvious that, to some extent, all the pharmacists delivered the service differently, with some of them providing more intensive interventions than others. However, they do share some common perceptions of tobacco cessation and the service they provided. Four of the seven pharmacists interviewed believe that behavioral modifications are the most important component of a tobacco cessation service and patients' commitment to the modifications largely determines whether they would be successful or not.

Even though tobacco cessation counseling with pharmacists is not covered by medical insurance yet and Healthy People 2020 does not specifically state increasing tobacco cessation counseling in pharmacy setting as an objective, pharmacists might actually be better candidates for delivering this kind of service compared to other health professionals. Apart from the fact that pharmacists are capable of delivering effective tobacco cessation services if given with right training, the pharmacists we interviewed unanimously responded that they were

the best choice for delivering the service. Quitting tobacco is a challenging task that takes time and requires social support. Having a health professional who understands the addiction and have an intimate knowledge of patients' medical history and life would help ease the task. Pharmacists seem to fit this description equally or better than any other health care providers.

Study limitations

Our study has several limitations. The major limitation is that nearly 50% missing on patients' smoking status occurred at all three follow-ups. We presume that the missing is mainly due to patients' lack of success and data collection problems. The majority of the pharmacists believed that loss to follow-up happened because the patient started to use tobacco again. The primary goal of the program was not for conducting research, therefore data collection was not a priority during the implementation of the program. There were two data collection issues. Pharmacist 3 and 7 did not follow up with patients as indicated by protocol, which contributed loss to follow-ups. Missing information on continuous abstinence status also caused 456 subjects being censored right at the beginning of the observation in the survival analysis. Although this censorship did not bias the results among patients who completed at least one follow-up, loss of statistical power could not be prevented. Missing on follow-up dates and length of continuous abstinence was also the reason that we had to make assumptions when assigning the time of abstinence, which is the second limitation of this paper. Even though we made the data assumptions carefully and conservatively, there is no way to test these assumptions. Lastly, the data was limited to what was on the intake questionnaire, so the multivariate pattern analysis did not include other potentially relevant variables such as general health and morbidities.

Study strengths

Despite the limitations, our study provides valuable information and has strengths over previous studies. Compared to the pharmacists-assisted tobacco cessation programs reported in the literature, our study sample, consisting of 1486 patients, is unprecedentedly large. Other than calculating point prevalence success rates, we also presented quit rates from a longitudinal perspective and used time to relapse as a unit of analysis instead of a "quit or not" dichotomous outcome. Despite of the importance of understanding quitting process, there have been very few studies that assessed quitting process or characterized quitting patterns emerged during quitting attempts. Our study is one of the few studies that assessed patients' quitting experience longitudinally. Additionally, observing and studying how patients' quitting-behaviors change during or after intervention would enable researchers to understand the process of quitting, identify critical windows during which smokers are most likely to relapse, and tailor interventions to patients' needs. Our study contributes to this body of knowledge by characterizing quitting patterns presented by the patients in the program, comparing patients with different patterns with respect to their characteristics, and identifying critical windows of relapse. Moreover, our findings in quitting patterns provide background knowledge for future studies to reveal the changes or events behind each pattern, which in turn, would further enhance our understanding of quitting process and enable individualized interventions. In addition, to our best knowledge, intra-program variation in effectiveness and the reasons behind the heterogeneous success rates in a same program have never

been explored before. Our findings would enhance the understanding of what makes an effective intervention and provide useful information for improving future interventions.

Conclusions

Pharmacists are capable of delivering tobacco cessation services. Patients' likelihood of quitting tobacco depends both on themselves and the intervention they receives. Intensive counseling and close follow-up are important elements of an effective tobacco cessation intervention. Most of the pharmacists that provided the program believe that commitment to behavioral modifications is the most important determinant of one's success in quitting tobacco.

Different quitting patterns exist among patients. For each pattern, the patients have distinctive characteristics in terms of level of nicotine dependence, pharmacotherapy used, motivational factors and demographic factors. Future research is needed to study quitting patterns more closely and to find out, apart from patient characteristics, the reasons for observing different quitting patterns among patients.

Appendices

Appendix A

Fagerstrom Test of Nicotine Dependence (FTND)

1- How soon after you wake up do you smoke your first cigarette?

Within 5 minutes--3
6-30 minutes—2
31-60 minutes--1
after 60 minutes--0

2- Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. at the mosque (church), at the bus?

Yes--1
No--0

3- Which cigarette would hate most to give up?

The first one in the morning--1
All others--0

4- How many cigarettes/day do you smoke?

31 or more—3
21-30--2
11-20--1
10 or less--0

5- Do you smoke more frequently during the first hours after waking than the rest of the day?

Yes--1
No--0

6- Do you smoke when you are so ill that you are in bed most of the day?

Yes--1
No—0

Appendix B Interview Script

Part I-Pharmacy

1. Type of pharmacy (independent, chain, or other?)

2. Including you, how many pharmacists are employed in this pharmacy?

3. On average, how many prescriptions does your pharmacy fill each day?

Part II-Pharmacist

1. Have you done smoking cessation counseling other than the NMPHA program?

2. Was there a packet you use or protocol you follow to help patients quit? Can you tell me what the packet/protocol contains?

3. About how many times did you follow up with each patient you manage in the course of the program?

4. Was there any contact outside of follow-up schedule?

5. How long did the initial contact and each follow-up last?

6. What approaches did you use to follow up with patients? (face-to-face follow-up, via telephone, or other)

7. Did you find it difficult to follow-up with patients? How did loss to follow-up happen (give top 3 reasons)?

8. What was the form of the counseling? (group based or individually?)

9. What kind of resources did you provide to patients?

10. What is the major thing that you think that helps keep patients quit?

11. What is the major thing that you think that prevents patients from quitting?

12. What were the barriers for you to providing the service?

13. Compared to other health professionals, do you think that pharmacists have more advantages for delivering tobacco cessation services? Can you tell me why?

14. Is there anything I have not mentioned that you would like to tell me? (e.g. important things you did in practice for helping patients quit)

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