CHEST

Original Research

SMOKING CESSATION

"Tobacco Free With FDNY"*

The New York City Fire Department World Trade Center Tobacco Cessation Study

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Context: **After the World Trade Center (WTC) collapse, 15% (1,767) of rescue workers from the Fire Department of the City of New York (FDNY) considered themselves to be current cigarette smokers. Post-WTC collapse, 98% reported acute respiratory symptoms, and 81% reported health concerns. Nonetheless, 29% of current smokers increased tobacco use, and 23% of ex-smokers resumed cigarette smoking.**

Objective: **To determine the effect of a comprehensive tobacco-cessation program using combination tobacco-dependency treatment medications adjusted to the individual's daily tobacco use.**

Design: **FDNY cigarette smokers enrolled in "Tobacco Free With FDNY," a no-cost quit-smoking program providing counseling, support, and medications. At the end of the 3-month treatment phase and at the 6-month and 12-month follow-up visits, abstinence rates were confirmed by expired carbon monoxide levels or by the verification of a household member.**

Setting: **FDNY Bureau of Health Services between August 1, 2002 and October 30, 2002.**

Participants: **A total of 220 current cigarette smokers from the FDNY.**

Results: **At study enrollment, the mean (± SD) tobacco use was 20 ± 7 cigarettes per day, and the mean tobacco dependency, as assessed by a modified Fagerstrom test score, was 6.7 ± 2.5 (maximum score, 10). Based on tobacco use, 20% of enrollees used three types of nicotine medications, 64% used two types, 14% used one type, and 3% used no medications. Additionally, 14% of enrollees used bupropion sustained release. The confirmed continuous abstinence rates were 47%, 36%, and 37%, respectively, after 3 months of treatment and at the 6-month and 12-month follow-up. Abstinence rates did not correlate with the history of tobacco use but correlated inversely with tobacco dependency. Adverse events and maximal nicotine medication use were unrelated, and no one experienced a serious adverse event.**

Conclusion: **Tobacco dependency treatment using combination nicotine medications is effective and safe. Future studies should consider the following: (1) both history of tobacco use and withdrawal symptoms to determine the number and dose of nicotine medications; and (2) continuing combination treatment for > 3 months.** ***(CHEST 2006; 129:979–987)***

Key words: firefighters; tobacco cessation; World Trade Center

Abbreviations: CO = carbon monoxide; FDNY = Fire Department of the City of New York; IRB = Institutional Research Review Board; SR = sustained release; WTC = World Trade Center

Virtually every rescue worker from the Fire Department of the City of New York (FDNY) was exposed to dust and smoke from the World Trade Center (WTC) during the extensive rescue and recovery operations that occurred during and after the collapse of the WTC on September 11, 2001. In the aftermath of the WTC collapse, the FDNY Bureau of Health Services instituted a WTC medical screening program.[1] During the first year after September 11, 2001, 11,777 FDNY rescue workers (*ie*, firefighters, emergency medical service health-care workers, and officers) participated in this screening, which included a self-administered tobacco questionnaire. Regardless of their history of tobacco use, 98% of rescue workers reported respiratory symptoms[1] during their acute WTC exposures, and 81%

reported concerns about serious health consequences from their WTC exposures. A total of 1,767 FDNY rescue workers (15%) classified themselves as current tobacco smokers, 29% of current smokers reported increasing their daily tobacco use, and 23% who formerly were ex-smokers reported resuming cigarette smoking after September 11, 2001.

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Responding to continued and increased tobacco use in an exposed and concerned workforce, the FDNY Bureau of Health Services instituted the "Tobacco Free with FDNY" tobacco-cessation program. This new joint labor-management initiative provided a comprehensive voluntary program that was offered at no charge to participants, and used WTC exposures and related health concerns as follows: (1) a "teachable moment" to educate our workforce that tobacco use increased the risk for developing cardiopulmonary diseases and cancer, and that, unlike WTC exposures, the risk from tobacco could be eliminated; and (2) as a "reachable moment" to enroll FDNY tobacco users and their household family members into our tobacco-cessation program.

The "Tobacco Free with FDNY" program used therapy with combined multiple nicotine medications, which were prescribed according to the individual's history of tobacco use. It was designed with asthma therapy as its model, using control/maintenance medication (primarily a 16-h continuous-release nicotine patch and occasionally bupropion sustained release [SR]) to minimize withdrawal symptoms and rescue medication (*eg*, a nicotine inhaler and/or nasal spray) to reduce episodic cravings. We hypothesized that improved abstinence rates would result from a tobacco-dependency treatment program providing counseling, support, and combination medications, with the latter adjusted according to an individual's tobacco use. This article describes our protocol and results.

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Materials and Methods

Through mailings, postings, and media exposure, the FDNY Bureau of Health Services invited all FDNY tobacco users and their household family members who smoked to attend the "Tobacco-Free with FDNY" program. Enrollment in this study was from August 1, 2002, to October 30, 2002. Introductory meetings were held monthly at designated FDNY facilities during off-duty hours. With labor-management support, all workers understood that decisions to enroll, participate, or withdraw at any time were voluntary and nonpunitive. The sole exclusion criterion was uncontrolled hypertension. The FDNY Institutional Research Review Board (IRB) at Montefiore Medical Center approved this study. All enrollees signed written consent.

A certified tobacco treatment specialist led the introductory meeting through a group participatory discussion concerning the following: (1) the health risks of tobacco smoke, emphasizing the synergistic risks for FDNY rescue workers who had been exposed to fires and "WTC Dust"; (2) the use, safety and efficacy of tobacco-cessation medications; and (3) cessation anxiety, concerns, and questions. Afterward, each attendee provided an expired breath carbon monoxide (CO) sample (The Micro Smokerlyzer Carbon Monoxide Monitor; Bedfont Scientific LTD; Medford, NJ) and met individually with a trained tobacco dependence specialist (*ie*, physician, nurse practitioner, psychologist, or substance abuse counselor) who assessed the attendee's tobacco use history, prior quit attempts, withdrawal symptoms, and tobacco dependency. We calculated tobacco dependency[2,3] using the revised Fagerstrom Questionnaire,[3] in which a maximum score of 10 indicated the greatest tobacco dependency.

At this introductory meeting, all attendees selected their quit day before their next follow-up visit in 2-weeks, were instructed how to use nicotine medications and bupropion SR, and were advised about possible adverse side effects. We gave those who agreed to return for follow-up a 2-week supply of medications, thus providing them with medications well in advance of their target quit date. The treatment protocol recommended and provided combination medications based on daily cigarette consumption (Table 1). Treatment specialists had discretion to individualize treatment recommendations according to withdrawal symptoms, cessation anxiety, adverse responses, and quit attempt history.

Introductory meeting attendees became enrollees in our program when they returned for the first follow-up visit. The treatment phase of our program provided counseling, support, and medications for 3 months with visits every 3 to 4 weeks. All enrollees had our phone mail number and e-mail address through which access to a trained counselor was provided to answer questions concerning their treatment. At each follow-up visit, the therapeutic intervention was repeated, as follows: (1) a tobacco treatment specialist led group participatory discussions concerning the health risks of smoking and tobacco cessation concerns; (2) expired breath CO measurements; and (3) individual enrollee meetings with tobacco treatment specialists to discuss cigarette use, CO level, and adverse event symptoms, and to answer questions. Enrollees rated the intensity of each of the following adverse events using an 11-point Likert scale ranging from 0 (absent) to 10 (most extreme): headache; difficulty concentrating; drowsiness; dizziness; nightmares/vivid dreams; rash at patch site;

Table 1—*"Tobacco Free With FDNY" Medication Protocol With Proposed Treatment Assignments Based on Protocol (Tobacco Use Alone) vs Actual Regimen (Maximum Number of Medications Used)***

Cigarettes Smoked per Day on Study Entry, Average No.	Daily Medication Regimen	Enrollees	
		Based on Protocol Alone	Actual Regimen
1–5	Inhaler as needed (0–6 cartridges)	11 (5)	17 (8)
6–19	Inhaler as needed (0–6 cartridges) or patch (15 mg) while awake	34 (15)	13 (6)
20–30	Inhaler as needed (0–12 cartridges) and patch (15 mg) while awake	111 (50)	97 (44)
31–40	Inhaler as needed (0–12 cartridges) and patch (30 mg; two patches) while awake	52 (24)	43 (20)
> 40	Inhaler as needed (0–12 cartridges) and patch (30 mg; two patches) and spray prn for immediate relief	12 (5)	44 (20)
Severe tobacco-cessation anxiety	Add bupropion SR (150 mg bid) to any of the above regimens		30 (14)

*Values are given an No. (%), unless otherwise indicated. Note that six enrollees (3%) used no medications (not shown), and 30 enrollees (14%) used bupropion SR in addition to their nicotine medication. Inhaler = Nicotrol inhaler (Pfizer; New York, NY).

increased sweats; nasal or throat irritation; bleeding gums; chest pain; palpitations; and abdominal distress. The specialist readjusted medications according to cessation results and adverse events, providing each enrollee with medications of sufficient quantity to last until the next visit. After the 3-month treatment phase, all enrollees were asked to return for 6-month and 12-month follow-up assessments of tobacco use and CO levels in expired breath. During this follow-up phase, enrollees were not restricted from the further use of medications for the treatment of tobacco dependency, but if they continued it was their responsibility to obtain medications.

We defined enrollment into the study as a return for the first follow-up visit, regardless of medication use or outcome. We defined the term *7-day point prevalence abstinence from smoking* as a self-report of nonsmoking for the 7 days before the visit, and the term *continuous abstinence* as a self-report of nonsmoking starting from the first follow-up visit. Abstinence required biochemical confirmation (expired air CO level, < 8 ppm) or in its absence (due to a missed visit) a phone interview with the enrollee to ascertain abstinence, followed by phone interview confirmation with a household member. We classified enrollees as smoking if the following conditions appeared: (1) they were lost to follow-up; (2) they self-reported as currently smoking; (3) there was an expired CO level of ≥ 8 ppm, regardless of self-report; or (4) there was household member report of current smoking. Abstinence rates were calculated at the end of the 3-month treatment phase, and at the 6-month and 12-month follow-up visits.

Statistical Analysis

The percentages of enrollees using a nicotine inhaler, a 15 mg/d nicotine patch, a 30 mg/d nicotine patch (*ie*, two 15 mg/d nicotine patches), nicotine nasal spray, and bupropion SR were compared between the study enrollment visit and the last visit (McNemar test). Agreement between the self-reported and chemically confirmed point prevalence of abstinence was assessed with the κ statistic. The mean age at study enrollment (*t* test for independent samples), the mean number of cigarettes smoked daily (*t* test for independent samples), the percentages of male enrollees (χ^2 test), and median Fagerstrom scores (Mann-Whitney *U* test) at study entry were compared between those who reported abstinence at 3, 6, or 12 months (point prevalence or continuous) and those who did not. Associations between abstinence rates at 3, 6, and 12 months (point prevalence or continuous) and the maximum number of medications during the study, controlled for the modified Fagerstrom score at study entry, were assessed with binomial logistic regression.

The incidence and intensity of adverse events were assessed using: (1) the summary score for the intensity of all 11 adverse events, with a maximum value of 110, (2) a summary score for the presence or absence of all adverse events, regardless of intensity (0 vs 1), with a maximum value of 11, (3) the intensity and presence/absence of cardiac adverse events (*ie*, chest pain and palpitations), and (4) the intensity and presence/absence of nightmares/vivid dreams. Scores were computed for each study visit of interest. Enrollees with missing data were considered not to have experienced adverse events for the visit for which data were missing.

Relationships between the presence/absence or intensity of adverse events at the study visit with the following: (1) the maximal number of nicotine medications prescribed (Kruskal-Wallis H test and χ^2 test) and (2) abstinence (point or continuous) at each time point of interest (Mann-Whitney *U* test and χ^2 test) were analyzed. Additionally, differences in the presence/absence or intensity of adverse events at the first follow-up visit between enrollees who did return after the first follow-up visit and those who did not (Mann-Whitney *U* test and χ^2 test) were analyzed. Finally, for enrollees with more than one follow-up visit, differences in the intensity or presence/absence of adverse events between the enrollee's first and last follow-up visit (Wilcoxon rank sum test and McNemar test) were assessed.

Results

Between August 1, 2002, and October 30, 2002, the "Tobacco Free with FDNY" program enrolled 164 FDNY rescue workers (9% of FDNY rescue workers acknowledging tobacco use on the WTC Medical Screening Evaluation) and 56 household family members for a total of 220 enrollees. Table 2 shows enrollee characteristics. The mean tobacco use during the prior year was 20 ± 7 cigarettes per day, the mean expired CO levels at study entry were 20 ± 11 ppm, and the mean Fagerstrom test score was 6.7 ± 2.5. At the 3-month, 6-month, and 12-month follow-up visits, smoking status (confirmed by

Table 2—*Tobacco Use During the Year Prior to Study Enrollment

Variables	Values
Age, yr	41 ± 8
Male gender	156 (71)
Cigarettes smoked, No./d	20 ± 7
Smoking	22 ± 8
Total No. yr	
Pack-yr	22 ± 8
Expired CO level on entry	20 ± 11 ppm
Modified Fagerstrom test score	6.7 ± 2.5
Prior quit attempts, median No.	3.0

*Values are given as the mean (± SD) or No. (%), unless otherwise indicated.

expired CO or household member phone interview) was available for 197 (90%), 194 (88%), and 189 (86%) enrollees, respectively.

Figure 1 shows the maximum number of nicotine medications used by enrollees during our program. Forty-four enrollees (20%) used 3 medications (patch, inhaler, and spray), 140 enrollees (64)% used 2 medications (with 97% using a patch and an inhaler), 30 enrollees (14%) used 1 medication (29% using patch, 71% using an inhaler, and 0% using spray), and 6 enrollees (3%) used no medication. Table 1 contrasts the maximum number of nicotine medications actually used by enrollees to the protocol recommendations and indicates that three nicotine medications were used by nearly four times the number of enrollees than our protocol would have assigned based on tobacco use alone. Thirty enrollees (14%) used bupropion SR in addition to the nicotine medications assigned by protocol. The vast majority of bupropion SR users smoked > 40 cigarette per day and expressed significant anxiety about the cessation of smoking tobacco. We lack the data to determine whether bupropion SR use resulted from our tobacco counselor's assessment or the enrollee's own health-care provider prescribing it for non-tobacco use cessation, mental health needs. Six enrollees used no medication (nicotine or bupropion SR) but otherwise participated in the program and, therefore, contributed to our outcome analysis. Over the 3-month treatment phase, the number of enrollees who used nicotine inhalers and low-dose patches (15 mg/d) declined significantly (Fig 2). After the 3-month treatment phase ended, enrollees reporting the continued use of tobacco dependency medications numbered 38 (17%) at 6 months and 26 (12%) at 12 months.

At each time point, the number of enrollees with self-reported tobacco smoking status confirmed by measurements of CO in expired breath or by phone interview with a household member is shown in Table 3. At 3, 6, and 12 months, respectively, 24, 26, and 31 enrollees were unavailable for follow-up evaluation and, thus, were considered to be active tobacco smokers. At 3, 6, and 12 months, self-reported abstinence was confirmed by expired CO measurements in 36, 4, and 0 enrollees, respectively, and by phone interview in 80, 95, 79, respectively. CO levels in expired breath and self-reports of abstinence agreed closely with each other; CO levels

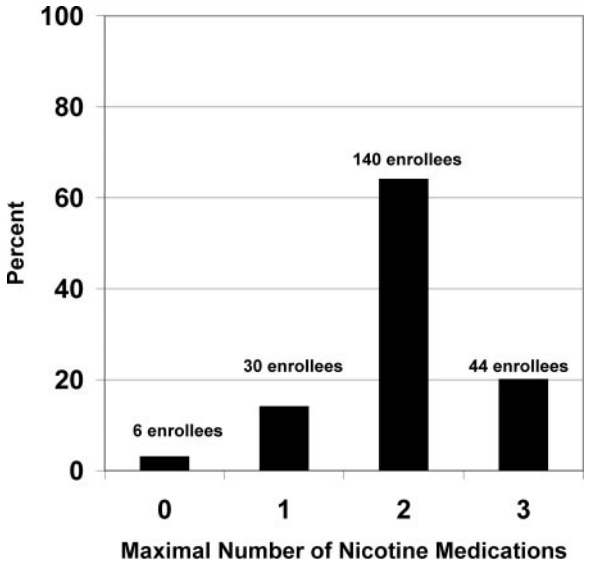

FIGURE 1. The percentage of those enrolled using one, two, or three types of nicotine medications. The number of medications shown is the maximum number used at anytime during the 3-month treatment phase.

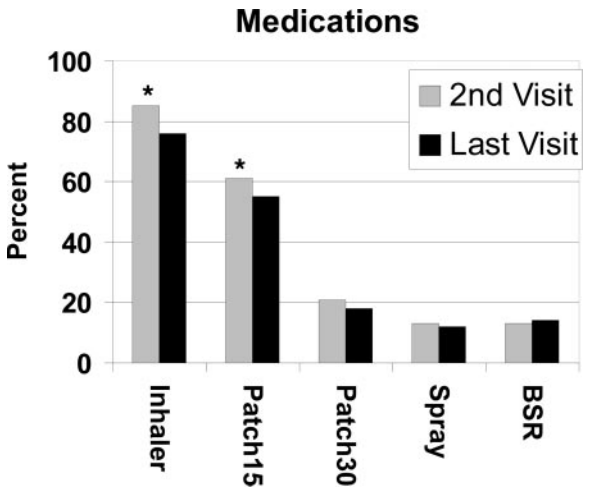

FIGURE 2. The percentage of enrollees using each type of tobacco-dependency treatment medication is shown for the first follow-up visit (gray bars) and for the last visit during the 3-month treatment phase (black bars). Over the 3-month treatment phase, the number of enrollees who used nicotine inhalers and low-dose (15 mg/d) patches declined significantly. * = $p < 0.05$.

Table 3—*Follow-up and Confirmation of Self-Reported Tobacco Smoking Status in 220 Enrollees*

Follow-up Visit	Expired Breath CO Measurement, ppm	Phone Interview With Household Member, No.	Lost to Follow-up, No.
3 mo	52	145	23
6 mo	11	183	26
12 mo	0	189	31

confirming "not abstinent" in 27 of 27 enrollees and "abstinent" in 36 of 43 enrollees (3-month data; $\kappa = 0.824$; $p < 0.001$). At 3, 6, and 12 months, the 7-day point prevalence abstinence rates were 53%, 45%, and 36%, respectively, and the continuous abstinence rates were 47%, 36%, and 33%, respectively (Fig 3).

At all time points, age, gender, and self-reported daily number of cigarettes smoked did not significantly affect abstinence rates (Fig 4, *top*, *A*). At 3, 6, and 12 months, the abstinence rates (point prevalence and continuous) varied inversely with Fagerstrom test scores ($p < 0.05$) [Fig 4, *bottom*, *B*]. At all time points, the abstinence rates (point prevalence and continuous) varied inversely with the number of nicotine medications used ($p < 0.05$), but this association with the number of nicotine medications used was no longer significant after controlling for Fagerstrom test score. Too few enrollees used bupropion SR to test for its interaction with nicotine medication use.

No enrollee experienced any serious adverse drug event, as defined by the Food and Drug Administration or our IRB. Adverse events reported at the first follow-up visit included the following: headache (36%); vivid dreams (32%); rash at patch site (12%); bleeding gums (13%); chest pain (26%); palpitations (21%); and abdominal distress (15%). The intensity of adverse events at the first follow-up visit did not vary significantly among those who dropped out of the program after their first follow-up visit and those who continued to participate. The total number of follow-up visits and adverse events were unrelated. The number of nicotine medications used and adverse events were unrelated (Table 4). The effect of nicotine dose on adverse events could not be determined because dosing data for nicotine inhaler or spray were not collected. Enrollees who relapsed reported significantly more frequent palpitations (48% vs 32%, respectively; $p = 0.027$) and significantly more frequent nightmares/vivid dreams (58% vs 38%, respectively; $p = 0.014$) than did those who

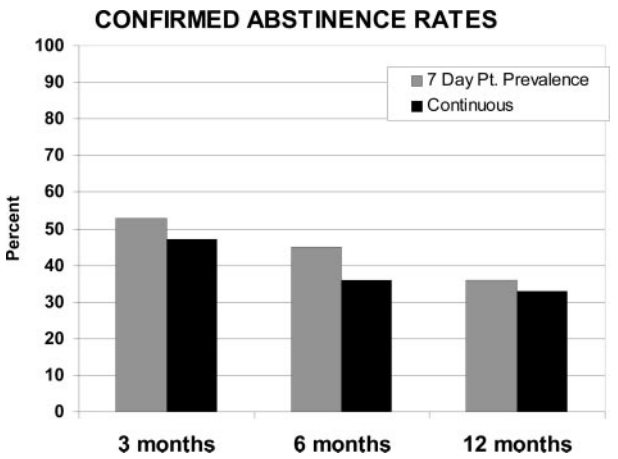

FIGURE 3. Confirmed 7-day point prevalence and continuous abstinence rates at the end of the 3-month treatment phase and at the 6-month and 12-month follow-up visits. Abstinence rates were confirmed by measurement of CO levels in expired breath or by household member telephone verification of smoking status.

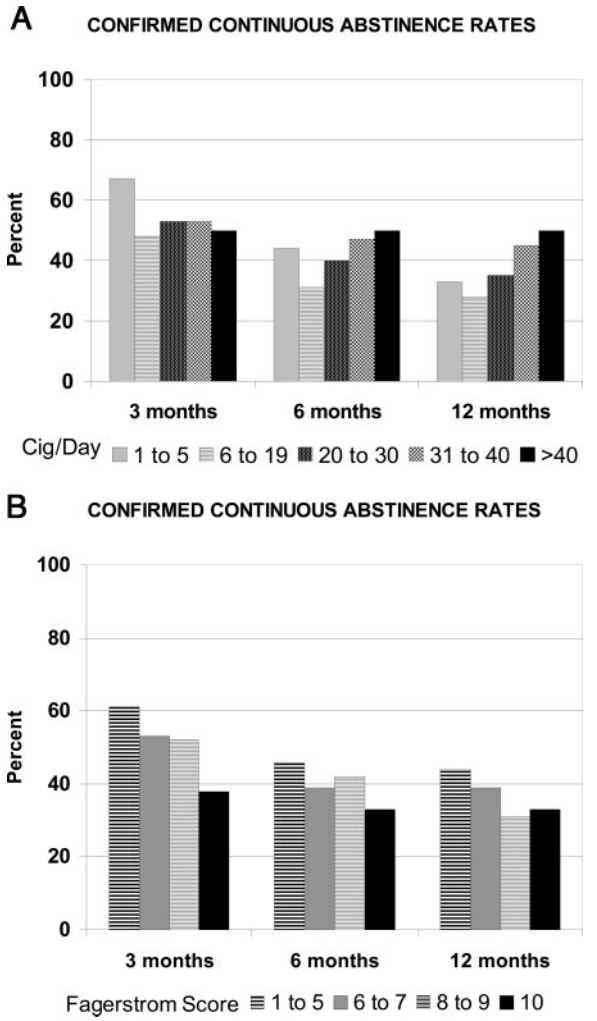

FIGURE 4. Continuous abstinence rates distributed according to daily tobacco use history (*top*, *A*) or according to tobacco dependency as assessed by the modified Fagerstrom test score (*bottom*, *B*).

Table 4—*Incidence of Nicotine Medication-Related Adverse Events by Maximal Number of Nicotine Medications Prescribed*

Nicotine Medications, Maximal No. (No. of Enrollees)	Any Adverse Event*		Chest Pain		Palpitations		Nightmares/VD	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
0 (6)	4	(67)	3	(50)	3	(50)	3	(50)
1 (30)	18	(59)	21	(70)	15	(50)	16	(53)
2 (140)	84	(60)	49	(35)	47	(33)	60	(43)
3 (44)	33	(75)	15	(34)	17	(39)	21	(48)

*Adverse events reported included: headache, abdominal discomfort, gum bleeding, concentration difficulties, chest pain, palpitations, drowsiness, sweating, nightmares/vivid dreams, dizziness and rashes; reported at the visit at which the maximal number of nicotine medicines were prescribed.

reported 7-day abstinence at 3 months or those who were continuously abstinent throughout their 3 months of treatment (palpitations, $p = 0.044$; nightmares/vivid dreams, $p = 0.024$). Although there were significant increases in the intensity of palpitations and nightmares/vivid dreams among those who relapsed, Likert scores revealed little clinical significance, with 90% reporting the intensity of palpitations or nightmares/vivid dreams at < 1 in 11 and 3 in 11, respectively. Relapse did not result in significant differences in chest pain frequency or severity. Comparing reports from the first and last follow-up visits, the intensity of all adverse events declined ($p = 0.015$), as did the intensity of chest pains ($p = 0.012$), palpitations ($p = 0.029$), and nightmares/vivid dreams ($p = 0.041$).

Discussion

After September 11, 2001, the presumed synergy between tobacco smoking and WTC exposure to produce potential serious health consequences stimulated the FDNY Bureau of Health Services to design and implement a unique postexposure intervention by offering to FDNY rescue workers who were tobacco smokers a free, voluntary, nonpunitive, comprehensive tobacco-dependence treatment program. Of the nearly 12,000 rescue workers screened, 15% reported active cigarette smoking. Assuming that the period after the WTC exposure was a "teachable, reachable moment" when FDNY rescue workers would be especially receptive to efforts to promote tobacco cessation in order to improve health and reduce disease risk, the FDNY Bureau of Health Services invited all FDNY cigarette smokers and their household family members who were current smokers to participate in the "Tobacco-Free with FDNY" program. Less than 1 year after September 11, this intense program providing outreach, education, counseling, medical treatment, and ongoing support, all at no cost to the FDNY participants and their families, was fully operational. During the first 3 months, 9% of FDNY rescue workers who were current smokers enrolled in this program. With the addition of rescue workers' family members, the actual treatment cohort was somewhat larger. After the conclusion of this study, the "Tobacco Free with FDNY" program continued, albeit with less intense outreach, treating an additional 124 FDNY rescue workers over the next 2 years. Thus, enrollment has reached a total of 288 FDNY rescue workers or 16% of current FDNY tobacco users. Although we think that our enrollment rate was substantial, we are not able to compare our enrollment rate to other programs because most programs do not know the number of persons in the pool of eligible participants from which they draw participants and therefore are unable to calculate enrollment rates. However, as our enrollment was less than a third of the eligible participants, it indicates that, despite their unique WTC exposure, self-reported concern about serious health consequences, aggressive outreach, and a no-cost comprehensive cessation program, tobacco dependency is difficult to address let alone overcome.

While our main goal for the "Tobacco Free with FDNY" program was to provide a comprehensive smoking-cessation program to this potentially high-risk group of smokers, we also attempted to test the hypothesis that increasing combinations of medications for the treatment of tobacco dependence according to personal tobacco history (*ie*, the number of cigarettes smoked daily) would improve abstinence rates. The daily cigarette use of our cohort was higher than the reported national averages.[4] Every enrollee received the same ongoing evaluation, education, advice, and support. The "Tobacco Free with FDNY" Program demonstrated that combination medications with comprehensive tobacco-cessation counseling can be delivered successfully in a voluntary, nonpunitive, occupational setting even for highly addicted tobacco smokers experiencing ex-

treme interpersonal and work-related stress. The confirmed 7-day point prevalence abstinence rates were 53%, 45%, and 36% of participants, respectively, at 3, 6, and 12 months. Confirmed continuous abstinence rates were 47%, 36%, and 33% of participants, respectively, at 3, 6, and 12 months. We think that our self-reported abstinence rates were reliable because at 3 months there was excellent agreement with CO levels measured in expired breath, and at 6 and 12 months, when CO levels in expired breath were often unavailable, self-reported abstinence was confirmed by phone interview with a household member. We found no significant effect of gender on tobacco abstinence rates, but only 29% of our participants were women.

Our approach of scaling the number of nicotine medications (and hence the nicotine dose) to the enrollees' reported tobacco use did not increase the frequency or intensity of adverse events. Importantly, no one experienced a serious adverse event as defined by the Food and Drug Administration or our IRB. While the frequency of adverse events in our study cohort appears somewhat large, our sensitivity to reports of these events was very high, and most enrollees reported only mild and tolerable symptoms. Moreover, the participation of our study groups in the WTC rescue/recovery effort may have contributed to more frequent chest discomfort, palpitations, and nightmares/vivid dreams because of posttraumatic stress, medical disorders, or heightened concern for WTC-associated health consequences. Adverse events occurred more frequently and intensely among those who used nicotine medications and continued to smoke, but even in this group the intensity of these symptoms was relatively minor. Adverse events did not inhibit the continuation of enrollees in the program, and chest pains, palpitations, and nightmare/vivid dreams declined significantly over the program course, especially among those who quit smoking, despite the continued use of nicotine medications. Our data support the safety of our treatment approach and raise questions regarding the extent to which adverse events resulted from nicotine medications or from the smoking-cessation effort.

Compared to other published studies using nicotine medications, abstinence rates among our participants far exceeded the rates reported in prior studies using the nicotine patch alone[5–9] and at least equaled the rates reported in prior studies using combination nicotine medications.[5–8] Blondal et al[6] reported continuous abstinence rates at 3, 6, and 12-months of 37%, 31%, and 27%, respectively, among those receiving combination nicotine medications with a patch and nasal spray, and Bohadana et al[7] reported continuous abstinence rates at 3, 6, and 12 months of 42%, 25%, and 20%, respectively, among those receiving combination nicotine medications with a patch and inhaler. Probably, multiple factors of our program contributed to its success (33% continuous abstinence rate at 12 months) including the following: (1) the impact of WTC exposure on study enrollment and quitting smoking among FDNY rescue workers; (2) an intensive support program with monthly meetings that included standard tobacco-cessation educational and counseling information that was reinforced with information about the potential for tobacco cessation to improve health outcomes following WTC exposure; (3) the use of combination medications for the treatment of tobacco dependency; (4) rarely used but nevertheless available phone or e-mail contact with a counselor for emergencies; (5) peer support in this unique occupational setting; (6) the voluntary inclusion of household members who also smoked tobacco; and (7) the option, actually chosen by many, to continue nicotine medications for 6 to 12 months. Our data did not allow us to separate the relative importance of these factors.

At all time points, the self-reported number of cigarettes smoked daily did not significantly affect abstinence rates, while abstinence rates varied inversely with Fagerstrom test scores ($p < 0.05$). These findings suggest that our program succeeded equally for all levels of cigarette smoking but that the intensity of tobacco dependence and withdrawal symptoms rather than the number of cigarettes smoked may be a more useful criterion for selecting tobacco-dependency medication treatment guidelines. In choosing the number of cigarettes smoked as the primary criterion for determining the number of medications used for the treatment of tobacco dependence, we did not account for the following: (1) the tendency for self-reported tobacco histories to underestimate actual use, (2) nicotine content per cigarette, (3) the number of cigarettes actually smoked (vs burned) per day, (4) the frequency, duration, and depth of inhalation, and (5) the psychological reasons for smoking, or even the relation of the enrollee's smoking to September 11 (presumably an important factor since $> 50\%$ of WTC rescue workers either increased or resumed their smoking). However, others have shown[10,11] that treatment success decreases as tobacco dependency increases. The Fagerstrom score is weighted more toward the intensity of withdrawal symptoms than to daily cigarette use (only one of six items in the score). Our data suggest that addiction and withdrawal symptoms, the biological effects of nicotine, more likely predict an individual's treatment success than does daily cigarette use. Adjusting the number and/or dose of combination medications used according to

the addictive effects of tobacco (*ie*, the Fagerstrom test score) rather than simply the number of cigarettes smoked may be similar to adjusting asthma therapy according to an asthma symptom score rather than the number of asthma triggers. Although our protocol permitted adjusting medications for tobacco dependency symptoms, our protocol guidelines were primarily based on tobacco use. Nonetheless, our data indicated that the treatment specialists deviated from protocol guidelines; three nicotine medications were used by nearly four times the number of enrollees than our protocol would have recommended based on tobacco use alone (Table 1), presumably because of excessive withdrawal symptoms and/or tobacco-cessation anxiety.

We think that the high abstinence rates found in this and other studies using combination medications for the treatment of tobacco dependency support therapeutic logic that stresses the use of combination medication protocols based on adjusting the number, the dose, and the mode of medication administration as tobacco dependency increases. Each medication and delivery pathway has benefits that are complimentary and could work synergistically to improve tobacco-cessation quit rates. Transdermal nicotine patches and/or bupropion SR are continuous release "control" medications that help to reduce tobacco-cessation craving anxieties and other withdrawal symptoms. Nicotine inhalers, sprays, and other oral nicotine medications (*ie*, gum and lozenges, which were not used in this study) are rescue medications that help with breakthrough withdrawal cravings by providing additional nicotine and oral gratification. In fact, the nicotine inhaler mimics the hand-to-mouth ritual of smoking, which for some may be an additional benefit. By allowing the patient to titrate the dose of nicotine needed, abstinence is hopefully facilitated through the potential psychological benefits of self-control and empowerment. Because our enrollees did not record the daily number of nicotine inhaler cartridges or nicotine nasal spray doses used, we could not determine the relationship between specific dosing and abstinence or between specific dosing and the number of adverse events.

Fiore et al[10] noted in his metaanalysis of nicotine patch therapy that overall quit rates did not vary whether treatment was of < 8 weeks duration or > 8 weeks. In those studies, treatment did not continue for 6 to 12 months. However, some studies[12] have begun to address the possible benefits of longer medication treatment for subpopulations with the highest tobacco use and/or dependency. During the follow-up phase of our study, 69 patients (32%) selected, on their own, to continue or resume medications for tobacco dependency treatment. Our study was not designed to determine whether abstinence rates could be improved by treatment for > 12 weeks. However, if we recalculate the abstinence rates at 6 and 12 months, assuming that these 69 patients would not have remained abstinent if medications had been unavailable, then we would have found lower continuous abstinence rates at 6 months (29% instead of 36%; $p < 0.001$) and 12 months (23% instead of 33%; difference not significant), suggesting that the prolonged use of medications for 6 months was beneficial and supporting the concept that tobacco dependency is a chronic disease that may merit prolonged therapy.

In conclusion, 15% of FDNY rescue workers continued, increased, or restarted tobacco use after September 11, 2001. The FDNY Bureau of Health Services designed and implemented the "Tobacco Free with FDNY" program as a unique post-WTC exposure intervention to help tobacco smokers quit smoking and, hopefully, to mitigate the potential health impact of WTC exposures. Even with aggressive outreach and a comprehensive program that was offered at no cost to participants, only a minority of current smokers enrolled in the study, demonstrating the power of tobacco addiction. For those who enrolled in our program, the study demonstrated that the use of combination medications, administered as part of comprehensive tobacco-dependency treatment program, was effective and safe, with continuous abstinence rates exceeding most other published studies. Abstinence rates did not correlate with reported pretreatment tobacco use and correlated inversely with pretreatment physical dependency. Future studies should: (1) include the use of withdrawal symptoms and tobacco dependence with tobacco use to determine the number and/or dose of combination medications and (2) continue combination treatment for tobacco dependency for > 3 months for smokers who so choose.

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