Helping Hospitalized Smokers

A Factorial RCT of Nicotine Patches and Counseling

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Introduction: Most smokers abstain from smoking during hospitalization but relapse upon discharge. This study tests the effectiveness of two proven treatments (i.e., nicotine patches and telephone counseling) in helping these patients stay quit after discharge from the hospital, and assesses a model of hospital–quitline partnership.

Study design: This study had a 2×2 factorial design in which participants were stratified by recruitment site and smoking rate and randomly assigned to usual care, nicotine patches only, counseling only, or patches plus counseling. They were evaluated at 2 and 6 months post-randomization.

Setting/participants: A total of 1,270 hospitalized adult smokers were recruited from August 2011 to November 2013 from five hospitals within three healthcare systems.

Intervention: Participants in the patch condition were provided 8 weeks of nicotine patches at discharge (or were mailed them post-discharge). Quitline staff started proactively calling participants in the counseling condition 3 days post-discharge to provide standard quitline counseling.

Main outcome measures: The primary outcome measure was self-reported 30-day abstinence at 6 months using an intention-to-treat analysis. Data were analyzed from September 2015 to May 2016.

Results: The 30-day abstinence rate at 6 months was 22.8% for the nicotine patch condition and 18.3% for the no-patch condition (p=0.051). Nearly all participants (99%) in the patch condition were provided nicotine patches, although 36% were sent post-discharge. The abstinence rates were 20.0% and 21.1% for counseling and no counseling conditions, respectively (p=0.651). Fewer than half of the participants in the counseling condition (47%) received counseling (mean follow-up sessions, 3.6).

Conclusions: Provision of nicotine patches proved feasible, although their effectiveness in helping discharged patients stay quit was not significant. Telephone counseling was not effective, in large part because of low rates of engagement. Future interventions will need to be more immediate to be effective.

Trial Registration: This study is registered at www.clinicaltrials.gov NCT01289275.

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Introduction

Smokers are more likely to be hospitalized than nonsmokers.[1,2] Because accredited U.S. hospitals are required to be smoke free indoors, hospitalized smokers often have a period of imposed abstinence.[3,4] However, most return to smoking upon discharge.[5,6] Continued smoking is associated with re-admittance, higher morbidity, and higher mortality.[7–10] A health crisis that precipitates hospitalization can be a powerful motivator for behavior change and provides an opportunity to help smokers quit.[11,12] Helping smokers quit and stay quit after hospitalization can reduce the

human toll and the costs to the healthcare system from smoking-related disease.[13–17]

There are a number of interventions that have been proven effective for smoking cessation, including pharmacotherapies such as nicotine-replacement therapy, bupropion, and varenicline, and behavioral therapy.[18,19] But these interventions are not always well integrated into the hospital setting and, if provided, rarely extend after discharge. Clinical Practice Guidelines recommend screening, treatment, and follow-up of all hospitalized smokers, although they also acknowledge that system-level issues may make it difficult for hospitals to fully comply.[20] According to the 2015 annual report of the Joint Commission, hospitals had high rates of screening for tobacco use (94.1%), less success with providing or offering treatment during hospitalization (51.2%), and poorer showings on providing or offering treatment at discharge (36.4%).[21] Hospitals are focused on acute care, so even fewer follow up with tobacco users after discharge. Practical interventions are needed that can boost the effect of what hospitals are currently able to provide.

Given that many hospitalized smokers stop smoking during their hospital stay (not always willingly), but can be expected to relapse quickly, one possible intervention would be to increase the rate at which hospitals provide treatment at discharge. As patients often leave the hospital with other medications, it should be possible to ensure that all smokers who are willing leave the hospital with pharmacotherapy to use as they transition home. Another possible intervention would be to link hospitalized smokers to behavioral cessation treatment. Unlike hospitals, telephone-based quitlines are designed to provide ongoing support for smokers interested in quitting.[22] The quitline infrastructure is set up to receive referrals from healthcare providers and proactively contact smokers to offer services. Counseling services are focused and individualized.[23] Quitlines are scalable and can provide services to large numbers of smokers. They can also provide the extended care that has been shown to be associated with quitting smoking.[13,19]

A key to the success of these interventions would be creating a partnership between hospitals and quitlines that capitalizes on the strengths of each. Hospitals would identify smokers and offer services, such as pharmacotherapy, to help them cope during their stay. They could also provide patients with pharmacotherapy at discharge and refer the patient to the quitline for counseling and extended cessation support after leaving the hospital. Ideally, the process would be fully integrated into the hospital workflow so that patients would experience seamless and unified support. An integrated process would also make the intervention more scalable.

Although such a hospital–quitline partnership holds promise, the selected interventions have not been proven to be practical and effective in the hospital setting. This study tested the effect of providing nicotine patches as smokers leave the hospital, the effect of telephone counseling provided within days of discharge, and the possibility of an additive effect of the two interventions using a factorial design. Nicotine patches were purchased using grant funds and provided to the hospitals that were then responsible for dispensing them at discharge. Telephone counseling was provided by the state quitline, which was responsible for proactively contacting participants. In addition to testing the interventions effects, this study assessed the feasibility of a practical hospital–quitline partnership to extend treatment to hospitalized smokers to help them stay quit as they transition out of the hospital. This study is part of the Consortium of Hospitals to Advance Research on Tobacco, which was designed to translate proven smoking-cessation interventions into effective interventions.[24]

Methods

Study Design

This study used a 2×2 (nicotine patches by counseling) factorial design. Hospitalized patients were recruited from five hospitals across three healthcare systems: University of California, San Diego (UCSD), Scripps Healthcare in San Diego, and the University of California, Davis (UCD). Recruitment occurred between August 2011 and November 2013. Initial recruitment at Scripps was slow, so additional hospital systems were phased in; recruitment at Scripps started August 2011, followed by UCSD in May 2012 and UCD in January 2013.

The study protocol was reported previously,[25] but a brief overview is provided here. Subjects who provided consent were stratified by recruitment site and cigarettes per day (CPD; six to ten or ≥11) and randomly assigned by computer to one of four groups: usual care, nicotine patches at discharge, proactive quitline counseling, or both. Blocks of eight were used to balance characteristics across the four groups. Self-reported smoking status and quitting behavior were evaluated 2 and 6 months after enrollment with participants receiving $20 for each completed evaluation. Subjects who at 6 months reported 7-day abstinence were sent a saliva kit and asked to return a sample. Samples were analyzed at Salimetrics and results were used to biochemically confirm abstinence using 10 ng/mL as a cut off.[26] Embedded in the current study was a randomized trial comparing the effect of monetary incentives on return rate (half of them were offered $20 and the other half offered $100), which will be reported in a separate paper.

Participants

Hospitalized smokers were eligible for inclusion if they were aged ≥18 years, had smoked in the last 30 days, smoked at least six CPD on the days they smoked, were interested in quitting or staying quit, spoke English or Spanish, provided sufficient contact

information for intervention and evaluation (i.e., name, address, phone number), were cognitively and physically able to give consent and participate, were not pregnant, were interested in staying quit after discharge, and had an MD's approval for their study participation. Obstetrics, Surgery, and Behavioral Health units were excluded from participation. The study, including signed consent procedures, was approved by the IRBs at UCSD (#110410), UCD (using the approved intercampus procedure to rely on UCSD #110410), and Scripps Health (#11-5695); the study was registered in clinicaltrials.gov (NCT01289275).

Recruitment procedures differed between healthcare systems based on the personnel involved and the hospital's reliance on electronic medical records (EMRs). At Scripps, recruitment was the responsibility of Respiratory Therapists, whose job duties already included going to the bedside of each potential smoker. They encouraged patients to stay quit after discharge and provided resources for additional cessation services (e.g., state quitline number). Recruitment was embedded into their workflow. As they visited patients, they assessed eligibility for the study and obtained consent for participation. They contacted a physician to get approval to include the patient in the study and entered study-related information into a secure website that randomized the subject.

By contrast, UC facilities used dedicated research staff to recruit patients. Each morning, an automated electronic report was available via the EMR that listed patients who were admitted the previous day and who had smoked within the last year. Physicians in these facilities indicated in the EMR if they did not want their patient to be approached about study participation.

Intervention

The interventions are detailed elsewhere but are discussed briefly here.[23,25] Randomization into the nicotine patch condition triggered a flag in the EMR indicating that the patient was to be given a package at discharge that included 8 weeks of patches, with dosing that varied by the number of cigarettes smoked prior to hospitalization. Those who smoked six to ten CPD were provided 6 weeks of 14-mg patches and 2 weeks of 7-mg patches. Those who smoked $\geq$11 CPD were provided 4 weeks of 21-mg patches and 2 weeks each of 14-mg and 7-mg patches. Protocol dictated that patches be dispensed at discharge and the patient encouraged to put a patch on prior to leaving the hospital. This procedure was intended to reinforce the intention to stay smoke free. If the patient left the facility without receiving them, the patches were mailed the next day to the address on file.

Randomization into counseling triggered an automated referral with expected date of discharge to the state quitline. Quitline staff began proactive attempts to reach the study participants 3 days after discharge. Ten attempts were made, varying days and times of attempts, before coding them as not reached. Counseling was the standard telephone counseling provided by the state quitline.[23] Counseling focused on motivation and planning to stay quit, or for those who had relapsed following discharge, planning a new quit attempt.

Standard practice in all hospitals was to provide smokers with the quitline number. After randomization, participants also received the quitline number from recruitment staff. Beyond that, hospital systems, individual hospitals, and even individual units had their own approach to usual care for smokers with differences in providing counseling or prescribing quitting aids during hospitalization. In this study, there was no attempt to constrain these activities. Therefore, subjects might have received support for quitting while in the hospital. However, no hospital system routinely provided follow-up cessation care.

Measures

Baseline measures included age, gender, ethnicity, education, CPD, and living with a smoker. Patients also reported on high blood pressure, heart attack, stroke, arrhythmia, angina, or a severe allergy to adhesive tape, which are potential contraindications to nicotine patch use. For patients with these conditions, their doctor or hospitalist determined appropriateness for inclusion in the study. Primary discharge diagnosis was extracted from the hospital record; ICD-9 codes were collapsed into smoking-related categories of neoplasms (140–239), circulatory (390–459), and respiratory (460–519) and into mental disorders (290–319) or other.

Participants were contacted by telephone 2 and 6 months after enrollment by evaluation staff who were independent of recruiting staff, counselors, or hospital staff. Evaluation asked about abstinence (7-day and 30-day), use of quitting aids, and use of counseling and other cessation services. Those who reported being abstinent for 7 days at 6 months were sent saliva collection kits and asked to send a sample to test for cotinine. The overall return rate was 57%; the counseling condition had a lower return rate than the no counseling condition (52.2% vs 62.5%, p=0.03).

Statistical Analysis

The study was originally planned for one hospital system (Scripps), and was powered to detect a 7% difference for both patch and counseling conditions with 1,200 participants. Owing to slow recruitment, the study was expanded to two more hospital systems (UCSD and UCD) and the sample size increased (n=1,640) to account for potential site effects. At a research consortium Data Safety and Monitoring Board meeting, the sample size was reset to 1,200 as the site effect was expected to be small. Evaluation data were collected through July 2014 and data were analyzed September 2015 to May 2016.

The primary outcome was self-reported 30-day abstinence at 6 months, as outlined by the Consortium of Hospitals to Advance Research on Tobacco research design committee.[24] Analyses were intention to treat, where participants lost to follow-up were considered to be smoking.[27] Cotinine-corrected 7-day abstinence rates at 6 months were analyzed in which subjects who were lost to follow-up and self-reported nonsmokers who failed to return a saliva sample or who tested positive for smoking (cut point of 10 ng/mL) were imputed to be smoking.

The primary analysis was to determine the effect of patch and counseling. The unit of analysis was the individual. A generalized linear (binomial) mixed model was used to study the effect of treatment; clustering was accounted for with hospital-specific random effects.[28] The interaction between patch and counseling was analyzed and was followed by a test of main effects. For all other analyses comparing proportions between groups, chi-squares were calculated and 95% CIs were presented.[29] Analyses were performed using SAS, version 9.2.

Results

A total of 26,851 patients admitted to one of the five participating hospitals during the recruitment period were identified as potential subjects. Recruiters assessed 14,100 (52.5%) of them for study eligibility. The remaining patients were not assessed owing to time constraints. Of the 1,349 patients who met criteria (9.6% of the total), 1,270 (94.1%) provided consent and were randomized into one of the four groups. The most common reasons for exclusion were not being available for assessment (n=3,655), not smoking in the past 30 days (n=2,483), not smoking at least six CPD on the days they smoked (n=1,049), not being physically or cognitively able to participate (e.g., being intubated, having dementia; n=1,837), not being interested in quitting smoking (n=1,547), and not having sufficient contact information to participate (n=1,160). Figure 1 presents the flow of subjects through the randomized trial. Evaluation rates were 71.4% at 2 months (71.7% vs 71.1% for no patch vs patch and 73.7% vs 69.1% for no counseling vs counseling) and 67.5% at 6 months (67.1% vs 67.8% for no patch vs patch and 68.6% vs 66.4% for no counseling vs counseling).

Table 1 presents baseline characteristics of the randomized groups (usual care, nicotine patches only, counseling only, counseling plus nicotine patches); consistent with random assignment, there were no significant differences between groups on any measure. Overall, 56.7% were male, mean age was 49.9 (SD=13.2) years, and 46.7% had some college education. The ethnic breakdown was 51.2% non-Hispanic white, 22.9% Hispanic, 18.7% black, 2.6% Asian, and 4.5% another ethnicity or mixed ethnicity. Mean CPD prior to admission was 14.6 (SD=7.9); 47.2% lived with a smoker. The most common comorbid condition was high blood pressure (49.8%). There were no significant differences in primary discharge diagnoses across groups.

Table 2 shows the use of pharmacotherapy and behavioral interventions and reflects fidelity in delivering the intended intervention. The top of the table presents the use of nicotine patches, both those provided by the project and those obtained independently. Of those in the patch condition, 11 (1.7%) refused patches at discharge. Overall, 98.3% were provided with patches; 63.9% received them at discharge as intended. The remaining (36.1%) were mailed post-discharge and 7.5% of mailings were returned. At their first evaluation, 42.2% of the participants stated they had used pharmacotherapy during the hospital stay and 66.7% had used pharmacotherapy (including patches provided by the project) after leaving the hospital.

Of those randomized into the no-patch condition, 35.2% reported using pharmacotherapy during their hospital stay. This is lower than the 42.2% reported for the patch condition likely because some of those who received patches at discharge put one on before leaving the hospital, as directed, and reported this as use

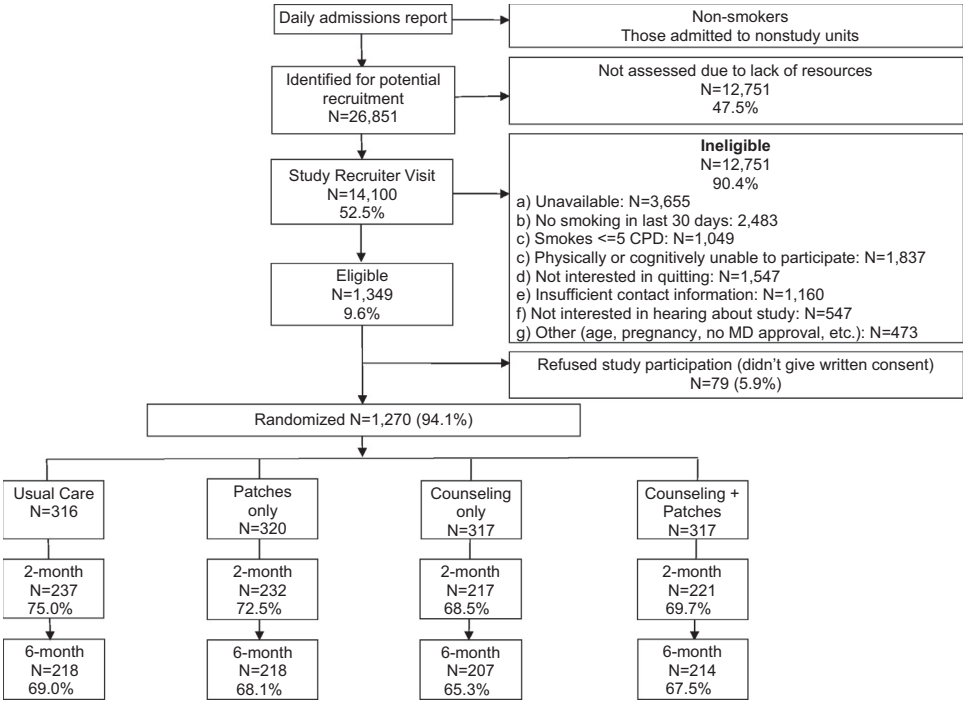

Figure 1. CONSORT diagram.
CPD, cigarettes per day.

Table 1. Baseline Characteristics and Primary Reason for Hospitalization by Randomly Assigned Condition

Characteristics	Overall (*n*=1270)	Usual care (*n*=316)	Patches (*n*=320)	Counseling (*n*=317)	Patches + counseling (*n*=317)
Male sex	56.7	57.0	58.1	57.1	54.6
Age, years, M (SD)	49.9 (13.2)	49.7 (13.0)	51.1 (13.5)	49.6 (13.0)	49.1 (13.2)
Education					
≤12 years	53.3	56.3	48.6	54.0	54.6
>12 years	46.7	43.7	51.4	46.0	45.4
Ethnicity					
White (non-Hispanic)	51.2	50.3	51.4	52.4	50.8
Black (non-Hispanic)	18.7	21.0	19.6	15.6	18.7
Hispanic	22.9	21.7	22.7	23.8	23.5
Asian/Pacific Islander	2.6	1.9	2.2	2.9	3.5
Other	4.5	5.1	4.1	5.4	3.5
Cigarettes per day, M (SD)	14.6 (7.9)	14.8 (8.1)	14.1 (7.5)	14.7 (8.1)	14.8 (8.0)
Live with a smoker					
Live alone	3.6	1.9	5.7	2.6	4.2
No	49.2	53.1	47.3	50.5	46.0
Yes	47.2	45.0	47.0	47.0	49.2
Comorbid condition,[a]					
High blood pressure	49.8	50.5	51.3	49.8	47.6
Heart attack	12.6	12.3	13.5	14.1	10.4
Stroke	10.3	11.0	10.2	11.3	8.5
Arrhythmia	16.4	19.8	13.7	14.5	17.7
Angina	8.5	8.4	11.3	7.1	7.5
Severe allergy to adhesive	0.3	0.0	0.3	0.3	0.6
At least one health issue	59.1	59.2	60.6	58.0	58.4
Primary diagnosis,[b]					
Circulatory system	13.3	15.2	16.3	11.4	10.4
Respiratory system	11.9	13.6	12.2	10.7	11.0
Neoplasms	3.5	4.1	1.9	3.8	4.1
Mental disorders	3.7	2.2	4.1	5.0	3.5
Other	67.6	64.9	65.6	69.1	71.0

Note: Data are percentages unless otherwise noted.
[a]Self-reported comorbid conditions; total may exceed 100%.
[b]Primary discharge diagnosis from electronic medical record using ICD-9 codes.

during their hospital stay. In the no-patch condition, 27.6% reported having used pharmacotherapy after discharge.

The bottom of Table 2 shows engagement in counseling and other behavioral programs. Of those randomized into counseling, only 46.7% received quitline counseling,

Table 2. Use of Pharmacotherapy and Behavioral Intervention

Intervention	No patch	Patch
Application of patch intervention, *n*	633	637
Delivery of patches, % (95% CI)	NA	98.3 (97.3, 99.3)
Given at discharge, % (95% CI)	NA	63.9 (60.1, 67.7)
Mailed post-discharge, % (95% CI)	NA	36.1 (32.3, 39.9)
Self-report from evaluation, *n*	500	498
In hospital		
Used any pharmacotherapy, % (95% CI)	35.2 (31.0, 39.4)	42.2 (37.8, 46.5)
Post-discharge		
Used any pharmacotherapy, % (95% CI)	27.6 (23.7, 31.5)	66.7 (62.5, 70.8)
	No counseling	**Counseling**
Application of counseling intervention (counseling database), *n*	634	636
Quitline counseling, first session, %	1.4	46.7
Follow-up counseling calls,[a] M (SD)	1.7 (2.2)	3.6 (4.5)
Use of behavioral help (self-report from evaluation), *n*	506	492
Telephone counseling, % (CI)	14.2 (11.2, 17.3)	58.8 (54.2, 62.9)
Other behavioral help, % (CI)	8.9 (6.4, 11.4)	8.3 (5.9, 10.8)
Any behavioral help, % (CI)	21.9 (18.3, 25.5)	68.3 (64.2, 72.4)

[a]Of those who received any quitline counseling.

despite repeated attempts to reach them after discharge. The mean number of follow-up counseling calls for those who received any counseling call was 3.6 (SD=4.5). Some participants (18.3%) declined counseling when reached (data not shown); the remaining were not reached after a mean of 10.6 attempts. Of those randomized to the no-counseling condition, nine (1.4%) called the quitline on their own and received counseling with a mean of 1.7 (SD=2.2) follow-up calls.

At evaluation, participants were asked if they received telephone counseling post discharge; 58.5% of the counseling group and 14.2% of the no counseling group stated that they had. In both conditions, these numbers exceed the rate of documented quitline counseling by about 13 percentage points. Overall, 8.6% of evaluated participants had received other behavioral services. Of those, 58.3% cited the source as healthcare providers, 20.2% the Internet, 15.5% in-person group, 6.0% in-person individual, and 4.8% other (multiple answers result in exceeding 100%). Altogether, 68% of those in the counseling condition reported receiving some form of behavioral assistance post-discharge, compared with 22% of those in the no-counseling condition.

To assess quitting outcomes, the authors first tested the interaction between the patch and counseling factors, which was not significant (p=0.91). Coding subjects lost to follow-up as smokers, the 30-day abstinence rates at 6 months for the four randomized groups were 18.7% (95% CI=14.4, 23.0) for usual care, 23.4% (95% CI=18.8, 28.1) for the patch-only condition, 18.0% (95% CI=13.7, 22.2) for the counseling-only condition, and 22.1% (95% CI=17.5, 26.7) for the patch plus counseling condition. Then, the standard approach was followed for analyzing a factorial design when the interaction is not significant: all further results were reported by main effects.

Table 3 presents the quitting outcomes. Analysis of the patch effect found no significant differences for any of the outcome measures. The self-reported 30-day abstinence rates at 6 months (i.e., primary outcome measure) were 18.3% and 22.8% in the no patch and patch conditions, respectively (p=0.051).

Likewise, there was no significant counseling effect using any of the measures at 2 or 6 months. At 6 months, the 30-day abstinence rates were 21.1% and 20.0% for no counseling and counseling conditions, respectively (p=0.65).

The rate of return for cotinine analysis samples was low (57%). After imputing smoking to all of those lost to follow-up and to self-reported nonsmokers who failed to return a sample or who tested positive for smoking, rates

Table 3. Smoking Cessation by Intervention Condition

Intent to treat	No patches	Patches	No counseling	Counseling
2-month, *n*	633	637	636	634
Quit 30 days+, % (95% CI)	19.0 (15.9, 22.0)	23.2 (19.9, 26.5)	20.4 (17.3, 23.6)	21.8 (18.6, 25.0)
Quit 7 days+, % (95% CI)	22.6 (19.3, 25.9)	27.2 (23.7, 30.6)	24.4 (21.0, 27.7)	25.4 (22.0, 28.8)
6-month, *n*	633	637	636	634
Quit 30 days+, % (95% CI)	18.3 (15.3, 21.3)	22.8 (19.5, 26.0)	21.1 (17.9, 24.2)	20.0 (16.9, 23.2)
Quit 7 days+, % (95% CI)	22.0 (18.7, 25.2)	26.2 (22.8, 29.6)	24.8 (21.5, 28.2)	23.3 (20.0, 26.6)
Cotinine (10 ng) corrected 7-day, % (95% CI)	6.0 (4.2, 7.9)	6.9 (4.9, 8.9)	8.0 (5.9, 10.1)	4.9 (3.2, 6.6)

of abstinence dropped substantially. Cotinine analysis also found a lack of treatment effect for both patches and for counseling.

Discussion

Using a factorial design, this study found no significant effect for nicotine patches or for quitline counseling in helping hospitalized smokers abstain from smoking, although this does not mean that these treatments were not useful for those who received them. The study was designed to test whether systematic application of these interventions could fill the gap between hospitals' usual care and what is needed to help smokers stay quit after leaving the hospital. Against a background of the standard of care, which likely varied across hospital system, individual hospitals, or individual physicians, there was no additional effect of either patches or counseling on extending abstinence.

Both nicotine patches and telephone counseling are well-established methods of smoking cessation.[18,19,22,30,31] What explains the inability of these proven treatments to translate into robust effects among hospitalized smokers?

One possible explanation is the difficulty in delivering interventions. Certainly, there are interventions that worked well in efficacy trials but not in real-world application. Sometimes this is because the interventions are not applied as well as they had been in the trials.[32]

Application of the patch intervention was relatively straightforward. Patches were provided to the hospitals, and randomization to the patch condition flagged the patients' records to indicate that they were to be provided patches at discharge. Two thirds of those in the patch condition received them at the time of discharge. The remainder were mailed, although some never reached the participants. Mailing patches also meant that the opportunity was lost to reinforce the intention to stay quit by putting a patch on prior to leaving the hospital. Still, the fact that many of the patients did receive them in a timely way likely explains why the patch appeared to have more potential than counseling (Table 3, self-reported outcomes). Routinely providing hospitalized smokers with patches upon discharge could increase their quitting success if all patches were delivered as they leave the hospital.

Counseling proved much more difficult to implement. The study was set up to maximize the likelihood that participants would receive counseling, yet less than half did so. The study only included smokers interested in staying quit after discharge and excluded those with no address or phone number. Quitline counselors made repeated attempts to reach study participants, varying days and times of attempts. Even so, the rate of counseling was low. Addresses and phone numbers were not always accurate and patients were not always released back to their homes. In addition, nearly 20% of individuals refused counseling when reached, either because they did not feel well enough to talk or had relapsed and were no longer interested in quitting. Additionally, it was difficult to time the counseling because discharge dates often changed. As a result, there was often a substantial delay between discharge and engagement in counseling, which failed to capitalize on the gains made during the hospital stay.

A second possible explanation for the lack of results lies in the context of the study and the population itself. Hospitals regularly screen for smoking and most smokers stop smoking during their hospital stay. Many also receive pharmacotherapy or counseling while hospitalized. The precipitating health crisis can be a powerful motivator for change even without intervention.[11,12,33] The margin of improvement from any additional intervention is likely to be smaller here than in other intervention contexts. The relatively high self-reported abstinence rates overall suggest that the population was motivated to stay quit, making it more difficult to detect an additional intervention effect.

Taken together, the results of this study suggest immediacy in delivery might be critical to achieve

intervention effects. This is supported by other effectiveness trials. For example, requiring smokers to take one additional step to obtain free-of-charge pharmacotherapy rendered an intervention ineffective, even though half of smokers eventually used the pharmacotherapy.[34,35] Future research in helping hospitalized smokers quit needs to develop creative and practical procedures to improve the timeliness of interventions.

A goal of this study was to create a hospital–quitline partnership that would be a model for other organizations. Implemented across three healthcare systems, this study yielded important information about the practicality of such a partnership. Attempts to completely embed the study into the hospital workflow and use hospital staff (i.e., Respiratory Therapists) proved problematic, given the competing priorities of their clinical work. The alternate model of using external staff to visit patients at bedside worked better, as did the more automated approach in which the order set for study participation was built into the EMR. Recent efforts to automate referrals to quitlines are a step in that direction.[36] Even so, the hospital environment is fast paced; there is often little lead time before a patient is released or transferred. There appears to be a need for dedicated hospital staff and for interventions that are standardized and seamlessly embedded.

This study had several strengths. First, the study used a factorial design, which was an efficient way of assessing the two interventions and their potential synergistic effect. Second, the sample was ethnically diverse and included many individuals from populations typically under-represented in research studies. Third, although expanding the study to five hospitals across three healthcare systems was originally done to increase recruitment, the fact that each system had its own procedures and each hospital its own "culture" informed the lessons learned about building hospital–quitline partnerships.

Limitations

One limitation of the study was the high number of hospitalized smokers who were not included in the study (>90%). If the intervention had proven successful, this would have limited the generalizability of the findings. Many smokers were excluded simply because there were not sufficient resources to assess all smokers for inclusion. In this study, smokers had to be interested in quitting and smoke at least six CPD. These exclusions were considered necessary at the time the study was designed because there was concern about providing nicotine patches to light smokers or smokers who continued to smoke. The low return rate for the cotinine testing (57.0%) was also a limitation, although the low return rate did not affect the conclusions.

Conclusions

This study was designed to translate efficacious cessation strategies into a practical model of hospital–quitline collaboration. Despite the large sample size and strong factorial design, neither nicotine patches nor telephone counseling was effective in helping hospitalized smokers stay quit. The need for a practical intervention for hospitalized smokers continues. Efforts to develop efficient new processes are already underway, but could be facilitated by making tobacco a required quality performance measure for hospitals and providing greater incentives for embedding additional services, such as nicotine patches, at discharge into their workflow.

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SHZ was the Principal Investigator of the grant and designed the study. SEC helped with design, supervised implementation, and wrote the first draft. CAK was project manager. ACG assisted with design issues and was responsible for the analytic plan. GJT helped to develop the protocol and supervised the quitline counselors. KB, GS, HKC, ET, and EC contributed to research protocol, worked to recruit sites, and supervised the study in the hospitals. All authors contributed to the final draft.

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