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A Proactive Smoking Cessation Intervention with Hospitalized Smokers: A Randomized Controlled Trial

A dissertation submitted in partial satisfaction of the requirements for the degree of Doctor in Philosophy

in

Public Health (Health Behavior)

By

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2011

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DEDICATION

This dissertation is gratefully dedicated to the important people in my life who provided guidance, support and understanding:

- To the many instructors, advisors and mentors who taught me to love learning, with special acknowledgements to my doctorate advisor, Shu-Hong Zhu, who believed in me and paved the way. To my advisors, Drs Daley, Elder, Lindsay, Navarro and Pierce.

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EPIGRAPH

Knowledge comes, but wisdom lingers.

Alfred Lord Tennyson

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ABSTRACT OF THE DISSERTATION

A Proactive Smoking Cessation Intervention with Hospitalized Smokers: A Randomized Controlled Trial

By

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Doctor of Philosophy in Public Health (Health Behavior)

University of California, San Diego, 2011

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Smoking interferes with the recovery and healing process for hospitalized patients. The Joint Commission on Accreditation of Hospital Organizations (JCAHO) requires that hospitals offer smoking cessation assistance, which involves brief bedside counseling for patients of certain diagnoses. It is generally recognized that hospitalization creates a "teachable moment" for smoking cessation. In fact, most smokers quit smoking while hospitalized. However, most of them relapse soon after

discharge. There is a need to develop intervention programs that can increase the long-term quit rate of these patients post discharge.

The present study is a small randomized controlled trial. It compares the usual-care condition, where smokers received bedside counseling from respiratory therapists, to an enhanced treatment condition, which included provision of eight weeks of nicotine patches at discharge plus proactive telephone counseling from a quitline up to two months post discharge. Hospitalized smokers of all diagnoses were included in the study, except those hospitalized for psychiatric reasons and pregnant women. A total of 126 smokers were recruited into the study. The sample size was not powered to find a statistically significant result on the long-term quit rate, but it is large enough to provide a good estimate of effect size for the intervention.

Study participants were evaluated at two and six months for their smoking status. At two months 78.0% of the sample was contacted. In an intent-to-treat analysis in which all those not contacted are assumed to be smokers, 26.6% in enhanced-treatment (ET) group and 6.5% in usual-care (UC) group had quit smoking for at least 30 days (OR=5.2, $p<0.01$). At six months, 57.9% were contacted. An intent-to-treat analysis found 9.4% in ET and 6.4% in UC had quit for at least 180 days (OR=1.5, $p=0.74$).

This study found that an intervention that combined nicotine replacement therapy (NRT) and telephone counseling had a significant effect, up to two months. There was substantial relapse between two and six months, but the odds ratio between

the two conditions was still respectable. Future studies would include a larger sample size and would also investigate ways to reduce relapse rate in the long term.

INTRODUCTION

Smoking and Disease

Smoking is the leading cause of preventable death and disability in the United States, with annual death rates of 440,000 attributed to the habit (Centers for Disease Control and Prevention [CDC], 2008; Mokdad, Marks, Stroup, & Gerberding, 2004; National Center for Health Statistics, 2010; U.S. Department of Health and Human Services, 2004). On average, smokers die 13 to 14 years earlier than nonsmokers (CDC, 2006), and while the prevalence of smoking in the United States has declined almost by 50% since 1965, it still remains a significant public health issue. The most recent survey data from the CDC show that 20.6% of U.S. adults were current smokers in 2009 (CDC, 2010).

Research has demonstrated that there are significant benefits when smokers stopping smoking (U.S. Department of Health and Human Services, 1990, 2001, 2004). For example, smoking cessation lowers the risk for lung and other types of cancer. Cessation reduces the risk for coronary heart disease, stroke, and peripheral vascular disease. More specifically, risk of coronary heart disease diminishes within one to two years of cessation. Smoking cessation also reduces respiratory symptoms, such as coughing, wheezing, and shortness of breath, and the rate of decline in lung function slows among persons who quit smoking (U.S. Department of Health and Human Services, 1990, 2001, 2004). Smoking cessation reduces the risk of developing chronic obstructive pulmonary disease (COPD), a major cause of premature death in the United States (U.S. Department of Health and Human Services, 2004). Given the

serious health consequences of smoking and the clear benefits of quitting, developing new methods to increase smoking cessation rates represents one of the most important ways to reduce morbidity and premature mortality in the United States.

Smoking Cessation and Hospitalized Patients

The American Hospital Association (2008) reports that, annually, more than 35 million people spend time hospitalized in an inpatient setting, of whom an estimated six million (17%) are cigarette smokers. *The Health Consequences of Smoking: A Report of the Surgeon General* reported that patients who smoke have a slower recovery from all health problems, including postsurgical procedures (U.S. Department of Health and Human Services, 2004). Patients with cancer who continue to smoke have an elevated risk for a second cancer. Helping hospitalized smokers quit would likely result in shorter hospital stays, better health outcomes, and increased quality of life for individuals (Bock, Becker, Niarura, & Partridge, 2000; France, Glasgow, & Marcus, 2001).

Most smokers quit, at least temporarily, while hospitalized as they may not leave the hospital during treatment and smoking is forbidden within the hospital (Rigotti et al., 2000). However, the majority of smokers return to smoking soon after hospital discharge. The high relapse rate may occur due to many factors including the following: 1) the cessation of smoking was due to external factors (e.g., hospital policy), and there is no motivation to maintain abstinence, 2) nicotine dependence may exist among the smokers, and withdrawal symptoms following a brief hospitalization may promote a return to the behavior, 3) the high probability of

exposure to environmental and behavioral smoking cues once discharged from the hospital including friends, family, and social networks who smoke, and 4) the motivation to quit may wane as the individual's health condition improves (Christakis & Fowler, 2008; Hajek, Stead, West, Jarvis, & Lancaster, 2009; Sciamanna, 2000).

When these smokers quit during hospitalization and then remain abstinent after discharge, they will reap significant health benefit individually, and society will reap benefit collectively in terms of reduced healthcare costs. This makes it imperative that we test new cessation programs that can help prevent relapse (Lancaster, Stead, Silagy, & Swoden, 2000; Quist-Paulsen, Bakke, & Gallefoss, 2006; Royal College of Physicians, 2000; Rigotti, Munafo, & Stead, 2007).

Fortunately, hospitalization represents a "teachable moment." Individuals are more receptive to advice related to health because they tend to focus on their health while hospitalized (Clark Haverty, & Kendall, 1990; Rigotti, Munafo, & Stead, 2008; Silagy, Mant, & Fowler, 2000; West, McNeill, & Raw, 2000). Due to the need for hospitalization, patients may experience anxiety and fear that can increase their motivation to change (Frazier et al., 2002). The combination of experiencing these emotions and prompting from clinical staff may fuel a desire to change one's lifestyle, including an improved diet, more exercise, moderation of alcohol use, and smoking cessation. Additionally, hospitalized patients may have more time to listen and contemplate behavior change than they possess during their daily activities when not hospitalized.

Hospital Quality of Care: Tobacco Measure

Current quality of care guidelines from the Joint Commission and the Centers for Medicare & Medicaid (CMS) include a tobacco measure. These measures require hospitals to assess the proportion of current or past-year smokers who received advice, counseling, or medication during a hospitalization for acute myocardial infarction, congestive heart failure, or pneumonia and post the outcome of these patients quarterly on a public website. The data from these reports comprises a portion of the new pay-for-performance reimbursement programs (Joint Commission on Accreditation of Healthcare Organizations [JCAHO], 2007; U.S. Department of Health and Human Services, 2007). In addition to the Tobacco Measure requirements, the National Institutes of Health's Comprehensive Cancer Center Program now also encourages hospitals to offer smoking cessation education and support for patients with cancer and as a preventive measure (American College of Surgeons, 2009).

These requirements for hospitals to offer smoking cessation assistance to inpatients have provided an impetus for many studies with hospitalized smokers (The Joint Commission, 2009; Rigotti et al., 2008). Studies have shown that hospitals that identify the smoking status of all patients provide a forum for directive advice from physicians and other healthcare professionals, and offering counseling can increase quit rates and promote behavior change (Chouinard & Robichaud, 2005; Dornelas, Sampson, Gray, Waters, & Thompson, 2000; Emmons & Goldstein, 1992; Mohiuddin et al., 2007; Orleans, Kristeller, & Gritz, 1993). Stead, Perera, Bullen, Mant, and Lancaster (2008) expand on this point by recommending that respiratory therapists,

physicians, and other health providers receive training in counseling techniques and the use of smoking cessation medications. The training makes healthcare providers more confident in providing cessation advice. Other studies have reported that patients tend to see a provider's advice at bedside as an indicator of caring and appreciate this, even if they do not intend to quit (Ockene & Zapka, 1997; Rice, 1999).

Cessation Treatment for Hospitalized Smokers

A meta-analysis of randomized trials on interventions for hospitalized smokers shows that behavioral counseling can significantly increase the long-term cessation rate of these patients if the length of treatment extends to least one month post discharge (Rigotti et al., 2008). Counseling that is shorter than one month has only marginal effects. Interestingly, in contrast to many studies that have shown NRT to be effective treatment for general smokers, this meta-analysis also found that NRT has only a marginal effect for hospitalized smokers.

In practice, however, a typical hospital does not possess the resources to provide month-long post-discharge behavioral counseling for smokers (Rigotti et al., 2008). Additionally, some medical professionals view smoking as a behavioral health problem that does not fit into the scope of treatment that a hospital setting should provide (Stead, Perera, & Lancaster, 2006). Additional barriers to implementing empirically supported interventions into practice include logistical realities. For example, most patients actually quit smoking while in the hospital, so it seems unnecessary for clinical staff or hospital management to follow-up with these patients

(Duffy, Reeves, Hermann, Karvonen, & Smith, 2008; McCarty, Hennrikus, Lando, & Vessey, 2001).

There is, therefore, a need to study cessation treatments that are not only effective but also practical so that they will have a greater chance of actually being implemented in practice. This study is one such attempt. It uses NRT to motivate hospital staff to get more involved with helping hospitalized smokers. It uses an existing state quitline to conduct post-discharge counseling.

Overview of the Present Study

The present study randomized a group of hospitalized smokers (N=126) into receiving the usual care (UC) and enhanced treatment (ET). The study followed the patients two months and six months post discharge to assess their smoking status. Specifically, the study has two main aims:

1. To examine the feasibility of an intervention model for hospitalized smokers in which the hospital staff collaborate with a state tobacco quitline to provide a comprehensive treatment to smokers that starts at the bedside and extends to two months post discharge.

2. To compare the effect of an enhanced treatment against a usual care condition using a randomized controlled design. The usual care included bedside intervention currently delivered by respiratory therapists in the hospital. The enhanced protocol included provision of nicotine patches upon discharge plus proactive telephone counseling in a two-month period after discharge.

A Collaborative Care Model

The California Smokers' Helpline (CSH) has partnered with Scripps Mercy Hospital for many years to assist hospitalized smokers after discharge. As part of their usual care, respiratory therapists (RT) at Scripps Mercy deliver brief smoking cessation education to all in-patient smokers. RTs then refer the patients to the Helpline. RTs in Scripps have also tried to refer these patients to the Helpline for cessation counseling after discharge by having the patient fill out a consent form, which the RT faxed to the Helpline for proactive follow-up counseling. Thus, RTs in the hospital and the counselors at the Helpline have worked together in providing counseling to both self-referred and fax-referred smokers.

Potential Impact of the Study

Previous studies on hospitalized smokers have mostly focused on specific subgroups of smokers, such as cardio-pulmonary patients (Rigotti et al., 2008). The present study will focus on patients with all diagnoses, except those who are contraindicated for cessation medication and those who might have trouble providing informed consent at the time of the hospitalized (e.g., patient hospitalized for acute psychiatric episode). If proven effective, the model will help hospitals be in compliance with the upcoming new JCAHO requirement, which is believed to mandate hospitals to treat all smokers regardless of their diagnosis (unless contraindicated).

The study will work with a well established state quitline in California, which has been a leader in the field of quitlines. From the dissemination perspective, a

success with this state quitline will make it easier to disseminate to other state quitlines, so they could also adopt a similar partnership with hospitals in their respective states.

LITERATURE REVIEW

This section starts with brief review of social cognitive theory because it is a general theoretical model that underlies much smoking research. Then it will review the empirical literature related to smoking cessation and treatment for hospitalized smokers. They are called salient cessation studies and are grouped into the following categories: 1) studies utilizing post-discharge follow-up, 2) studies utilizing telephone counseling, 3) studies utilizing nicotine replacement therapy (NRT), and 4) studies utilizing NRT and behavioral counseling.

Social Cognitive Theory

Social Cognitive Theory (SCT) views behavior change as an interaction between the environment, the behavior, and factors unique to each individual. Therefore, understanding the dynamic between the person who smokes and their environment could lead to interventions that produce more effective and sustained behavior changes (Bandura & Adams, 1977).

Two key concepts related to SCT are important: self-efficacy and the role of modeling. Self-efficacy involves one's belief in their ability to achieve a goal, and modeling refers to the learning that occurs by watching peers or role models (Bandura, 1994; Bandura & Adams, 1977). These two concepts appear in the literature in the form of interventions that assume that one can learn how to quit smoking (Vogt, Hall, Hankins, & Marteau, 2009). Additionally, SCT-based interventions assume environmental factors can significantly influence smokers' behavior, such as not being allowed to smoke while in hospital and receiving strong advice from healthcare

providers to quit (Vogt et al., 2009). The present study adopts an intervention philosophy that can be generally classified under the rubric of SCT. It assume that smoking is a learned behavior and thus can be unlearned by practice. The intervention needs to promote smokers' self-efficacy. At the same time, there needs to be accountability for change in smokers' environment, either coming from the healthcare provider or the cessation counselors or from smokers' immediate social circle. A protocol that utilizes both the psychological variables (e.g., self-efficacy) and the environmental variables is more likely to produce significant change among smokers.

Salient Studies in Smoking Cessation

Moving from a theoretical discussion to a review of empirical studies, a search of the literature yielded 50 randomized control trials relevant for discussion regarding the research reported in this paper. The 50 studies were categorized into the following four categories 1) ones that utilized post-discharge follow-up, 2) ones that utilized proactive telephone counseling, 3) ones that utilized Nicotine Replacement Therapy (NRT) interventions, and 4) ones that used both medication and behavioral counseling.

Prior to delving into the specific studies, a brief history regarding the use of inpatient interventions to target smoking cessation is warranted. Interventions delivered at bedside represent a new level of care and of recent practice that continues to evolve. Historically, an informal statement from a medical practitioner would represent the only "intervention" to address smoking with a hospitalized individual, and this occurred on a voluntary and inconsistent basis. Thus, the current usual care

intervention for smoking cessation with a hospitalized population represents a significant and positive change. Typically, the usual care intervention consists of some level of bedside counseling provided by health professionals and printed material provided to the patient prior to discharge (Fiore, 2000; Fiore, Bailey, & Cohen, 1996; Lancaster & Stead, 2004). The delivery of the current usual care intervention varies greatly from setting to setting and practitioner to practitioner, however it represents significant positive progress.

The employment of the current usual care approach is due to hospital accreditation and licensing mandates, and it represents a recent increased standard of care. Thus, the field of research to determine the most efficacious approaches for smoking cessation that commences during an inpatient hospital visit remains largely unexplored. As the discussion of empirical studies unfolds in the coming paragraphs, keep in mind the variability of these usual-care interventions. This variability is a limitation in the research, which makes cross-study comparisons difficult and a meta-analysis of the existing literature challenging.

Interventions with Post-Discharge Patient Follow-Up

Researchers have had mixed success in achieving long-term smoking cessation through the use of inpatient interventions with post-discharge follow-up (Bolman, de Vries, & van Breukelen, 2002; Croghan et al., 2005; Ortigosa, Gomez, Ramalle-Gomara, Reta, & Esteban, 2000). Studies of hospitalized smokers indicate that interventions with insufficient follow-up after discharge serve as ineffective (Hennrikus, Lando, McCarty, 2005; Rigotti et al., 2007, 2008; Silagy, 2004a; Stead,

2008). However, studies with interventions that include contact with patients after hospital discharge (for at least one month) can be effective (Ortigosa et al., 2000; Rigotti et al., 2007; Stevens, Glasgow, Hollis, & Lichtenstein, 1993; Stevens, Glasgow, Hollis, & Mount, 2000).

Whatever the reasons, and they certainly remain unclear, the data speaks rather loudly: without support, many individuals who stop smoking during hospitalization relapse after discharge (Rigotti et al., 2007; Warner, Patten, Ames, Offord, & Schroeder, 2004; West, 2002; Wolfenden et al., 2003). Clearly, post-discharge follow-up serves as a critical element contributing to long-term smoking cessation (Abrams et al., 1996; An, Zhu, et al., 2006; Brandon, Collins, Juliano, & Lazev, 2000; Corelli & Hudmon, 2004; Glasgow, Lando, Hollis, McRae, & LaChance, 1993; Hollis, Vogt, Stevens, & Biglan, 1994; Munafo, Rigotti, Lancaster, Stead, & Murphy, 2001), and smoking cessation interventions delivered during hospitalization with short-term or no follow-up are ineffective for smoking cessation (Croghan et al., 2005; Rigotti et al., 2007).

Wolfenden et al. (2003) provide the most direction for future research and interventions through detailed suggestions regarding length and frequency of interventions. Wolfenden et al. identify that the initial smoking cessation counseling interventions should be 20 minutes or greater in duration and accompanied by extended post-discharge follow-up of at least five intervention contacts via phone or in person over a period of at least one month. Simon, Carmody, Hudes, Snyder, and Murray (2003); Munafo et al. (2001); and Rigotti et al. (2008) also suggest that

smoking cessation interventions that begin during hospitalization, and include one month or more of follow-up supportive services, are more effective than those with shorter or no follow-up. Finally, Pieterse, Seydel, DeVries, Muddle, and Kok (2001) and Wolfenden et al. both conclude in separate studies that in addition to counseling and extended post-discharge counseling, the most effective interventions also include the use of Nicotine Replacement Therapy (NRT). Details about studies utilizing NRT appear in the coming paragraphs.

Telephone Counseling

Telephone counseling provides another modality for helping recently hospitalized patients maintain abstinence from smoking upon discharge from the hospital. Quitlines represent a popular medium for this intervention, and they exist in a variety of formats, including those based solely on contact commenced and maintained by the smoker and those that provide proactive contact from the quitline counselor to the smoker. Many studies Orleans et al., 1991; Zhu et al., 2002; Zhu, Stretch, et al., 1996; Zhu, Tedeschi, Anderson, & Pierce, 1996) have shown that proactive counseling can increase 12-month prolonged quit rates when compared to providing smokers with self-help materials. Meta-analysis has shown that telephone counseling is now a well established efficacious treatment for smoking cessation (Stead et al., 2006).

The meta-analysis not only shows that proactive telephone counseling can help smokers quit, it also shows there is a dose-response relationship in more sessions that tends to be associated with a high quit rate (Metz et al., 2007; Stead et al., 2006).

However, there seems to be a threshold effect where the effect of intervention (when at least three or more calls are delivered to smokers) is clearly noticeable when compared with self-help groups (Metz et al., 2007; Stead et al., 2006). This is important as we consider using telephone counseling as a bridge between inpatient smoking cessation and post-discharge interventions. This highlights an important area of research (Cummins et al., 2002; France et al., 2001; Sherman et al., 2004).

During an inpatient hospitalization, smokers may be more open to a referral to a quitline than they would have been prior to receiving medical treatment. Wolfenden et al.'s (2003) study showed a 64% acceptance rate among surgical patients of an offer to be referred to the quitline by preoperative clinic staff. In this study, acceptance of an offer of referral was defined as participants' consent for providers to fax a completed referral to a quitline service for smoking cessation assistance. Of the patients referred, 74% were reached by the quitline after discharge and reported satisfaction with the quitline service and the referral process.

Nicotine Replacement Therapy (NRT) and Counseling

Various pharmacological agents have been used in the past to aid smokers. NRT has been shown to be effective, and many have concluded making NRT available in all smoking cessation programs represents an important priority (Alberg & Stashefsky, 2004; Fiore et al., 1996; Lancaster & Stead, 2004; Thorndike, Biener, & Rigotti, 2002). Studies have found quit rates in control groups without NRT ranging from 1.5% to 12% (Silagy, Lancaster, Stead, Mant, & Fowler, 2004). In intervention groups, quit rates ranged from 5% without NRT to 21% when NRT was added in

conjunction with other interventions, such as telephone counseling (Silagy et al., 2004b; Simon et al., 2003).

Compared with other cessation medication, NRT possesses further benefits. Research has shown that transdermal nicotine patches represent a safe treatment, even for patients with known health problems such as heart disease or who have had recent surgery (Joseph & Fu, 2003; Meine, Patel, Washam, Pappas, & Jollis, 2005). And easy over-the-counter access combined with the broad-scale advertising of both nicotine-containing gum and the transdermal nicotine patch have helped increase population-wide awareness of NRT and decrease barriers on those seeking smoking cessation assistance. Although both forms of NRT (the patch and the gum) have demonstrated clinical effectiveness, in general the patch is preferable for routine clinical use, while gum may be preferable in certain clinical presentations (e.g., people who prefer the oral stimulation that the gum provides; Molyneux, 2004). Alternative forms of NRT exist including a nicotine nasal spray available by prescription and a nicotine inhaler that helps satisfy the "hand to mouth urge" (Skaar, Tsosh, & McClure, 1997).

Most studies of NRT with hospitalized smokers have included behavioral counseling; thus, it is difficult to ascertain the effectiveness of NRT independent of counseling (Rigotti et al., 2007). Pooled analyses estimated a 47% increase in the odds of quitting when pharmacotherapy was added to counseling (Debusk et al., 1994; Fiore et al., 1994; Fiscella & Franks, 1996; Richmond, Harris, & Netch, 1994). Interestingly, this increase is not statistically significant (Rigotti et al., 2008).

In fact, a meta-analysis of all studies that focused on NRT use for hospitalized smokers found the NRT has only a marginal effect (Rigotti et al., 1999; Rigotti et al., 2008). Several possible reasons could account for this lack of effect, including the following: 1) hospitalized smokers' motivation to stay abstinent (after discharge) may be weaker compared with smokers who volunteer for NRT trials, 2) the lack of rigorous experimental studies utilizing a control group to compare the NRT intervention with a matched sample of smokers attempting to quit without NRT may explain the lack of statistical support for NRT alone as an effective intervention, 3) non-significance demonstrated in the literature may be related to the logistical barriers present in the real world application of NRT as an intervention (access challenges due to cost, transportation, etc), and 4) environmental cues faced by the smoker upon return to their home environment after discharge from the hospital milieu in combination with experiencing potential acute withdrawal symptoms (Hyland et al., 2009; Messer, Mills, White, & Pierce, 2008). Consider that an established smoker likely exhibits dependence on nicotine and, as such, may still experience withdrawal symptoms following a brief hospitalization (less than two days) in which they do not smoke. Returning these individuals to their home environment, where they can resume smoking (which eliminates the often uncomfortable withdrawal symptoms), in combination with the high probability of exposure to smoking cues after they leave the hospital creates the potential for high relapse rates that would undermine the apparent efficacy of NRT in a study (Hyland et al., 2009; Messer et al., 2008).

In spite of the lack of support in the literature for efficacy of NRT with hospitalized smokers, researchers generally agree that hospitalized smokers should be given pharmacotherapy even without counseling (Feeney et al., 2001; Simon et al., 2003). Of note, in current practice, not all smokers receive NRT during hospital stays and of those who do, many stop using it after discharge, which greatly diminishes its effectiveness (Emmons et al., 2000; Rigotti et al., 2000; Rigotti et al., 2007). Clearly, a great need exists in the literature for additional well designed experimental studies to test the efficacy of NRT alone and in combination with other interventions for smoking cessation.

Interventions That Combined NRT and Behavioral Intervention

Mohiuddin et al. (2007) conducted a well-defined experimental study in which 209 hospitalized patients with cardiovascular disease were randomized to receive either an intensive smoking cessation intervention (described below) or the usual care intervention of bedside counseling with the provision of literature prior to discharge. In this study the treatment group consisted of at least 12 weeks of behavior modification counseling and individualized pharmacotherapy (nicotine replacement therapy) all provided at no cost to the participant. Upon discharge both the treatment and control groups were followed for two years to obtain cessation data. Compared with the usual-care group, the intensive-treatment group had significantly greater continuous cessation smoking rates at each follow-up interval. At 24 months continuous smoking cessation rates were 39% in the intensive-treatment group compared with 9% in the usual-care group ($p<.0001$). During the course of the two-

year study, 41 patients in the usual-care group and 25 patients in the intensive-treatment group were re-hospitalized, which translates to a relative risk reduction of 44% at the 95% confidence interval (16%-63%; *p*=.007). All-cause mortality was 2.8% in the intensive-treatment group and 12.0% in the usual-care group, providing relative risk reduction of 77% and the 95% CI (27%-93%; *p*=.014).

This study demonstrated that an intensive treatment combining pharmacotherapy and behavioral counseling can significantly increase sustained smoking cessation rates, and as a result, researchers referring to this study in the literature concluded that hospitalized smokers, especially those with cardiovascular disease, should undergo treatment with a structured intensive cessation intervention for an initial period of three months (Lancaster, Stead, et al., 2000; Rigotti et al., 2007).

In addition to the 2007 study by Mohiuddin et al., other research also supports the recommendation that inpatients receive a structured, intensive smoking cessation intervention: Lancaster (2005) with an initial treatment interval of three months in combination with a transdermal nicotine patch and Feeney et al. (2001) in this study of 198 in-patients. Feeney et al. reported a quit rate of 1% at 12 months in the control group and 34% in the intervention group. The intervention group received physician and nurse counseling and eight proactive follow-up sessions. The control group also included physician and nurse counseling with the offer of follow-up counseling. However, the providers did not initiate any follow-up. In a similar study, Simon et al. (2003) validated quit rates as high as 30% at one year among inpatients provided with

educational materials, nicotine patches, and five counseling sessions. The control group, which received minimal counseling and two months of transdermal nicotine, had a quit rate of approximately 20%. Simon et al. concluded that the addition of nicotine replacement and counseling initiated during hospitalization may account for the increase in long-term quit rates in the intervention group.

Although the studies described above clearly demonstrate efficacy, it remains unclear how to implement the practical aspects of such intensive treatment programs. Most hospitals do not have 12 weeks of intensive behavioral counseling for their patients, nor do insurance carriers currently pay for these extensive services. Additional research to demonstrate the cost-benefit analysis to insurance carriers may ultimately elevate the standard of care. However, it likely will take time for research to inform practice in this area without additional mandates from licensing bodies or other external factors to help evoke change.

Summary

Hospitalization provides an opportunity for intervention by clinical staff in addition to a temporary change of environment where cues linked to smoking do not exist and smoking is not allowed (Halpern, Schmier, Ward, & Klesges, 2000; Rigotti et al., 2008). However, upon discharge the patient typically returns to their home milieu where the smoking cues exist, and the intention to commit to quitting may diminish. The previous studies have shown that both NRT and telephone counseling are effective methods of aiding smoking cessation (An, Schillo, et al., 2006; Lancaster, 2005; Molyneux et al., 2003; Stead et al., 2006). No study to date,

however, has examined how efficacious a combination of NRT and phone counseling will be for hospitalized smokers, especially if they are added on top of the bedside advice that is currently usual care in a randomized trial.

STUDY DESIGN AND METHODS

Problem to Be Investigated

This study had two main aims. The first was to examine the feasibility of an enhanced cessation intervention for hospitalized smokers beyond the brief counseling they typically receive while in the hospital. This intervention, in which smokers who quit smoking when hospitalized were provided with nicotine patches as they left the hospital and with proactive telephone counseling after discharge, is the result of a collaboration between a hospital and a telephone based quitline (i.e., the California Smokers' Helpline). This collaboration used the strengths of the two systems to add nicotine patches to the discharge procedures of the hospital and to provide proactive telephone counseling from the quitline for up to two months post discharge.

The second aim of the study was to use a randomized design to examine whether cessation outcomes for hospitalized smokers could be improved by the enhanced intervention compared to the usual care condition. The study was not powered for statistical significance between the groups but rather to obtain an estimate of the effect size to determine whether this collaborative model would be worth pursuing in a larger design.

Study Design

This study used a two-group randomized controlled design to evaluate the difference in smoking cessation rates between hospital inpatients who received a standard bedside intervention and those who received a proactive counseling program and pharmacotherapeutic intervention in addition to the usual care. The usual care

consisted of cessation education in the hospital provided by respiratory therapists, free smoking cessation educational materials developed by the California Smokers' Helpline, and a faxed referral to the California Smokers' Helpline.

The enhanced intervention group received the usual care intervention as well as eight weeks of nicotine patches provided at discharge and up to five proactive telephone counseling sessions from the Helpline after discharge. Figure 1 depicts the overall study design (see Appendix A for figures and tables).

Setting

The study took place in San Diego County, California. San Diego is located on the U.S.–Mexico border and is the second largest county in California and the fourth largest in the United States (U.S. Census Bureau, 2010). According to the U.S. Census Bureau (2010), San Diego County had a population of approximately 3.0 million people in 2010. The racial/ethnic distribution of non-Hispanic White was 50.4%, Hispanic/Latino was 31.3%, African American was 5.6%, Asian American/Pacific Islander was 10.4%, and American or Alaska Native was 1.0% (U.S. Census Bureau, 2010).

Scripps Mercy Hospital is part of a not-for-profit, community-based health care delivery network (i.e., Scripps Health) in San Diego, California. This study was funded by a $50,000 grant from the Scripps Clinical Research Development Award for new investigators at Scripps Health. This hospital was chosen as the recruitment site for several reasons. First, there was a pre-existing relationship between the hospital and the California Smokers' Helpline that could be expanded. Second, there

was support for the project from the top level of hospital management. Third, the hospital provides services to a diverse patient population. Finally, the hospital is one of five hospitals in the Scripps Health network, which would allow for dissemination of the model if it should prove to be effective.

In 2010, Scripps Mercy Hospital provided services to 113,207 patients (inpatients and outpatients) with an ethnic distribution of 25% Hispanic/Latino, 14% African American, 5% Asian American/Pacific Islander, 0% Native American, 2% other, 53% White, and 1% unknown. Of those patients, 35% were covered by private insurance, 26% by Medicare, 25% by Medi-Cal, and 14% without insurance or self-pay.

Eligibility Criteria

English speaking adult smokers (age 18 and up) who were admitted to the hospital for more than 24 hours, smoked at least 10 or more cigarettes per day prior to admission, and had quit smoking during hospitalization were considered potential study participants. Additional inclusion criteria included the need to have a telephone and no plans to move from current address in the next six months.

Smokers were excluded if they were: pregnant, hospitalized for psychiatric treatment, terminally ill (prognosis less than 12 months), or unable to communicate verbally. Patients with the following medical conditions were also excluded: stroke or acute cerebrovascular accident within the previous year, angina, arrhythmia, uncontrolled diabetes or insulin dependence. They were excluded because these conditions are considered contraindicated for nicotine patches.

Respiratory Therapists used the Scripps computerized data system as well as a screening tool developed for this project to determine whether a participant met eligibility criteria.

Screening and Recruitment

Subjects were recruited from Scripps Mercy Hospital. As part of standard care, a list of all smokers who were admitted for at least 24 hours was generated each morning by the Scripps electronic medical record system called Centricity and faxed to the Scripps Mercy Respiratory Therapy Department. Respiratory Therapists (RTs) delivered bedside cessation education and explained the study to eligible patients and completed an eligibility survey. RTs made up to three attempts to visit patients on their shift; patients not reached would appear on the list for the next shift until contact was made. See Appendix B for a copy of this eligibility tool. If a patient was deemed eligible, an RT called the attending physician to obtain approval for the patient's participation. Patients who agreed to participate in the study and had physician approval were asked a series of baseline questions and additional contact information. Patients who were not eligible or not interested in the study received usual care by the RT. Screening, consent, and baseline forms were placed in a confidential folder in the RT office, and the Principal Investigator (PI) picked up this information daily and reviewed it.

In addition, the PI created a postcard and worked with hospital admissions to include the card in all patient rooms; the card allowed the patient to proactively contact the RT if they were interested in being in the study (Appendix C).

Informed Consent

Patients who agreed to be in the study signed a consent form prior to randomization. This form explained the purpose of the study and expected recruitment numbers, the randomization procedure, the possible group allocation, and the evaluation process. In addition, it included information about limits to liability and whom to contact about questions or complaints. Institutional Review Board approval was granted from San Diego State University (# 249042), University of California San Diego (HRPP#081488) and Scripps Health (#08-9000). All three institutions reviewed the study yearly and approved all surveys and other study activities.

Randomization

Participants who were eligible, agreed to participate, and signed a consent form were randomized at the bedside. Randomization took place after the RT collected baseline data, provided bedside counseling, and obtained consent; thus RTs were blind to group assignment during those procedures. The RT contacted the PI who told the RT what treatment the patient should receive. The PI used computer-generated randomization lists so that randomization was stratified by the RT and subjects were allocated to treatment condition using blocks of four. The RT was then responsible for flagging the charts of subjects in the enhanced treatment condition with a florescent sticker to ensure that those patients received patches upon discharge. Patients who left the hospital without the patches (four out of 64) were mailed the patches within 24 hours. Subject contact information and group allocation was faxed

to the Helpline for follow-up with counseling (if they were in the enhanced condition) or for evaluation (all subjects).

Control group (usual care). All participants received a brief bedside intervention by an RT, which is the standard care at Scripps Mercy Hospital. The 10 to 15 minute counseling included encouragement for quitting and staying quit plus education materials. RTs used the *Ask, Advise, and Refer* method to assess each patient's tobacco use. The model for this education is *Ask, Advise, and Refer*, a system developed by the University of California, San Francisco's Smoking Cessation Leadership Center to assess individual tobacco use and offer tailored education, referrals, and support resources (Schroeder, 2005). This was adapted from a more comprehensive process that was deemed too time consuming for busy health professionals (Raw, McNeil, & West, 1998, 2000). "Ask" refers to the identification and collection of data related to inpatient smokers. Once identified during intake, all smokers are then referred electronically to an RT. "Advise" refers to a brief educational session offered by the RT to encourage patients to quit, and "Refer" prompts a list of counseling services and support groups in the area. Included in this referral process is a fax to the California Smokers Helpline. This successful approach was adopted based on evidence that brief advice can impact smoking cessation when delivered by a physician or other health professional (Fiore et al., 2000; Lancaster & Stead, 2004). It is now a part of the hospital system, laying the foundation for this study. This was the extent of the intervention for the usual care control condition (i.e., no patch/no counseling).

Table 1 compares the treatment components of the standard bedside intervention (usual care) to the enhanced intervention.

Enhanced intervention group. The enhanced intervention group received the same standard bedside intervention as the control group. In addition, they received an eight-week supply of nicotine patches prior to discharge and telephone counseling for up to two months post discharge.

The patches supplied were HabitrolTM brand, which was manufactured by Novartis Consumer Health, Inc. The box included 56 patches with instructions to use a fresh patch each day for eight weeks following the step-down program (three steps: 21 mg, 14 mg, and 7 mg). The patient was told to use 21 mg patches for 4 four weeks, 14 mg for two weeks, and 7 mg for the final two weeks. The purpose of providing patches at discharge was twofold. First, the nicotine in the patches would help the patient manage any withdrawal symptoms they might have. Second, putting on the patch prior to discharge would serve as a declaration to oneself and to others of the intent to stay quit upon leaving the hospital.

Quitline staff made up to 10 attempts to reach subjects to initiate counseling. The telephone counseling was provided by a veteran counselor at the California Smokers' Helpline. All counseling clients were mailed standard Helpline self-help materials to their home. The counseling protocol used was the standard program that has been empirically validated in several large randomized trials conducted at the Helpline (Zhu et al., 2002; Zhu, Tedeschi, et al., 1996). The telephone counseling protocol used has several distinguishing features that have been described previously

(Zhu, Tedeschi, et al., 1996), namely proactive counseling, a structured counseling protocol, and relapse-sensitive scheduling (Zhu & Pierce, 1995; Zhu, Tedeschi, et al., 1996). The counseling addressed both behavioral and cognitive issues that the individual smoker faces in his/her attempt to quit. Counseling consisted of a comprehensive initial call (about 30 minutes) to set up or solidify the quitting plan and up to five follow-up calls (about 10-15 minutes each). Calls were front loaded when the probability of relapse was highest and spaced out as the client experienced success in quitting; such relapse-sensitive scheduling of calls has been shown to be effective in preventing relapse (Zhu, Stretch, et al., 1996). In follow-up calls, the counselor evaluated the effectiveness of coping strategies, examined slip or relapse situations, worked with the subject to revise the plan as needed, bolstered self-efficacy and motivation, and helped the subject develop a self-image as a nonsmoker. The final counseling call took place at about two months post-discharge, when most subjects would have finished their use of the nicotine patches.

Training

More than six months were spent on preparing the hospital staff for the study. Formal training was conducted by the Principal Investigator (K. Brandstein) separately for each group of hospital staff, depending on their role. Respiratory Therapists received a one-time five-hour training, which included information about the rationale of the study; eligibility criteria and baseline survey implementation; the consent, physician approval, and randomization processes; and the process for delivering the nicotine patches to the patient prior to discharge. To ensure proper

implementation, study guidelines and steps were posted on the RT office stations (Appendix D) and RT staff was contacted weekly to debrief any problems and/or provide further training or technical support. A total of five out of over 100 overall RTs were selected to participate in the study. These RTs were chosen because they were already providing smoking cessation at bedside, worked full time, were highly involved in patient education, and expressed enthusiasm for the study. The PI contacted these RTs daily to ensure quality and answer any questions.

The PI provided one-hour trainings for nurses on four occasions. Eighty nurses attended one of the trainings (roughly 40% of the total). The rest were told about the study by their fellow nurses. As with the RT training, general information was provided on the purpose of the study, the consent procedure, and the intervention conditions. More detailed information was provided about participant eligibility and the process by which patients were to receive their nicotine patches. In order to reinforce this information, educational materials were developed and detailed instructions describing the role of the nurses were posted at each nursing station on each floor. Nurse involvement in the study was considered key to ensure the proper distribution of the patches to all subjects in the enhanced condition (Appendix E). One to two hours prior to discharge, the nurse in charge of the participant's care would contact the RT department to ask the RT on staff to retrieve the nicotine patches from the pharmacy. Each patient in the enhanced group had a labeled bag at the pharmacy that included the eight-week course of Nicoderm CQ patches and written instructions about using the patch. The RT delivered the bag to the patient and

encouraged him/her to put on a patch prior to discharge. Each week the PI called the nursing station and spoke with the charge nurse to remind him/her about the study procedures for delivering the patches to the enhanced intervention patients prior to discharge.

Physicians were core to the study because physician approval was necessary for patients to participate. As a result, it was important that the physicians fully understood the purpose of the study and their role in it. Physicians were informed of the study using both written and verbal modes of communication. Four one-hour meetings were held as part of the Physician Leadership Counsel, during which the PI presented an overview of the study and described the role of the physicians. Approximately half of the 50 members of the physician leadership team attended. Physician feedback from pilot work indicated that physicians were more likely to respond to the study if its importance was communicated to them by another physician. Therefore, Dr. Edward Chaplin used his role as Quality Control Director at Scripps Mercy Hospital to communicate to his fellow physician leadership team about the study in a systematic one-to-one way. To further raise physician awareness of the study, an informational poster was developed and placed in the physician lounge for one year. Also, a variety of articles were prepared by the Chief of Pulmonology and published monthly in *Mercy MD* and *Around Mercy* (in-house publications) to offer information about the study (Appendix F).

The pharmacy also played a critical role in ensuring that all patients assigned to the enhanced intervention were discharged with their nicotine patches. The

pharmacy kept a detailed log book that documented who received patches at discharge (Appendix G). The process of distributing the patches to the proper patient required greater interaction among RTs, physicians, nurses, and pharmacy staff than is typical. The RT contacted physicians for authorization to enroll the patient. The Charge Nurse called the RT team prior to discharge to notify them about the need to collect the patches. The RT picked the patches up from the pharmacy and took them to the patient. Strong relationships between RTs, nurses, physicians, support of hospital management, and clear protocols built and reinforced the collaboration needed to ensure patients received the patches prior to discharge.

Measures

Data were collected from the subject at baseline and during two evaluations (at two months and six months post enrollment). In addition, administrative data were collected that related to the whether the intervention was delivered as planned; for example, whether enhanced intervention subjects were contacted proactively for counseling, whether they accepted counseling, and how many counseling sessions they received. The primary quit outcome measure was self-reported smoking status at the time of evaluation.

Three survey instruments were developed for study purposes. The first was used by the RTs to screen smokers for study eligibility. It captured information about the number of smokers who were approached about the study and how many of them opted not to participate. A second instrument was used to gather baseline information for smokers who were interested in the study (Appendix H). A third instrument was

used to collect the smoking status and quitting experience from the two- and six-month telephone evaluations that were conducted by Helpline evaluation staff (Appendix I and Appendix J).

Eligibility survey. The admitting nurse was responsible for determining whether the patient was a current smoker or had smoked in the year prior to hospitalization. Each morning the RT department received a list that indicated which patients needed a visit. The RT examined chart records to obtain information such as whether the patient had a psychiatric illness or a terminal illness. Other information was collected at the bedside using the eligibility survey. This eligibility form included demographic variables (language, age, and sex), contact information (e.g., phone number and address), and whether they planned to move from their home in the next six months. The RT also verified smoking status by asking the patient, *Before you were admitted to the hospital, did you smoke cigarettes every day, some or not at all?* Patients who smoked some days were asked how many days per week they smoked on average, and patients who smoked daily or some days were asked, *On average, how many cigarettes did you smoke per day (on the days you smoked).* Patients were asked whether they smoked during their hospitalization and whether they planned to stay quit after discharge.

Because the intervention included the use of nicotine patches, several questions were asked about chronic health conditions that could make their use problematic. These conditions included uncontrolled high blood pressure, insulin-dependent diabetes, recent heart attack or stroke, arrhythmia, and angina. The

questions were as follows: *Have you been told by a doctor that you have high blood pressure?* If the answer was yes, patients were asked, *Is it under control?* and were ineligible if it was not. *Do you have diabetes?* If the answer was yes, patients were asked, *Do you control it with insulin? Have you ever had a heart attack? Was it within the last year? Have you ever had a stroke? Was it within the last year? Have you ever been told you have angina? Have you ever been told you have arrythmia?* Patients with any of these health concerns were ineligible for the study.

Baseline survey. Patients who agreed to the study were asked by the RT a series of baseline questions that included years smoked, number of cigarettes smoked per day, previous quit attempts, and how many of those attempts lasted for 24 hours or longer. Additional demographic and other information collected included name, birth date, phone number, email address, ethnicity, and education. A number of other possible predictors of quitting success were measured at baseline, including self-efficacy, support, environmental challenges, and insurance coverage. *Self-efficacy* was measured by asking the participant how confident they were that they could quit (or stay quit) for at least one week. Answers were coded as very confident, confident, or less than confident. *Social support* was measured at baseline by asking the participant what degree of support for quitting they received from those around them and coded support as a lot and less than a lot. *Environmental challenges* included having another smoker living in the home (yes/no) and the presence of restrictions were categorized into two groups either having *complete restrictions* and *not complete restrictions*, which included those with no restrictions or with partial restrictions

Two and six month evaluation survey. A separate group of evaluators (not counseling staff) conducted follow-up interviews with subjects by telephone at two and six months after randomization. The evaluation survey included questions about satisfaction with the services received and a detailed quitting history from the time of randomization (e.g., number of quit attempts, dates of quit attempts, and slips/relapses), as well as questions about self-efficacy, relapse situations, other smokers in the household, use and type of quitting aids or medications (including whether they used the nicotine patches they were provided with and their length of use) and use of any other behavioral counseling services.

Prior to the two-month evaluation survey, a letter was sent to participants thanking them for their participation in the study and encouraging them to take the evaluation call. A $2 bill was enclosed as a "thank-you" for their participation. This served as a non-contingent incentive, which has been shown to increase response rates (Hawley, Cook, & Jensen-Doss, 2009; Trussell & Lavrakas, 2004).

Effort to Improve Accuracy for Self-Report

At six-months, all participants were sent a cotinine sample kit and asked to supply a saliva sample. They were told that the saliva could be tested to determine the "amount of nicotine" they'd been exposed to. This procedure acts as a "bogus pipeline," thus increasing the likelihood that respondents would tell the truth about their smoking status (Roesé & Jàmieson, 1993). Participants who returned the saliva sample were given a $ 10 gift certificate to Target. Appendix K for a copy of the letter sent.

Data Management and Quality Control

Data from the hospital were collected on hardcopies and entered by the PI into an electronic spreadsheet using SPSS PC+. To ensure data quality, double data entry was conducted in Excel at the Helpline and by the PI on 100% of the data. The quality of the double data entry was assessed to assure accuracy. The final dataset was analyzed using SAS.

Sample Size and Power Determination

This study was not designed to detect a statistically significant intervention effect at the sixth month. That would require a randomized trial with quite a large sample, which is not feasible for a Ph.D. dissertation. Based on previous studies on smoking cessation, it was decided that a total 120 subjects randomized into two groups would be a good size study. In the year prior to the study, Scripps Mercy Hospital identified almost 3,000 smokers from among the hospitalized patients. Thus, it was considered reasonable to assume that 120 participants could be recruited within a year with the help of five RTs.

It was estimated that the quit rate of the intervention group would be at least 2.5 times that of the usual care group if all patients assigned to the enhanced intervention received nicotine patches before discharge and if 70% of them received counseling. This was based primarily on a study of hospitalized smokers by An, Zhu, et al. (2006) in which the quitting success of combined pharmacotherapy and telephone counseling (using the protocol developed by the California Smokers' Helpline) condition was 2.5 times that of the usual care condition. When the original

dissertation proposal was submitted to the committee, the evaluation timeline was set at four months after randomization, and it was estimated that the three-month prolonged abstinence rate at four-months was 10% for the usual care group and 25% for the enhanced intervention group. A sample size of 120 participants gave the study a power of 58% (SAS/STAT 9.2) with an alpha of .05 for picking up real difference between the groups on smoking outcome, assuming the quit rates were 10% and 25% in the usual care and enhanced intervention groups, respectively. The committee recommended the evaluation time be extended to six months post randomization. Thus, the estimates of quit rate were adjusted for prolonged abstinence at six months. It was assumed that prolonged abstinence rates at six months would be 8% and 20% for usual care and 20% of enhanced intervention group, respectively. Under this condition, 120 subjects would give the study a power of 47%.

Because the evaluation time was extended to six months, it was decided that another evaluation would be conducted at two months. The main reason was that many of these hospitalized smokers are a difficult-to-reach population. If the study waited for too long to contact them, the attribution rate would be too high. Two-month evaluation would provide a chance to update contact information. It would also provide information on short-term quit rate.

Data Analysis

To check whether randomization was successful, bivariate analyses were conducted to compare the groups on all baseline variables including age, education, gender, ethnicity, and medical diagnosis. Chi-squared tests were used to analyze

categorical variables (age, sex, education, ethnicity, diagnosis) at baseline. Age was not used as a continuous variable due to the need to be able to see the differences between groups. Age was categorized by the following: 18-24, 25-34, 35-44, 45-54, 55-64 and 65+. Education was categorized as ≤ 12 years or >12 years. Ethnicity was categorized as non-Hispanic White and other ethnicity. The reasons for hospitalization were categorized into the following diagnostic categories: "injury/orthopedic/musculoskeletal," "Pulmonary/respiratory," "Gastrointestinal/abdominal," "Infection," "Cardiac," "Neurological, Genitourinary/renal," "Ear, nose, throat," and "Vascular and Cancer." Other variables including history of smoking were included in the univariate analysis.

A multiple logistic-regression, with continuous abstinence for 30 days at two months as the outcome, was conducted to evaluate potential predictors.

The primary outcomes were prolonged abstinence rates at two and six months. At two months, a 30-day prolonged abstinence rate was used. This is also a common measure for quitline studies (An, Zhu, et al., 2006). At a six-month evaluation, we compared the two groups on their 180-day prolonged abstinence.

To follow the Society for Nicotine and Tobacco Research's recommendation on using multiple outcomes, this study also computed the seven-day point prevalence at both evaluation times. The seven-day point prevalence is a short-term quitting measure, but it also allows for cotinine validation, thus it appears in the literature often. This study, however, did not test for cotinine. It only asked the subjects to turn in saliva sample as a way of enhancing self-report accuracy.

RESULTS

Participants

This study randomized 126 participants into either the Enhanced Intervention (N=64) or the Care as Usual Control (N=62). Recruitment took place from January 28, 2009 to September 27, 2009. Figure 2 details a consort table and the flow of study participants through the trial. During the recruitment period, 1,729 patients were admitted to the hospital and identified as a smoker by the admissions nurse. Of these, 739 (42.7%) were seen at bedside by a Respiratory Therapist (RT) and the remaining 990 were either not seen by an RT while hospitalized or the visit was not documented in the chart. Smokers were not visited primarily due to time constraints on the RT and the hospital policy of giving priority to intervening with patients diagnosed with pneumonia or cardiovascular disease, as required to meet hospital accreditation. Of the 739 patients seen at bedside, 566 patients expressed interest in the study and were screened for study eligibility. Of the 566 potential subjects, 216 declined to participate (38%) and 224 were ineligible (39.6%). Most common reasons for ineligibility were: denying being a smoker when asked by the RT (n=21), a history of angina or arrthymia (n=45), or a recent (within one year) history of heart attack or stroke (n=16). A number of potential subjects were deemed ineligible by the RT without specifying the reason (n=61). The recruitment yielded 126 eligible subjects who gave their consent to be in the study, all of whom received physician approval for their participation.

Participant Demographic Characteristics and Reason for Hospitalization

Table 2 compares the baseline characteristics of the randomized groups on demographics and reason for hospitalization. There were no significant differences on gender, ethnicity, age, education, or reason for hospitalization. Men comprised 65% of the sample. The majority of participants identified their ethnicity as non-Hispanic White, n=81 (64.3%). Other ethnicities reported were Black or African American, n=21 (16.7%), Hispanic or Latino, n=18 (14.3%), Asian or Pacific Islander, n=2 (1.6%), American Indian or Alaska Native, n=1 (.8%), some other ethnicity, n=1 (.8%). Two subjects failed to provide ethnicity (1.6%). Because each minority ethnic group was small, for statistical comparison, ethnicity was categorized as *non-Hispanic White* and *other ethnicities*. The average age of participants in the study was 47 years (*SD*=13.7). Of those who responded to the education question, 62 (54.5 %) reported they had completed some college.

Primary reasons for hospitalization given by the patient were injury including orthopedic and/or musculoskeletal n=25 (19.8%), pulmonary or respiratory issues n=14 (11.1%), gastrointestinal or abdominal issues n=16 (12.7%), infection n=20 (15.9%), and unknown n=17 (13.5%). For statistical purposes, less frequently mentioned reasons were classified as *other*; these consisted of cardiac n=2 (1.6%), neurological n=5 (4.0%), genitourinary/renal n=2 (1.6%), ear, nose, and throat n=4 (3.2%), vascular n=3 (2.4%), cancer n=5 (4.0%), and other conditions n=13 (10.3%). There was no significant difference between the randomized groups on reason for hospitalization (p=0.51).

Smoking History and Environmental Variables of Study Participants

Table 3 compares the enhanced intervention and the care-as-usual groups on smoking history and environmental factors. There were no significant differences between the groups on the number of cigarettes they smoked each day, whether they lived with another smoker, household restrictions, quit attempts in the past 12 months, confidence in their ability to quit, support for quitting, or whether they used quitting aids in the past.

By design, all participants smoked 10 or more cigarettes daily prior to hospitalization. The mean cigarettes per day and the standard deviation for the enhanced group were 16.8 (*SD*=7.2) and for care as usual was 17.3 (*SD*=7.8; $p<.54$). For statistical comparison, cigarettes per day was categorized as either *between 10 and 20* or *more than 20*. Only 10% said they smoked more than 20 cigarettes per day.

Of the 126 participants, seventy-two participants in the study reported that they had made at least one attempt to quit smoking in the previous year. Of the total sample, participants who attempted to quit, 21 (16.7%) had made one attempt, 23 (18.3%) had made two attempts, and 23 (18.3%) had attempted to quit three or more times. One participant refused to answer and 58 (46.0%) had never made a quit attempt.

Of the total participants, a total of 61 subjects had made a quit attempt in the last 12 month and answered the question about using quitting aids, 33 (26.2%) stated they had tried quitting *cold turkey*. Another 13 (10.3%) had used the nicotine patch, whereas only three (2.4%) had used nicotine gum and even fewer (n=2, 1.6%) had

used Chantix® (varenicline). Only one person (.8%) had ever used counseling to help them quit smoking. Eight people (6.3%) indicated they had used two or more methods. One person refused to answer and another had missing data. There were no significant differences between the randomized groups on previous use of quitting aids (p=0.61).

Participants were asked about their home environment and if there were other smokers in the home. Almost half of the respondents (48.0%) reported that there was another smoker in their home.

Sixty-one subjects (48.4%) reported having no restrictions when it came to household smoking. A total of 58 (46.0%) had a complete ban on smoking in the home and another four (3.2%) had some restrictions, either restricted to some people or some rooms. Two subjects responded that they did not know if there were restrictions, and data for one subject was missing. There were no significant differences between the randomized groups on household smoking restrictions (p=.46). For statistical comparison of the groups, household restrictions were categorized into two groups: either having *complete restrictions* and *not complete restrictions*, which included those with no restrictions or with partial restrictions.

When asked about social support for quitting, 53 (42.1%) subjects reported that they had a lot of support from friends, family, and others; 66 (52.4%) subjects reported having either some support or no support, which for statistical comparison were collapsed into *less than a lot* of support. Data from seven participants (5.5%)

was unavailable. There was no significant difference between the randomized conditions on social support (p=.40).

Interestingly, majority of these patients expressed confidence in quitting smoking. Less than 25% of them stated that they were less than confident or they were not sure of their confidence level. There is again no difference between the two randomized groups.

Delivery of Counseling and Patches

All subjects in the enhanced condition (N=64) received the package of nicotine patches; 60 received them at the time of discharge, as intended. Four were discharged without receiving the patches, but the package was mailed to their home using UPS. In the two- and six-month evaluations, subjects were asked if they used any quitting aids since their enrollment in the study. A total of 66.7% of participants in the enhanced group used at least some of the nicotine patches provided by the study. The care-as-usual group was not provided with nicotine patches, however 22.7% of subjects in this condition used a quitting aid; 90% of which were nicotine patches. More than three quarters of the subjects in the enhanced condition (76.6%) received at least one proactive counseling session from the California Smokers' Helpline post discharge. The first session was the most comprehensive, with a median length of 14 minutes and a mean of 17 minutes. Of those subjects in the enhanced condition who received counseling, the median number of follow-up counseling calls was three, so the total calls received was four. No subjects in the care-as-usual group received counseling from the Helpline.

Return Rate for Saliva Sample

At six months, all participants who were evaluated (n=73) were sent a collection kit and asked to submit a saliva sample. This request operated more like a bogus pipeline than an actual test of cotinine level (Roesé & Jàmieson, 1993) because it was expected the return rate will be low. The aim was to ensure that there was no differential return rate. An average of 34.7% of all those who were requested to return their saliva sample did so. There was no significant difference in compliance with the request between the randomized groups: 35.0% for the enhanced intervention group and 34.3% for the usual care group (p=0.95).

A secondary comparison is to compare the return rate of those who reported they have quit and with those that report continuing smoking. The rate was higher for the former, 57.1% vs. 29.5% (p<0.05).

Satisfaction with Respiratory Therapist Services

In both the two- and six-month evaluations, subjects were asked to rate their satisfaction with the services they received from the Respiratory Therapist in the hospital. There was no difference in satisfaction between the two conditions at two months, 57.5% of respondents in the enhanced group reported their satisfaction as "very good" compared with 42.5% in the control group (p=0.34). Data shows a similar trend in the six-month follow-up (p=0.26).

Short-Term Quitting (Two-Month Evaluation)

Table 4 presents outcomes by treatment group at two and six months. Evaluators made up to 50 attempts to reach subjects. Subjects that were successfully

reached for evaluation had a median number of attempts of three (range 1-39), whereas subjects that were never successfully reached had a median number of attempts of 21 (range 3-47) before being labeled as *no contact*.

The evaluation contact rate at two months was 78.0%. There was no significant difference in contact between the groups; 79.6% and 74.0% were evaluated in the enhanced and control conditions, respectively (p=.46). The primary outcome measure at two-month evaluation was a 30-day prolonged abstinence. When analyzing data from those who were reached for evaluation (i.e., responder rate), 33.3% of the enhanced care group had been quit for 30 days or more at the time of the evaluation compared with 8.7% of the care-as-usual group (p<0.005). The odds ratio (OR) was 5.2.

A secondary outcome measure of seven day abstinence reflected the same pattern. More than 40% of subjects in the enhanced group had been abstinent from cigarettes for seven days or more at the time of the evaluation compared with 13.0% in the care-as-usual group (p<0.005). The OR was 4.7.

Longer-Term Quitting (Six Month)

The contact rate for the six-month evaluation was 57.9%. There was no significant difference in contact between the groups; 62.5% and 56.4% were evaluated in the enhanced and control conditions, respectively (p=.48). The primary outcome measure at the six-month evaluation was 180-day prolonged abstinence. The 180-day prolonged abstinence rate was 15.0% and 11.4% for the enhanced and care-as-usual groups (p=.65). The odds ratio is 1.4. Likewise, the quit rates of the two groups were

not different using seven-day and 30-day abstinence. It was 22.5% and 14.3% for the enhanced and care-as-usual groups, p=.36, OR=1.7).

Intent-to-Treat Analysis

Table 5 shows the intent-to-treat analysis for the two evaluation time periods (i.e., two- or six-month) and for each of the quitting outcomes, seven-day abstinence, 30-day abstinence, and 180-day abstinence. In these analyses, participants who were not reached for follow-up evaluation were considered to be smokers. The pattern for the intent-to-treat analyses mirrors the findings from the evaluated subjects, although the absolute abstinence rates are lower.

At two months, more participants in the enhanced condition had been quit for 30 days or more than in the care-as-usual condition (26.6% vs. 6.4%, OR=5.2, p<0.01) and for seven days or more (32.8% vs. 9.7%, OR=4.6, p<0.005).

The six-month intent to treat analyses revealed no significant difference between the enhanced and care-as-usual groups on the 180-day prolonged abstinence rate, 9.4% vs. 6.4% (p=0.74), with an odd ratio of 1.5. Using seven-day and 30-day abstinence as the secondary measure, the analysis also found no significant difference between the groups (14.1% vs. 8.1%).

Potential Predictor Variables

A multiple logistic-regression, with continuous abstinence for 30 days at two months as the outcome, was conducted to evaluate potential predictors. The analysis found that treatment condition was a significant factor and none of the other independent variables contributed significantly to the model.

DISCUSSION

The present study has two main aims: 1) to examine the feasibility of an enhanced cessation intervention for hospitalized smokers via a collaborative model in which a state-run quitline and a community hospital work together to provide smoking cessation services post discharge and 2) to employ a randomized design to examine whether cessation outcomes for hospitalized smokers could be improved by an enhanced intervention and to provide an effect size estimate for a potential larger trial in the future. The results indicate that the study has achieved both aims, and it has identified a promising model for future research and practice.

Feasibility of an Enhanced Intervention

This study demonstrated feasibility of the enhanced intervention in a hospital setting as evidenced by successful completion of the study; feedback from study participants, study researchers, quitline staff, and hospital staff; successful implementation of the enhanced intervention condition; and increased quit rates among smokes assigned to the enhanced intervention condition. Several factors contributed to the success.

First, the study hospital has a good foundation in providing smoking cessation service. The Scripps Mercy Hospital has a well established system of cessation service that is part of quality assurance-procedure aiming to comply with JCAHO requirements. This includes identifying smokers at admission, assigning bedside counseling responsibility to specific groups of hospital staff Respiratory Therapists

(RTs), usual care intervention to hospitalized smokers, and establishing an effective communication between RTs, nurses, physicians, and pharmacists at the hospital. More importantly, the Principle Investigator (PI) obtained support from the hospital leadership. While the fact that the PI is an employee of Scripps Mercy Hospital certainly helped, the support of the hospital leadership made all the difference. It meant that it was much easier for the PI to obtain support from the physicians and other hospital staff. Because all hospital staff, including physicians, RTs, nurses, and pharmacists had heavy workloads, the study added additional work to their already busy schedule. Without the support of the hospital leadership, it would have been very difficult to recruit this many subjects in a relative short period of time.

Second, thorough training for the hospital staff was another logistic detail that made the project a success. It was important that the significance of the study was made clear to the hospital staff, not only in terms of helping smokers but also in terms of its benefit to the hospital (e.g., making the hospital more competitive locally because of patient satisfaction with the service). Also important was that the procedure involved in identifying eligible smokers for the study be made simple and easily understood so that the staff would know that they were not asked to do much more than what they already do with the smokers.

Third, providing free nicotine patches was a major incentive for many hospital staff to get involved with the study. Most hospitalized smokers do not receive NRT while at the hospital, and fewer of them leave the hospital with NRT. Being able to give some patients free nicotine patches turned out to be a major attraction of the

study. Thus, what would have presented as a logistical challenge to the researcher (because it takes quite a bit of coordination between nurses responsible for the discharge process and pharmacists that keep the patches) was presented to the hospital staff as a benefit. It was truly motivational: the PI received several complaints from the psychiatric unit because it was excluded from the recruitment effort, thus leaving their patients without the access to the free patches.

Fourth, the stronger support from the California Smokers' Helpline made it easier for the hospital leadership to support the project. The Helpline is a well known group in the field of tobacco cessation and it has provided leadership among the quitline movement in the United States. Moreover, the Helpline had experience in running clinical trials, including recruitment, training of project staff, counseling, and evaluation and statistical analysis. The Helpline had also worked with the Scripps Mercy Hospital before the project started. Thus, it was not hard to gain support for the project when the Director of the Helpline came to present to the hospital leadership.

Finally, the most attractive aspect of the Helpline is that it can provide proactive telephone counseling post discharge. It is very difficult for the hospital to provide any follow-up to patients about their smoking problems after they are discharged. It is simply not part of their protocol. It is also very difficult to get smokers to attend any face-to-face cessation clinics once they are discharged. In fact, very few of them will even call the toll-free number of the Helpline. However, this study employed a proactive outreach model. Smokers' names and their contact phone

numbers are faxed to the Helpline after the hospital staff obtained permission from the patients to call. When the Helpline called, smokers understood that it was with the hospital support that the Helpline was calling them. It provided a good foundation for the Helpline counselors to launch into what is effectively a psychological service to help smokers deal with a difficult additive habit.

In short, the study tested a collaborative care model in which the hospital identified the smokers, provided brief bedside counseling and an NRT patch for the smokers to take with them upon discharge, obtained consent for follow-up, and then linked with the Helpline by faxing the smokers' information to the counselors. The Helpline then took up where the hospital left off and provided proactive counseling to help prevent these patients from relapsing and to help them quit again if they had already relapsed. Because quitlines are available in all U.S. states, the study provided a feasible model for a possible large-scale implementation if the effectiveness of the whole intervention protocol can be demonstrated.

Effects of Enhanced Intervention

The study was not designed with sufficient power to detect a statistically significant difference in quitting outcome. However, the effect size for the 30-day abstinence rate at two months was much larger than what was hypothesized. The odds ratio was 5.2, as opposed to the estimated 2.5. And the difference between the two treatment conditions was found to be highly significant. This suggests that the combination of dispersing nicotine patches at the point of discharge and of follow-up with proactive counseling can increase the abstinence rate of hospitalized smokers

above and beyond what they have received in the hospitals. This seems to be true at least for the short term.

The six-month data, however, show a much smaller effect size for the 180-day prolonged abstinence rate (OR=1.5). This suggests there is a high relapse rate between two months and six months. The interpretation of data in this study is somewhat hampered by the fact that the contact rate at six months was relatively low (less than 60%). This makes it more difficult, as the sample size is not that large and it is not clear whether the data pattern for six months would be different had we had a higher contact rate. However, whether we use intention-to-treat analysis or use the data for responders only, the odds ratio for six months is much smaller than that for two months. Thus, the relapse from two to six months appears to be high.

The published literature on hospitalized smokers to date has not specifically addressed the relapse process for this group of smokers. It is well known for smokers at large that most will relapse in the first month when they attempt to quit smoking (Hughes, Keely, & Naud, 2004; Zhu & Pierce, 1995). For the hospitalized smokers, many of them are forced to quit smoking due to their hospitalization. It is expected that most of them will relapse within the first few weeks post discharge. The enhanced intervention was able to prevent many relapses in the first two months. However, it appears that many of them relapse later. This is a result that needs to be examined again in a larger study because the small sample of subjects in this study could have been responsible for the lack of stability in result.

Previous studies have indicated that the effects of an enhanced intervention compared to usual care in the hospital depend on the length and the frequency of contact post discharge (Debusk et al., 1994; MacKenzie, Pereira, & Mehler, 2004; Rigotti et al., 2000). A meta-analysis has concluded that intervention has to extend at least one month post discharge in order to have a sustained result (Rigotti et al., 2008). The counseling in this study extended up to two months post discharge. In addition, smokers in the enhanced condition were given eight weeks of nicotine patch to take home when they were discharged. The process data also indicated that a sufficiently large proportion of smokers in the enhanced condition had received at least some counseling (76.6%) and had used some of the nicotine patch given to them (66.7%). Thus, it is not that the intervention was too weak to produce a significant effect. However, the much smaller effect size for the six-month data suggested that a future larger study needs to consider whether counseling should be delivered over a longer period of time and to examine how well the patch is used over time.

Limitations, Challenges, and Lessons Learned

A small sample size was one limitation of this study. This was not a reflection of inability to recruit smokers. The hospital had a large number of smokers and the hospital staff was very cooperative in recruitment. It was limited by the budget allowed. To recruit a sufficient number of smokers to test the hypothesis in a randomized trial would require a large amount of funding that is not available for a Ph.D. dissertation project. With the California Smokers' Helpline's support, however,

the study did recruit a respectable number of smokers (N=126) and followed them up to six months for a long-term quit rate measure.

The lack of a biological measure to confirm self-reported quitting represented a further limitation as did the high attrition rate in the six-month follow-up. Future studies should explore some monetary incentive to increase the follow-up rate as well the rate of compliance with the request of saliva sample.

One challenge identified by the study was the difficulty to call the patients immediately after discharge. The difficulty had to do with the fact that many patients transition to places other than home following discharge from the hospital including group homes, rehabilitation centers, or home care. Also, in spite of efforts to secure reliable contact information, several participant phone numbers were invalid. Despite these challenges, the contact rate for telephone cessation counseling for this study was 76%, and the participants considered that the telephone counseling was helpful to them.

Another challenge presented by the study also exists for a lot of other hospital-based smoking research. Given the severity of their illnesses and fear of judgment by health providers, some patients are reluctant to report their smoking status or the exact number of cigarettes smoked prior to hospitalization. This becomes a barrier to accurately identifying hospitalized smokers and recruiting potential subjects for the study. On the other hand, this means that those who do report their smoking status and therefore are recruited into the study are probably less likely to misreport their smoking/quitting status in the later evaluation call.

One significant lesson learned from this study was that it is very important to work with pharmacist to dispense the patches to the patients prior to discharge. This was critical because the project called for having patients put on the patches before they left the hospital. If they left the hospital without the patch, it would likely increase their probability of relapse soon after discharge.

Another lesson was that there needs to be a systematic approach to connecting with physicians. Promotion of the study to physicians occurred through several leadership forums, posters, and educational newsletters. The study required that physicians be reached in a timely manner to obtain their approval for patient participation in the study because cessation medication was involved. Oftentimes, attempts to reach physicians would take from one to three hours, which required time and perseverance on the part of the RTs. For future studies a solution may be for RTs to use technology such as an electronic page, text, or email to communicate their needs to physicians, eliminating the need for telephone contact. Implementing the use of technology would not only assist with the overall study flow but also with the process of obtaining a physician order for patches at discharge and with the communication of verbal order requirements by the physician to the pharmacy.

Summary and Conclusions

This study tested the feasibility of collaborative model in which hospital staff provided counseling at bedside, provided NRT at the time of discharge, and then transmitted the patient contact information to a state quitline, which proactively followed up with the patients for up to two months. The study found that not only was

this feasibility, but it had an additional motivational effect on hospital staff. When the hospital staff learned that the quitline would proactively follow up with their patients after their discharge, they became more motivated in assessing smoking status of their patients and in advising them to stay quit after they left the hospital. This suggests that such a collaborative model has a good chance of becoming a sustained service after an experimental study.

This study found that most of those who participated in the study received telephone counseling, and the majority of them also used the nicotine patch that was given to them at the time of discharge. There is a significant difference at the two-month follow-up between the enhanced intervention and the usual care condition, even though the study was not powered to detect a statistical difference. There is also a sizable difference at the six-month follow-up, although it is not statistically significant. These pilot results provide a basis for effect size estimation that can be used for a larger trial that will provide more definitive evidence for intervention effects.

On a grander scale, the hospital-quitline partnership employed by this study could have a substantial impact if adopted by all state quitlines. Currently, there are 50 U.S. state quitlines, which collectively serve more than 500,000 individuals annually. But hospitalized smokers are generally not among those served. Most hospitalized smokers do not call the quitline after they are discharged, and most of them will relapse soon after discharge. What is needed is a proactive outreach approach from the quitlines in which quitline counselors take the initiative to call the smokers soon

after their discharge. However, the quitlines need the cooperation of the hospitals in that the latter need to provide patient contact information before they are discharged. With new JCAHO requirements being debated and soon to be released, the hospitals may be required to do more than just provide bedside counseling. To have a quitline as a partner can greatly facilitate the hospital's compliance with the new JCAHO requirements. Studies like this one can provide immediately useful information for the hospitals, and the collaborative model tested in this study holds the promise of being adopted by hospitals across the nation.

Appendix A

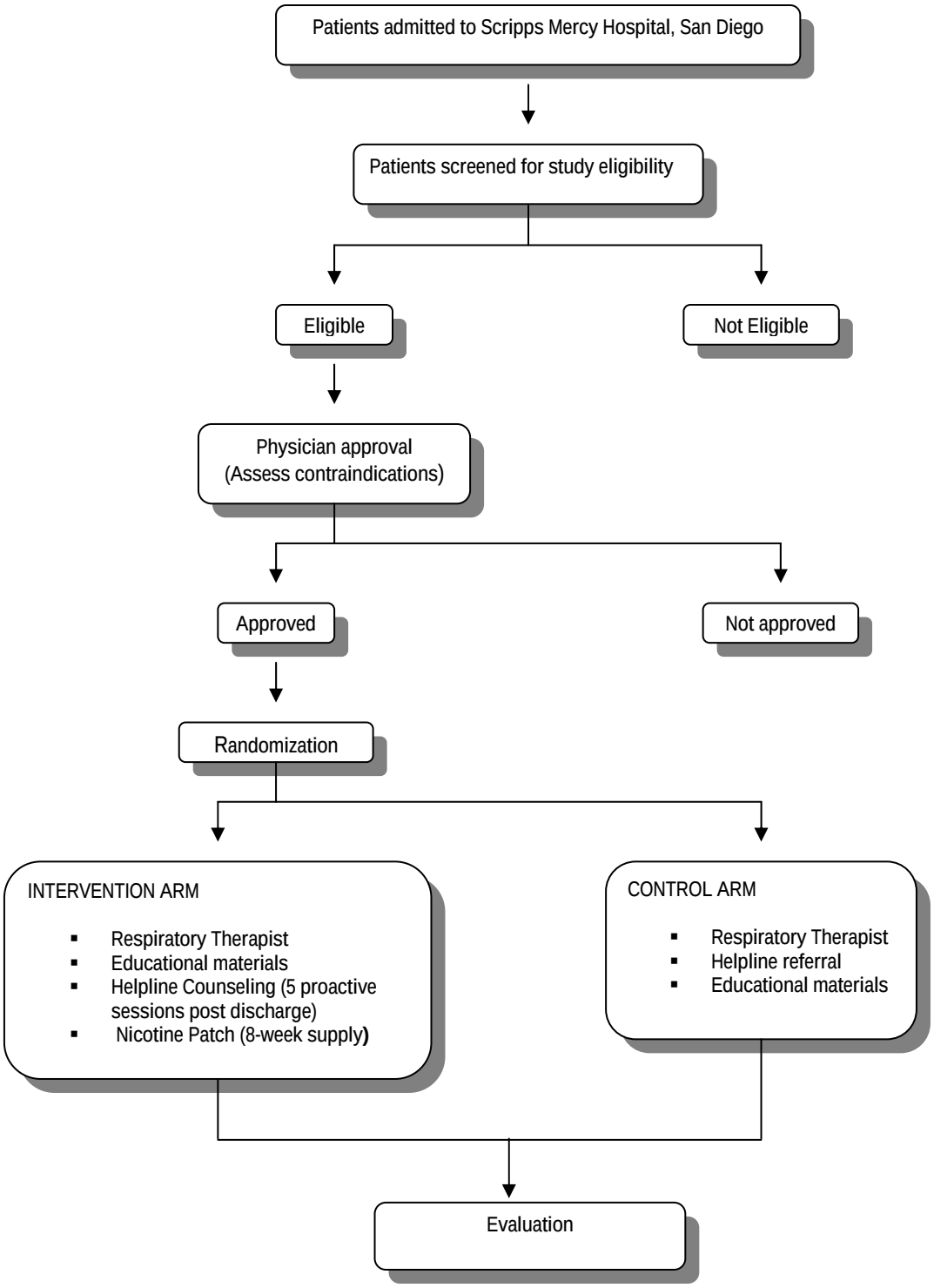


Figure 1: Study flow chart: Proactive intervention with hospitalized smokers.

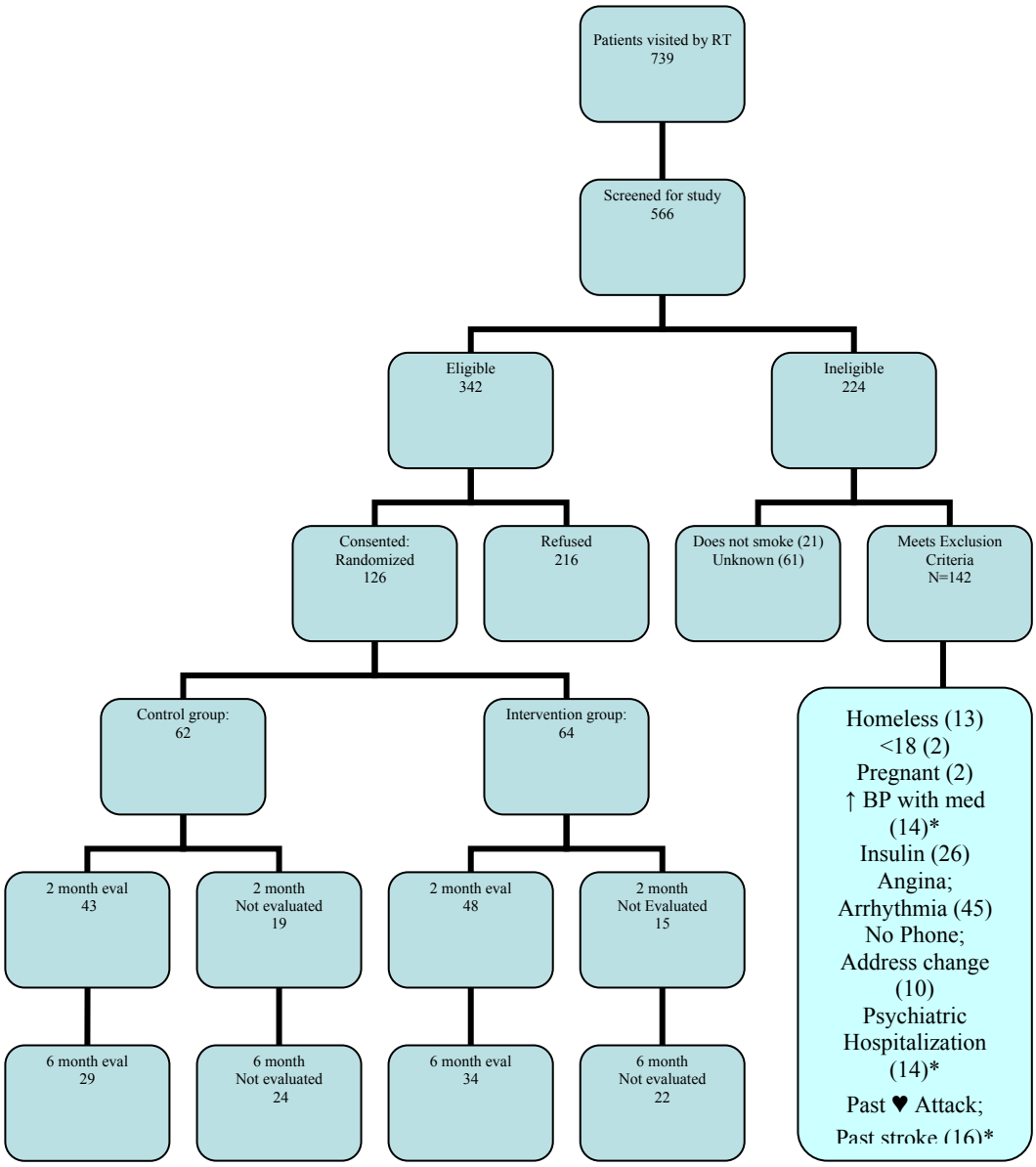


Figure 2: Consort table.

Table 1: Usual Care and Enhanced Intervention Components

	Care as Usual	Enhanced Group
Respiratory Therapist	X	X
Fax Referral to Helpline	X	X
Multiple Proactive Counseling		X
Nicotine Replacement Therapy		X
Educational Materials	X	X

Table 2: Baseline Demographic Characteristics and Reason for Hospitalization by Treatment Group

Characteristic	Enhanced $N = 64$ %	Care as Usual $N = 62$ %	Significance
Gender			
Men	64.1	66.1	.80
Women	35.9	33.9	
Ethnicity			
Non-Hispanic White	62.5	66.1	.49
Other Ethnicity	37.5	30.6	
Unknown		3.3	
Age (years)			
18-24	7.8	11.3	.07
25-34	6.3	14.5	
35-44	18.8	19.4	
45-54	28.1	38.7	
55-64	25.0	12.9	
65+	14.0	3.2	
Education			
≤ 12 Years	39.0	43.5	.47
>12 Years	53.1	45.1	
Unknown	7.9	11.4	
Reason for Hospitalization			
Injury/orthopedic/	20.3	19.4	.51
musculoskeletal	10.9	11.2	
Pulmonary/respiratory	9.0	16.1	
Gastrointestinal/abdominal	14.0	17.7	
Infection	32.8	21.0	
Other	13.0	14.6	
Unknown			

Table 3: Smoking History and Environmental Factors by Treatment Group

	Enhanced *N* = 64 %	Care as Usual *N* = 62 %	Significance
Cigarettes per Day			.46
10-20	90.6	87.0	
20 +	9.4	11.3	
Unknown		1.7	
Quit attempts in past 12 mo			.21
0	42.2	51.6	
1	23.4	9.6	
2	17.2	19.4	
3+	17.2	19.4	
Ever use any of the following:			.61
Nicotine gum	3.0	1.6	
Nicotine patch	9.0	11.2	
Chantix/varenicline	3.0	0	
Counseling	0	1.6	
Cold turkey	26.6	26.0	
Other	1.0	0	
2+ methods	6.0	6.4	
Unknown	51.4	53.2	
Live with Other Smoker			.61
Yes	23.4	30.6	
No	32.0	35.5	
Unknown	44.6	33.9	
Household Restrictions			.46
Complete restrictions	51.6	45.3	
Not complete restrictions	45.3	46.8	
Unknown	3.1	7.9	
Support for quitting			.40
A lot	40.7	43.5	
Less than a lot	54.7	50.0	
Unknown	4.6	6.5	
Confidence in ability to quit			.65
Very confident	29.7	25.9	
Confident	45.3	53.2	
Less than confident	22.0	17.8	
Unknown	3.0	3.1	

Table 4: Smoking Quit Rates at Two- and Six-Month Evaluation (Responder Rates)

Time	2 Month evaluation			6 Month Evaluation		
	N	%	OR[a] (95% CI)	N	%	OR[a] (95% CI)
7-Day Abstinence						
Enhanced	51	41.2	4.7 (1.7, 13.0)	40	22.5	1.7 (0.5, 5.8)
Care as usual	46	13.0	1.0	35	14.3	1.0
30-Day Abstinence						
Enhanced	51	33.3	5.2 (1.61, 17.0)	40	22.5	1.7 (0.5, 5.8)
Care as usual	46	8.7	1.0	35	14.3	1.0
180-Day Abstinence						
Enhanced				40	15.0	1.4 (0.4, 5.3)
Care as usual				35	11.4	1.0

Note. Contact rate=78.0% at 2 months and 57.9% at 6 months.
[a]OR=odds ratio.

Table 5: Smoking Quit Rates at Two- and Six-Month Evaluation (Intent-to-Treat Rates)

Time	2 Month Evaluation			6 Month Evaluation	
	N	%	OR[a] (95% CI)	%	OR[a] (95% CI)
7-Day Abstinence					
Enhanced	64	32.8	4.6 (1.7, 12.3)	14.1	1.9 (0.6, 5.9)
Care as usual	62	9.7	1.0	8.1	1.0
30-Day Abstinence					
Enhanced	64	26.6	5.2 (1.6, 16.6)	14.1	1.9 (0.6. 5.9)
Care as usual	62	6.4	1.0	8.1	1.0
180-Day Abstinence					
Enhanced	64			9.4	1.5 (0.4, 5.6)
Care as usual	62			6.4	1.0

Note. Contact rate=78.0% at 2 months and 57.9% at 6 months. No-contacts were coded as smokers in the intent to treat analysis.
[a]OR=odds ratio.

Appendix B

Proactive Intervention with Hospitalized Smokers Eligibility Questionnaire

Hi, my name is _____ and I'm a Respiratory Therapist at Scripps Mercy Hospital. Right now we have our usual service to help our patients to quit smoking, but we're also trying to find other ways that we think will help smokers quit, and more importantly to stay quit. Either way, you'll receive quality assistance in quitting. Would you be interested in participating in this study to help us improve our services?

☐ YES Great, I just have some questions for you. [Go to question 1]

☐ NO [End screening]
Comments, If any_____

_____ _____
Respiratory Therapist Date

_____
Patient Name

1) Do you speak either English or Spanish fluently? ☐ YES ☐ NO

2) Are you at least 18-years or older? ☐ YES ☐ NO

3) Before you were admitted to the hospital, did you smoke cigarettes every day, some days, or not at all?

☐ EVERY DAY… [Go to question 3A]

3A) On average, how many cigarettes did you smoke per day?

_____cigarettes/day ☐ Don't know ☐ Refused

☐ SOME DAYS
☐ NOT AT ALL

4) Have you stopped smoking since being admitted to the hospital?

☐ YES ☐ NO ☐ DON'T KNOW ☐ REFUSED

5) Do you plan to stay quit after you're discharged from the hospital?

☐ YES ☐ NO ☐ DON'T KNOW ☐ REFUSED

6) Now I have a few health questions related to smoking. Have you ever been told by a doctor that you have high blood pressure?

- YES… [Go to question 6A]
  - 6A) Is it currently under control?
    - Yes, with medication
    - Yes, without medication
    - No, not controlled
- NO
- DON'T KNOW
- REFUSED

7) Have you ever been told by a doctor that you have diabetes?

- YES… [Go to question 7A]
  - 7A) Do you use insulin?
    - Yes
    - No
    - Don't know
    - Refused
- NO
- DON'T KNOW
- REFUSED

8) Have you ever had a heart attack?

- YES… [Go to question 8A]
  - 8A) Was it within the past year?
    - Yes
    - No
    - Don't know
    - Refused
- NO
- DON'T KNOW
- REFUSED

9) Have you ever been told by a doctor that you have angina (serious heart pain/ chest pain with exertion)?

- YES
- NO
- DON'T KNOW
- REFUSED

10) Have you ever been told by a doctor that you have arrhythmia (an irregular heart beat/ rhythm that requires medication)?

- YES
- NO
- DON'T KNOW
- REFUSED

11) Have you ever had a stroke?

- YES… [Go to question 10A]
  - 10A) Was it within the past year?
    - Yes
    - No
    - Don't know
    - Refused
- NO
- DON'T KNOW
- REFUSED

12) < IF FEMALE > Are you pregnant? □ YES □ NO
□ DON'T □ REFUSED

13) Do you have a phone?

□ YES □ NO □ DON'T KNOW □ REFUSED
□ OTHER_____

14) Do you have any plans to move from your current address in the next 6 months?

□ YES □ NO □ DON'T KNOW □ REFUSED

15) <<DO NOT ASK PATIENT □ VERIFY PATIENT CHART>>
Patient hospitalized for psychiatric condition □ YES □ NO

Appendix C


Do you smoke?
Do you want to quit?
We are helping our patients quit smoking for good.
At Scripps Mercy Hospital, we are offering all of our inpatients a time-limited opportunity to participate in a smoking cessation program. You may qualify for an eight-week supply of nicotine patches and telephone counseling. If you would like to stop smoking and enroll in this free program, please dial extension 8411 from the phone in your room, and a respiratory therapist will visit you shortly.
Scripps Mercy Hospital

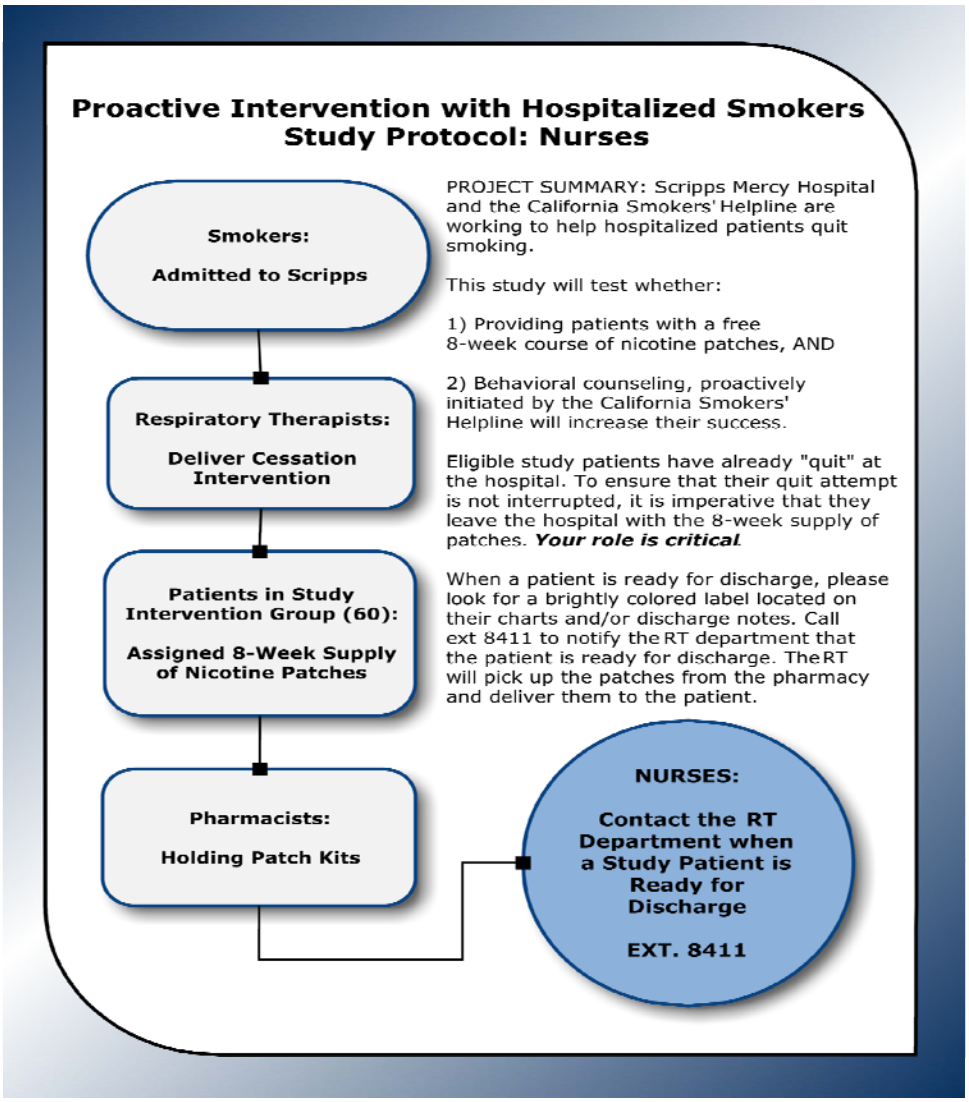
Appendix D

Proactive Intervention with Hospitalized Smokers

Respiratory Therapist Checklist

- ☐ 1. Ask patient if interested in study participation
- ☐ 2. Administer ELIGIBILITY questionnaire
- ☐ 3. *If eligible*, proceed to CONSENT form
- ☐ 4. Contact Kendra (619 200-8294 or Julie (858) 300-1058 to determine whether the patient is in **enhanced intervention** (patch group) or **usual care**
- ☐ 5. Proceed to BASELINE SCREENING Questionnaire and write number assigned for enhanced intervention or control
- ☐ 6. If patient is in enhanced intervention group, call for PHYSICIAN AUTHORIZATION
- ☐ 7. *If physician approves*, RT to write verbal order and fax to pharmacy.
- ☐ 8. If patient is in the enhanced intervention (patch group) place florescent sticker on front of chart. If patient in usual care group please be sure to provide usual smoking cessation education and give The Take Control Guide.
- ☐ 9. Give copies of The Take Control Guide to all study patients only.
- ☐ 10. *If patient is in the patch group*, assure patient leaves with 8-week supply of patches (from pharmacy)
- ☐ 11. Submit completed forms in blue folder

Appendix E


Proactive Intervention with Hospitalized Smokers
Study Protocol: Nurses
Smokers:
Admitted to Scripps
Respiratory Therapists:
Deliver Cessation Intervention
Patients in Study Intervention Group (60):
Assigned 8-Week Supply of Nicotine Patches
Pharmacists:
Holding Patch Kits
PROJECT SUMMARY: Scripps Mercy Hospital and the California Smokers' Helpline are working to help hospitalized patients quit smoking.
This study will test whether:
1) Providing patients with a free 8-week course of nicotine patches, AND
2) Behavioral counseling, proactively initiated by the California Smokers' Helpline will increase their success.
Eligible study patients have already "quit" at the hospital. To ensure that their quit attempt is not interrupted, it is imperative that they leave the hospital with the 8-week supply of patches. Your role is critical.
When a patient is ready for discharge, please look for a brightly colored label located on their charts and/or discharge notes. Call ext 8411 to notify the RT department that the patient is ready for discharge. The RT will pick up the patches from the pharmacy and deliver them to the patient.
NURSES:
Contact the RT Department when a Study Patient is Ready for Discharge
EXT. 8411

Appendix F

Help Our Patients Quit Smoking for Good

Smoking is the leading cause of preventable premature deaths in the U.S., and smokers are more likely than non-smokers to develop serious, life-threatening diseases. Smokers are more likely than non-smokers to be hospitalized, but many quit smoking during their hospitalization. The ones who do not quit and those who relapse after discharge are more likely to be hospitalized again than people who quit smoking for good.

To help our patients quit smoking, Scripps Mercy has joined forces with one of the most effective smoking cessation programs available. Scripps Mercy and the California Smokers Helpline have implemented a study to test whether an enhanced intervention is more effective in getting people to quit smoking permanently than the normal standard intervention, consisting of patient education and a faxed referral to the helpline.

This enhanced intervention will provide nicotine replacement therapy before the patient is discharged and for eight weeks after discharge. The California Smokers Helpline will also initiate five follow-up telephone counseling sessions to be delivered within the first month after discharge.

This study is currently in effect and recruitment will be continuing through **Feb. 28, 2009.** For more information on this program, please contact Kendra Brandstein at 619-862-6601, or Glenn Tanaka at 619-260-7333.

Appendix G

Proactive Smoking Cessation Study
Scripps Mercy Hospital
Sign Out Log

Research Study: Proactive Smoking Cessation Study

Investigator: Kendra Brandstein Scripps IRB#: MER 08-9000

Patient #	Medication Name	Strengths/ Lot #	Quantity Dispensed	Amount Remaining (Out of 60 Patches)	Pharmacist Initials	RT's Initials

Appendix H

Proactive Intervention with Hospitalized Smokers

Baseline Screening Questionnaire

RT Name _____ Date: _____

1) First Name _____MI_____ Last Name _____

2) What is your date of birth? _______________
Month Day Year

3) What is the best phone number where you can be reached?

(_____) _____ - _____

□ Cell □ Home □ Work □ Other _____
□ No Phone □ Refused

3a) Is there another phone number where you can be reached?

(_____) _____ - _____

□ Cell □ Home □ Work □ Other _____
□ No Phone □ Refused

4) Do you have an email address?

□ YES… [Go to question 4a] □ NO
4a) What is your email address? □ REFUSED

_____@_____

5) What are you being treated for while you're here in the hospital? _____

6) In the past year, have you tried to quit smoking?

□ YES [Go to questions 6a thru 6c]
6a) How many times have you tried to quit smoking? _____
6b) Of those times, how many times were for more than 24 hours? _____
6c) Have you ever tried quitting aids or other methods? (Check all that apply)

□ Nicotine patch □ Chantix/ verenicline □ Other (specify):
□ Nicotine gum □ Behavioral counseling _____
□ Zyban/ buproprion □ Cold turkey _____

□ NO
□ DON'T KNOW
□ REFUSED

7) How confident are you that you will stay quit for at least 1 month after discharge?

□ Very confident □ Confident □ Somewhat confident □ Not confident
□ Don't Know □ Refused

8) How much support for quitting do you think you will receive from the people around you…would you say a lot, some, or very little?

□ A lot □ Some □ Very little (None) □ Don't know □ Refused

9) Are there any other smokers living with you?

□ Yes, How many?_____ □ No □ Don't know □ Refused

10) Are there any restrictions on smoking in your household? (For example, rules set by you, family roommates or building/landlord restrictions.)

□ Yes, there are restrictions. No smoking allowed anywhere in home.
□ No, there are no restrictions
□ Some restrictions (some people or some rooms)
□ Refused
□ Don't know

11) What is your ethnic background?

□ White □ Hispanic/Latino □ Don't know
□ Black/African American □ Asian/Pacific Islander □ Refused
□ American Indian/Alaska Native □ Other_____

12) What is the highest level of education you have completed?

- □ Never attended school
- □ Grades 1-8
- □ Grades 9-12 (No Diploma)
- □ GED
- □ High school diploma
- □ Some college of trade school, no degree
- □ 2-yr college degree (AA)
- □ 4-yr, college or univ degree (BA, BS)
- □ Post-graduate degree (Masters, PhD)
- □ Don't know
- □ Refused

13) We would like to send you some materials in the mail. What is your mailing address?

Address _____

Number Street Apt. No.

_____

City State Zip Code

□ Don't know

□ Refused

Appendix I

□ Cross check: _____/_____/_____ by: _____
□ Back entered: _____/_____/_____ by: _____

California Smokers' Helpline

SCRIPPS 2mo EVAL

ENGLISH

Client Name: _____ NID _____ Screen date: ____/____/_____

Evaluator: ____ Length: __min. Attempts: ___ Date today: ____/____/_____

Hi, this is _____ calling to evaluate the quality of service provided by the Scripps Mercy smoking cessation program. In order to improve the program, I would like to follow up with your progress and get your feedback on the services that you received. The call will just take a few minutes and all of your responses will be kept confidential. Is that okay?

SECTION A: SERVICE QUESTIONS

1. How would you rate Scripps Mercy, using a scale from 0-10 where 0 is the worst hospital possible and 10 is the best?

   [_____] ☐ DK ☐ R

2. Would you recommend this hospital to your friends and family? Would you say: definitely yes, probably yes, definitely no, or probably no?

   ☐ DEFINITELY YES
   ☐ PROBABLY YES
   ☐ DEFINITELY NO
   ☐ PROBABLY NO

3. Overall, how would you rate the services you received to help you quit smoking from your respiratory therapist? Would you say the service was very good, good, fair, poor, or very poor?

   ☐ VERY GOOD
   ☐ GOOD
   ☐ FAIR
   ☐ POOR
   ☐ VERY POOR

4. Do you currently smoke cigarettes everyday, some days or not at all?

☐ Everyday… ***Go to 6***
☐ Some days… ***Go to 5***
☐ Not at all … ***Go to 9***
☐ Smoking…***(Partials only)***
☐ Don't know… ***Go to 13a***
☐ Refused… ***Go to 13a***
☐ Not asked… ***Go to 13a***

****

SECTION B: SMOKING

5. How many days per week do you smoke? _____ days/week

6. On average, how many cigarettes do you smoke per day? _____ cigs/day

7. How soon after you wake up do you usually smoke your first cigarette?

☐ 0-5 mins ☐ 6-30 mins ☐ 31-60 mins ☐ More than 60 mins
☐ DK ☐ R

8. Since you were admitted to Scripps Mercy on the week of _____/_____/_____ have you tried to quit smoking?
(Screen Date)

☐ Yes… ***Continue***
☐ No... ***Go to 13a***
☐ DK... ***Go to 13a***
☐ R... ***Go to 13a***

a. How many times did you try to quit? _____ ☐ DK ☐ R

b. Out of those times, how many were for 24 hours or more?
_____ ☐ DK ☐ R

c. How much support for quitting did you have from the people around you…would you say a lot, some, or very little?

☐ A lot ☐ Some ☐ Very little (None) ☐ DK ☐ R

Go to 13

****

SECTION C: NOT SMOKING

9. When did you smoke your last cigarette? _____/_____/_____
   ☐ DK***… Go to 9a***
   ☐ R***… Go to 9a***

   9a. Approximately how long ago did you quit? [_____]
   days/weeks/months

10. Since you were admitted to Scripps Mercy on the week of _____/_____/_____ how many times did you try to quit smoking?
(Screen Date)

   Number of times: [_____] ☐ DK ☐ R

10a. Out of those times, how many were for 24 hours or more?

   Number of times: [_____] ☐ DK ☐ R

11. How much support for quitting did you have from the people around you…would you say a lot, some, or very little?

☐ A lot ☐ Some ☐ Very little (None) ☐DK ☐ R

12. How confident are you that you will stay quit for the next month? Would you say very confident, confident, or not confident?

☐ Very Confident ☐ Confident ☐ Not Confident ☐ DK ☐R

****

SECTION D: GENERAL QUESTIONS

13a. Did you use any quitting aids since leaving the hospital such as the nicotine gum, patch, Zyban, Chantix or others?

☐ Yes… fill in chart ***then go to 13b***
☐ No…***Go to 13b***
☐ Don't know… ***Go to 13b***

Which ones did you use?	**How long?**
☐ Nicotine Gum	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Nicotine Patch	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Zyban/Buproprion	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Chantix/Varenicline	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Other: _____ _____	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Don't Know ☐ Refused	

13b. Did you use any methods for quitting smoking since leaving the hospital such as counseling, cold turkey or any others?

☐ Yes… fill in chart ***then go to 14***
☐ No…***Go to 14***
☐ Don't know…***Go to 14***

Which ones did you use?	**How long?**
☐ Counseling	_____ sessions ☐ Don't Know ☐ Refused
☐ Cold Turkey	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Other: _____ _____	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Don't Know ☐ Refused	

14. Do you currently use any other form of tobacco, such as chew/snuff, cigars or pipes?

☐ Yes…***Continue***
☐ No……***Go to 15***
☐ Don't know……..***Go to 15***
☐ Refused……... ***Go to 15***

IF YES to Q14: Which ones?

☐ Chew
☐ Cigars
☐ Pipes
☐ Other: _____

IF CHEW/SNUFF: How much tobacco do you use per week?

_____
Code: less than 1 as 1

☐ DK ☐ R

If CHEW/SNUFF: Is that cans or pouches?
☐ Cans ☐ Pouches

If CIGARS: How many do you smoke per week?

_____

Code: less than 1 as 1

☐ DK ☐ R

15. Is there another smoker in your household?

☐Yes ☐No ☐DK ☐R

16. Are there any restrictions on smoking inside your household?

☐ Yes, there are restrictions. No smoking allowed anywhere in home.
☐ No, there are no restrictions
☐ Some restrictions (some people or some rooms)
☐ Don't know
☐ Refused

END EVAL: Those are all the questions I have for you. Thank you for your time.

Comments:_____

_____

Appendix J

□ Cross check: _____/_____/_____ by: _____
□ Back entered: _____/_____/_____ by: _____

California Smokers' Helpline

SCRIPPS 6mo EVAL ENGLISH

Client Name: _____ NID _____ Screen date: ____/____/_____

Evaluator: ____ Length: __min. Attempts: ___ Date today: ____/____/_____

Items to know before calling client:

2mo FINAL STATUS: E / NE *(select one)*

2mo SMOKING STATUS: SMOKING / NOT SMOKING *(select one)*

Hi, this is _____ calling to evaluate the quality of service provided by the Scripps Mercy smoking cessation program. I have a few questions to follow up with your progress. The call will just take a few minutes and all of your responses will be kept confidential. Is that okay?

I want to let you know that we're interested in the amount of nicotine that smokers are exposed to before, during and after they quit smoking. You **MAY** be selected to provide a saliva sample that we can use to measure cotinine, a chemical that forms as nicotine is broken down in your body. If selected, we'll send you a saliva kit and you will receive a $10 gift certificate for sending it back.

E at 2mo***... START AT 4***

NE at 2mo***... START AT 1***

SECTION A: SERVICE QUESTIONS

1. How would you rate Scripps Mercy, using a scale from 0-10 where 0 is the worst hospital possible and 10 is the best?

[_____] ☐ DK ☐ R

2. Would you recommend this hospital to your friends and family? Would you say: definitely yes, probably yes, definitely no, or probably no?

☐ DEFINITELY YES
☐ PROBABLY YES
☐ DEFINITELY NO
☐ PROBABLY NO

3. Overall, how would you rate the services you received to help you quit smoking from your respiratory therapist? Would you say the service was very good, good, fair, poor, or very poor?

☐ VERY GOOD
☐ GOOD
☐ FAIR
☐ POOR
☐ VERY POOR

4. Do you currently smoke cigarettes everyday, some days or not at all?

	2 month info		
	EVALUATED		NOT EVALUATED
6mo Smoking Status	Smoking	Not Smoking	
☐ Everyday	*Go to 7*	*Go to 5*	*Go to 7*
☐ Someday	*Go to 6*	*Go to 5*	*Go to 6*
☐ Not at all	*Go to 10*	*Go to 11*	*Go to 10*
D/R/Z	*Go to 13*	*Go to 13*	*Go to 13*

☐ Smoking… ***(Partials only)***

****

SECTION B: SMOKING

5. When was your first cigarette since we last spoke to you on **(LAST CONTACT DATE)**? ___ / ___ / _____

5a. How many days in a row did you smoke, including the first day?
_____ day(s).

☐ Ever Since***… Go to 6***
☐ Don't know

5b. When did you return to smoking on a regular basis after **(date of first cig/puff)?** ___ / ___ / _____

6. **(IF SOMEDAYS):** How many days per week do you smoke?
_____ days/week

7. On average, how many cigarettes do you smoke per day? _____ cigs/day

8. How soon after you wake up do you usually smoke your first cigarette?

☐ 0-5 mins ☐ 6-30 mins ☐ 31-60 mins ☐ More than 60 mins
☐ DK ☐ R

9. Since we last spoke to you on _____/_____/_____ have you tried to quit smoking?
(LAST CONTACT DATE)

☐ Yes… ***Continue***
☐ No... ***Go to 13***
☐ DK... ***Go to 13***
☐ R... ***Go to 13***

9a. How many times did you try to quit?

Number of times: [_____] ☐ DK ☐ R

9b. Out of those times, how many were for 24 hours or more?

Number of times: [_____] ☐ DK ☐ R

9c. How much support for quitting did you have from the people around you…would you say a lot, some, or very little?

☐ A lot***… Go to 9d***
☐ Some***… Go to 9d***
☐ Very little (None) ***… Go to 13***
☐ DK***… Go to 13***
☐ R***… Go to 13***

9d. Who did you receive the most support from?

☐ Brother
☐ Daughter
☐ Father
☐ Friend
☐ Mother
☐ Other Relative
☐ Significant Other/Partner
☐ Sister
☐ Spouse
☐ Son
☐ Nurse/hospital staff
☐ Other _____

Go to 13

****

SECTION C: NOT SMOKING

10. When did you quit? ***Most recent quit date?*** _____/_____/_____
… Go to 10b
☐ DK***… Go to 10a***
☐ R***… Go to 10b***

10a. Approximately how long ago did you quit?
[_____] days/weeks/months

10b. Since we last spoke to you on _____/_____/_____ how many
(LAST CONTACT DATE)
times have you tried to quit (including this time)?

Number of times: [_____] ☐ DK ☐ R

10c. Out of those times, how many were for 24 hours or more?

Number of times: [_____] ☐ DK ☐ R

10d. How much support for quitting did you have from the people around you…would you say a lot, some, or very little?

☐ A lot***… Go to 10e***
☐ Some***… Go to 10e***
☐ Very little (None) ***… Go to 11***
☐ DK***… Go to 11***
☐ R***… Go to 11***

10e. Who did you receive the most support from?

☐ Brother
☐ Daughter
☐ Father
☐ Friend
☐ Mother
☐ Other Relative
☐ Significant Other/Partner
☐ Sister
☐ Spouse
☐ Son
☐ Nurse/hospital staff
☐ Other _____

11. Have you had a cigarette, or even a puff, since you quit on ***(most recent quit date)***?

☐ Yes . . . . . When was your **first** cig./puff? _____/_____/_____
Go to 11a
☐ No . . . . . ***Go to 12***
☐ Don't know…***Go to 12***
☐ Refused… ***Go to 12***
☐ Not asked… ***Go to 12***

11a. How many days in a row did you smoke, including the first day?
_____ day(s)

☐ Ever Since – THIS MEANS CX IS SMOKING, CONFIRM…***Go to 4***
☐ Don't Know
☐ Refused
☐ Not asked

11b. When was the last time you had a cigarette, or even a puff?
_____/_____/_____

☐ Don't know
☐ Refused
☐ Not asked

12. How confident are you that you will stay quit for the next month? Would you say very confident, confident, or not confident?

☐ Very Confident ☐ Confident ☐ Not Confident
☐ DK ☐R

****

SECTION D: GENERAL QUESTIONS

13. Did you use any quitting aids since leaving the hospital such as the nicotine gum, patch, Zyban, Chantix or others?
☐ Yes… fill in chart ***then go to 13b*** ☐ No... ***Go to 13b***
☐ Don't know... ***Go to 13b***

Which ones did you use?	**How long?**
☐ Nicotine Gum	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Nicotine Patch	_____ days/weeks/months ☐ Don't Know ☐ Refused

☐ Zyban/Buproprion	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Chantix/Varenicline	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Other: _____ _____	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Don't Know ☐ Refused	

13b. Did you use any methods for quitting smoking since leaving the hospital such as counseling, cold turkey or any others?

☐ Yes… fill in chart ***then go to 14***
☐ No…***Go to 14***
☐ Don't know…***Go to 14***

Which ones did you use?	**How long?**
☐ Counseling	_____ sessions ☐ Don't Know ☐ Refused
☐ Cold Turkey	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Other: _____ _____	_____ days/weeks/months ☐ Don't Know ☐ Refused
☐ Don't Know ☐ Refused	

14. Do you currently use any other form of tobacco, such as chew/snuff, cigars or pipes?

☐ Yes…***Continue***
☐ No……***Go to 15***
☐ Don't know……***Go to 15***
☐ Refused……. ***Go to 15***

IF YES to Q14: Which ones?

☐ Chew
☐ Cigars
☐ Pipes
☐ Other: _____

IF CHEW/SNUFF: How much tobacco do you use per week?
_____ ☐ DK ☐ R
(Code: less than 1 as 1)

If CHEW/SNUFF: Is that cans or pouches?
☐ Cans ☐ Pouches

If CIGARS: How many do you smoke per week?

_____ ☐ DK ☐ R
(Code: less than 1 as 1)

15. Is there another smoker in your household?

☐Yes ☐No ☐DK ☐R

16. Are there any restrictions on smoking inside your household?

☐ Yes, there are restrictions. No smoking allowed anywhere in home.
☐ No, there are no restrictions
☐ Some restrictions (some people or some rooms)
☐ Don't know
☐ Refused

****

SECTION E: HEALTH STATUS QUESTIONS

Now I have a few health questions. Which of the following statements best describes how you're doing?

17. ☐ I HAVE NO PROBLEMS WALKING ABOUT
☐ I HAVE SOME PROBLEMS WALKING ABOUT
☐ I AM CONFINED TO BED
☐ Don't know
☐ Refused

18. ☐ I HAVE NO PROBLEMS WITH SELF-CARE
☐ I HAVE SOME PROBLEMS WASHING OR DRESSING MYSELF
☐ I AM UNABLE TO WASH AND DRESS MYSELF
☐ Don't know
☐ Refused

19. ☐ I HAVE NO PROBLEMS WITH PERFORMING MY USUAL ACTIVITIES (e.g., work, study, housework, family, or leisure activities)
☐ I HAVE SOME PROBLEMS WITH PERFORMING MY USUAL ACTIVITIES
☐ I AM UNABLE TO PERFORM MY USUAL ACTIVITIES
☐ Don't know
☐ Refused

20. ☐ I HAVE NO PAIN OR DISCOMFORT
☐ I HAVE MODERATE PAIN OR DISCOMFORT
☐ I HAVE EXTREME PAIN OR DISCOMFORT
☐ Don't know
☐ Refused

21. ☐ I AM NOT ANXIOUS OR DEPRESSED
☐ I AM MODERATELY ANXIOUS OR DEPRESSED
☐ I AM EXTREMELY ANXIOUS OR DEPRESSED
☐ Don't know
☐ Refused

22. How would you rate your current health on a scale from 0 to 100, where 0 is your worst health state and 100 is the best?

[_____] (0-100) ☐ DK ☐ R

23. Since you were first admitted to Scripps Mercy back in _____ how many times have you been re-hospitalized for at least 24 hours? **(MONTH CX WAS SCREENED)**

# of times re-hospitalized	**What was the reason for your stay?** (List the reason for each stay)
☐ None…***Go to 24***	
☐ 1	_____ _____ _____ _____ _____ _____ ☐ DK ☐ R
☐ 2	1 _____ _____ _____2 _____ _____ _____ ☐ DK ☐ R
☐ 3 or more	1 _____ _____ _____2 _____ _____ _____ 3_____ _____ _____ _____ _____ ☐ DK ☐ R
☐ DK…***Go to 24*** ☐ R …***Go to 24***	

24. We want to maintain your current contact information. What is your mailing address?

(ACCESS UPDATE CLIENT INFO IN VISION TO REVIEW ADDRESS)

- ☐ Same address/No changes
- ☐ Update address

END EVAL: Those are all the questions I have for you. Thank you for your time.

Comments:_____

_____

Appendix K

June 23, 2009

«AddressBlock»

Dear «GreetingLine»,

Thank you for participating in the Scripps Mercy Smoking Cessation Program. I hope this letter finds you well. We are currently trying to see how the program is working and we would like to hear from you. We have one final request. Whether you are smoking or not, we would like you to provide us with a saliva sample. Enclosed in this letter is a kit for a saliva sample and directions. If you return the sample, we will show our appreciation by sending you a $10 gift certificate. If you have any questions please call 1 (800) 890-1668.

Again, your support and participation is greatly appreciated.

Sincerely,

Kendra Brandstein, MPH, MSW

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