Available online at www.sciencedirect.com

SCIENCE DIRECT

Preventive Medicine 40 (2005) 249–258

Preventive Medicine

www.elsevier.com/locate/ypmed

The TEAM project: the effectiveness of smoking cessation intervention with hospital patients

Deborah J. Hennrikus, Ph.D.,[a,*] Harry A. Lando, Ph.D.,[a] Maribet C. McCarty, Ph.D., M.P.H., R.N.,[a] David Klevan, M.D.,[b] Neal Holtan, M.D., M.P.H.,[c] Jacquelyn A. Huebsch, Ph.D., R.N.,[d] Sharon Jestus, R.N.,[e] Paul R. Pentel, M.D.,[e] Donald Pine, M.D.,[f] Susan Sullivan, Ph.D., M.P.H.,[f] Karen Swenson, R.N., M.S., A.O.C.N.,[f] and John Vessey, Ph.D.[g]

[a] *Division of Epidemiology, School of Public Health, University of Minnesota, Minneapolis, MN 55454, USA*
[b] *HealthPartners Medical Group, Michigan City, IN 46360, USA*
[c] *St. Paul Division of Public Health, St. Paul, MN 55101, USA*
[d] *Regions Hospital, St. Paul, MN 55101, USA*
[e] *Hennepin County Medical Center, Minneapolis, MN 55415, USA*
[f] *Park Nicollet Health System, Minneapolis, MN 55440, USA*
[g] *Wheaton College, Wheaton, IL 60187-5593, USA*

Available online 8 July 2004

Abstract

Background. This study evaluated the effectiveness of three smoking cessation interventions for this population: (1) modified usual care (UC); (2) brief advice (A); and (3) brief advice plus more extended counseling during and after hospitalization (A + C).

Methods. Smokers (2,095) who were in-patients in four hospitals were randomly assigned to condition. Smoking status was ascertained via phone interview 7 days and 12 months post-discharge. At 12 months, reports of abstinence were validated by analysis of saliva cotinine. Intent to treat analyses were performed.

Results. At 7-day follow-up, 24.2% of participants reported abstinence in the previous 7 days. There were no differences between conditions. At 12-month follow-up, self-reported abstinence was significantly higher in the A + C condition (UC (15.0%) vs. A (15.2%) vs. A + C (19.8%)). There was no significant difference among conditions in cotinine-validated abstinence, however (UC (8.8%) vs. A (10.0%) vs. A + C (9.9%)).

Conclusions. These interventions for hospital in-patients did not increase abstinence rates. Features of the study that might have contributed to this finding were the inclusiveness of the participation criteria, the fact that pharmacological aids were not provided, and a stage-matching approach that resulted in less intensive counseling for participants unwilling to set a quit date.

Keywords: Hospital; Smoking cessation; Validation of self-report; Counseling

Introduction

Hospitalization is an opportunity to reach a large number of smokers at a time when they might be particularly receptive to advice to quit [1–4]. Smokers are more likely to use hospital services than are nonsmokers [5], so hospitalization represents a good access point for smoking cessation intervention, and the experience of impaired health might make smokers more receptive to health-related messages [2]. In addition, hospital smoking bans and the break in routine that occurs with hospitalization are conditions that should aid cessation efforts. In fact, quit rates after hospitalization are often significantly higher than the rates that would be expected in the general population, even in the absence of smoking cessation intervention [6,7].

There is a growing literature about the effectiveness of smoking cessation interventions in hospitals [8,9]. France et

* Corresponding author. Division of Epidemiology, School of Public Health, University of Minnesota, 1300 South Second Street, Suite 300, Minneapolis, MN 55454. Fax: +1-612-624-0315.
E-mail address: hennrikus@epi.umn.edu (D.J. Hennrikus).

0091-7435/$ - see front matter © 2004 The Institute For Cancer Prevention and Elsevier Inc. All rights reserved.
doi:10.1016/j.ypmed.2004.05.030

al. [9] reviewed studies performed before 1999 and found a total of 20 studies examining the effectiveness of hospital-based smoking cessation interventions that included a control or comparison condition. Results regarding efficacy of interventions were mixed; only eight found statistically significant differences between the control and intervention groups. As noted by the authors of this review, the studies differed in several important dimensions, including reach, intensity of in-hospital counseling, duration of relapse prevention counseling after discharge, and level of training of the intervention staff, which might explain differences in findings. A clear conclusion was that a relapse prevention program that is sustained during the 3- to 5-month period after discharge is an important determinant of success in hospital-based smoking cessation interventions. Less clear was the importance of a high intensity in-hospital intervention performed by staff who are highly trained in smoking cessation counseling and whose effort is dedicated to providing this service. However, Stevens et al. [4] and Hajek et al. [10] found that smoking-cessation interventions performed by hospital staff were inconsistently carried out and did not result in cessation rates that were significantly different from those of controls.

Many of the reviewed studies limited their reach to groups that might be more receptive to smoking cessation messages, such as patients with specific illnesses related to smoking [11–13] or those who were thinking seriously about quitting [14–16]. As would be expected, quit rates were typically lower in studies that had fewer exclusions. Three controlled trials did not exclude patients based on readiness to quit or type of illness. Stevens et al. [17] found a significant difference between intervention and control groups in long-term abstinence rates, but abstinence was not biochemically validated. The finding of no effect of counseling interventions on long-term abstinence in the other two studies could have been due to features of the interventions [4,18]. The relapse prevention components in both studies were briefer than the 3- to 5-month period identified as effective in the France and Glasgow review. Rigotti et al. [18] provided three counseling phone calls in the month after discharge from hospital to patients trying to quit. Stevens et al. [4] provided only one post-discharge counseling phone call and noted that the respiratory therapist interventionists failed to reach many of the patients assigned to the intervention condition.

The present study, the TEAM (Teachable Moment) Project, assessed systems-based interventions implemented in four hospitals in the Twin Cities area. A low-intensity intervention provided by doctors and nurses during regular patient care and a high-intensity intervention in which trained staff using a motivational interviewing approach provided one in-hospital counseling session and up to six counseling phone calls in the 6 months after discharge were compared with a modified usual care (UC) condition in which patients were provided with smoking cessation manuals, but no advice or counseling. The high-intensity condition included features identified as effective in previous studies, such as a strong relapse prevention component and well-trained counselors dedicated to the study. Unlike most previous studies of smoking cessation in hospital inpatients, recruitment was not limited to those with specific medical conditions or to those who were ready to quit. A question of particular interest was whether a treatment condition that included many of the components related to successful outcomes in other studies would be effective in a largely unrestricted patient population.

Method

Hospitals

Four hospitals participated in this study. Two were county facilities in downtown settings and two were private and were in suburbs. During the course of the study, one of the county hospitals was purchased by a managed care organization. The study was approved by Institutional Review Boards at the University of Minnesota and at each participating hospital.

Participants

Participants were drawn from general admissions to the four study hospitals. Patients were potentially eligible if they had smoked a cigarette in the week before admission and considered themselves to be regular smokers for at least 1 month during the year before admission. Patients who were pregnant and those with chemical dependency or psychiatric disturbances as the primary reason for admission were excluded from the study. Other eligibility requirements included age between 18 and 75 years, length of hospital stay of 24 h or greater, ability to understand the consent process, and availability for telephone contact. In addition, patients who were in severe physical or mental distress were not approached.

Participant recruitment

In each hospital, a research assistant obtained a list of all admissions from the previous day and then screened patients meeting age and admission diagnosis requirements for smoking status and other eligibility criteria. Research assistants then approached eligible patients for informed consent, asked consenting patients to complete a baseline interview, and randomized them to one of three treatment conditions by looking up the next available group assignment on a list on which the three conditions were randomly ordered within blocks of 30 assignments.

Intervention

The three treatment groups varied in intervention intensity. In the modified usual care condition (UC), participants

received two smoking cessation manuals tailored for hospital in-patients [19,20] and a directory of smoking cessation programs and resources in the community.

In the brief provider advice (A) condition, participants were given the smoking cessation manuals and the directory of community resources, and the research assistant placed labels in patient records to cue the nurses and physicians providing medical care to these patients to give brief (60-s) smoking cessation advice and to document that advice. Labels cueing physicians to provide advice were placed in patient charts in all four hospitals, but the location of the label to cue nurse advice was determined by consultations with nurses in each hospital about where they would be most likely to see and act on the prompt. The label that cued advice told the provider that the patient was a smoker who was participating in the study and included prompts to provide brief advice to quit, to mention that quitting is associated with positive health benefits and that the hospital stay can be an opportunity to quit, and to direct the patient to the cessation manuals that the research assistant had given them when they were enrolled in the study. The provider was asked to sign and date the label to indicate that he or she had provided advice.

An important feature of the provider advice (A) condition was active and frequent efforts to inform the providers about the study and to encourage them to provide smoking cessation advice when they saw a TEAM Project label. These efforts were led by TEAM Project physician and nurse investigators in each hospital and they varied by hospital. Promotional efforts included articles in hospital and staff newsletters; letters to physicians; informational sessions for nurses in each ward; presentations to physician groups; posters about the effects of smoking placed in nurse and physician lounges; small incentives for those who provided advice (e.g., US$2 gift certificates for the hospital coffee shop); entry into a monthly lottery for a US$50 gift certificate for nurses who documented advice; and snacks from the TEAM Project provided at the desk in each ward. In addition, the research assistant attempted to alert nurses when patients they were caring for had been randomized to a provider advice condition. Participants in the advice condition also received a letter after discharge signed by the physician and nurse investigators for their hospital that reiterated that their health care providers would like them to quit and asked them to read the smoking cessation manuals that they had received in the hospital and two additional pamphlets enclosed with the letter.

In the advice + counseling (A + C) condition, participants received the interventions delivered in the two other conditions (e.g., manuals, resource directory, brief provider advice, and a letter after discharge) plus a more extended bedside counseling session in the hospital and three to six telephone calls from a research nurse during the 6 months following discharge. If the nurse could not provide the first counseling session in the hospital, it was delivered over the phone as soon as possible after discharge. This usually occurred because the participant's hospital stay was very short. Research nurses used motivational interviewing [21] and relapse prevention [22] approaches, first assessing factors that might affect the participant's ability and willingness to quit, including stage of change and self-efficacy in relation to quitting, and then either counseling to increase motivation or discussing quit strategies, depending on the participant's current stage of readiness to change. Counselors encouraged undecided participants to examine their ambivalence about quitting and voice reasons for quitting. Counseling for those who decided to quit focused on review of the barriers to cessation, strategies to cope with urges to smoke, and development of an action plan for quitting. Maintaining motivation to stay off cigarettes and generating strategies to cope with continuing urges to smoke were the focus with participants who had succeeded in quitting smoking. Nicotine replacement therapy (NRT) was available over the counter during the period of the study and bupropion (Zyban) was available by prescription, but neither NRT nor bupropion was available free of charge from the study. However, the nurse counselors provided information about cessation aids and helped to direct A + C condition participants who needed further help to other smoking cessation programs in the community. Counseling sessions were more closely spaced after the participant had set a quit date to avoid relapse. The protocol called for counseling sessions to occur 2–3 days, 1 week, 2–3 weeks, 1 month, 3 months, and 6 months after the quit date. Counseling calls were scheduled roughly 1 month apart for participants who had not yet set a quit date, but the protocol for timing of calls based on a quit date and counseling to develop an action plan was initiated if the participant set a date. If the participant had not set a quit date after 2–3 sessions and he or she indicated no desire for further sessions, counseling was discontinued. The flexibility of this counseling approach is consistent with recommendations of the 2000 clinical practice guideline: Treating Tobacco Use and Dependence [23].

Research nurses received about 12 h of initial training in smoking cessation counseling and were provided with a detailed manual that included counseling guidelines and general information about the health effects of smoking, quit techniques, and pharmacological aids for smoking cessation. Training sessions included didactic presentations and role-playing. Throughout the study, counselors met regularly to review cases and discuss problems they were encountering with participants.

Data collection

A baseline interview was conducted in the hospital before randomization to treatment. Follow-up interviews were conducted by the Division of Epidemiology's Telephone Survey Center 7–18 days (median = 9 days, mean = 9.4 days) and 12 months (median = 369 days, mean = 373.1

days) after hospital discharge. Having a window of 12 days to reach subjects for the initial follow-up interview was not optimal in that those reached at the end of the window would have had more time to quit or relapse before the interview took place. Although overall estimates of quit rates might have been affected by this problem, there were no significant differences among the conditions in time between discharge and the first follow-up interview.

Measures

Demographic characteristics measured at baseline included age, gender, ethnicity, marital status, and education.

To determine smoking status at baseline, respondents were first asked if they had ever smoked cigarettes on a regular basis, that is, more than 100 cigarettes in their lifetimes. Those who had smoked regularly were then asked whether they now smoked cigarettes. If they were not current smokers, they were asked if they had smoked in the 7 days before hospitalization and, if so, whether there had been a period of at least 1 month in the past year when they generally smoked every day. Other smoking variables measured at baseline included number of cigarettes smoked per day (daily smokers only) or per week (occasional smokers); age of initiation of smoking; number of years as a smoker; stage of change [24]; level of addiction to nicotine as indicated by a Fagerstrom scale item (time between waking and the first cigarette of the day [25]); percentage of friends who were smokers; and level of self-efficacy for cessation measured by a single item that asked participants to rate on a scale from 0 to 10 their confidence that they could quit permanently if they decided to do so.

The main cessation outcome assessed during the follow-up was 7-day point prevalence of smoking, that is, participants were asked whether they had smoked even a puff or used other tobacco products in the previous 7 days [26]. At the 12-month interview, they were also asked whether they considered themselves to be current smokers and whether they were currently using nicotine replacement products. At the 7-day interview, subjects who had not smoked or used tobacco products in the previous 7 days were considered to be abstinent by self-report. At the 12-month interview, subjects who reported not using tobacco products in the previous 7 days, not considering themselves current smokers, and not using nicotine replacement products were considered abstinent by self-report. Participants who reported abstinence during the 12-month interview were asked to provide a saliva sample to test for cotinine, a metabolite of nicotine. If respondents consented to do so, they were sent a kit with materials for saliva collection and, 3 days later, were sent a postcard reminding them to return the sample. Those who failed to return the sample within 9–12 days of the original mailing received a telephone reminder and, if necessary, were mailed a second kit. Those who returned a sample by mail were sent an incentive payment of US$25. This method of collecting saliva samples for biochemical validation has been used in previous studies [27].

Discharge diagnosis was based on information abstracted from the participant's medical record by hospital personnel trained in nosologic coding. Information on primary and secondary discharge diagnoses, in the form of codes based on the International Classification of Diseases, 9th version, Clinical Modification (ICD-9-CM) [28], was returned to the university. The participants' primary discharge diagnosis was then classified as smoking-related or not based on classifications in the Surgeon General's Report on the health consequences of smoking [29,30]. The method of classification is further described in Lando et al. [31].

For participants in the two provider advice conditions (A and A + C), charts and nursing records were audited to determine whether providers had documented smoking cessation advice by initialing stickers that prompted them to give advice. Research nurses completed a form after each counseling session with a participant in the A + C condition that noted the timing and length of counseling sessions.

Analysis

Analyses were conducted using the SAS statistical package, version 8.1 [32]. The outcome variable, abstinence from tobacco use, is dichotomous and as such, multivariate analyses were conducted using logistic regression techniques. Because cotinine samples and information about the use of nicotine replacement products were not collected during the 7-day interview, analyses of these data were conducted using only self-reported use of tobacco products as the outcome. Analyses of the 12-month data were conducted using two different versions of the outcome variable: self-reported abstinence; and self-report adjusted for the results of the cotinine analyses. For each follow-up, patients who refused the interview or who could not be contacted were considered smokers (intent to treat analysis). In the cotinine-corrected 12-month outcome, those with cotinine values greater than or equal to 15 ng/ml or who refused or failed to provide a saliva sample were also considered smokers. Subjects who had died or who were too ill to participate were excluded from analyses. The Mantel–Haenszel test for homogeneity of effects was performed for each of these outcomes to determine whether the results from the four hospitals could be pooled. Chi-square analyses of the relationships between treatment condition and each outcome measure were performed. Finally, in an effort to examine the effect on outcome of accepting patients regardless of stage of change or diagnosis, separate logistic regression analyses were run to examine the relationships of stage of change and the presence of a smoking-related illness to each of the 12-month cessation variables.

Results

Participant recruitment and follow-up rates

Fig. 1 is a CONSORT flowchart that describes recruitment, intervention, and follow-up rates [33]. Research assistants screened 55,120 patients during the period from January, 1997, to June, 1999. Thirteen thousand seven hundred thirty-one (24.9%) were smokers and, of those, 5,166 patients were eligible for study participation and 3,988 were approached for consent. We enrolled 2,095 patients (52.5% of patients approached for consent). Major reasons for ineligibility of identified smokers were admission for a psychiatric problem or chemical dependence (18.7% of all subjects approached for consent), unavailability for follow-up because of a lack of a phone (6.4%), too ill to participate (10.1%), and length of stay less than 24 h (8.2%). That 22.8% of those eligible for the study were not approached for consent was largely due to the brevity of many hospital stays. Study staff made multiple attempts to talk to patients eligible for the study, but patients were often unavailable (e.g., sleeping, away for tests and procedures, busy with visitors).

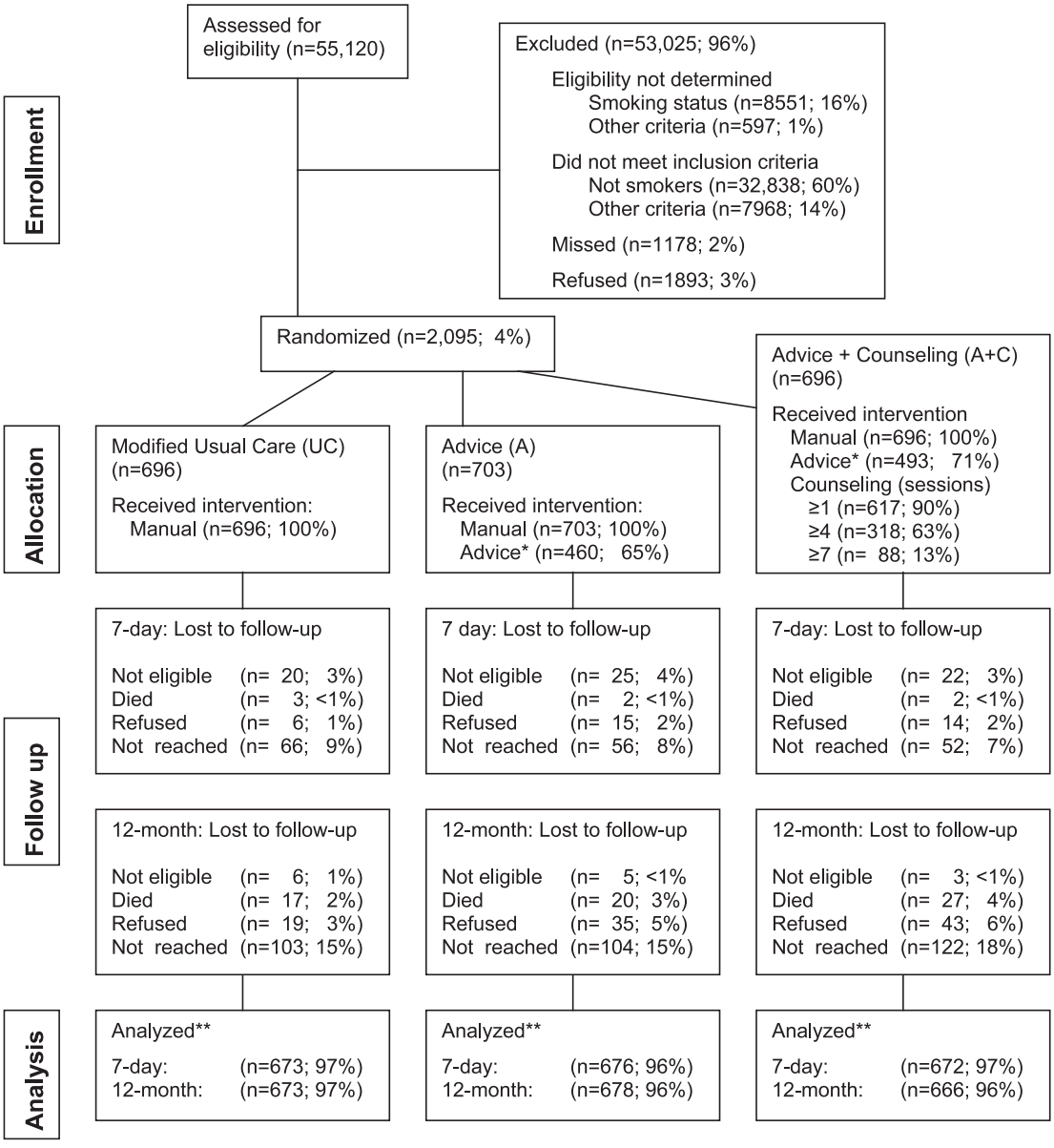

Fig. 1. Flow of patients through each stage of the study.

Of 2,095 participants enrolled in the study, 1,812 (86.5%) completed the first follow-up interview and 1,591 (75.9%) completed the final follow-up. Completion rates were very similar among the study conditions for the 7-day interviews. The completion rate at the 12-month follow-up was somewhat lower in the advice + counseling (A + C) group due to higher rates of refusal and failure to reach the participant. Separate logistic regression analyses for each follow-up occasion in which interview completion was the dependent variable and participant characteristics were included as covariates showed that loss to follow-up was not significantly related to study condition at either the 7-day or the 12-month follow-up, however. Those whose educational level was no greater than high school graduation, those of African-American ethnicity, and those in the precontemplation and preparation stages of change were significantly less likely to complete interviews at both the 7-day and the 12-month follow-ups. Males were significantly less likely to complete the 7-day interview, but there was no difference between the sexes in completion of the 12-month interview.

Table 1 presents the characteristics at baseline of participants in each of the three treatment conditions. There were no outstanding differences between the groups on these baseline characteristics.

Table 1
Characteristics of participants randomized to the study conditions

Characteristic	Modified usual care (UC) (n = 696)	Advice (A) (n = 703)	Advice + counseling (A + C) (n = 696)
Male	323 (46.4%)	331 (47.1%)	335 (48.1%)
Mean age and (SD) in years	47.1 (13.2)	47.9 (13.1)	47.5 (13.2)
Education			
High school or less	337 (48.6%)	380 (54.2%)	347 (50.0%)
Some college	243 (35.1%)	222 (31.7%)	244 (35.1%)
College graduate	113 (16.3%)	99 (14.1%)	105 (15.1%)
Married	380 (54.7%)	365 (52.1%)	366 (52.7%)
Ethnicity			
White	551 (79.2%)	541 (77.5%)	547 (78.9%)
Black	115 (16.5%)	114 (16.3%)	113 (16.3%)
Other	30 (4.3%)	43 (6.2%)	33 (4.8%)
Stage of change			
Precontemplation	113 (16.4%)	139 (20.0%)	106 (15.3%)
Contemplation	298 (43.1%)	301 (43.4%)	335 (48.5%)
Preparation	280 (40.5%)	254 (36.6%)	250 (36.2%)
First cigarette of day			
Within 5 min	261 (37.8%)	281 (40.3%)	284 (41.0%)
6–30 min	216 (31.3%)	220 (31.5%)	192 (27.8%)
31–60 min	86 (12.5%)	81 (11.6%)	93 (13.4%)
More than 60 min	127 (18.4%)	116 (16.6%)	123 (17.8%)
Confidence in ability to quit/mean (SD) of 0–10 scale	7.0 (2.8)	6.8 (2.8)	6.9 (2.7)
Age of starting smoking			
14 years or younger	185 (26.7%)	180 (25.8%)	181 (26.0%)
15–16 years	180 (26.0%)	188 (26.9%)	189 (27.2%)
17–18 years	137 (19.8%)	154 (22.0%)	137 (19.7%)
19 years or older	190 (27.5%)	177 (25.3%)	188 (27.1%)
Smoking-related diagnosis	217 (31.5%)	182 (26.2%)	208 (31.0%)
Percentage of friends who are smokers			
Almost all	207 (29.8%)	227 (32.6%)	219 (31.7%)
More than half	62 (8.9%)	66 (9.5%)	74 (10.7%)
About half	166 (23.9%)	149 (21.4%)	125 (18.1%)
Less than half	117 (16.8%)	115 (16.5%)	138 (19.9%)
Almost none	130 (18.7%)	134 (19.2%)	129 (18.6%)
Hospital			
A	139 (20.0%)	136 (19.4%)	138 (19.8%)
B	290 (41.7%)	290 (41.3%)	287 (41.2%)
C	158 (22.7%)	164 (23.3%)	156 (22.4%)
D	109 (15.7%)	113 (16.1%)	115 (16.5%)

Intervention fidelity

Fig. 1 provides information about intervention rates. All patients enrolled in the study received the smoking cessation manuals. The medical records of participants in the advice (A) and the advice + counseling (A + C) conditions were audited to determine whether providers had documented provision of brief smoking cessation advice by initialing the advice reminder labels. Physician reminder labels were available for audit for 96.2% of the relevant charts and nurse reminder labels were available in 93.3%. According to documentation on the labels, 47.5% of participants in these conditions received brief advice from at least one physician, 51.2% of participants in these conditions received advice from at least one nurse, and 72.0% received advice from at least one source. There were no differences between the A and the A + C conditions in brief provider advice rates, but there was a significant difference in rates among hospitals: rates of advice from at least one source ranged from 58.3% in Hospital A to 90.7% in Hospital D (chi-square = 80.84, $P < 0.0001$).

Examination of counseling records indicated that 590 (88.6%) of the 666 participants in the A + C condition received at least one counseling session and 37.2% received five or more; the median number of sessions provided was 4. Almost half (43.5%) of the initial counseling sessions were conducted on the phone soon after discharge rather than in the hospital; the median length of the initial session was 20 min, but 25% of these sessions were 30 min or longer. The median length of phone sessions was 10 min, but phone calls ranged in duration from very brief (1 min) to more than 40 min.

Quit rates

Mantel–Haenszel tests for homogeneity of effects found no differences among hospitals in the relationships between treatment conditions (UC vs. A and UC vs. A + C) and each of the smoking outcome variables, indicating that results could be pooled over hospitals. Five hundred six participants (27.9% of those completing the interview; 24.2% of all enrolled participants) reported quitting on the 7-day survey; 1,119 participants (61.8% of those completing the

interview; 53.4% of all enrolled participants) reported a quit attempt that lasted at least 24 h.

A total of 336 participants (21.1% of those completing the interview; 16.0% of all enrolled participants) reported not using tobacco or nicotine replacement products in the previous 7 days on the 12-month survey, but only 241 of these provided analyzable saliva samples. Table 2 details the rates at which saliva samples were returned by participants who reported abstinence on the 12-month interview. Small numbers of participants refused to provide samples and some were not asked because they were currently using nicotine replacement products. Larger numbers agreed to return a sample, but did not. Of the 241 samples analyzed, 48 (19.9%) had concentrations of cotinine consistent with being smokers (i.e., equal to or greater than 15 ng/ml). The number of disconfirmations was greatest in the advice + counseling (A + C) condition. An analysis of the occurrence of any problem with cotinine value or provision (i.e., disconfirmation or refusal or failure to provide a sample) by condition among those interviewed at 12-month follow-up indicated that problems were significantly related to study condition (chi-square = 12.06, $P = 0.0015$): problems were significantly more likely to occur in the advice + counseling condition (9.9%) than in the modified usual care (6.1%) or advice (5.2%) conditions.

Table 3 presents results of bivariate analyses of the 7-day self-reported quit rates and 12-month self-reported and cotinine-validated quit rates. There were no significant differences in abstinence among the three study groups at the 7-day follow-up interview. The abstinence rate was significantly higher in the advice + counseling condition in the 12-month follow-up self-report data, but this difference was not significant in the cotinine-corrected analysis. The advice condition was not significantly different from the usual care condition in either analysis. The same pattern of results was found in multivariate analyses that controlled for possible moderating variables.

Table 2
Number of participants available for follow-up by study condition

	Modified usual care (UC)	Advice (A)	Advice + counseling (A + C)
Subjects available for analysis	673	678	666
Eligibility for saliva sample			
Lost-to-follow up[a]	122 (18%)	139 (21%)	165 (25%)
Not eligible			
Has smoked in previous 7 days	432 (64%)	420 (62%)	352 (53%)
Using NRT	16 (2%)	12 (2%)	15 (2%)
Considers self a smoker	2 (<1%)	4 (1%)	2 (<1%)
Abstinent (eligible)	101 (15%)	103 (15%)	132 (20%)
Saliva sample return and analysis among those eligible			
No sample provided			
Refused to provide sample	4 (1%)	2 (<1%)	4 (1%)
Did not return sample	20 (3%)	22 (3%)	39 (6%)
Technical problems[b]	4 (1%)	2 (<1%)	4 (1%)
Returned sample	74 (11%)	78 (12%)	89 (13%)
Disconfirmation of self-report (≥15 ng/ml cotinine)	15 (2%)	10 (1%)	23 (3%)

[a] Refused or not reached at 12-month interview.
[b] Subjects not asked for saliva in error or saliva not analyzed due to technical problems.

Table 3
Relationship between study condition and abstinence at the 7-day and the 12-month interviews

Group	*N* per group	*n* (%) quit	Chi-square	*P*
7-day follow-up: self-report data intent to treat analysis				
Modified usual care	673	175 (26.0%)		
Advice	676	162 (24.0%)		
Advice + counseling	672	169 (25.2%)	0.84	>0.05
12-month follow-up: self-report intent to treat analysis				
Modified usual care	673	101 (15.0%)		
Advice	678	103 (15.2%)		
Advice + counseling	666	132 (19.8%)	7.17	<0.05
12-month follow-up: cotinine-corrected intent-to-treat analysis				
Modified usual care	673	59 (8.8%)		
Advice	678	68 (10.0%)		
Advice + counseling	666	66 (9.9%)	0.75	>0.05

Logistic regression analyses examining the relationships between stage of change, treatment condition, and the 12-month outcome variables found that stage of change was significantly related to both self-reported and cotinine-corrected 12-month quit rates: precontemplators had lower quit rates than did contemplators or those in preparation. Self-reported quit rates for precontemplators, contemplators, and those in preparation were 7.2%, 19.1%, and 18.1%, respectively, while the corresponding cotinine-corrected rates were 2.9%, 12.6%, and 9.2%. The interaction between stage of change and treatment condition was not significant for either outcome variable.

Logistic regression analyses examining the relationship between having a smoking-related diagnosis, treatment condition, and the 12-month outcome variables found a significant interaction between diagnosis and treatment condition for both outcomes. Quit rates were higher among those with smoking-related diagnoses in each treatment condition, but the difference was more pronounced in the provider advice condition. For the cotinine-corrected outcome, for instance, quit rates for those with a smoking-related diagnosis vs. those without such a diagnosis were 13.0% vs. 7.0% in the modified usual care condition, 22.4% vs. 5.6% in the advice condition, and 14.2% vs. 8.4% in the advice plus counseling condition.

Discussion

Advantages of this study were a large sample of patients from a diverse set of hospitals, biochemical validation of self-reported cessation, and the inclusion of a comparison group that received only smoking cessation manuals. The

most intensive condition included many elements identified as effective in previous studies, such as a long-term relapse prevention component and well-trained counselors dedicated to the study. It was therefore a relatively strong test of the effectiveness of smoking cessation interventions in a general admissions population of hospital in-patients.

Results of the interview conducted 7–18 days after discharge from the hospital provide evidence that hospitalized patients can be engaged in smoking cessation programs and that this engagement will often result in efforts to quit: 52.5% of subjects who were invited to participate in a smoking cessation study consented and about half of those attempted to quit smoking during the period immediately following discharge and were able to stay off cigarettes for at least 24 h and one-quarter reported not using tobacco for a period of at least 7 days. This was true of participants in all three treatment groups. The hospital stay is a promising recruitment point for smoking cessation intervention.

The study results do not provide support for the interventions used in the present study, however. There was no difference among treatment groups in short-term (i.e., 7–18 days after discharge from hospital) abstinence rates. There was a significant difference in self-reported abstinence 12 months after discharge: the cessation rate in the advice + counseling condition (19.8%) was higher than those in the modified usual care (15.0%) and advice (15.2%) conditions. However, this difference disappeared when self-reported results were corrected for the results of biochemical validation.

It is difficult to compare the overall quit rates found in this study with those of other studies because of differences among studies in eligibility criteria, intensity of intervention, and extent of loss-to-follow-up, a factor that greatly affects quit rates in an intent-to-treat analysis. The validated long-term quit rates in the present study are somewhat higher than those found by Rigotti et al. [18] (i.e., 8.1% in the intervention group and 8.7% in the control group), in a study with an unrestricted sample and a weaker relapse prevention component, and Miller et al. [15] (i.e., 20%, 22%, and 27% in the usual care, minimal intervention, and intensive intervention groups, respectively), in a study that was restricted to patients ready to quit, and that had a strong relapse prevention component, free nicotine replacement therapy, and little loss-to-follow-up. An examination of subgroup results in the present study indicated that inclusiveness did depress overall quit rates: precontemplators and patients who did not have a smoking-related diagnosis had lower 12-month quit rates. For the most part, the inclusion of these groups did not affect abstinence rates in one condition more than the others, however.

A second factor that may have led to lower overall quit rates was that pharmacological aids for smoking cessation were not provided. Although counselors provided information about nicotine replacement products and bupropion, these were out of the financial reach of many of the participants. Previous hospital-based research suggests that greater use of pharmacological aids in conjunction with the relapse-prevention program may have produced better results [8].

Finally, it should be noted that the counseling in the A + C condition was discontinued if the patient had not set a quit date after 3–4 counseling sessions. Consequently, only 63% of the participants in the advice and counseling group received four or more counseling sessions and only 13% received the maximum possible number of sessions. We believe that this was a reasonable approach given that the participants were not selected based on readiness to quit: multiple calls to patients who indicated little interest in making concrete steps toward quitting even after counseling to increase motivation did not seem warranted or practical. This meant, however, that many subjects in the counseling condition did not receive as intensive an intervention.

The discrepancy between self-report and cotinine-corrected results at 12-month follow-up and the finding that the A + C condition had higher rates of disconfirmation and failure to return samples is perplexing. Other studies of smoking cessation in hospital patients have reported low levels of biochemical validation [15,18]. Rigotti et al. [18] confirmed self-reported nonsmoking in only 54% of the 82 patients from whom they requested saliva samples at 6-month follow-up. Unlike the present study, the differences in confirmation rates between the study conditions were not significant in either the Miller et al. or the Rigotti et al. studies, but in the latter the difference was in the expected direction (60% in the control group vs. 48% in the intervention group). The differences in disconfirmation between conditions in the present study are somewhat consistent with the conclusion of Velicer et al. [34] that validation of self-report, although not necessary in surveillance studies or those testing very low intensity treatments, is necessary when testing more intensive interventions. It should be noted, however, that the disconfirmation rate in even the low intensity modified usual care (UC) condition was 44%, a rate similar to that found in the control group in the Rigotti et al. [18] study. Even though other studies of hospital in-patients have not reported differences in disconfirmation between conditions, the results of the present study raise strong cautions about relying on self-report to determine the outcome in this setting.

It should be noted that a major reason for disconfirmation of self-report in the present study was failure to return saliva samples. Of the self-reported abstainers asked to provide saliva samples, 14% provided samples that tested positive for cotinine, 3% refused to provide a sample, and 25% agreed to provide a sample but did not. Rigotti et al. [18] also reported that the major reason for disconfirmation of self-report in their study was failure to obtain a sample, even though a financial incentive was provided and sample collection was made as easy as possible for the participant. Failure to provide samples in the present study could have

been due to several causes, only one of which is reluctance to admit to smoking. The time to provide the sample, complete the accompanying brief survey, and mail these items, although brief, may have constituted a significant barrier. The relationships of both loss to follow-up and disconfirmation of self-reported abstinence with treatment condition in this study indicate that intent to treat analysis and validation of self-report are necessary, but it is important to remember that they probably provide conservative estimates of abstinence rates and they pose significant problems for large population-based studies with lengthy follow-up periods. We believe that the true results of the study are somewhere between the self-reported quit results and the cotinine-corrected intent-to-treat results. The loss to follow-up and disconfirmation rates found in this study also point to the importance of improving methodologies both for reaching participants for follow-up and for obtaining samples for biochemical validation of self-report.

Rigorous reviews of the literature have concluded that strong smoking cessation interventions for hospital inpatients are effective [6,8]. The reasons for the lack of effect in the present study are unclear, but the results raise a cautionary note both for hospital-based smoking cessation interventions and using self-report to evaluate outcome in hospital-based programs.

Acknowledgment

This research was supported by grant HL54132 from the National Institutes of Health.

References

[1] Orleans CT, Kristeller JL, Gritz ER. Helping hospitalized smokers quit: new directions for treatment and research. J Consult Clin Psychol 1993;61:778–89.
[2] Emmons KM, Goldstein MG. Smokers who are hospitalized: a window of opportunity for cessation interventions. Prev Med 1992;21:262–9.
[3] Goldstein MG. Missed opportunities to assist hospitalized smokers. Am J Prev Med 1999;17:317–8.
[4] Stevens VJ, Glasgow RE, Hollis JF, Mount K. Implementation and effectiveness of a brief smoking-cessation intervention for hospital patients. Med Care 2000;38:451–9.
[5] Haapanen-Nieme N, Miilunpalo S, Vuori I, Pasanen M, Oja P. The impact of smoking, alcohol consumption, and physical activity on use of hospital services. Am J Public Health 1999;89:691–8.
[6] Glasgow RE, Stevens VJ, Vogt TM, Mullooly JP, Lichtenstein E. Changes in smoking associated with hospitalization: quit rates, predictive variables, and intervention implications. Am J Health Promot 1991;6:24–9.
[7] Rigotti NA, Singer DE, Mulley AG, Thibault GE. Smoking cessation following admission to a coronary care unit. J Gen Intern Med 1991;6:305–11.
[8] Rigotti NA, Munafo MR, Murphy MFG, Stead LF. Interventions for smoking cessation in hospitalised patients. Cochrane Database Syst Rev 2001;(2) (CD001837).
[9] France EK, Glasgow RE, Marcus AC. Smoking cessation interventions among hospitalized patients: what have we learned? Prev Med 2001;32:376–88.
[10] Hajek P, Taylor TZ, Mills P. Brief intervention during hospital admission to help patients to give up smoking after myocardial infarction and bypass surgery: randomised controlled trial. Br Med J 2002;324:1–5.
[11] DeBusk RF, Miller NH, Superko HR, Dennis CA, Thomas RJ, Lew HT, et al. A case-management system for coronary risk factor modification after acute myocardial infarction. Ann Intern Med 1994;120:721–9.
[12] Taylor CB, Houston-Miller N, Killen JD, DeBusk RF. Smoking cessation after acute myocardial infarction: effects of a nurse-managed intervention. Ann Intern Med 1990;113:118–23.
[13] Ockene J, Kristeller JL, Goldberg R, Ockene I, Merriam P, Barrett S, et al. Smoking cessation and severity of disease: the coronary artery smoking intervention study. Health Psychol 1992;11:119–26.
[14] Lewis SF, Piasecki TM, Fiore MC, Anderson JE, Baker TB. Transdermal nicotine replacement for hospitalized patients: a randomized clinical trial. Prev Med 1998;27:296–303.
[15] Miller NH, Smith PM, DeBusk RF, Sobel DS, Taylor CB. Smoking cessation in hospitalized patients: results of a randomized trial. Arch Intern Med 1997;157:409–15.
[16] Taylor CB, Miller NH, Herman S, Smith PM, Sobel D, Fisher L, et al. A nurse-managed smoking cessation program for hospitalized smokers. Am J Public Health 1996;86:1557–60.
[17] Stevens VJ, Glasgow RE, Hollis JF, Lichtenstein E, Vogt TM. A smoking-cessation intervention for hospital patients. Med Care 1993;31:65–72.
[18] Rigotti NA, Arnsten JH, McKool KM, Wood-Reid KM, Pasternak RC, Singer DE. Efficacy of a smoking cessation program for hospital patients. Arch Intern Med 1997;157:2653–60.
[19] Stillman FA, Warshow MA, Stern EB, Jones CV. Quit smoking for good while you're in the hospital. Baltimore (MD): Johns Hopkins University; 1990.
[20] Stillman FA, Warshow MA, Stern EB, Jones CV. Stay quit for good after you leave the hospital. Baltimore (MD): Johns Hopkins University; 1990.
[21] Miller WR, Rollnick S. Motivational interviewing: preparing people to change addictive behavior. New York (NY): Guilford Press, 1991.
[22] Marlatt GA, Gordon JR. Relapse prevention: maintenance strategies in the treatment of addictive behaviors. New York: Guilford, 1985.
[23] Fiore MC, Bailey WC, Cohen SJ, et al. Treating tobacco use and dependence. Clinical Practice Guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service, 2000 (June).
[24] Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consult Clin Psychol 1983;51:390–5.
[25] Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom K. The Fagerstrom test for nicotine dependence: a revision of the Fagerstrom tolerance questionnaire. Br J Addict 1991;86:1119–27.
[26] Lichtenstein E, Glasgow RE. Smoking cessation: what have we learned over the past decade? J Consult Clin Psychol 1992;60:518–27.
[27] McBride CM, Curry SJ, Lando HA, Pirie PL, Grothaus LC, Nelson JC. Prevention of relapse in women who quit smoking during pregnancy. Am J Public Health 1999;89:706–11.
[28] Centers for Disease Control. 2000. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). World Wide Web address (5/24/00), http://www.cdc.gov/nchs/about/otheract/icd9/abticd9.htm
[29] Centers for Disease Control. Cigarette smoking-attributable mortality and years of potential life lost–United States, 1990. Morb Mortal Wkly 1993;42:645–9.
[30] Shopland DR. Tobacco use and its contribution to early cancer mor-

tality with a special emphasis on cigarette smoking. Environ Health Perspect 1995;103(Suppl. 8):131–42.
[31] Lando HA, Hennrikus DJ, McCarty M, Vessey J. Predictors of quitting in hospitalized smokers. Nicotine Tob Res 2003;5:215–22.
[32] SAS Institute. SAS Version 8.1. Cary, NC: SAS Institute, 1999
[33] Davidson KW, Goldstein M, Kaplan RM, Kaufmann PG, Knatterud GL, Orleans CT, et al. Evidence-based behavioral medicine: what is it and how do we achieve it? Ann Behav Med 2003;16:161–71.
[34] Velicer WF, Prochaska JO, Rossi JS, Snow MG. Assessing outcome in smoking cessation studies. Psychol Bull 1992;111:23–41.