Randomized Controlled Trial of a Computer-Based, Tailored Intervention to Increase Smoking Cessation Counseling by Primary Care Physicians

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OBJECTIVE: The primary care visit represents an important venue for intervening with a large population of smokers. However, physician adherence to the Smoking Cessation Clinical Guideline (5As) remains low. We evaluated the effectiveness of a computer-tailored intervention designed to increase smoking cessation counseling by primary care physicians.

METHODS: Physicians and their patients were randomized to either intervention or control conditions. In addition to brief smoking cessation training, intervention physicians and patients received a one-page report that characterized the patients' smoking habit and history and offered tailored recommendations. Physician performance of the 5As was assessed via patient exit interviews. Quit rates and smoking behaviors were assessed 6 months postintervention via patient phone interviews. Intervention effects were tested in a sample of 70 physicians and 518 of their patients. Results were analyzed via generalized and mixed linear modeling controlling for clustering.

MEASUREMENTS AND MAIN RESULTS: Intervention physicians exceeded controls on "Assess" (OR 5.06; 95% CI 3.22, 7.95), "Advise" (OR 2.79; 95% CI 1.70, 4.59), "Assist–set goals" (OR 4.31; 95% CI 2.59, 7.16), "Assist–provide written materials" (OR 5.14; 95% CI 2.60, 10.14), "Assist–provide referral" (OR 6.48; 95% CI 3.11, 13.49), "Assist–discuss medication" (OR 4.72; 95% CI 2.90, 7.68), and "Arrange" (OR 8.14; 95% CI 3.98, 16.68), all p values being <0.0001. Intervention patients were 1.77 (CI 0.94, 3.34, p=0.078) times more likely than controls to be abstinent (12 versus 8%), a difference that approached, but did not reach statistical significance, and surpassed controls on number of days quit (18.4 versus 12.2, p<.05) but not on number of quit attempts.

CONCLUSIONS: The use of a brief computer-tailored report improved physicians' implementation of the 5As and had a modest effect on patients' smoking behaviors 6 months postintervention.

KEY WORDS: smoking cessation; computer-tailored intervention; primary care.

Despite steady decline in the United States smoking prevalence over the past decade, roughly 45 million adults continue to smoke. Tobacco use remains the leading preventable cause of morbidity and mortality.[1] Although advances in high-intensity, clinic-based interventions have yielded moderate to high abstinence rates, such treatments reach few smokers. To reach a larger spectrum of smokers, effective low-intensity interventions are needed.

The Public Health Service Clinical Practice Guideline on Tobacco Use and Dependence[2] acknowledges the unique role health care providers play in promoting smoking cessation efforts by a large number of smokers in the community. The Guideline recommends that in every visit, physicians perform 5As: *ask* about smoking status; *advise* smokers to quit; *assess* readiness to quit; *assist* in quitting; and *arrange* follow-up. Over 70% of smokers see a physician annually,[3] making the medical visit a critical "teachable moment" for delivery of smoking cessation messages. Even brief interventions delivered by primary care physicians have been shown to increase cessation.[4,5]

Despite the potential impact, data indicate that few smokers are offered smoking cessation assistance during routine medical visits.[6–8] A medical chart review study revealed that only 21% of physicians provided smoking cessation counseling, and only 1.3% regularly recommended nicotine replacement therapy.[9] Patient reports also yield a low rate of physician delivery of smoking cessation services. One statewide survey documented that 51% of smokers were asked about smoking; 45.5% were advised to quit; 14.9% were offered assistance to quit; and 3% were scheduled for smoking-related follow-up.[10] Incorporating smoking cessation counseling into medical practice remains a challenge.

Technology offers another promising approach that has the potential to extend the reach of interventions that could otherwise only be offered by experienced clinicians. An expert system is a computer program that implements decisional algorithms similar to those an experienced clinician might practice. A system based on the stage-of-readiness framework evaluates an individual's smoking history and provides a personalized feedback report with counseling messages tailored to the smoker's readiness for change. Results from several studies indicate that providing smokers with a personalized, stage-based report enhances cessation rates.[11–17]

In the current study, we tested an intervention that integrates a brief, tailored expert-system report with face-to-face physician-delivered counseling in a primary care setting. Based on patients' assessment responses, a tailored report was generated and distributed to physicians and their patients who smoke. The current intervention was innovative in several ways. Unlike previous computer-tailored interventions that were directed toward patients only, the current intervention targeted both patients and physicians in "real time" during the medical visit. Also, to maximize its use in the time-strapped primary care environment, the tailored report was considerably shorter than the previously tested versions. The intervention had two objectives: (1) to bolster the rate at which physicians delivered smoking cessation services and (2) to increase patients' quit rates. Providing both the smoker and his/her physician with a report at the time of the health care visit was expected to cue physicians to deliver smoking cessation counseling as well as activate patients to elicit such counseling. In addition to its cuing function, the report was intended to compensate for limitations in physician time and knowledge of counseling techniques, thus bolstering treatment capacity. We hypothesized that the intervention would surpass usual care on physician implementation of the 5As, quit rate, length of quit attempts, number of quit attempts, and stage-of-change progression.

METHODS

Study Design and Recruitment

A randomized controlled trial was conducted to examine the effectiveness of a tailored smoking cessation intervention directed toward physicians and patients during a routine office visit. In partnership with a leading New York City (NYC)-managed care organization, we identified potentially eligible physicians in the four largest metropolitan boroughs, Bronx, Brooklyn, Manhattan, and Queens. The boroughs were divided into different geographic areas, and physicians were sampled from each area to ensure geographic representation.

The study was approved by the institutional review board. All participants underwent an informed consent process. Physician recruitment was initiated via facsimile invitation followed by telephone calls from a physician recruiter. Physicians who consented to participate were contacted by the study director and screened for eligibility. Eligibility criteria included internal or family medicine specialty, plans to continue practicing in current location for at least 1 year, at least 75 patient visits per week, primarily English-speaking patients, and fewer than 25% geriatric patients. All physicians were paid $150. Physicians in the intervention condition received an additional $50 in recognition of greater time commitments expected of them. A random number generator was used to assign physicians to intervention or usual care control. Physicians learned their group assignment after signing the informed consent. Physician recruitment occurred between September 2002 and May 2004. Of the total 579 physicians contacted by facsimile, 70 were successfully recruited and completed the study (see flowchart, Fig. 1).

Project staff screened patients in physicians' waiting rooms. All identified smokers were offered the opportunity to participate. Study staff continued to recruit at each physician office for up to 10 days or until 10 smokers were enrolled, whichever came first. Initial assessment was completed immediately before the patient's appointment and included information necessary to generate the report. The second assessment occurred immediately after the medical visit and contained questions regarding the physician's 5A performance. Patients in the usual care condition completed the same assessments but did not receive the report. Patients were contacted 6 months after the initial enrollment for a telephone follow-up interview to assess outcomes. Self-reported abstinence was biochemically validated with the use of a saliva–cotinine test.

Smokers were paid $20 for completing initial assessments and $10 for the follow-up interview. To be eligible, smokers were required to be at least 18 years old, to have smoked in the past 7 days, and to have smoked more than 100 cigarettes in their lifetime. Participants were also required to be English-speaking and to plan to retain their physician for the next 12 months. Of the total 5,826 smokers and nonsmokers screened, 580 met eligibility criteria and agreed to participate. Sixty-two were withdrawn due to computer malfunction, scheduling, or time constraint. A total of 518 smokers completed initial assessments; 465 completed the 6-month assessment (see Fig. 1).

Initial Patient Assessment

Several measures were used to tailor the expert-system report. The Contemplation Ladder assessed readiness to quit[18,19] based on the stages identified by Prochaska and DiClemente.[20] Patients were classified into: precontemplation (not considering quitting at all), contemplation (considering quitting in the next 6 months), preparation (planning to quit in the next 30 days), and action (recently quit smoking). The Fagerstrom Test for Nicotine Dependence[21,22] was used to measure dependence level. The Pros and Cons Scale was used to identify perceived positive and negative features associated with smoking.[23] The Self-Efficacy Scale identified main temptations to smoke and measured patients' confidence to not smoke in specific situations.[24] Additional information used to tailor the report included smoking quantity and duration, past quit attempt duration, and existing medical conditions exacerbated by smoking.

Smoking Cessation Expert-System Intervention

A health educator provided individual physician training in brief smoking cessation counseling based on the 5As Clinical
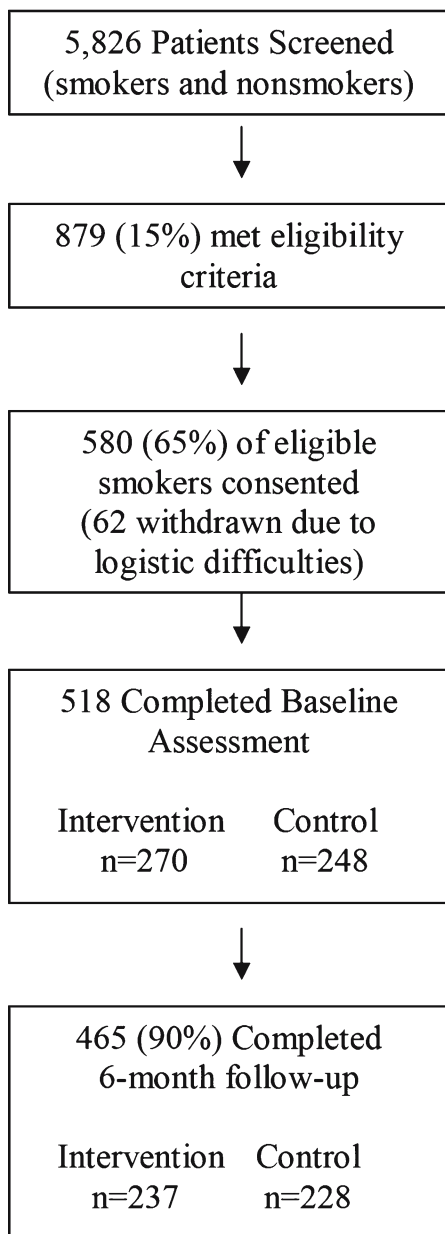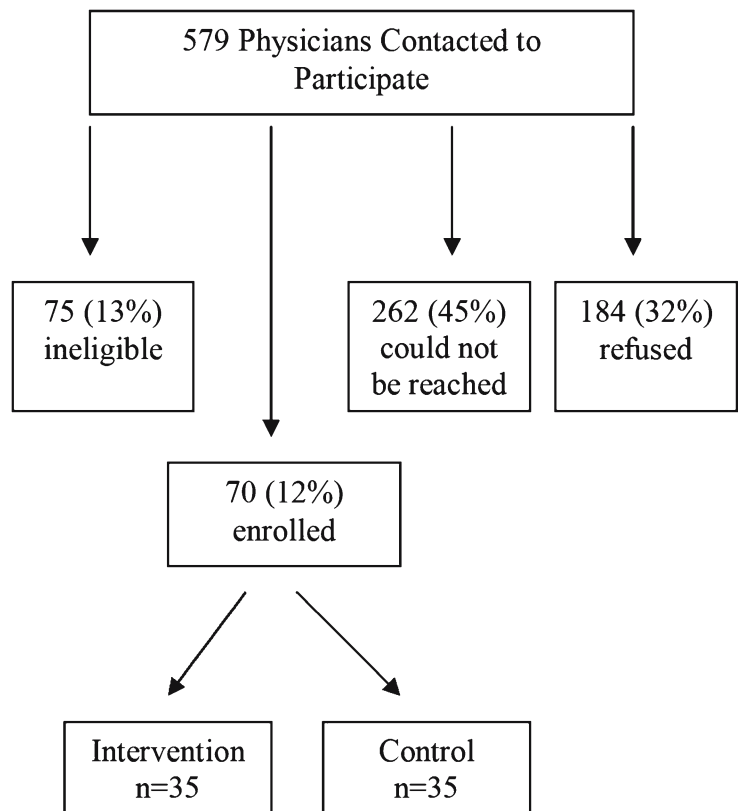
Patient Recruitment Flow-chart

Physician Recruitment Flow-chart

Figure 1. Patient and physician recruitment flowcharts.

Practice Guideline. The training was conducted during a 40-minute visit to the physician's office and followed an "academic detailing" approach.[25] The educator explained the use of the report and encouraged physicians to review it with each patient enrolled in the study. Physicians in the control condition were not given any training and were instructed to continue their usual smoking cessation practices.

The report contained smoking-related information and recommendations based on the information provided during the patient assessment (see Fig. 2 for sample). To minimize time burden and maximize user friendliness, the patient assessment lasted for 5–10 minutes, and the report was one page. Patients entered their information directly into a laptop

computer with minimal assistance from research staff. Two copies of the report were automatically printed upon assessment completion. Research staff gave one copy to the patient. They handed the other (physician report) to the office staff who placed it in the patient's chart for physician review before and/or during the appointment.

Outcome Measures

Performance of 5As. Physician 5A performance was measured via an exit assessment completed by patients. The assessment contained the following yes/no questions: "Did your doctor…" "ask whether you smoke?" (Ask), "ask whether you are ready to

Smoking Status Expert System Report

Name: John Doe   **Age:** 33

Smoking Status: Smokes 20 cigarettes/day   Medium Physical
                             Has smoked for 5-10 years   Dependence

Health Conditions   **Readiness to Quit Smoking:**
Worsened by Smoking: Asthma   Thinking About It
                             Overweight
Pros of Smoking: Enjoyment   **Longest Quit Period:**
                             Relaxation   A Few Weeks
Cons of Smoking: Feeling Foolish   **Main Temptation to Smoke:**
                                                               Others smoking, Stress

Recommendations:
1. Think about how smoking is affecting you. Do you know that smoking can worsen your asthma and problems associated with being overweight? Have you felt any physical effects of smoking?
2. It sounds like you enjoy smoking. Can you think of other things to do to relax (like go for a walk, listen to music, or read)? It also sounds like you feel that smoking helps you to relieve stress. Can you think of another way to relieve tension (like practicing deep breathing, taking a brisk walk, calling a friend)?
3. It sounds like you're feeling like people think you're foolish for continuing to smoke.
4. It's great that you were able to quit for a short while. How about trying out some ways to avoid being around smokers? Also consider trying out some new ways to cope with stress besides smoking.

Suggested Doctor-Patient Discussion Topics:
1. How smoking affects asthma and being overweight.
2. Provide a brochure about smoking, and discuss medications and programs that can help patient quit when ready.
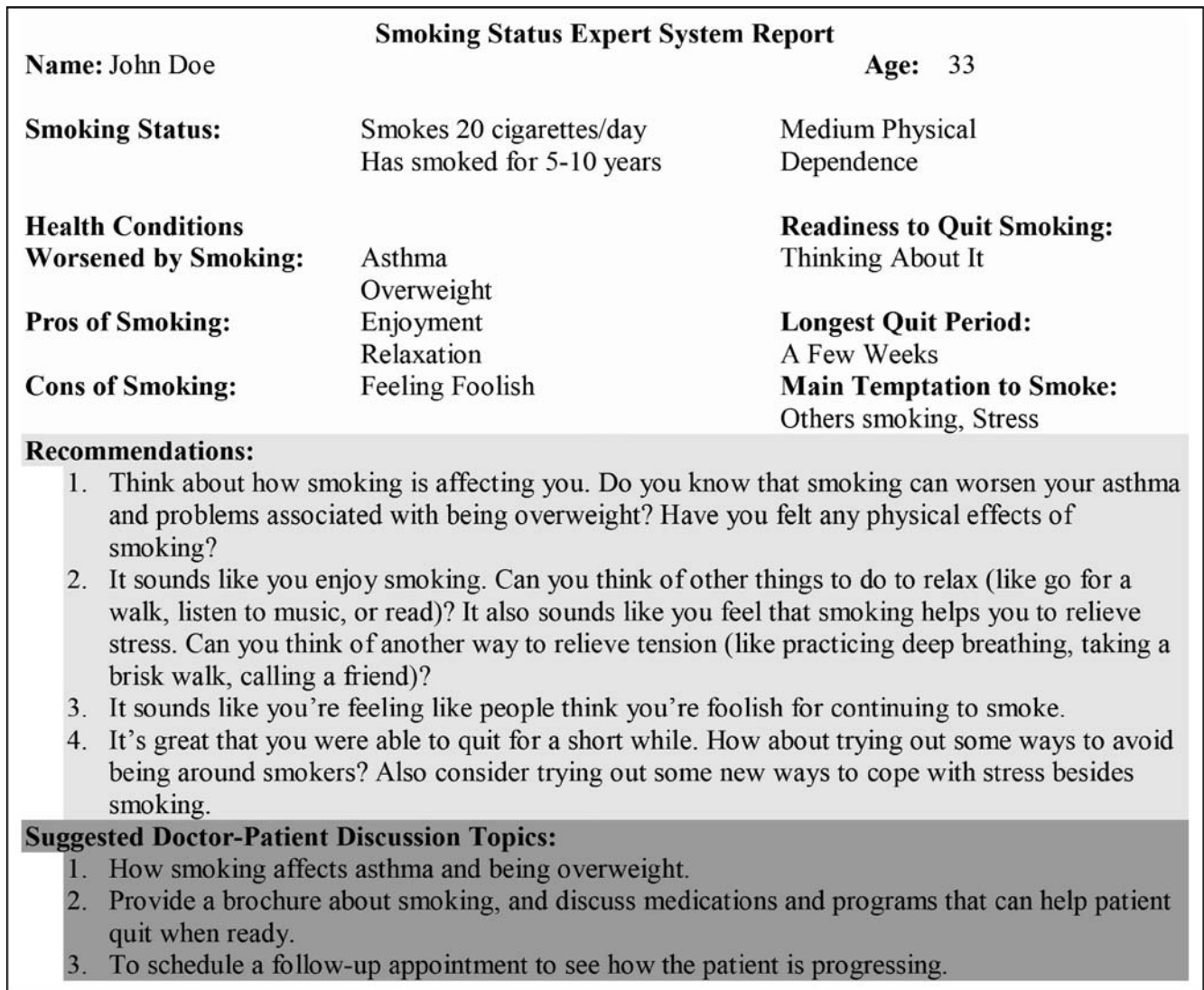3. To schedule a follow-up appointment to see how the patient is progressing.

Figure 2. Sample expert-system report.

quit?" (Assess), "advise you to quit smoking?" (Advise), "help you set goals about quitting?" (Assist 1), "give you written materials about quitting?" (Assist 2), "refer you to a quit-smoking program?" (Assist 3), "talk to you about quit-smoking medications?" (Assist 4), and "make a follow-up appointment to discuss smoking?" (Arrange). These questions have been previously assessed and found to yield reliable responses in a prior study of 3,037 adult smokers.[26]

Measures of Smoking Behavior. The primary outcome measure was 7-day point-prevalence abstinence, defined as not smoking at all in the past 7 days. Secondary smoking outcomes included longest quit attempt (in days), total number of 24-hour quit attempts, and stage-of-change progression. Saliva–cotinine samples were obtained from a 35% subsample of self-reported quitters. Abstinence was bioverified in 88% (14 of 16) of samples collected (cotinine <25 ng/ml), consistent with studies of self-report quit rates.[27] There was no evidence of differential reporting accuracy between intervention and control groups based on bioverification. Stage-of-change pro-

gression was assessed by examining the difference between baseline and 6-month stage.

Statistical Analysis

Based on computer-tailored intervention studies,[11,14] we assumed a 12.5 and 7.5% quit rate in the treatment and control groups, respectively. For power=0.80 and alpha=0.05, the *N* required to detect this low-moderate size group difference is 564. Descriptive statistics were used to characterize the sample at baseline. Differences between groups were determined using the Pearson's chi-square test for categorical variables and the independent sample *t* test for continuous variables. When differences were found, these variables were incorporated as covariates into subsequent outcome analyses. An important element of the design was nesting of patients within physician practice.

Physician performance of each of the 5As was analyzed using a hierarchic generalized linear model analysis of variance, controlling for baseline variables identified as covariates. Patient 7-day point-prevalence abstinence was analyzed via a generalized linear model using Logit Link function, with
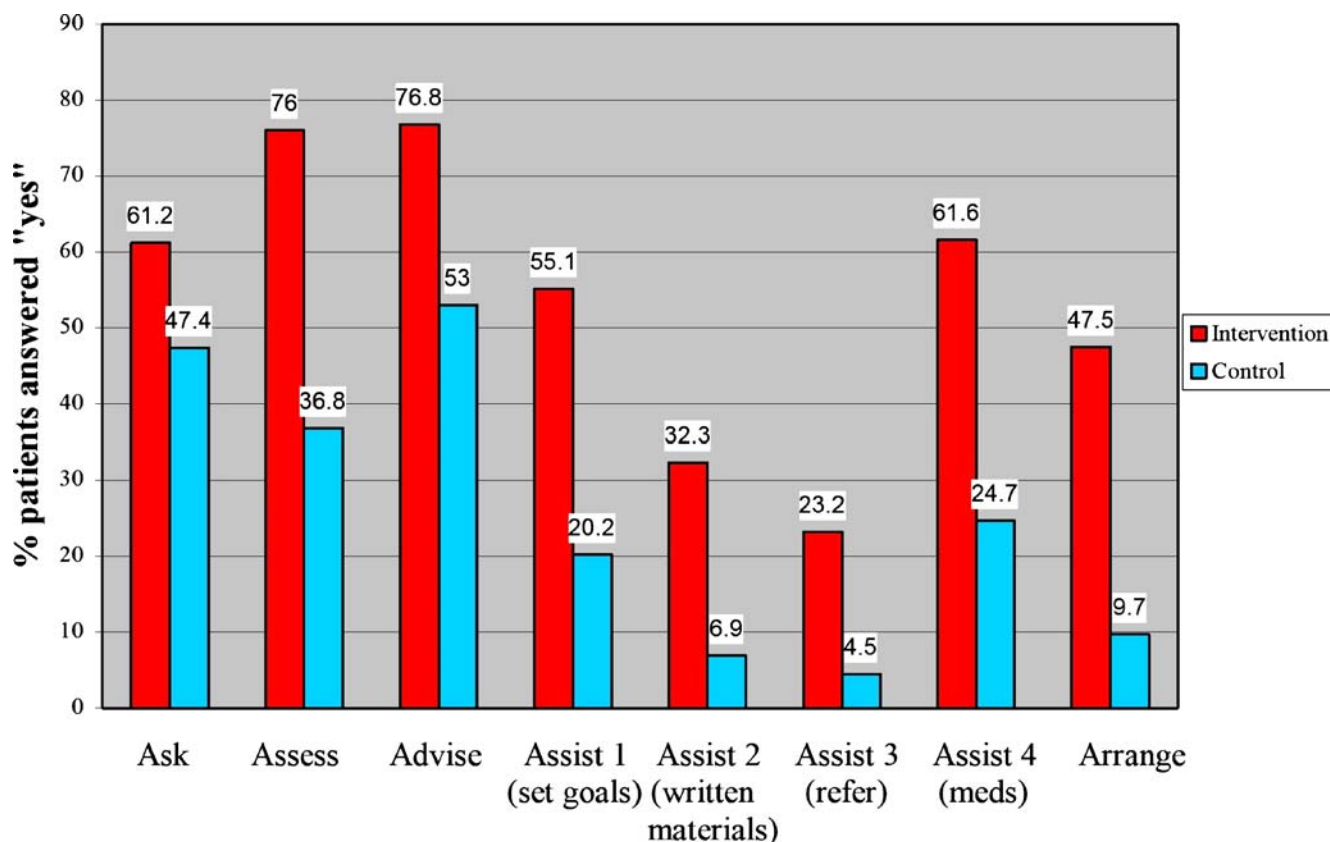
Figure 3. Patient-reported "5A" performance by physicians (*n*=518). Ratings are based on patient exit interviews occurring immediately postvisit. All group differences, except "Ask", are statistically significant.

physician as clustering variable. Mixed linear modeling, with physician as clustering variable, was used to examine longest quit attempt, number of quit attempts, and stage-of-change progression.

RESULTS

Sample Characteristics

Physician participants were 83% Caucasians, 13% Asians, and 1% African Americans. The average age of the physicians was 51.1 (SD=8.1); 74% were males. The average years postmedical school was 24.3 (SD=8.6). Physician specialty was 68% Internal Medicine and 32% Family Medicine. Four percent of the physicians were "current smokers", 67% were "never smokers", and 29% were "former smokers". There were no differences between physicians randomized to intervention and control groups on any measured demographic or medical practice factor.

Patient demographic and smoking characteristics are presented in Table 1. A majority of patients were Caucasians and females. Intervention and control groups did not differ on any demographic variables. Patients smoked an average of 14 cigarettes daily and reported mild-to-moderate nicotine dependence. Intervention and control groups differed only on chronicity of daily smoking: the intervention group had more smokers with >25–year smoking history. Consequently, number-of-years smoked was controlled in all smoking outcome analyses.

Physician 5A Performance

GEE generalized linear modeling indicated that intervention physicians exceeded controls on "Assess", "Advise", "Assist", and "Arrange" (*p*<0.0001) (see Fig. 3). Per patient report, twice as many intervention as control physicians assessed patients' readiness to quit smoking (OR 5.06; 95% CI 3.22, 7.95). More intervention than control physicians advised their patients to quit smoking (OR 2.79; 95% CI 1.70, 4.59). Two-to-four times as many intervention as control physicians provided quit-smoking assistance including: set goals (OR 4.31; 95% CI 2.59, 7.16), provided written materials (OR 5.14; 95% CI 2.60, 10.14), discussed smoking cessation medication (OR 4.72; 95% CI 2.90, 7.68), and referred to a quit-smoking program (OR 6.48; 95% CI 3.11, 13.49). Finally, intervention physicians arranged a follow-up to discuss smoking at 5 times the rate of control physicians (OR 8.14; 95% CI 3.98, 16.68).

Six-Month Smoking Cessation Outcomes

Smoking outcomes are presented in Table 2. Seven-day point-prevalence abstinence was higher in the intervention group (12%) than the control group (8%), a difference that approached, but did not reach significance (OR 1.77; 95% CI 0.94, 3.34, *p*=.078). Intervention patients surpassed controls on number of days quit but not on number of 24-hour quit attempts.

Stage-of-change progression was analyzed by creating a "change" score variable, calculated as the difference between baseline and 6-month stage scores. Intervention condition was a significant predictor of "change", indicating that a larger pro-

Table 1. Baseline Characteristics of Study Participants

	Intervention (*n*=270)	Control (*n*=248)
Age: M (SD)	43.5 (14.7)	42.8 (14.2)
Gender: % ♀	58	64
Race (%):		
Caucasian	61	63
African American	20	20
Other	19	17
Hispanic (%)	15	19
Education: % BA+	32	37
No. of cigs./day: M (SD)	13.3 (8.7)	14.4 (9.9)
Fagerstrom: M (SD)	3.5 (2.7)	3.8 (2.6)
Smoked daily: % ≤25 years	64.4	71.0*, *p*<0.05
% >25 years	35.6	29.0*, *p*<0.05
Longest quit attempt		
% ≤1 month	58.5	50.2
% >1 month	41.5	49.8
Stages of change (%)		
Precontemplation	5.6	8.5
Contemplation	53.7	50.0
Preparation	40.7	41.5

*Statistically significant difference between the groups.

portion of intervention than control patients displayed forward movement through the stages (*F*=3.84, *df*=465, *p*<0.05).

DISCUSSION

This study tested the effectiveness of a brief computer-tailored intervention to increase provision of smoking cessation counseling by physicians and the quit rate among their patients who smoke. Our primary finding is that physicians who received the intervention were more likely to perform the 5As. Specifically, the intervention increased the rate at which physicians advised patients to quit, and more than doubled the rate at which they assessed readiness to quit, assisted in quitting, and arranged follow-up. All "assist" and "arrange" activities, those that have been shown to be most problematic in terms of physician adherence,[6,8] were significantly increased by the intervention.

Despite the large intervention effect on physician 5A performance, 6-month smoking cessation rates were only modestly higher among patients who received the intervention, an effect that approached but did not reach statistical significance. The intervention did result in longer quit attempts, one of the strongest determinants of cessation success,[28] and greater stage-of-change forward movement, which have been associated with enhanced quit attempts.[19] The 12% quit rate observed among intervention patients is consistent with quit rates achieved by other interventions in primary care settings.[29–32] However, the control group cessation rate (8%) was higher than that predicted by secular trends,[33] resulting in a small between-group difference and treatment effect. One factor that may have contributed to the relatively high control-group quit rate is that smokers in the control condition were exposed to an active treatment ingredient. Namely, as part of the assessment, patients were asked about their smoking status and assessed for readiness to quit, which are two of the 5As. The assessment may have sensitized smokers in the control group to consider quitting smoking.

Another possible reason for the small cessation effect is the less than anticipated sample size and consequent reduction in statistical power to detect group differences. The average

patient caseload per physician was lower than that expected on the basis of focus groups conducted before study commencement. In addition, the proportion of patients identified as smokers (15%) was significantly less than the expected 20–30% found in other primary care studies[29,34] and less than the estimated 25% smoking prevalence in NYC when the study was designed. Thus, we did not attain our intended enrollment target. The low smoking base rate in the current study may reflect the 11% smoking prevalence decline observed in NYC, presumably attributable to comprehensive citywide tobacco control measures that were implemented concurrently.[35]

An important limitation of this study is that a minority of the physicians contacted to participate were enrolled because a large proportion refused participation or could not be reached. Although demographic information on nonparticipators is not available, physicians in the current study may be a highly select group.

Even though the intervention had only a modest effect on smoking behaviors, the innovative integration of computer technology during routine medical visits was highly effective in enhancing 5A adherence. In its impact on physicians' behavior, the current intervention compares favorably to other primary care interventions.[29,31,34,36,37] For instance, it produced more comprehensive improvements in 5A performance than interventions that featured a vital sign stamp[34] or a smoking assessment questionnaire only.[29] It also produced greater gains in "Advise" and "Assist" compared to a significantly more intensive, five-component intervention that included a physician tutorial, vital sign stamp, physician performance feedback, nicotine replacement therapy, and telephone counseling.[31] Smoking outcomes with the current intervention were also comparable to an intervention consisting of training physicians in brief cessation counseling.[36] Cessation rates surpassed those of an intervention consisting of a 2-hour tutorial plus prompt.[37] Because 70% of U.S. smokers visit their physician annually, even modest cessation rates can translate into significant public health benefit. Although other public health approaches, such as telephone quitlines, are available, physician advice and referral are important to maximize use of these resources.[38,39]

Another important aspect of this intervention is the minimal time burden and staff resources needed for implementation. Intervention physicians spent an average of 3.8 minutes discussing smoking. Minimal burden increases the likelihood of integration into a busy clinical practice. The main requirements for integration are availability of a patient-accessible computer with printer and encouragement of all smokers to complete the assessment before their physician visit. Incorporating computer-tailored programs into routine medical practice can be challenging. The current intervention addressed some previously identified barriers[40] by streamlining administration time and directly targeting patients who were current smokers.

Table 2. Smoking Cessation Outcomes 6 Months Postintervention:

Outcome Measure	Intervention (*n*=237)	Control (*n*=228)	*p*-Value
7-Day point-prevalence abstinence	12%	8%	0.078
Longest quit attempt in days: M (SD)	18.4 (36.7)	12.4 (29.6)	0.05
Number of 24-hour quit attempts: M (SD)	2.1 (3.4)	2.1 (3.5)	0.91

Research staff recruited patients into the current study. Although this practice helped to reduce demand on office staff, it diminished the number of smokers that could be reached and the possibility of readministering the intervention to returning smokers, both of which may enhance intervention impact. A manuscript describing cost effectiveness of the intervention is currently under review.

The current study shows that a brief computer-tailored intervention can significantly increase primary care physicians' implementation of the 5As and result in modest effects on smoking outcomes. This intervention holds promise in reaching the main objective of the Smoking Cessation Clinical Practice Guideline: to intervene with all smokers who visit their physician. Increased rates of guideline implementation can potentially have an enormous public health impact. Further research is needed to increase the potency of the intervention with regard to quit rates and to determine how best to integrate it into outpatient health care settings.

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