Comparing an Opt-out to an Opt-in approach for smoking cessation in primary care: A cluster randomized trial

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Abstract

Background: Behavioral treatments for smoking cessation are effective but underused. Most programs use an "opt-in" approach, requiring individuals to actively enroll.

Objective: To assess the effectiveness of an opt-out approach for increasing primary care behavioral treatment delivery.

Design: Cluster randomized trial, with primary care teams randomized to an Opt-in vs. an Opt-out approach.

Participants: All team nurses at one Veterans Health Administration (VA) hospital system were included.

Intervention: Electronic reminders strongly encouraged nurses to refer patients who smoke to the state Quitline and/or text messaging. Opt-in patients completed a form for treatment referral, whereas Opt-out patients were automatically referred unless they completed a form.

Measurements: Primary outcome measures – rates of referral, engagement and abstinence. Post-visit surveys assessed perceptions of care. We used a longitudinal patient survey and the electronic health record (EHR) to assess abstinence. Mixed-effects logistic regression models and cumulative link models were used for comparisons.

Results: We randomized 23 teams (12 Opt-in, 11 Opt-out), representing 46 nurses. Patients in the Opt-out arm were much more likely to be referred to text messaging (47% vs. 4%, aOR 23.5, 95% CI 12.7-43.6) or the Quitline (46% vs. 4%, aOR 23.6, 95% CI 13.3-41.9) than in the Opt-in arm. Those in the Opt-out arm were much more likely to participate in text messaging (44% vs 4%, aOR 21.0, 95% 11.8-37.2) than in the Opt-in arm. There was no difference between the two arms in long-term abstinence based on patient survey or EHR.

Limitations: One VA hospital system

Conclusion: The Opt-out approach resulted in much higher rates of referral and behavioral treatment engagement but not a higher abstinence rate.

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Introduction

Smoking is the leading preventable cause of death in the United States (US). While the prevalence of smoking has declined, there are still approximately 28 million US adults who smoke cigarettes.[1] In addition, rates of smoking remain even higher in certain populations, such as people with mental health diagnoses,[2] those below the poverty line[3] and others.

While much of the initial decline in smoking prevalence was due to public health efforts,[4] health care systems have greatly improved their efforts at helping people quit. Electronic health records (EHRs), combined with requirements of the Affordable Care Act, have helped ensure that smoking status is assessed and documented for nearly all patients. Many systems now report near-universal rates of offering tobacco use treatment to people who smoke.[5, 6]

While rates of offering tobacco use treatment have increased, patient use of treatment remains relatively low due to a variety of factors. One such factor is that people who use tobacco must opt in to treatment. Experts have called for changing the default so that people receive tobacco treatment unless they opt out of it.[7] A recent study demonstrated that an opt out approach increased delivery of tobacco use treatment among inpatients,[8] but few studies have tested its impact in ambulatory care. We conducted a randomized controlled trial comparing an opt in to an opt out approach to delivery of tobacco use treatment by nurses in primary care.

Methods

Study design and setting

As described in a protocol paper,[9] this was a type 1 hybrid effectiveness/implementation study to evaluate two population-based approaches for increasing use of two evidence-based behavioral approaches to tobacco use treatment – Quitline and text messaging. This cluster randomized controlled trial was conducted in primary care clinics at the VA New York Harbor Healthcare System's Manhattan and Brooklyn campuses. Primary care at the campuses is delivered by Patient-Aligned Care Teams (PACTs),[10] an adaptation of the Patient-Centered Medical Home model.[11] Each PACT is composed of a primary care provider, registered nurses, nursing assistants and a clerk, all working collaboratively to deliver patient-centered care.

All VA facilities currently use nationally-developed VA EHR clinical reminders to address tobacco in primary care, as recommended by the PHS tobacco treatment guidelines.[12] Smoking status is assessed at least yearly unless the person has been abstinent over 7 years. Nurses receive a clinical reminder annually requiring them to advise the patient to quit tobacco use and to encourage the patient to use tobacco use treatment to help quit. Primary care providers see a separate, linked annual clinical reminder, encouraging them to offer medications, counseling and referral. Annual rates of offering tobacco use medications and counseling have each consistently been over 93% nationally since 2012.

Participants and Recruitment

This study included three distinct cohorts: one nurse cohort and two patient cohorts. The ***Nurse Cohort*** consisted of all primary care nurses affiliated with PACTs at the VA New York Harbor Healthcare System during the study period (January 1, 2021 – December 31, 2022). PACTs were randomly assigned to either an Opt-In or an Opt-Out approach to treatment. Nurses who declined to participate received the opt-in reminder, but we did not include their data or that of the patients in their PACT in our analyses.

The ***Patient Survey Cohort*** included English-speaking patients who completed a baseline study survey administered prior to implementation of the intervention. They also must have

been documented as currently using tobacco at their last clinic visit prior to study rollout and have had at least one encounter with a participating study nurse within the 12 months preceding the study period.

The ***EHR Cohort*** consisted of all patients who had been documented as currently using tobacco at their last clinic visit prior to study rollout and had at least one visit with a participating nurse during the study period, with no other exclusion criteria. This broader cohort was used to analyze clinical encounter data (i.e., referral to and engagement with cessation services). It was also used to assess abstinence, to complement the data from the Patient Survey Cohort.

Interventions
In the Opt-In arm, nurses received annual clinical reminders prompting them to refer patients who smoke to the state Quitline or to a text messaging program provided by Agile Health. Patients expressing interest in treatment completed a brief paper referral form to enroll in their chosen service(s). Study staff reviewed the referrals daily and transmitted the information to the Quitline or text messaging program within 2 days.

The annual clinical reminder for nurses in the Opt-Out arm similarly prompted them to refer all patients who smoke to the state Quitline or to the text messaging program. Nursing staff were instructed to inform patients that they were already being referred to both the Quitline and text messaging service, but patients could actively opt out of either referral (or both) by completing a brief form. Study staff processed the referrals just as they did with the Opt-in arm.

Patients who opted in or did *not* opt out were referred electronically to the New York State Quitline and/or to the text messaging program. The Quitline provides one proactive call and unlimited reactive calls. Counselors at the New York Quitline make up to 5 attempts to reach people for the proactive call.

Bidirectional text messaging was provided by Agile Health, through their *Kick Butts* program. We did not use the text messaging service provided by the National Cancer Institute (Smokefree.TXT) or the VA (Smokefree.VET) as both required the participant to have a quit date on enrollment, and we hypothesized that many people referred from this study might be more ambivalent and therefore not yet ready to set a quit date. All patients received 2 weeks of motivational enhancement messages through Agile Health's *Quit-decision Support* program and then moved into the 6-month quit phase, where the messages focused on assisting with quitting, managing cravings and avoiding temptations. Patients were able to move their quit date both forward or backward based on their needs, although very few participants did this. At any time, patients could text "STOP" to quit the program.

We originally started the intervention (i.e., turned on the clinical reminders) in January 2020, but it was disrupted by the COVID-19 pandemic when most primary care visits occurred virtually in the context of multiple competing priorities. As a result, we paused the study (turned off the clinical reminders) in March 2020 and started anew in January 2021, when nearly all visits had returned to in-person.

Data sources and curation

Administrative data
Patient-level clinical data, including smoking status, completion of the clinical reminder and receipt of smoking cessation medications from a PACT provider, were extracted from the VA's Corporate Data Warehouse (CDW). To assess cessation service utilization, we obtained Quitline

engagement data from the New York State Smokers' Quitline and text messaging program participation data from Agile Health.

Nurse and patient surveys
We conducted five separate surveys – baseline and follow-up surveys of nurses, baseline and follow-up surveys of patients and a patient post-visit survey. The nurse surveys, which occurred at baseline and at the end of the 2-year intervention period, assessed nurse demographics (baseline only), personal health habits and attitudes toward tobacco treatment and the clinical reminder system.

The Patient Survey Cohort included a random sample of patients who were listed in the electronic health record as currently smoking. The sample was stratified by nurse, with the goal of obtaining 62 patients per nurse. We subsequently limited the sample to patients from participating nurses, which reduced the baseline sample from 1,361 to 979. The survey assessed demographic characteristics, smoking behaviors, prior treatment utilization and preferences for cessation methods. Patients on participating PACTs who completed the baseline survey were surveyed again 2 years later, with the follow-up questionnaire repeating core measures while adding detailed questions about their cessation progress during the intervening period.

We conducted post-visit patient phone surveys, contacting patients via telephone within 24 hours of their primary care visit to gather real-time feedback about the tobacco treatment referral conversation and process. The goal was to survey 20 patients per nurse. The survey included five questions. Patients were asked whether the nurse notified them that the facility's goal is to refer all smokers to smoking cessation treatment and whether they were referred to treatment. They were also asked whether they were strongly encouraged to receive a referral for treatment and whether they felt forced to receive the referral. Finally, they were asked to rate the overall quality of their discussion with the nurse.

All survey data were collected and stored electronically using REDCap (Research Electronic Data Capture), a secure web-based platform designed for research data management. Research staff entered intervention process data, retrieved from patients' electronic health records, into the REDCap database at the conclusion of each study day to ensure timely and accurate documentation.

Outcomes
We had three sequential primary outcomes: 1) the proportion of patients referred to smoking cessation treatment during the 2-year intervention period, 2) the proportion of patients who participated in treatment, and 3) abstinence from smoking at the end of the intervention period. Referral status was determined through the EHR and the forms completed by patients. We considered patients to have participated in the Quitline if they enrolled and completed the proactive call. For text messaging, we considered individuals to be participants if they started the program, meaning they did not reply STOP at the beginning to turn off messages.

We assessed abstinence from smoking in two ways. On the follow-up survey, patients were considered abstinent if they reported no smoking in the prior 7 days. With the EHR Cohort, we used information from a patient's most recent smoking health factor (the way data from VA clinical reminders are stored) following their first visit with the study nurse. [13, 14, 15, 16].

Smoking medications

We extracted data on smoking cessation prescriptions (bupropion, varenicline and nicotine replacement therapy) from the CDW. We calculated the counts and proportions of patients who received these medications within 2 weeks after their first visit with a study nurse in which the reminder was triggered. On the 2-year patient survey, participants were asked about use of smoking cessation medications in the last year (*"During the past year, have you used any medication to help you quit smoking?"*). We calculated the counts and proportions of patients who reported use of these medications in the year prior to survey completion.

Statistical Analysis
Survey responses were summarized using means and standard deviations (SD) for continuous variables and counts and percentages for categorical variables. Outcomes (referral to and participation in cessation services and abstinence at 2 years) were compared between study arms using the intent-to-treat principle, with each patient analyzed based on the first PACT cluster they saw during the study. Responses from the 100 patients who switched arms were excluded from analysis.

For primary outcome comparisons between arms, we fit mixed-effects logistic regression models with random intercepts at the PACT level to account for clustering effects. These models produced adjusted odds ratios (aORs) with 95% confidence intervals (CIs) to estimate intervention effects. Post-visit survey responses (ordinal scales) were dichotomized and analyzed using similar mixed-effects approaches. At the population level, we also assessed smoking cessation using mixed-effects models. All statistical tests were two-sided with $P < 0.05$ indicating statistical significance. All data cleaning and analyses were performed with R, version 4.3.3 (R Project for Statistical Computing).

This study was approved by the Institutional Review Board at the VA New York Harbor Healthcare System prior to any contact with participants or data collection. It was registered with ClinicalTrials.gov (NCT03477435) on March 19, 2018.

Funding source
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Results
We mailed baseline surveys to 3,906 patients and received completed questionnaires from 1,361 people. We subsequently eliminated 382 people whose nurse was not participating, leaving a final sample of 979 patients (Patient Survey Cohort). Of those completing the baseline survey, 632 (64.5%) completed the 2-year follow-up survey. The EHR Cohort comprised 1,895 eligible patients. Baseline characteristics of patients in the Patient Survey Cohort and EHR Cohort were quite similar (Supplemental Table 1), with 91-93% being male, mean age 64 years old and approximately 1/3 White, 1/2 Black or African American and about 1/5 Hispanic. Most patients (1,556; 82.1%) had a single study visit where the study reminder was triggered, while 17.9% had the reminder triggered multiple times during the intervention period (317 at two visits, 22 at three visits).

We randomized 23 PACTs (12 Opt-In, 11 Opt-Out), representing 46 nurses in this study (Figure 1). Eleven nurses did not participate, and an additional 9 nurses left during the study and thus were not included in analysis. Baseline characteristics of participating nurses are shown in

Supplemental Table 2. The vast majority (80-81%) in each arm were female, and none currently reported using tobacco.

As shown in Table 1, rates of referral were significantly higher in the Opt-out arm for both text messaging (47.2% vs. 4.3%, aOR 23.5, 95% CI 12.7-43.6) and telephone counseling (46.2% vs. 3.9%, aOR 23.6, 95% CI 13.3-41.9) as compared to the Opt-in arm. Similar results were seen for engagement with text messaging (43.8% vs. 4.4%, aOR 21.0, 95% CI 11.9-37.2) and to a lesser extent with telephone counseling (4.9% vs. 0.6%, aOR 8.9, 95% CI 3.8-21.0). For text messaging, 443 people were referred and 413 people participated. Of these, 333 continued participation for the entire program (approximately 210 days). Eighty people replied STOP to withdraw and their median length of participation was 49.5 days.

We assessed abstinence with the Patient Survey Cohort and the EHR Cohort, with patient inclusion for the EHR analyses shown in Figure 2. Neither set of analyses found a difference between the two arms in abstinence from smoking (Table 2).

Few study visits resulted in receipt of smoking cessation medications, with EHR data showing that 222 (13%) of patients filled a prescription for smoking cessation medications within 2 weeks of the clinical reminder being triggered (Supplemental Table 3). There were no differences between the two arms in overall use of medications or of any individual medication. Only 27% of the prescriptions (4% of all patients seen) were for the most effective medications (varenicline or combination nicotine replacement therapy).

We assessed patients' perspectives with a post-visit survey. Patients in both arms overwhelmingly reported that the nurse notified them that the facility's goal is to refer all patients who smoke to cessation treatment (Table 3). The majority of participants reported feeling strongly encouraged to receive a referral for smoking cessation treatment. We found no difference between the Opt-out and Opt-in arms on any attitudes or perceptions.

Discussion

We found that patients in the Opt-out arm were much more likely to be referred to text messaging and to engage in it than those in the Opt-in arm. For the Quitline, patients in the Opt-out arm were much more likely to be referred than those in the Opt-in arm. While a similar pattern was seen for engagement with the Quitline, the effect was smaller as overall rates of engagement were quite low. Unfortunately, these high rates of behavioral treatment engagement did not translate into higher abstinence rates. Attitudes were quite similar between the two arms, and people in the opt out arm did not feel more coerced than people in the opt in arm.

Studies that have used an opt out approach have consistently found higher rates of treatment. Richter et al conducted a trial among inpatients in a tertiary care hospital in Kansas City.[8] Patients in the opt-out arm were much more likely to receive smoking cessation medications after discharge and to receive at least one counseling call, but rates of abstinence at 6-month follow-up did not differ between the two arms. Similarly, in a cluster randomized trial among primary care providers in Switzerland and France, Selby et al found that an opt-out approach with a smoking cessation decision aid increased use of medications but did not affect abstinence rates at 6 months.[17] These results are both similar to our findings, with increased use of evidence-based treatment but not an increase in long-term abstinence.

Bidirectional text messaging is an effective method for helping people quit smoking,[18] but it is seldom used within health care. In an 11-month period, 2,188 people enrolled in the VA national

texting service (<0.3% of people who smoke).[19] Within 32 UK primary care practices, 776 people who smoke were screened for enrollment into a text messaging project (1% of people who smoke).[20] Analysis of the “Florence” text messaging program in the UK showed similar very low use and engagement.[21] This is the first study to test an approach to broadly increase use of text messaging within health care, and it resulted in high rates of referral and engagement.

Why didn't markedly increased rates of evidence-based behavioral treatment lead to more people quitting? People referred by this method may be more ambivalent about treatment than in prior treatment studies. This is consistent with the relatively lower engagement rates for the Quitline, where participants are receiving calls days later from a number that is new to them. Prior studies have shown people successfully quit smoking regardless of their interest in quitting at baseline. Most studies, however, involved medications, and our study only involved referral to behavioral treatment. Only 13% of patients filled a prescription for smoking cessation medications within 2 weeks of the study reminder being triggered, and this did not differ between the two arms.

Our study has several limitations. It was conducted at both campuses of one health care system, which may affect its generalizability. Additionally, this study was conducted within the Veterans Health Administration, which has a comprehensive tobacco control program and very high (>90%) rates of offering tobacco use treatment each year. Finally, abstinence was assessed by survey and by using EHR data, both approaches have limitations (albeit different ones) for assessing abstinence.

Our study provides strong support for using an opt-out approach to increase rates of referral to and engagement in tobacco use treatment. Future studies should examine how to translate this into higher abstinence rates. To further increase effectiveness, opt out care could connect patients to delivery of varenicline or combination NRT along with text messaging.

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The authors have no conflicts of interest to report.

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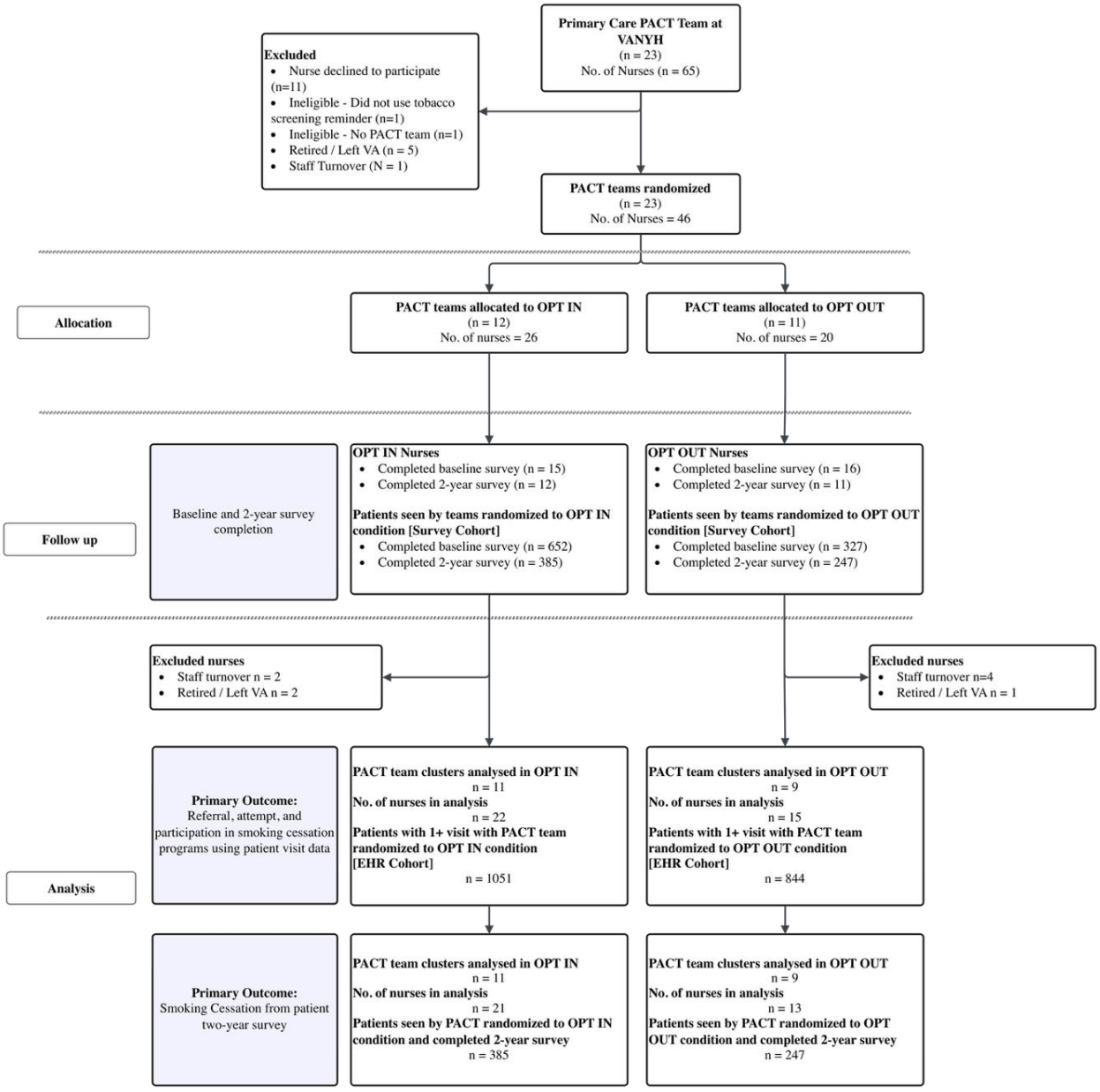
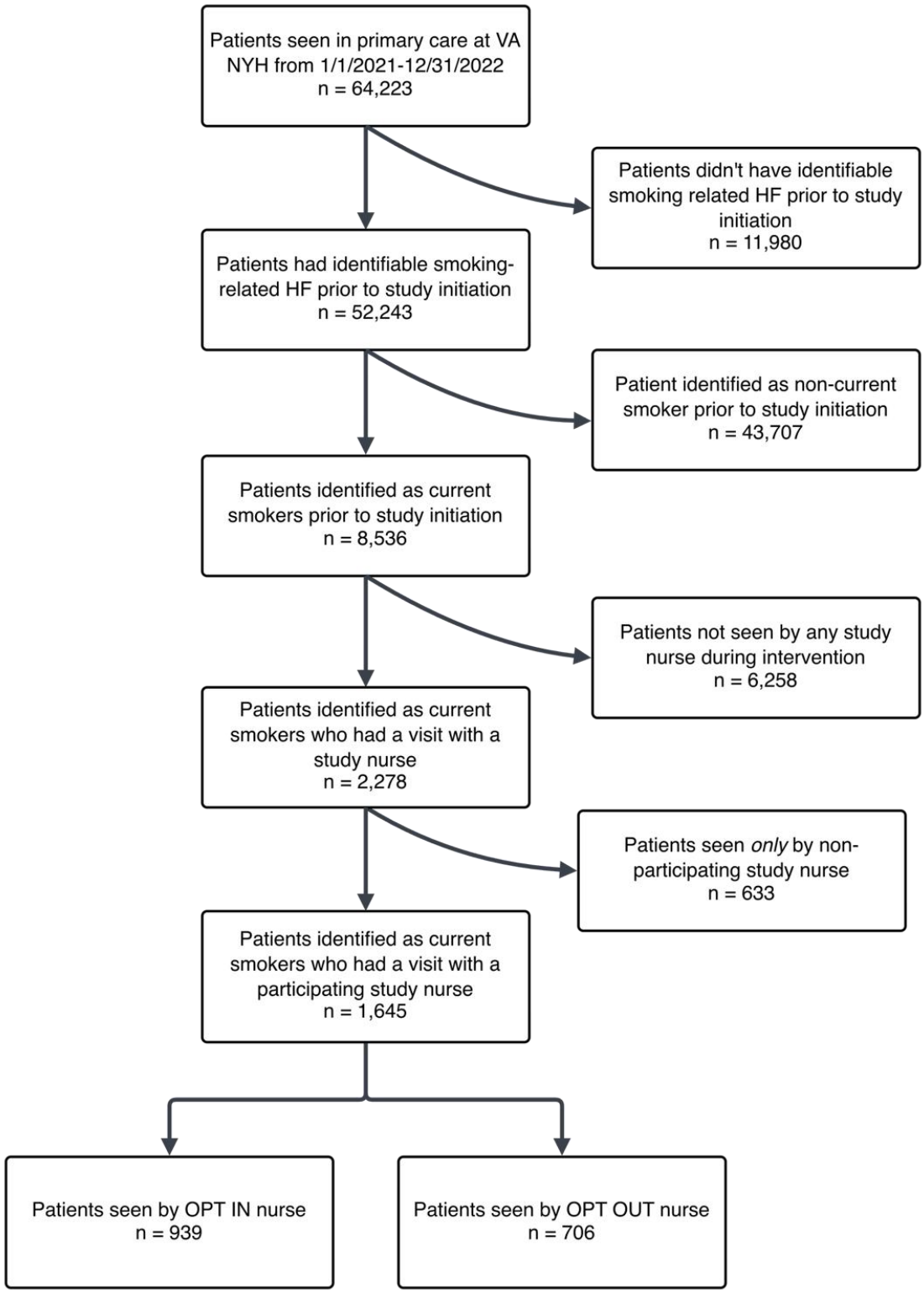
Figure 1. Flow diagram of the cluster randomization of Patient-Aligned Care Teams (PACTs), primary care nurses and patients at the medical center



Of note, the 11 nurses who declined to participate in the study received the Opt-In study clinical reminder as this most closely aligned with usual care. However, neither these nurses, nor the patients in their PACTs, were included in analyses. For the smoking cessation analyses, there was 1 nurse in each arm that did see any patients who completed the 2-year survey. Thus, only 21 and 13 nurses (and their patients) were included in the Opt-In and Opt-Out arms, respectively, for the final smoking cessation analyses.

PACT = Patient-Aligned Care Team

Figure 2. Flow diagram for patient participation in the electronic health record-based cessation analyses



HF = health factor

Table 1. Referral to and participation in smoking cessation program by treatment arm

Outcome	Opt-In Arm N (%)	Opt-Out Arm N (%)	Adjusted OR (95% CI)
Referred to text messaging	45 (4.3%)	398 (47.2%)	23.5 (12.7, 43.6)
Participated in text messaging	43 (4.4%)	370 (43.8%)	21.0 (11.9, 37.2)
Referred to Quitline	41 (3.9%)	390 (46.2%)	23.6 (13.3, 41.9)
Participated in Quitline	6 (0.6%)	41 (4.9%)	8.9 (3.8, 21.0)

OR = odds ratio, CI = confidence interval

Sample size was 1,051 for the Opt-In Arm and 844 for the Opt-Out Arm.

Table 2. Abstinence from smoking at the end of the intervention period by treatment arm

Outcome	Opt-In Arm N (%)	Opt-Out Arm N (%)	Adjusted OR (95% CI)
Patient Survey cohort (n = 632)	99/385 (25.7%)	63/247 (25.5%)	0.98 (0.61, 1.55)
EHR Cohort (n = 1,465)	244/939 (26.0%)	200/706 (28.3%)	1.13 (0.90, 1.40)

OR = Odds Ratio, CI = confidence interval, EHR = electronic health record

The Patient Survey Cohort completed a baseline survey prior to the start of the study and a follow-up survey at the end of the intervention period. People were considered abstinent on the follow-up survey if they reported they had not smoked a cigarette (even a puff) in the past 7 days (7-day point prevalence abstinence).

For the EHR Cohort, we included everyone who was listed in the EHR at baseline as currently smoking and had a visit with a participating nurse. For smoking status at the end of the intervention period, we used the most recent smoking status documented in the EHR.

Table 3. Assessment of patient attitudes, perceptions and reported care received

Post visit survey question	Opt-In Arm N (%)	Opt-Out Arm N (%)	Adjusted OR (95% CI)
Did the Nurse notify you that the Manhattan/ Brooklyn VA's goal is to refer all smokers to smoking cessation treatment? (Yes)	262 (87.6%)	241 (88.9%)	1.19 (0.58, 2.45)
Were you referred to smoking cessation treatment? (Yes)	119 (41.8%)	111 (42.2%)	1.07 (0.69, 1.66)
I was strongly encouraged to receive a referral for smoking cessation treatment? (Strongly agree/Agree)	194 (62.6%)	198 (69.7%)	1.36 (0.81, 2.27)
I felt forced to receive the referral to smoking cessation treatment? (Strongly agree/Agree)	61 (19.7%)	58 (20.4%)	1.06 (0.69, 1.63)
How would you rate the overall quality of your discussion with the Nurse regarding referral for smoking cessation treatment? (Excellent/Very good)	240 (77.4%)	219 (77.1%)	0.97 (0.64, 1.47)

OR = odds ratio, CI = confidence interval

Post-visit surveys were completed by 311 patients in the Opt-in Arm and 284 in the Opt-out Arm. Percentages for post-visit survey items were calculated based on the number of non-missing responses for each item.

The first two questions ("refer all smokers", "were you referred") were asked as yes/no. The third and fourth questions ("encouraged to receive a referral", "forced to receive the referral") were asked on a 5-point scale – strongly agree, agree, neither agree nor disagree, disagree, strongly disagree. The results shown for these two questions are the percent of people who reported strongly agree or agree. The fifth question ("overall quality") was asked on a 5-point scale – excellent, very good, good, fair, poor. The results shown for this question are the percent of people who reported excellent or very good.

Supplemental Table 1. Baseline characteristics of patient who completed a baseline survey (Patient Survey Cohort) and those in the EHR Cohort

Characteristic	**EHR Cohort**, N = 1645	**Survey Cohort**, N = 979
Sex		
Male	1530 (93%)	886 (91%)
Female	115 (7%)	93 (9%)
Age	64 (14)	64 (13)
Race		
White	571 (35%)	321 (33%)
Black or African American	802 (49%)	498 (51%)
Asian	36 (2%)	23 (2%)
Other/Unknown	236 (14%)	137 (14%)
Ethnicity		
Non-Hispanic	1273 (77%)	333 (79%)
Hispanic	319 (19%)	167 (17%)
Other/Unknown	53 (3%)	35 (4%)

Characteristics are presented as count (column %) or mean (SD) unless otherwise stated

Supplemental Table 2. Baseline characteristics of participating nurses who completed a baseline survey

Characteristic	**Opt in**, N = 15	**Opt out**, N = 16
Sex		
Male	3 (20%)	3 (19%)
Female	12 (80%)	13 (81%)
Age (years)	40 (31, 44)	56 (44, 61)
Race		
White	6 (40%)	4 (25%)
Black or African American	6 (40%)	6 (38%)
Asian	2 (13%)	3 (19%)
Other/Unknown	1 (7%)	3 (19%)
Ethnicity		
Non-Hispanic	10 (67%)	14 (88%)
Hispanic	2 (13%)	1 (6%)
Unknown	3 (20%)	1 (6%)
How many years have you been in practice?	10 (6, 20)	16 (12, 35)
Do you smoke cigarettes?		
Never smoked	7 (47%)	11 (69%)
Formerly smoked	8 (53%)	5 (31%)
During the last 7 days, on how many days did you do vigorous physical activities?	1 (1, 4)	3 (2, 5)
During the last 7 days, on how many days did you do moderate physical activities?	3 (2, 5)	5 (3, 5)
During the last 7 days, on how many days did you walk for at least 10 minutes at a time?	5 (5, 7)	7 (6, 7)
During the last 7 days, how much time did you spend sitting on a week day? (hours)	6 (5, 8)	5.5 (4, 8)

Characteristic	**Opt in**, N = 15	**Opt out**, N = 16
How many servings of fruit do you usually eat or drink each day?	2 (1, 3)	2 (2, 3)
How many servings of vegetable do you usually eat or drink each day?	1.5 (1, 3)	2 (2, 3)
In general, would you say your health is...?		
Excellent	0 (0%)	2 (12%)
Very good	5 (33%)	4 (25%)
Good	4 (27%)	5 (31%)
Fair	0 (0%)	3 (19%)
Unknown	6 (40%)	2 (12%)

For categorical variables, the numbers in the table are the number of nurses, with the percentile in parentheses. For continuous variables, the numbers are the median value with the interquartile range in parentheses.

Supplemental Table 3. Use of smoking cessation medications during the intervention period[1]

Survey Cohort (People who completed baseline survey), N = 979			
	Opt-In Arm	**Opt-Out Arm**	**OR (95% CI)**
Survey cohort[2]	N = 652	N = 327	
Medication use within 2 weeks of visit based on EHR			
Use of any smoking cessation medication	60 (9.2%)	38 (12%)	1.30 (0.84, 1.99)
Varenicline	5 (0.8%)	2 (0.6%)	0.80 (0.11, 3.72)
NRT (Combined or Mono Therapy)	48 (7.4%)	32 (9.8%)	1.36 (0.85, 2.17)
Bupropion	8 (1.2%)	9 (2.8%)	2.28 (0.86, 6.12)
Varenicline or combination NRT	18 (2.8%)	9 (2.8%)	1.00 (0.42, 2.19)
Medication use during the prior year based on EHR			
Use of any smoking cessation medication	131 (20.1%)	90 (28%)	1.51 (1.11, 2.06)
Varenicline	24 (3.7%)	6 (1.8%)	0.49 (0.18, 1.13)
NRT (Combined or Mono Therapy)	101 (15.5%)	80 (24.5%)	1.77 (1.27, 2.45)
Bupropion	26 (4.0%)	11 (3.4%)	0.84 (0.39, 1.68)
Varenicline or combination NRT	51 (7.8%)	30 (9.2%)	1.19 (0.74, 1.90)
Survey Cohort (Completed 2-year survey), N = 632			
	N = 385	N = 247	
Reported medication use during the prior year based on 2-year survey			
Use of any smoking cessation medication	153 (39.7%)	118 (48.8%)	
Varenicline	19 (4.9%)	15 (6.1%)	1.03 (0.49, 2.15)
NRT (Combined or Mono Therapy)	139 (36.1%)	110 (44.5%)	1.39 (0.55, 3.49)
Bupropion	16 (4.2%)	4 (1.6%)	0.30 (0.10, 0.92)
Effective therapy (Varenicline or combination NRT)	63 (16.4%)	51 (20.6%)	1.09 (0.67, 1.77)
Population-level cohort, N = 1645			
EHR cohort[2]	N = 939	N = 706	
Medication use within 2 weeks of visit based on EHR			
Use of any smoking cessation medication	138 (15%)	84 (12%)	0.78 (0.58, 1.05)
Varenicline	6 (0.6%)	5 (0.7%)	1.11 (0.32, 3.70)
NRT (Combined or Mono Therapy)	121 (13%)	72 (10%)	0.77 (0.56, 1.04)
Bupropion	17 (1.8%)	11 (1.6%)	0.86 (0.39, 1.82)
Varenicline or combination NRT	37 (3.9%)	24 (3.4%)	0.86 (0.50, 1.44)
Medication use during the prior year			
Use of any smoking cessation medication	274 (29%)	195 (28%)	0.93 (0.75, 1.15)
Varenicline	36 (3.8%)	16 (2.3%)	0.58 (0.31, 1.04)

NRT (Combined or Mono Therapy)	218 (23.2%)	164 (23.2%)	1.00 (0.79, 1.26)
Bupropion	62 (6.6%)	34 (4.8%)	0.72 (0.46, 1.09)
Varenicline or combination NRT	88 (9.4%)	71 (10.1%)	1.08 (0.78, 1.50)

EHR = electronic health record; OR = odds ratio; CI = confidence interval; NRT = nicotine replacement therapy.

[1] Percentages reflect the proportion of "any medication" users in each arm and period; medication categories represent "ever use," where patients with at least one prescription are included regardless of concurrent or subsequent medications.

[2] Patients included in the medication analysis were those who received at least one study health factor during the study period and were confirmed smokers via the most recent smoking-related health factor prior to the study period, reducing the survey cohort (N=1,363) to 684 and the population-level cohort (N=64,223) to 2,518.

For medication use within 2 weeks of a visit where the reminder was triggered, we used the EHR to determine whether they had a prescription filled for a smoking cessation medication at VA New York Harbor Healthcare System on or within 2 weeks of their first visit with a study nurse during the intervention period. Use of medications at other VA facilities or outside the VA was not assessed. Patients could receive more than one medication, so the sum of the individual medications is more than the number using any medication.

The survey cohort comprised those who completed a baseline survey prior to the start of the study (n = 979) and a follow-up survey at the end of the intervention period (n = 632). People were asked in the follow-up survey about which smoking cessation medications they had used in the prior year. Patients could report more than one medication, so the sum of the individual medications is more than the number using any medications.