A RANDOMIZED CLINICAL TRIAL IN A CHILD HEALTH CARE SETTING COMPARING TWO BRIEF INTERVENTIONS TO REDUCE ENVIRONMENTAL TOBACCO SMOKE EXPOSURE

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CHAPTER I

INTRODUCTION

Environmental tobacco smoke (ETS) is a major cause of morbidity and mortality in the United States (McGinnis & Forge, 1993; Mokdad, Marks, Stroup, & Geberding, 2004; US Department of Health and Human Services, 1989). The negative health effects of smoking begin in utero and can continue throughout the life a child. In infants and children, exposure to ETS can be linked to low birth weight, sudden infant death syndrome (SIDS), respiratory syncitial virus bronchiolitis, middle ear infections, and asthma (Aligne & Stoddard, 1997). In light of the numerous risks associated with ETS exposure, it is important to determine the rate of exposure and the source of the majority of the exposure.

ETS is defined as the smoke inhaled by an individual not actively engaged in smoking but due to ambient tobacco smoke (Klerman, 2004). Children are exposed to ETS in many places, including stores, restaurant, and other public spaces, but most concentrated exposure is in the home, from both residents and visitors, and on vehicle of smoking parents, caregivers, or others (Hovell, Wahlgren, Matt, & Emmons, 2000; Klerman, 2004). It is estimated that 21 million children under the age of 18 (36% of all children) live in households where the residents or visitors smoke in the home on a regular basis (Schuster, Franke, & Pham, 2002). Regular smoking is estimated to occur in 32% of the homes in which children are raised. Children's exposure to ETS is of particularly great concern, because it is involuntary (Emmons et al., 2001). Few children

are able to limit their own exposure, especially younger children who are less mobile and spend more time with their smoking caregiver.

ETS has been associated with increased rate of acute lower respiratory tract infections, wheezing and asthma, otitis media, sudden infant death syndrome, medical visits, hospitalizations, and school absences in children (Schuster et al., 2002; Mannino, Moorman, Kingsley, Rose, & Repace, 2001; McMartin et al., 2002; Lam, Leung, & Lai-Ming, 2001). ETS exposure in children is not only an important health issue, but also carries serious economic consequences for the health care system as a whole because of increased utilization (Lam et al., 2001). Given the burden of ETS exposure, consideration of services to address caregiver smoking seems prudent.

The health care system is an optimal place for delivering tobacco control interventions; however, identifying acceptable opportunities to intervene with parents who smoke is a challenge. The hospital is a teachable setting in which to provide advice and assistance to parents who smoke because parents interact more with their child's health care provider at this time. While evidenced based smoking cessation interventions exist for adults in hospital settings, lack of evidence for the success of smoking cessation interventions in child clinical settings is an important barrier to adoption of interventions among child health care providers (Curry et al., 2003). These interventions include systematically delivered primary care brief behavioral counseling interventions which result in a 5- 10 % annual cessation rate, doubling the rate of cessation to those who spontaneously quit each year (Whitlock, Orleans, Pender, & Allan, 2002). Helping parents reduce or stop smoking in the home is an important step to reducing the adverse health effects attributed to environmental tobacco smoke exposure in children.

There has been an increase in studies of counseling efforts to reduce children'

ETS exposure in recent years. These studies vary in their approach to reduce the amount of ETS exposure for children with caregivers who smoke. While some studies have used behavioral techniques to educate caregivers about the dangers of ETS exposure in an effort to reduce child health problems associated with exposure, others have utilized behavioral strategies to deliver smoking cessation services to parents during their visit with the health care provider. While studies using both strategies have been helpful in highlighting issues that need to improve in this arena, no strategy has been developed to systematically deliver services to smoking caregivers in the health care setting.

Environmentally, tobacco smoke exposure is related to increases in respiratory symptoms and disease and decreased lung function in children (Mannino et al., 2001; California Environmental Protection Agency, 1997; Cook & Strachan, 1999). Given the significant health risks to children, it may be important to decrease parent smoking and ultimately increase cessation in caregivers of children admitted to the Neonatal Intensive Care Unit (NICU) and Special Care Nursery in order to make the largest impact on child exposure. Smoking cessation interventions have historically focused on providing assistance to sick adults in the inpatient settings. While guidelines exist to provide services to patients in a uniform way, physicians still do not do so. Further, child health care providers use these guidelines less.

The present study is designed to examine the effectiveness of behavioral interventions aimed at decreasing the amount of ETS exposure in the home of children admitted to the NICU and Special Care Nursery. The *Clinical Practice Guideline for Treating Nicotine Dependence*, developed to address smoking cessation in the healthcare arena, was used as a framework to address environmental tobacco smoke exposure reduction in the home of smoking caregivers. Results of this study will add to the

existing literature highlighting the usefulness of behavioral interventions in the hospital setting. It is anticipated that parents receiving a specific intervention to address reducing ETS exposure in the home compared to the usual treatment, will have a lower amount of ETS exposure in the home and greater motivation to keep a smoke-free home, thus reduce the health risks to the child.

To accomplish this, a review of the literature is presented, examining the prevalence of ETS exposure in children and the health issues related to ETS exposure. Specific attention is given to the history of smoking cessation treatments, highlighting the shift in the delivery of behavioral interventions from intense treatment to the adoption of a public health perspective. The *Clinical Practice Guidelines to Treat Nicotine Dependence* are discussed as a framework for increasing the rate at which health care providers deliver smoking cessation to their patients. Finally, a review of studies utilizing behavioral strategies will illustrate the state of interventions aimed at reducing the problems associated with child ETS exposure as well as caregiver smoking cessation.

CHAPTER II

LITERATURE REVIEW

Epidemiology of Environmental Tobacco Smoke Exposure in Children

ETS exposure in children is an important preventable cause of morbidity and mortality among American children. It results in annual direct medical expenditures of $4.6 billion and loss of life costs of $8.2 billion (Aligne & Stoddard, 1997). Professional groups encourage their members who care for pregnant women, mothers, and children to act aggressively to reduce children's ETS exposure (Klerman, 2004). However, there are few interventions designed to address this problem specifically.

Low birth weight accounts for half of all infant deaths and marked long-term morbidity for many of the survivors. Maternal smoking is a contributing factor in 14 percent of all premature deliveries in the US (U.S. Department of Health and Human Services, Center for Substance Abuse Prevention, 1994). SIDS is the leading cause of death in infants between 1 month and 1 year of age, resulting in more than 5500 deaths per year in the United States (Aligne & Stoddard, 1997). Respiratory syncytial virus bronchiolitis is the leading cause of lower respiratory tract infections in infants and young children, leading to more than 90,000 hospitalizations and 4500 deaths each year. Middle ear infections are the most frequently diagnosed ailment and most single common reason for antimicrobial therapy in children (Lieu & Feinstein, 2002). Asthma is the most common chronic disease of childhood affecting 4.8 million children each year (Tanski, Klien, Winickoff, Auinger, & Weitzman, 2003). Achieving caregiver smoking cessation

would reap the benefits of consequential reduction in ETS for the child, in addition to the benefits for the ex-smoker.

ETS has been linked to numerous adverse health effects in children and to increased need for medical care (Klemran, 2004). While 26% of adults smoke, it is estimated that 43% of children under five years old are exposed to ETS by caregivers who smoke in their presence, placing nearly half of American children at risk for problems associated with ETS exposure (US. Department of Health and Human Services, 1989). One way to substantially decrease the rate of ETS exposure to children is for the caregiver to stop smoking given the amount of time children are in the presence of the caregiver. Despite cessation interventions and guidelines to address adult smoking, these techniques have not been widely adopted by child health providers.

Smoking Cessation

In 1964, the report of the Surgeon General brought documented and much needed attention to the serious health consequences associated with the use of tobacco (US Department of Health, Education, and Welfare, 1964). Since that time, there has been a commitment to developing both pharmacotherapy and behavioral strategies to encourage smoking cessation. Behavioral methods can be delivered through self-help material, including written leaflets and manuals, audiotapes, videotapes, and computer programs. Pharmocological treatments have been developed to decrease smoking urges in smokers trying to quit. Clinic approaches focus on individuals participating in multisession clinic interventions. These approaches include aversion strategies such as rapid smoking. Other behavioral strategies include nicotine fading, more specifically, scheduled reduced smoking and controlled smoking, as well as multicomponent programs delivered in clinical settings (Brandon, 2001; Lichtenstein, 1982).

Rapid smoking is an aversive strategy developed in the 1970s for smoking cessation (Brandon, 2001; Lichtenstein, Harris, Birchler, Wahl, & Schmal, 1973). Rapid smoking typically involved smokers in a controlled clinical setting who deeply inhaled on cigarettes at 6-second intervals. Up to nine cigarettes would be smoked per treatment session. Rapid smoking produced strong aversive reactions to cigarettes and these conditioned responses predicted long-term abstinence (Lichtenstein et al., 1973; Zelman, Brandon, Jorenby, & Baker, 1992). While rapid smoking has been found to be efficacious, use of this strategy has greatly declined as the use of nicotine replacement therapies increased. However, this strategy has been recently been investigated as an aftercare strategy to reduce cravings and prevent relapse (Brandon, 2001).

Scheduled reduced smoking involves three weeks of gradually reducing nicotine intake. An algorithm is used to determining when each cigarette is to be smoked based on the passage of time. The theoretical advantage of this strategy is that particular smoking related situation and moods do not continue to be reinforced by nicotine intake. Yet the gradual reduction of smoking allows for an attenuation of withdrawal symptoms as the patient learns to cope with most situations without cigarettes. Two studies have demonstrated the efficacy of this treatment (Cinciripini et al., 1995), and it has been included on a short list of cessation treatments with evidence of treatment (Compas, Haaga, Keefe, Leitenberg, & Williams, 1998).

Multicomponent coping skills training has common elements that include social support; didactic information about nicotine dependence, withdrawal symptoms, and situations that are risks for relapse; and in vivo training in the use of cognitive and behavioral responses to cope with urges to smoke that reduce the risk of relapse. They may also be instruction on how to recover from an initial smoking relapse without

progressing to full relapse. Pharmocotherapy is often integrated into multicomponent programs (Brandon, 2001).

Pharmacological treatments include nicotine treatments such as nicotine gum, the transdermal nicotine patch, the nicotine inhaler, the nicotine nasal spray, and most recently the nicotine lozenge. Two non-nicotine pharmacologic treatments, bupropion hydrochloride and clonidine have demonstrated efficacy and are recommended treatment options (Fiore et al., 1996, 2000; Niaura & Abrams, 2002).

Both behavioral interventions and pharmacological treatments have been shown to be effective with sustaining abstinence after smoking cessation (Lichtenstein & Glasgow, 1992, 1997; Niaura & Abrams, 2002). Further, an additive effect has been found when using the two interventions concurrently (Fiore et al., 2000).
Behavioral interventions currently emphasize motivating currently less-than-ready individuals to begin to make changes in thoughts and behaviors that will eventually propel them toward control of their addictions. Additionally, social support and problem solving/ maintenance strategies are a focus of current behavioral intervention research (Fiore et al., 2000; Niaura & Abrams, 2002).

It is important to acknowledge a serious drawback to traditional, clinic-focused, face-to-face behavioral treatments. Although behavioral therapies have received some of the highest reported long-term success rates (35% - 40%) for smoking cessation, it is reported that less than 5% of smokers will accept a referral and actually attend group sessions (Stevens & Hollis, 1989, Hill, Rigdon, & Johnson, 1993; Wadland, Stoffelmayr, Berger, Crombach, & Ives, 1999). While these clinically delivered programs are helpful, such programs are able to reach relatively few smokers warranting a need for a new approach to smoking cessation intervention delivery (Lichtenstein & Glasgow, 1997).

This led to the exploration of other avenues of delivering smoking cessation treatment. These avenues included self-help, work site, community, and health care setting interventions. Subsequently, a shift occurred in that smoking cessations interventions began moving from a predominantly clinical approach to a public health perspective. While the clinical approach provides intensive, efficacious intervention through multisession, this approach is limited because it cannot service the large number of smokers, as most do not attend formal cessation programs and prefer to quit on their own (Lichtenstein & Glasgow, 1992).

These considerations called for the adoption of a public health perspective that could reach more of the at-risk population (Lichtenstein & Glasgow, 1997; Mecklenburg, 2003). Ultimately, shifting the smoking cessation intervention setting to a population based approach, delivering less treatment and having greater impact by reaching many needful citizens who often cannot afford or do not seek expensive smoking cessation clinic programs (Lichtenstein & Glasgow, 1992, 1997; Niaura & Abrams, 2002). Clinical approaches continue to address the needs of high-risk medical patients or heavy, dependent smokers who have not been able to quit, providing them with cost effective means of quitting, while population based interventions focus on how to disseminate widely accepted, low-cost, efficacious treatments to the greatest number of smokers (Niaura & Abrams, 2002). This does not discount the need for intensive treatments for those who find it difficult to stop after brief intervention. Researchers continue to build new treatments to address heavily nicotine-dependent smokers who have been unable to quit via less intensive interventions.

Smoking Cessation in the health care setting

The health care setting is at the intersection of clinical and public health approaches in regard to smoking cessation intervention, as there is a large opportunity to bring to bear personalized assistance to a population of smokers (Lichtenstein & Glasgow, 1992; Lichtenstein, 1997). Many recognize the logical and potentially productive means of reaching smokers with a cessation message and promoting their successful cessation (Burns, 2002). An estimated 70% of smokers see a physician each year, providing health care professionals substantial opportunity to influence smoking behavior (Rigotti, 2002). Health care providers also have multiple occasions to provide personalized cessation interventions to patients who smoke. Although most physicians believe in the importance of addressing smoking with their patients, incorporating counseling into routine practice remains a challenge as only 50 percent of smoking patients report receiving any smoking cessation advice from their health care provider (Tanski et al., 2003).

The efficacy of brief advice by the primary care physician was first documented by Russell and colleagues in 1973. Randomized control trials conducted in primary care practices demonstrate that a physician' advice to stop smoking increases cessation rates by approximately 30 percent (Fiore et al., 2000). Additionally, interventions where health care providers deliver a brief period of counseling are more effective than interventions with simple advice to quit, doubling the cessation rates when compared to not intervention (Rigotti, 2002; Lancaster & Stead, 2002). Results from these interventions include the development of a practice guideline to address smoking cessation using methods shown to be effective in hospital settings, additionally, the application of behavioral counseling techniques to enhance motivation have also been used to help improve the delivery and effectiveness of these guidelines.

In 1996, the U.S. Agency for Health Care Policy and Research (AHCPR) issued their *Clinical Practice Guideline for Smoking Cessation* (Fiore et al., 1996). This guideline was an evidence-based and relied heavily on meta-analyses of approximately 3000 published research studies to formulate conclusions and recommendations. The need for the guideline was based on several factors, including tobacco use prevalence, related morbidity and mortality, the economic burden imposed by tobacco use, as well as the variation in clinical practice and the availability of methods for improvement of care using data to support these recommendations (Fiore et al., 2000).

In 2000, an update of the guideline was produced in conjunction with The U.S. Department of Health and Human Services Public Health Service, which resulted in the *Clinical Practice Guideline for Treating Tobacco Use and Dependence*. With an additional 3000 article reviewed, this evidence-based guideline provided clinicians with scientifically based recommendations that promote smoking cessation for the largest number of patients (Fiore et al., 2000). This guideline highlighted the fact that tobacco use imposes devastating costs on American health and welfare. Additionally, this guideline highlighted tobacco use produces true drug dependence. Finally, it emphasized the need to treat tobacco dependence using clinical interventions just like those used with other addictive disorders (Fiore et al., 2000).

Within the guideline recommendations, a brief intervention to encourage smoking cessation was developed to address smoking cessation in the healthcare setting, named the 5 *As*. This intervention aims to motivate clinicians to intervene with every patient who smokes regardless of the reason that brings them to the clinic. The *5As* include systematically identifying all tobacco users at every visit, strongly advising all smokers to quit, assessing all smokers willingness to make a quit attempt, and if appropriate, aiding

the patient in their quit attempt, including setting a quit day and recommending pharmacological aids. As a final step, the health provider arranges a follow-up visit to monitor patient progresses in during the cessation process. This guideline establishes clinical intervention as part of a standard practice, motivating physicians to want to learn more about how to provide effective and efficient help to their patients (Ockene et al., 1997).

Smoking cessation advice to smoking caregivers by their child's health care provider is less than what adult health providers report providing to their patients. While 79% of smoking caregivers report receiving any advice to reduce their child's environmental tobacco smoke exposure from their child's health care provider, rates of providing additional support to parents, such as referrals to smoking cessation programs, setting quit dates, or providing follow-up are low (Curry et al., 2003; Perez-Stable et al., 2001). Hospitalization provides an important opportunity to intervene with smokers and to encourage effective cessation strategies (Emmons et al., 2000). Studies conducted with hospitalized smokers conclude that smoking cessation interventions delivered during a period of hospitalization with follow-up and support increase cessation; this situation has also been called a teachable moment (Munafo et al., 2001; Rigotti et al., 2002; Rigotti, 2000). Thus, intervening with parents during their child's hospitalization may allow for the same type of teachable moment to address caregiver smoking behavior change.

Behavioral Change Counseling

Among physicians, the leading reason for failure to practice behavioral counseling is the belief that patients cannot or will not change their behavior (Prochaska, 2003). This belief is held by 65 percent of American physicians (lack of time and

reimbursement are second and third respectively. Additionally, physicians become demoralized by this assumption and conclude that attempts to change behavior are unlikely to succeed and it is not worth the effort. The stages of change provide a new paradigm in which to view the change process, allowing clinician to use motivation strategies to facilitate progression through the stages to achieve sustainable change.

The behavioral change process unfolds over time. The Transtheoretical Model (TTM) of change is the widely used model of change in health psychology. Although initially developed to examine smoking cessation and recovery in psychotherapy, it has been applied to a broad array of behaviors (Prochaska et al., 1994). These processes of change have played an integral role in the development of motivational interviewing and brief interventions using a motivational approach (DiClemente, 1999; Miller & Rollnick, 1991; Rollinick, Mason, & Butler, 1999). The stages of change involve progressing through a series of five stages including precontemplation, contemplation, preparation, action, and maintenance (DiClimente & Prochaska 1985, 1998; Prochaska & DiClimente 1983, 1994). The stage of precontemplation encompasses people who do not intend to take action in the next six months, but are highly ambivalent about it. People in the preparation state are convinced that the advantages of change outweigh the disadvantages and are ready to act within the next 30 days. The action stage involves successfully altering a behavior for any period of time between 1 day to 6 months (Weinstein, Rothman, & Sutton, 1998). After six months, patients progress to the maintenance stage. The TTM also recognizes that relapse is possible, even likely when moving through the stages of change. Effective use of motivational interviewing strategies can help motivate the individual to renew or recommence the journey through the early stages once again, to initiate another change attempt (Miller & Rollnick, 2002).

A challenge for many health care practitioners is adopting the more facilitative and collaborative spirit of motivational interviewing in place of the more prescriptive, practitioner-centered, and directive techniques that are traditionally employed in medical settings. Motivational interviewing interventions may result in improved provider-patient relationships and consumer satisfaction, which is an underdeveloped and potentially powerful selling point to providers and health care agencies (Prochaska, 2003; Miller & Rollnick, 2002). Motivational interviewing includes high-quality listening but also requires the strategic use of specific psychotherapeutic methods to diminish resistance, resolve ambivalence, develop discrepancy, and trigger behavior change (Miller & Rollnick, 2002). Given the extensive skills included in this approach, motivational interviewing interactions tend to happen less in brief opportunistic settings such as a hospital visit.

A style of counseling more conducive to the hospital setting may be behavioral change counseling. This style of counseling is derived from the patient-centered method (Stewart et al., 1995) with some principles and skills linked to the more specific subject of health behavior change (Rollnick et al., 1999) and motivational interviewing. Behavior change counseling lasts from 5 – 30 minutes and involves exchanging information with the patient. The context of behavior change counseling is often broader than for brief advice, including more problem areas and behaviors. The practitioner using behavior change counseling operates as an adviser to a patient who is an active and engaged participant. The encounter is more collaborative then typically observed brief advice. Behavior change counseling often has a task-oriented flavor. The spirit of this activity is one of shared decision making. The practitioner avoids engendering resistance and negotiates an agenda that is sensitive to the readiness of the person. The behavior change

interaction includes identifying the patients' goals and readiness and working to purposively to build motivation for change making it a nice fit with current hospital setting doctor-patient interactions (Rollnick & Miller, 2002).

Smoking cessation interventions have shifted from the predominantly intensive clinical approach to a public-health-based, broad dissemination perspective (Lichtenstein & Glasgow, 1992, 1997). Intensive treatments have demonstrated efficacy in tightly controlled research settings; their effectiveness remains low due to barriers such as the inability to reach the broadest segment of smokers and low utilization. The focus on delivering broader interventions to an at-risk population has resulted in the development of a public health intervention involving health providers delivering a brief intervention aimed at raising smokers' motivation to change their smoking behavior. Barriers also exist for this perspective, as many health care providers do not have the skills or time to deliver such interventions. The institution of a clinical guideline and training on behavioral counseling principals has aided in the facilitation of this strategy. These same strategies can be used when dealing with smoking caregivers.

Interventions with smoking caregivers in healthcare settings.

Identifying acceptable opportunities to intervene with caregivers who smoke is a challenge (Winickoff, Hillis, Palfrey, Perrin, & Rigotti, 2003b). Although smoking cessation would have the most far-reaching benefits, some parents may be more receptive to counseling to reduce ETS exposure for their child than to stop smoking altogether (Schuster et al., 2002). Several studies have examined caregiver smoking and the efficacy of counseling caregivers in different settings. Interventions range in their approach to reduce the amount of ETS exposure for children with caregivers who smoke. Some address ETS reduction specifically through education caregivers on the health risks

associated with childhood ETS exposures (Wahlgren, Hovell, Meltzer, Hofstetter, & Zakarian, 1997; Hovell et al., 2000) while others focus on counseling caregivers on ways to stop smoking (Groner, Ahijevych, Grossman, & Rich, 2000; Irvine et al., 1999; Wilson et al., 2001). The results of these studies vary in outcome, with some caregivers achieving reported reduced ETS exposure and with few attempts at smoking cessation in studies aiming to increase smoking cessation attempts. Other studies have attempted to illustrate the feasibility of providing smoking caregivers with a comprehensive smoking cessation services given their frequent interactions within the child health care setting (Curry et al., 2003; Winickoff, Hibberd, Case, Sinha, & Rigotti, 2001; Winickoff, Buckley, Palfrey, Perrin, & Rigotti, 2003a; Winickoff, Hillis et al., 2003b). Combining the results of these studies may allow for the development of an efficient and effective intervention that decreases children's overall ETS exposure and the negative health effects of such exposure as well as increase caregiver smoking cessation attempts.

Studies that identify ETS reduction as the primary approach to promoting smoking behavior change have been conducted in several settings with varying outcomes (Roseby et al., 2003). Wahlgren and colleagues (1997) delivered a three-month intensive counseling intervention to smoking parents of asthmatic children recruited from a pediatric allergy clinic. This intervention included counseling caregivers to change their behavioral patterns that led to the child's exposure and were informed that they would not be asked to quit smoking. At the 12 month follow-up parents reported a statistically significant reduction in cigarettes smoked per day in the presence of their child, with the intervention group reporting a 75 percent reduction in ETS and at nine months, 21.4% of the participants counseled quit smoking and maintained this result at the 30 month

follow-up period; demonstrating that a behavioral intervention produced substantial and durable changes that led to a decrease in ETS exposure for asthmatic children.

In a similar study, Hovell and associates (2000) provided a seven session behavioral intervention to women enrolled in supplemental program for women, infants, and children (WIC) both in person and over the phone. The intervention consisted of setting long-term goals and objectives for achieving and maintaining low ETS. Exposure to ETS was measured by parent report, child urine cotinine (a byproduct of nicotine) concentration, and nicotine monitors places in the home. Parents reported a significant reduction in the number of parent reported cigarettes per day in the presence of the child following the intervention. However, there was no change in nicotine absorption as measured by urinary cotinine. Conversely, cigarette smoke absorption for the control group increased from 9.4 ng/ml to 17.5 ng/ml over this time period, with almost no change in the intervention group (10.9 ng/ml at baseline, 10.5 ng/ml at the 12 month follow-up. While the intervention did not significantly decrease the amount of ETS exposure in the home, it did prevent the significant increase observed in the control group.

Several studies have delivered ETS education as a means to encourage reduced ETS and cessation. Groner and associates (2000) conducted a brief nurse delivered randomized controlled trial to determine if mothers receiving a smoking cessation intervention emphasizing the health risks of ETS for their children had a higher quit rate than mothers receiving routine smoking cessation advice or a control group. While there no impact was found on quit rates, the intervention stressing the health risks of childhood ETS exposure appeared to have a significant sustained effect on the location where parents reported smoking occurred. No biological confirmation of ETS exposure was

used to validate parental report of smoking location. Irvine and associates found similar results in a 1999 study investigating whether parents of asthmatic children stop smoking or alter their smoking when presented with the risks of child ETS exposure. At the one-year follow-up 98% of parents in both groups smoked with a small decrease in salivary cotinine concentrations found in the intervention and control group. These studies highlight the need to address parental smoking needs as a separate issue from the child's health.

Wilson and colleagues (2001) found that providing caregivers of asthmatic children with feedback about their smoking and ETS education resulted in the intervention group having significantly lower hospital utilization than the usual care group receiving usual information. The intervention supported but did not emphasize smoking cessation as a goal. It concentrated on eliminating smoking in all the indoor environments that would be frequented by the child. No change in cigarette smoking was reported. Limitations of this study included the lack of a biochemical measure to validate ETS reduction. Additionally, many participants could not differentiate the message being delivered, as many in the intervention reported receiving information that smoking could continue in other areas, such as the car.

Interventions emphasizing ETS exposure education have resulted in a reduction in parent report smoke exposure and childhood hospitalization in asthmatics patients. Little change in quit rates has occurred in any study. While some have argued that educating parents about ETS exposure is enough to reduce the risk to children (Hovell et al., 2000; Wahlgren et al., 1997), these studies highlight the need to address specifically the goal of smoking cessation in order to obtain a change in smoking behavior. Limitations of these studies include the lack of biochemical report of ETS exposure of the child. While parent

biochemical measures reflect little change, changes in childhood exposure could measure the actual effect of the changes in parent behavior. Further, some believe that a change environmental tobacco smoke exposure cannot be accomplished without also addressing cessation. (Curry et al., 2003; Winickoff, Buckley et al., 2003a).

Smoking Cessation Interventions in Child Health Care settings

Recently, smoking cessation interventions have been conducted in the pediatric setting to assess the feasibility of delivering cessation services to parents in the context of child health care. The results of these studies show that it is possible to deliver effective smoking cessation services to parents following the Clinical Practice Guideline, using a brief behavioral counseling strategy to facilitate this interaction. Curry and associates have used this teachable setting to evaluate the effectiveness in the outpatient setting (Curry et al., 2003). Winickoff and associates have examined both the inpatient and outpatient setting as setting that might provide an opportunity to influence parental smoking behavior (Winickoff et al., 2001; Winickoff et al., 2003a; Winickoff et al., 2003b). These studies illustrate the feasibility of engaging parents into a smoking cessation program as well as the achievability of implementing the evidence-based clinical guidelines for smoking cessation in pediatric practice.

Implementing cessation services in the pediatric setting is a novel, yet acceptable idea to smoking caregivers (Winickoff et al., 2001). Work by Curry and associates (2003) included conducting three session smoking cessation intervention based on the Clinical Practice Guideline and brief behavioral counseling conducted by the nursing staff in an outpatient pediatric clinic serving low-income families. A one-year follow-up study found that abstinence rates were twice as high in the intervention group as those for the treatment as usual control group at both the 3 and 12-month follow-up. Additionally,

using the same method in an inpatient and outpatient setting, Winickoff and colleagues (2001, 2003a, 2003b) have conducted studies to determine the feasibility of providing a comprehensive smoking cessation. Results of this work indicate that parents will use services while at the hospital. At 2-month follow-up, over half of the parents reported making at least one quit attempt, with one in five reporting total abstinence, however, there was not a control group or biochemical confirmation. Significant attitude change occurred in terms of the harms associated with ETS exposure and parents reported smoking significantly fewer cigarettes in the house and car. These studies and future studies illustrating the provision of comprehensive smoking cessation for smoking caregivers are an important step in encouraging providers to implement this evidenced-based approach with parents in a child health care setting, thus, increasing the number of people receiving smoking cessation treatment significantly.

Summary

There are many negative health of effects attributed to childhood ETS exposure. Interventions to address ETS exposure in the child health care setting have resulted in low reduction rates with little smoking cessation. A shift in smoking cessation interventions from clinical focus to at public health perspective lead to at broader utilization of cessation strategies in non-clinical settings, including the health care setting. This shift resulted in the development of effective intervention for health care providers to help patients in their efforts to stop smoking; however, these interventions are not widely utilized in the pediatric health care setting. The success of these interventions depends not only on the motivation of the individual to quit smoking, but also on the availability of health professionals to help patient choose the level of required support that is appropriate to their needs (Fagerström, 2002). Developing an effective and

efficient way to reduce harm to child while intervening with the caregiver will benefit both the child and the ex-smoker and allow child health care providers to gain confidence in their ability to help smoking caregivers in their cessation attempts.

CHAPTER III

GOALS OF THE PRESENT STUDY

Environmental tobacco smoke exposure is associated with several health problems in children. Concern over the effects of ETS on children and adults has prompted diverse actions. The United States has seen a boom in clean air ordinances for the public areas including the workplace. Although such laws exist for public spaces, they do have a direct effect on ETS exposure in other locations. The home for example, is the major site of ETS exposure for children (Mannino et al., 2001; Schuster et al., 2002). Legislation and litigation have been used in many communities to promote smoke-free public buildings and worksites. However, despite evidence that smoking restrictions in the home have been linked to successful smoking cessation efforts (Farkas, Gilpin, Distefan, & Pierce, 1999), not enough has been done to address smoking reduction in the home. Working to educate and assist smoking caregivers in changing their smoking behavior may have greater potential to reduce ETS in the private home.

This project compared smoking caregivers of children admitted to the Children's Hospital intensive care nursery. Participants were randomly assigned to three conditions including a Treatment as Usual Group, a Smoking Cessation Message group, or a Smoke-Free message group to address reducing their child's smoke exposure in the home. The **Treatment as Usual group** received only brief information about the hazards of ETS exposure routinely provided by nursing staff at discharge along with some advice from their physician and other staff on the unit. The **Smoking Cessation Message group**

received a brief intervention following the *Clinical Practice Guidelines for Treating Nicotine Dependence*, (5As), which included asking about smoking and assessing readiness to quit smoking. Assistance focused on setting a quit date and linking the participant with a community resource to aid in their quit attempt for the follow-up portion of the intervention. The **Smoke-Free message group** included asking about smoking in the home and assessing caregiver readiness to adopt a smoke-free home policy. Assistance focused on developing a plan to keep their home smoke-free and setting a day to implement the policy. While both experimental groups mentioned smoking cessation as the best way to reduce environmental tobacco smoke exposure, the cessation group received specific cessation information while the smoke-free home message emphasized ways to keep the home smoke-free.

Initial measures of recent caregiver smoking were assessed using a carbon monoxide (CO) monitor and caregiver-report. A three-month follow-up included a measure of ETS exposure (passive nicotine monitor) and caregiver-report measures of smoking and Readiness to Change smoking behavior. Groups were compared on nicotine levels in the home and parent report of smoking. Additional analyses were run to determine the effects of the stage of readiness to stop smoking on rate of nicotine exposure reduction. Comparing groups on nicotine exposure levels in the home at 3 months post discharge will help determine the strategies to use in the future to address caregiver smoking in the home while a child is hospitalized in an intensive care nursery.

CHAPTER IV

STATEMENT OF HYPOTHESES

For the present study, several hypotheses were proposed concerning post-study differences in passive nicotine monitor levels in the home, changes in Readiness to Change to have a Smoke-Free home, and differences in smoking behavior as a function of intervention group after discharge from the hospital.

Hypothesis 1: Smoking caregivers in the Treatment as Usual (TAU) group will have significantly higher passive nicotine monitor readings than those who receive the Cessation message (CESS) or Smoke-Free home message (SFH). The null hypothesis states that there will be no significant differences on the monitor readings as a function of group. The dependent variable for this hypothesis is the passive nicotine monitor reading (ug/m^3); and the independent variable is the group (TAU, CESS, and SFH.)

Hypothesis 2: Smoking caregivers who participate in the intervention group (CESS and SFH) will have significantly different passive nicotine monitor reading levels resulting in lower passive nicotine monitor levels for one of the groups (CESS or SFH). The null hypothesis states that there will be no significant differences between the two groups on passive nicotine monitor readings (ug/m^3) as a function of intervention group. The dependent variable for this hypothesis is the passive nicotine monitor reading; and the independent variable is the intervention group (CESS and SFH).

Hypothesis 3: Intervention group will have an impact on the stage of Readiness to Change to have a Smoke-Free home when comparing the baseline stage to the follow-up

stage. The null hypothesis states that there will be no differences between the intervention group and in change of stage of Readiness to Change when comparing baseline stage to follow-up stage of Readiness to Change to have a Smoke-Free home. The dependent variable for this hypothesis is change in stage of Readiness to Change to have a Smoke-Free home at baseline to follow-up; the independent variable will be intervention group (NON, CESS, SFH and TAU).

Hypothesis 4: Smoking caregiver participants will have significantly different smoking behavior at baseline when compared to follow-up smoking rates when comparing intervention group (CESS, SFH& TAU.) The null hypothesis states that there will be no differences between the intervention group and smoking behavior when comparing baseline and follow-up smoking rates. The dependent variable for this hypothesis is number of cigarettes smoked at baseline and follow-up; the independent variable will be the intervention group of the smoking caregiver.

CHAPTER V

METHODS

Sample

Participants were recruited from an intensive care nursery at the Oklahoma University Health Sciences Center Children's Hospital. This nursery is a 36-bed unit that provides maximum care for newborns who are born serious problems. Children born prematurely tend to be more susceptible to problems associated with ETS exposure as a result underdeveloped body systems. Exclusion criteria for the present study included non-English speaking caregivers and participants under 18. Initial entry into the study was determined by the research assistant assessing smoking in the home by asking, "Does anyone in the home smoke?" If the caregiver answered "yes," an effort was made to interview that caregiver during their hospital visit. However, families where the smoking caregiver was not available for an initial interview during the hospital visit were excluded from the study. If there were multiple smokers in the home, the person who completed the consent form was considered the smoking caregiver, and the identified participant. The limitation of this definition of a participant did not allow us to provide the intervention to all who lived in the home, as there was no protocol in the intervention included to aide a visiting caregiver to intervene with a smoking caregiver not visiting the hospital. A non-smoking caregiver group (NON) was recruited to serve as a benchmark to compare the level of passive nicotine in the home to the three smoking caregiver groups (CESS, SFH, & TAU.)

Smoking status identification

Carbon monoxide monitoring: The carbon monoxide monitor (CO) measures the amount of CO in breath, which is an indirect, non-evasive measure of blood carboxyheameglobin (an indicator of nicotine inhalation). Carbon monoxide (CO) measured in expired air is reasonably specific for detecting heavy cigarette smoking but is of marginal utility for detecting light smoking (Sonnenworth & Jarrett, 1980). The CO measurement was used in determining smoking status. Its sensitivity is limited by rapid elimination of CO, such that after 1 day of not smoking, CO levels are no different than those non smoking. Measuring CO in expired air is most easily conducted and provides feedback within seconds, its sensitive and specificity are both around 90% compared to plasma and saliva cotinine with 96-100% sensitivity and specificity. A typical cut-off point for CO in expired air is 8ppm. Assuming the level of CO during cigarette smoking begins at 40 ppm, it would require about three half lives to decline to 8ppm. Assuming a half-life of 2-3 hours, this would correspond to 6-9 hours to reach cut off (Coburn, Forster, & Kane, 1965). It should be noted that CO exposure from environmental sources could result in expired 2-6 ppm, depending on the extent of exposure to traffic exhaust and other pollution. (Society for Research on Nicotine and Tobacco Subcommittee on Biochemical Verification, 2002).

In the initial meeting, participants were to blow into the monitor before receiving the intervention to confirm smoking status. A person was classified as a smoker with a monitor reading of 8 ppm or more or self report. No members of the non-smoking caregiver group had a reading more than 8 ppm.

Baseline information

Baseline measures were obtained on demographic characteristics, smoking patterns, readiness to reduce child's environmental tobacco smoke exposure, and readiness to quit smoking.

The demographic questionnaire provided information about the household composition including age, race, and smoking status of each person in the home. The smoking patterns and quitting history was used to assess the amount smoked and the time to first cigarette as a proxy measure of dependence. This questionnaire was also used to estimate amount of nicotine exposure to the child by asking specific questions related to areas of smoking and if the child was present while smoking. The family's Smoke-Free home policy was assessed by asking where in the home, if any, smoking is allowed on a regular basis.

Readiness to Change environmental tobacco smoke exposure was assessed using stage based questions. Based on their response, the caregiver was placed in one of five categories related to the Transtheoretical model of change, including precontemplation, contemplation, preparation, action, and maintenance. Readiness to Change smoking behavior was measured similarly by asking how willing they were to stop smoking in the next thirty days. For all smokers, their stage of readiness to quit smoking was assessed using statements to each stage. Based on their response to stage based questions, they were placed in one of five categories related to the Transtheoretical model of change.

Interventions

Randomization

Smoking participants were randomly assigned to one of three conditions, including two intervention conditions (CESS and SFH) and one treatment as usual

condition (TAU.) Smoking participants picked a card from a bag with four cards for each smoking condition. The bag was refilled with 12 new condition cards after all 12 cards were chosen. The two intervention groups included using the 5 *As* to deliver advice about having a smoke free home, emphasizing either a smoking cessation intervention or a "smoke-free home" intervention with the smoking caregivers. The third group of smoking caregivers completed the initial assessment measures, discussed the Smoke-Free homes information brochure and received follow-up calls for the monitor placement, identical to the treatment groups. Beyond these calls, they did not receive additional services from the research personnel. The three-month follow-up visit followed a short face-to-face intervention follow-up protocol.

Each caregiver completed the baseline measures. Smoking caregivers who agreed to be in the study were randomized to one of three conditions. One group received a specific message targeting smoking cessation (CESS) as a way to decrease their child's environmental tobacco exposure. A second group of smoking caregivers received an intervention targeted at developing a strategy that specifically focused on environmental tobacco exposure reduction (SFH). Both interventions were modeled after the *Clinical Practice Guideline Treating Tobacco Use and Dependence* (Fiore et al., 2000) and included using a motivational style to conduct a brief behavioral change counseling session to facilitate the change process.

Smoking cessation message

After determining the caregivers smoking status, the smoking cessation message (CESS) intervention presented smoking cessation as the goal to be reached in order to reduce environmental smoke exposure to their child during the "Advise" portion of the intervention. The intervention focused on ways to help the parent quit smoking in order

to reduce the amount of smoke in the home. This intervention included asking each patient about their smoking status, advising them to quit smoking to benefit the child's health, assessing their readiness to change their smoking behavior, and providing assistance to quit by referring to local resources or providing cessation specific materials. The "Assist" portion of the cessation arm will include providing stage-based materials to the participant. All participants were given a Smoke-Free Homes brochure (EPA, 1999) indicating the dangers of environmental tobacco smoke exposure and ways to decrease exposure. Those agreeing to make a quit attempt in the next 30 days were referred to the Oklahoma Tobacco Helpline. The research assistant worked with the participant to develop a plan including a quit date and assessed barriers to quitting. This included brochures produced by the U.S. Department of Health and Human Services Public Health Service provided by the Oklahoma State Department of Health Tobacco Use Prevention Service.

Smoke-Free Home message

The Smoke-Free Home message (SFH) will present smoke reduction as the primary goal of the intervention. During the "Advise" portion of the intervention, the caregiver was advised that while quitting smoking is the most beneficial way to reduce the harm of environmental tobacco smoke to their child, reducing environmental tobacco smoke is also a way to reduce the amount of smoke a child is exposed to in the home. After assessing their willingness to change the rate of environmental tobacco smoke exposure to their child, the caregiver generated ways to reduce ETS exposure in the home. The Assist portion of the "Smoke-Free message" intervention included providing participants stage-based materials. These materials included a brochure with information about the dangers of ETS exposure and ways to decrease exposure in the home.

Participants ready to address ETS reduction in the home were assisted in developing a smoke-free home plan. This plan addressed barriers to making their home smoke-free and developing strategies to overcome these barriers. Further, if the plan for ETS reduction was for the caregiver to attempt to stop smoking, the caregiver was referred to the Oklahoma Tobacco Helpline.

Follow-Up survey

The follow-up procedure consisted of a one-month phone contact call and a three-month assessment visit post discharge. The contact call was for simply for an attempt to confirm the address and phone were correct. If there was not a working phone number, three attempts were made to contact the family by mail. The three-month follow-up was for assessment purposes only. This visit was scheduled by phone two weeks prior to the face-to-face three-month meeting. This visit included the readministration of the baseline measures and placement of the passive monitor in the home for one week. After seven days the monitor was retrieved and the participant was paid $50.00.

The three-month contact included updates on changes in the household and any changes in their child's health in the time since leaving the hospital. Caregivers were assessed for their Readiness to Change smoking in the home and the caregiver's current smoking behavior. Smoking patterns and quitting history of the caregiver was also updated. Additionally, passive air nicotine monitors were used to validate adult reports of smoking levels in the home.

Passive air nicotine monitor: The nicotine monitor consists of a sodium-bisulfate-treated filter held in a 37-mm polystyrene cassette with a windscreen, and relies on passive diffusion of nicotine to the filter (Hammond & Leaderer, 1987). Filter contents were desorbed in water and analyzed using gas chromatography at the

University of California, Berkeley, School of Public Health. Previous studies have found that air nicotine monitor readings correspond closely with self-reported measures of household smoking exposure (Glasgow, Foster, Hammond, Lichtenstein, & Andrews, 1998). The passive air nicotine monitor was placed as high in the room as possible (without obscuring them), so that they were not seen on a regular basis. Monitors were left in the home for 7 days, to limit/reduce reactivity. Additionally, consultation with the environmental scientist directing the monitoring helped address any other measurement issues that arose.

Training and Manipulation checks

Both the project coordinator and the research associate were appropriately trained in motivational interviewing strategies to facilitate the brief behavioral change counseling with the caregiver. They also completed on-line training on the delivery of the brief intervention recommended in the *Clinical Practice Guideline for Treating Tobacco Use and Dependence* (5 *As*). Several measures were taken to assure adherence to the intervention protocol. To ensure treatment fidelity, all sessions were taped, with 20% of each intervention being reviewed weekly by the research coordinator. Additionally, weekly meetings were held with the coordinator and research assistant to address any inconsistencies. An intervention sheet with the script for the 5 *As* was developed to define exactly which steps were to be taken for each section of the intervention. Training for the intervention included training by the research coordinator about MI principles and their use in behavioral change counseling. All research staff completed online training for the 5 *As* which included a brief test at the end. Roleplays addressing typical scenarios were conducted to provide live intervention opportunities. After

completing three roleplays competently (effectively delivering each intervention as defined by the intervention sheet), the research assistant began intervening with patients.

Data Analysis

Several analyses were conducted to test the primary hypotheses for the present study. Initially, a one-way analysis of variance (ANOVA) was conducted comparing passive nicotine monitor readings across smoking caregiver group. Smoking caregiver groups were compared to determine if the Smoking Cessation (CESS) message or Smoke-Free Home message (SFH) groups had a greater decrease in nicotine exposure than the Treatment As Usual (TAU) smoking caregiver group. To explore differences between the nicotine monitor reading levels by group, the Kolmogorov-Smirnov was used to compare the level ETS exposure of smoking caregivers to the ETS levels found in the non-smoking caregivers homes. Then, in an effort to look at Readiness to Change smoking behavior in the home among caregivers, chi-square analyses were conducted to assess differences in baseline to follow-up Readiness to Change smoking in the home measured by increase or no change/ decrease in stage. Finally, change in smoking behavior change was assessed using repeated-measures analysis of variance (ANOVA) to compare mean number of cigarettes smoked reported at baseline and follow-up.

CHAPTER VI

RESULTS

Sample Characteristics

A total of 132 caregivers were recruited to participate in the study. Of those recruited, 27 non-smoking caregivers and 64 smoking caregivers met criteria for participation in the study. The final sample consisted of non-smoking caregivers (n=25) and 78% (n=53) smoking caregivers who consented and enrolled in the present study (Figure 1).

Table 1 presents characteristics of the 78 enrolled caregivers by smoking status at baseline.

Smoking Caregivers

Table 2 presents baseline smoking characteristics of the 53 enrolled caregivers by smoking status at baseline.

Attrition

Results of analyses testing for significant differences between baseline demographic characteristics for the non-smoking caregivers (n=19) versus smoking caregivers (n=21) who returned the passive nicotine monitor after 3 months were not significantly different from those who were not followed at 3 months (all $p > .05$).

Primary Analyses

Hypothesis 1: Smoking caregivers in the Treatment as Usual (TAU) group will have significantly higher passive nicotine monitor readings than those who receive the

Cessation message (CESS) or Smoke-Free home message (SFH). The null hypothesis states that there will be no significant differences on the monitor readings as a function of intervention group. The dependent variable for this hypothesis is the passive nicotine monitor reading (ug/m^3); and the independent variable is the intervention group (TAU, CESS, and SFH.) The means for all smoking caregivers' monitor reading were compared to the mean passive nicotine monitor reading (u/mg^3) for the non-smoking caregivers using one-way analysis of variance (ANOVA). The results indicated that the means for the smoking caregivers were significantly different from the non-smoking caregiver passive monitor reading F (3, 36), p = .03.

The Kolmogorov-Smirnov test was used to compare the proportion of smoking caregivers with a low monitor reading to the proportion of non-smoking caregivers ETS monitor reading in the low category. The monitor readings were categorized into low, medium, or high based on the readings in the non-smoking group. The largest discrepancy between the two cumulative distributions by group occurred between the Treatment as Usual group and the non-smoking caregiver, with an observed value of 69, larger than the critical value at the p<. 05 level. Therefore, the monitor readings of the smoking caregivers who did not receive an intervention were significantly different from the non-smoking caregivers. Smoking caregivers with some smoke-free home intervention were not significantly different on the proportion of monitor readings in the low ETS exposure category.

Hypothesis 2: Smoking caregivers who participate in the intervention group (CESS and SFH) will have significantly different passive nicotine monitor reading levels resulting in lower passive nicotine monitor levels for one of the groups (CESS or SFH). The null

hypothesis states that there will be no significant differences between the two groups on passive nicotine monitor readings (ug/m^3) as a function of intervention group. The dependent variable for this hypothesis is the passive nicotine monitor reading; and the independent variable is the intervention group (CESS and SFH). Means for passive nicotine monitor reading were analyzed using independent sample *t*-tests where monitor reading served as the dependent variable; the independent variable was group. The results indicate that the means for the passive nicotine monitor level in the home for the CESS intervention group compared to the SFH group are not significantly different, $t(12) = -.822$, $p = .427$.

Hypothesis 3: Intervention group will have an impact on the stage of Readiness to Change to have a Smoke-Free home when comparing the baseline stage to the follow-up stage. The null hypothesis states that there will be no differences between the intervention group and in change of stage of Readiness to Change when comparing baseline stage to follow-up stage of Readiness to Change to have a Smoke-Free home. The dependent variable for this hypothesis is change in stage of Readiness to Change to have a Smoke-Free home at baseline to follow-up; the independent variable will be intervention group (NON, CESS, SFH and TAU).

Chi-square analyses were conducted to determine if the proportion of individuals who experienced an increase in Readiness to Change smoking in the home differed by caregiver group. Participants were separated into two categories: those who experienced an increase in Readiness to Change to have a Smoke-Free home vs. those who stayed the same or decreased in Readiness to Change to have a Smoke-Free home (Figure 4). The results indicate the frequency of individuals whose stage of Readiness to Change

increased differed when comparing the non-smoking caregiver group and the three intervention groups (χ^2) = 24.381, p = .0004; however, when only smoking caregivers means were compared, the frequencies were not significantly different (χ^2) = 3.226, p= .521)

Hypothesis 4: Smoking caregiver participants will have significantly different smoking behavior at baseline when compared to follow-up smoking rates when comparing intervention group (CESS, SFH& TAU.) The null hypothesis states that there will be no differences between the intervention group and smoking behavior when comparing baseline and follow-up smoking rates. The dependent variable for this hypothesis is number of cigarettes smoked at baseline and follow-up; the independent variable will be the intervention group of the smoking caregiver. Means for number of cigarettes smoked by smoking caregivers reported at baseline and follow-up (Figure 5) were compared using a 3 X 2 (Condition X Time) repeated-measures analysis of variance (ANOVA). For this hypothesis, number of cigarettes smoked by smoking caregivers reported at baseline and follow-up served as the dependent measure. Findings did not support the hypothesis as a main effect for time was not observed, F (1, 19) .003, p = .957, n.s.

CHAPTER VII

DISCUSSION

Previous studies have indicated that chronic, low levels of exposure of ETS in children is related to a higher incidence of various illnesses, intellectual deficits, lowered birth weights, and behavioral problems (Scherer, Meger-Kossien, Riedel, Renner, & Meger, 1999; Kum-Nji, Meloy, & Herrod, 2006; Weitzman, Byrd, Aligne, et al., 2002; Weitzman, Byrd, Aligne, Kahn, Khoury, & Nichols, 2003; Yolton, Dietrich, Auinger et al., 2005). While the PHS clinical guidelines recommend offering smoking cessation interventions to parents to limit children's exposure to ETS, little evidence exists for addressing ETS exposure for caregivers of children admitted to an intensive care nursery. This study demonstrates the feasibility of implementing an environmental tobacco smoke reduction program for this population in a hospital setting.

The present study tested whether a brief intervention emphasizing a Smoke-Free home message compared to a brief reduction intervention emphasizing a Smoking Cessation message with smoking caregivers, would lead to lower levels of passive nicotine monitor readings in the home after discharge from an intensive care nursery. Given the likely importance of motivational variables in the successful initiation and maintenance of smoking behavior change, the present study also sought to examine the utility of a brief ETS reduction intervention for increasing intentions to change for having a Smoke-Free home.

It appears that delivering a brief intervention emphasizing a Smoke-Free home message compared to a brief intervention emphasizing a Smoking Cessation message with smoking caregivers does not offer a significant difference in ETS exposure in the home as measured by a passive nicotine monitor or reduced number of cigarettes smoked at three months post-discharge from an intensive care nursery. However, there is an indication that a brief intervention (Smoke-Free or Cessation) emphasizing ETS reduction in the home compared to an information only group (Treatment As Usual), does offer lower levels of passive nicotine monitor and a change in intentions to have a Smoke-Free home. When compared to non-smoking caregivers with children admitted to the intensive care nursery, the Smoking Cessation message group had the lowest mean passive nicotine monitor reading. This reading was not significantly different from the non-smoking caregiver means. This may indicate that participants who received the smoking cessation and returned a passive nicotine monitor were more successful at reducing the ETS exposure to a level of a non-smoking caregiver. However, given the low level of return and the possible selective participation of smoking caregivers, this is unlikely.

Interestingly, there were no differences in smoking behavior as measured by number of cigarettes smoked per week by intervention arm. However, there were slight differences in Readiness to Change to have a Smoke-Free Home. Work by Hovell (2000) and others (Farkas, Gilpin, Distefan, & Pierce, 1999) would suggest that implementing a home smoking ban would be effective in reducing ETS in the home without immediate smoking behavior change. However, others state that smoking cessation is the best method because of the immediate reduction in smoking in the home (Winickoff et al, 2003a; 2003b). Results from this study do not support either hypothesis but do support

the idea that some effort to intervene with parents during hospitalization may aide in keeping ETS rates lower than those who do not receive intervention.

Limitations and Strengths

Limitations of the present study included issues related to recruitment and retention including a high drop-out rate among smoking caregivers which may have resulted in an overrepresentation of caregivers in the intervention groups with interest in reducing the ETS exposure in the home, thereby leading to lower nicotine monitor readings and greater changes in reported smoking behavior than might have occurred otherwise. Recruitment of the smoking caregivers was challenging. Because of the schedule in the intensive care nursery it was hard to reach potential participants during visiting hours. After attending frequent staff meetings and implementing a paging system, contacts did increase. An additional barrier occurred while interacting with the staff. In spite of substantial training and information about the study it was hard to focus their efforts to refrain from calling the study a "cessation" study, therefore, some of the early potential participants avoided study recruitment staff and became defensive when approached, likely affecting participation rates. Retention of participants was also a barrier in this study as a higher percentage of smoking caregivers were unreachable or simply refused to continue to participate in the study, than the non-smoking caregivers comparison group. Interpretation of the study results is also limited because of the nature of the population of the caregivers who all have children admitted to an intensive care nursery. As only a small percentage of women deliver children in this setting, these results may not generalize to the population of caregivers with children admitted to the general nursery with no significant health complications. However, as over 300,000 infants a year are admitted to the intensive care nurseries across the United States (Tated

& Frayer, 2003). Therefore, broad application of smoking cessation interventions in this population could reach the large number of caregivers admitted to the intensive care nursery every year.

Strengths of the investigation include the targeted study of high risk children for whom specialized ETS reduction interventions are not currently available conducted in an intensive care nursery setting. There are many advantages to doing research in a medical setting, including immediate contact with the patient populations and increased interaction with multidisciplinary teams (Palm, Mutnick, Antonuccio, and Gifford, 2003). Further, this practice can foster the development and dissemination of effective treatments that are acceptable within this environment. Attending to the day to day hassles in the intensive nursery environment were overwhelming at times; however, the staff were very receptive to the research study personnel. The relationship with staff was instrumental in the facilitation of the intervention and at times the retention of participants. This opportunity to conduct the study in a clinical setting set the stage for future projects and allows credibility for the study with practitioners (Glasgow, 2006).

Summary and Conclusion

In summary, strategies to address smoking behavior to reduce ETS exposure in the home have recently begun to be used with smoking caregivers (Hovell et al., 2000, Farkas et al., 1999) and early results suggested that such an approach would be helpful health care setting (Winickoff, 2003; Winickoff et al., 2005). The present study attempted to extend these findings within a population of smoking caregivers with children admitted to an intensive care nursery. The positive effect of the intervention conditions on lower passive nicotine monitor readings at follow-up and the increase in

intentions to change their home smoking policy in smoking caregivers suggest the possible benefits of ETS reduction interventions. However, the effects on these variables is modest, there was no overall effect of one specific intervention on passive nicotine monitor reading or smoking behavior. Despite these findings, brief intervention with smoking caregivers of children admitted to the intensive care nursery setting may help caregivers increase their intention to have a smoke-free home; therefore making an attempt to keep the home smoke-free or quit smoking more likely. Due to the low of follow-up rate of smoking caregivers, additional studies are needed to examine the impact of providing brief interventions with smoking caregivers in an intensive care nursery setting before a more definitive conclusion can be made about smoke-free home intervention delivery in this environment.

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APPENDICES

APPENDIX A

TABLES

Table 1 Baseline Demographic Information for All Caregivers

Variable	N	Total Mean ± SD	NON	TAU	CESS	SFH
Age	77	26.1 ± 6.1	25.5 ± 4.7	26.6 ± 7.2	25.1± 4.7	27.5 ± 7.6
Education (# years)	77	12.1 ± 1.7	12.4± 1.7	11.5± 2.2	12.7± 1.4	11.7± 1.7
Gender	78	N(%)				
Male		15(19)	1 (4)	3 (15)	5 (33)	6 (26)
Female		63(81)	24 (96)	17 (85)	10 (67)	12 (74)
Ethnicity	78	N(%)				
African-American		11 (14)	3 (12)	3 (15)	3 (20)	2 (11)
American-Indian		8 (10)	1 (4)	1 (5)	2 (13)	4 (22)
Asian-American		2 (3)	1 (4)	1 (5)	0	0
Caucasian		52 (67)	17 (68)	13 (65)	10 (67)	12 (67)
Hispanic		4 (5)	2 (8)	2 (10)	0	0
Other		1 (1)	1 (4)	0	0	0
Marital Status	77	N(%)				
Divorced		4 (5)	1 (4)	0	2 (13)	1 (6)
Married/ Partnered		47 (61)	18 (75)	14 (70)	8 (54)	10 (55)
Single		26 (34)	5 (21)	6 (30)	5 (33)	7 (39)
Income	78	N(%)				
<$14,000		35 (45)	8 (32)	11 (55)	7 (47)	9 (50)
$14,000-$18,000		10 (13)	5 (20)	1 (5)	2 (13)	2 (11)
$19,000-$25,000		13 (17)	4 (16)	5 (25)	2 (13)	2 (11)
$26,000-$41,000		10 (13)	5 (20)	1 (5)	0	4 (22)
$42,000-$65,000		7 (9)	2 (8)	2 (10)	3 (20)	0
>$65,000		3 (4)	1 (4)	0	1 (7)	1 (6)
Indoor Smoking Policy	76	N(%)				
Not allowed in home		56 (74)	22 (92)	13 (65)	10 (67)	11 (65)
Special areas		3 (4)	1 (4)	1 (5)	0	1 (6)
Special guests		8 (11)	1 (4)	2 (10)	3(20)	2 (12)
No restrictions		9 (12)	0	4 (20)	2 (13)	3 (17)

Baseline demographic characteristics for the non-smoking caregivers and smoking caregivers were not significantly different ($p > .05$).
Percentages may not add up to 100 due to rounding.

Table 2. Smoking Caregiver Baseline Characteristics

Variable	N	Total Mean ± SD	TAU	CESS	SFH
Smoking rate (cigarettes/day)	53	9.9±7.5	11.1±8.3	8.7±6.0	9.7 ±8.0
Fagerström (FTND)	51	3.8±2.2	3.7±2.2	3.8±2.0	3.9±2.6
Glover-Nilsson (GN-SBQ)	46	14.3±7.3	14.4±7.9	16.3±9.0	12.4±4.5
CO monitor Reading	53	16.5±12.7	15.9±15.0	15.7±8.29	17.9±13.5
Current Smoking Status	53	N(%)			
Pregnant Non-Smoker *		7 (13)	3 (15)	2 (15)	2 (11)
Smoker		46 (87)	17 (85)	13 (85)	16 (89)
Readiness – Cessation	53	N(%)			
Precontemplation		11 (21)	6 (30)	2 (13)	3 (17)
Contemplation		11 (21)	5 (25)	2 (13)	4 (22)
Preparation		23 (43)	6 (30)	9 (60)	8 (44)
Action		8 (15)	3 (15)	2 (13)	3 (17)
Readiness – Smoke-Free Home	53	N(%)			
Precontemplation		3 (6)	2 (10)	0	1 (6)
Contemplation		2 (4)	2 (10)	0	0
Preparation		19 (36)	5 (25)	6 (40)	8 (44)
Action		16 (30)	3 (15)	6 (40)	7 (39)
Maintenance		13 (25)	8 (40)	3 (20)	2 (11)
Pregnancy Smoking Status**	39	N(%)			
Quit During Pregnancy		17 (44)	8 (47)	6 (60)	3 (18)

* Pregnant smokers are defined as those smokers who quit during pregnancy and were not currently smoking during the baseline interview.

** Only Female data was used for this category. Male smokers were excluded from total group as well.

Table 3. Baseline Demographic Information for Caregivers Returning a Monitor

		Total	NON	TAU	CESS	SFH
Variable	N	Mean ± SD				
Age	40	26.2 ± 5.8	25.7 ± 5.1	27.4 ± 8.8	25.7± 3.1	26.9± 6.7
Education (# years)	40	12.3 ± 1.9	12.4± 1.9	11.1± 1.6	13.7± 1.5	12.0± 1.9
Gender	40	N(%)				
Male		6 (15)	1 (5)	1 (14)	2 (33)	2 (25)
Female		34 (85)	18 (95)	6 (86)	4 (67)	6 (75)
Ethnicity	40	N(%)				
African-American		4 (10)	3 (16)	1 (14)	0	0
American-Indian		3 (8)	1 (5)	0	1 (17)	1 (13)
Asian-American		1 (3)	1 (5)	0	0	0
Caucasian		29 (73)	11(58)	6(86)	5 (83)	7 (88)
Hispanic		2 (5)	2 (11)	0	0	0
Other		1 (3)	1 (5)	0	0	0
Marital Status	39	N(%)				
Divorced		3 (8)	1 (6)	0	1 (17)	1 (13)
Married/ Partnered		23 (59)	13 (72)	5 (71)	3 (50)	2 (25)
Single		13 (33)	4 (22)	2 (29)	2 (33)	5 (63)
Income	40	N(%)				
<$14,000		16 (40)	7 (37)	4 (57)	2 (33)	3 (38)
$14,000-$18,000		5 (13)	2 (11)	1 (14)	1 (17)	1 (13)
$19,000-$25,000		7 (18)	3 (16)	1 (14)	1 (17)	2 (25)
$26,000-$41,000		5 (13)	4 (21)	0	0	1 (13)
$42,000-$65,000		4 (10)	2 (11)	1 (14)	1 (17)	0
>$65,000		3 (8)	1 (5)	0	1 (17)	1 (13)
Indoor Smoking Policy	39	N(%)				
Not allowed in home		34 (87)	17 (94)	5 (71)	6 (100)	6 (75)
Special areas		1 (3)	0	1 (14)	0	0
Special guests		2 (5)	1 (6)	1 (14)	0	0
No restrictions		2 (5)	0	0	0	2 (25)

Baseline demographic characteristics for the non-smoking caregivers and smoking caregivers were not significantly different ($p > .05$).
Percentages may not add up to 100 due to rounding.

Table 4. Smoking Caregiver Baseline Characteristics for Caregivers Returning a Monitor

Variable	N	Total Mean ± SD	TAU	CESS	SFH
Smoking rate (cigarettes/day)	21	10.1±7.7	13.29±8.9	9.9±6.5	7.4 ±7.4
Fagerström (FTND)	21	3.6±2.1	4±2.2	3.5±1.7	3.3±2.5
Glover-Nilsson (GN-SBQ)	21	13.1±5.9	13.3±2.7	17±9.7	10.4±3.4
CO monitor Reading	21	17.5±13.7	22.2±18.2	16.5±8.6	14±12.7
Current Smoking Status	21	N(%)			
Pregnant Non-Smoker *		5 (24)	2 (29)	1 (17)	2 (25)
Smoker		16 (76)	5 (85)	5 (83)	6 (75)
Readiness – Cessation	21	N(%)			
Precontemplation		5 (24)	2 (29)	1 (17)	2 (25)
Contemplation		4 (19)	2 (29)	0	2 (25)
Preparation		9 (43)	2 (29)	5 (83)	2 (25)
Action		3 (14)	1 (14)	0	2 (25)
Readiness – Smoke-Free Home	21	N(%)			
Precontemplation		1 (5)	0	0	1 (13)
Contemplation		1 (5)	1 (14)	0	0
Preparation		5 (24)	1 (14)	2 (33)	2 (25)
Action		7 (33)	2 (29)	2 (33)	3 (38)
Maintenance		7 (33)	3 (43)	2 (33)	2 (25)
Pregnancy Smoking Status**	21	N(%)			
Quit During Pregnancy		11 (52)	3 (43)	3 (50)	5 (18)

* Pregnant smokers are defined as those smokers who quit during pregnancy and were not currently smoking during the baseline interview.

** Only Female data was used for this category. Male smokers were excluded from total group as well.

APPENDIX B

FIGURES

Figure 1. Recruitment and Randomization Information by Group

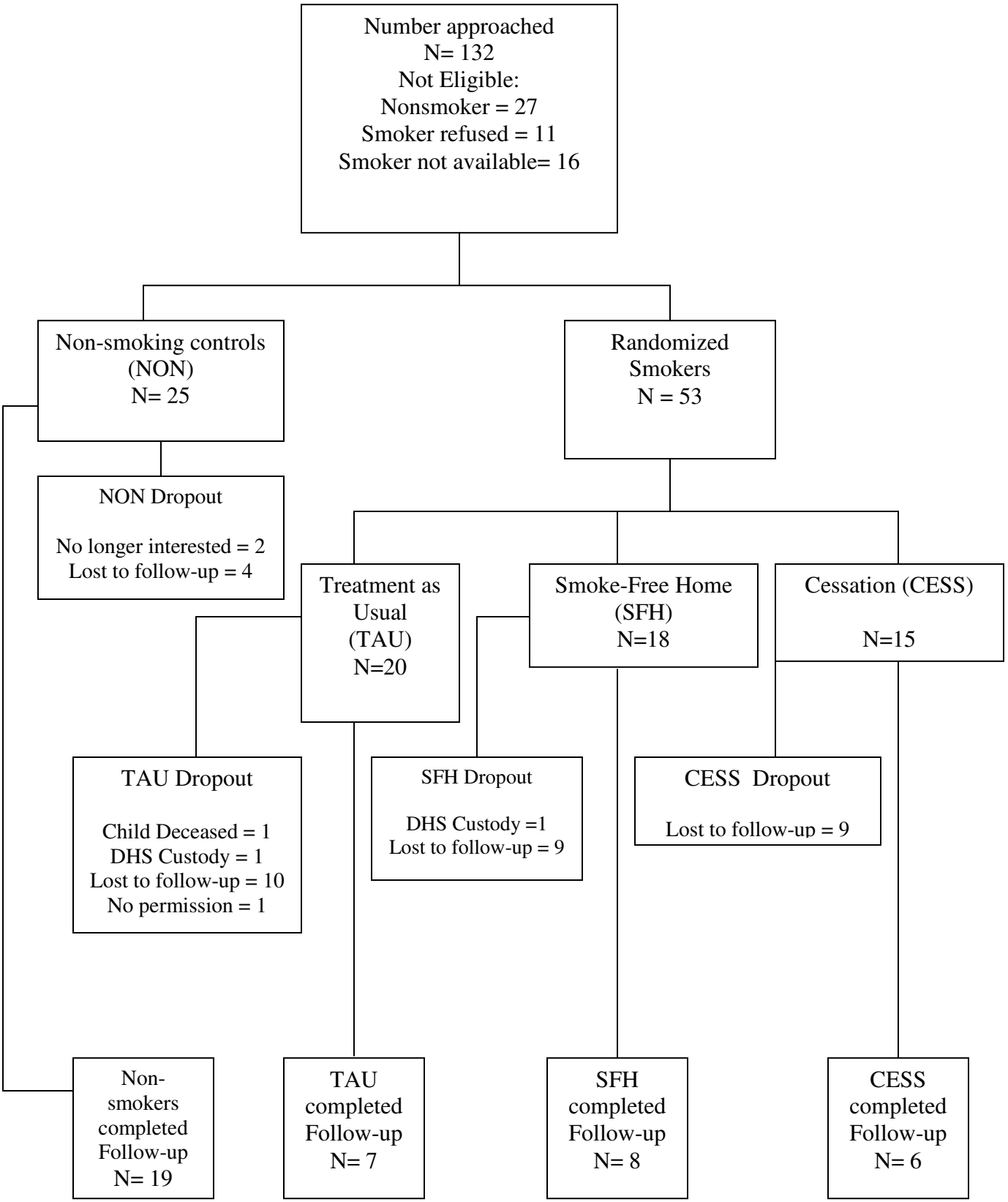


Figure 2. Mean Passive Nicotine Monitor Reading by Caregiver Group

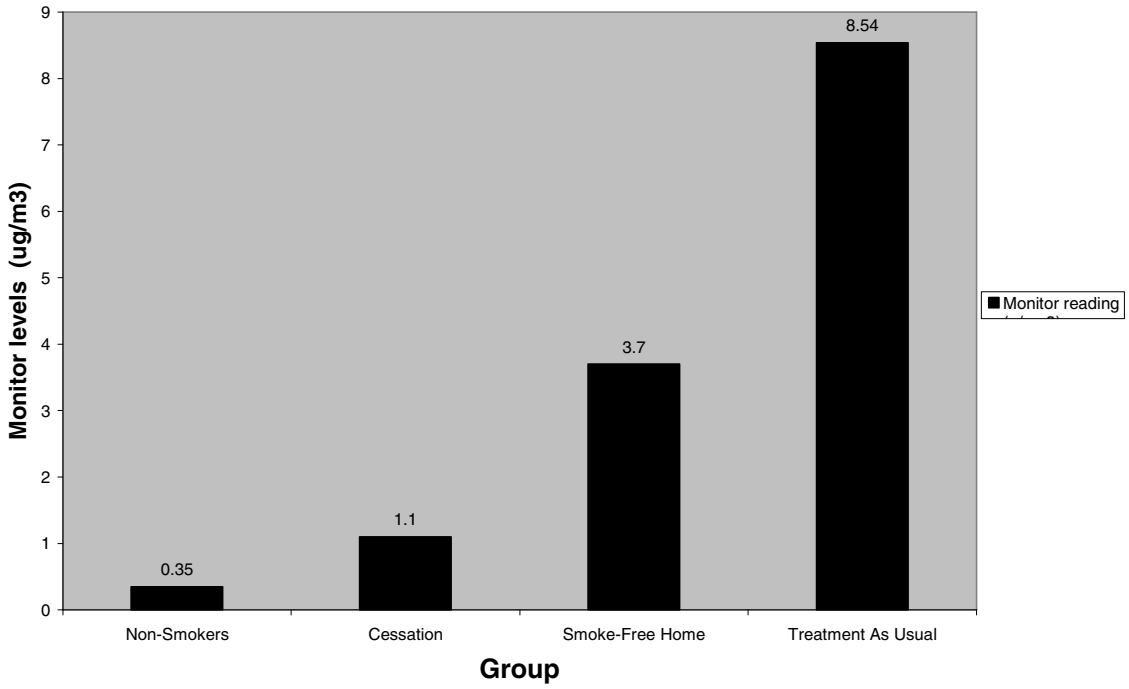


Figure 3. Passive Nicotine Monitor Reading by Intervention vs. Treatment as Usual

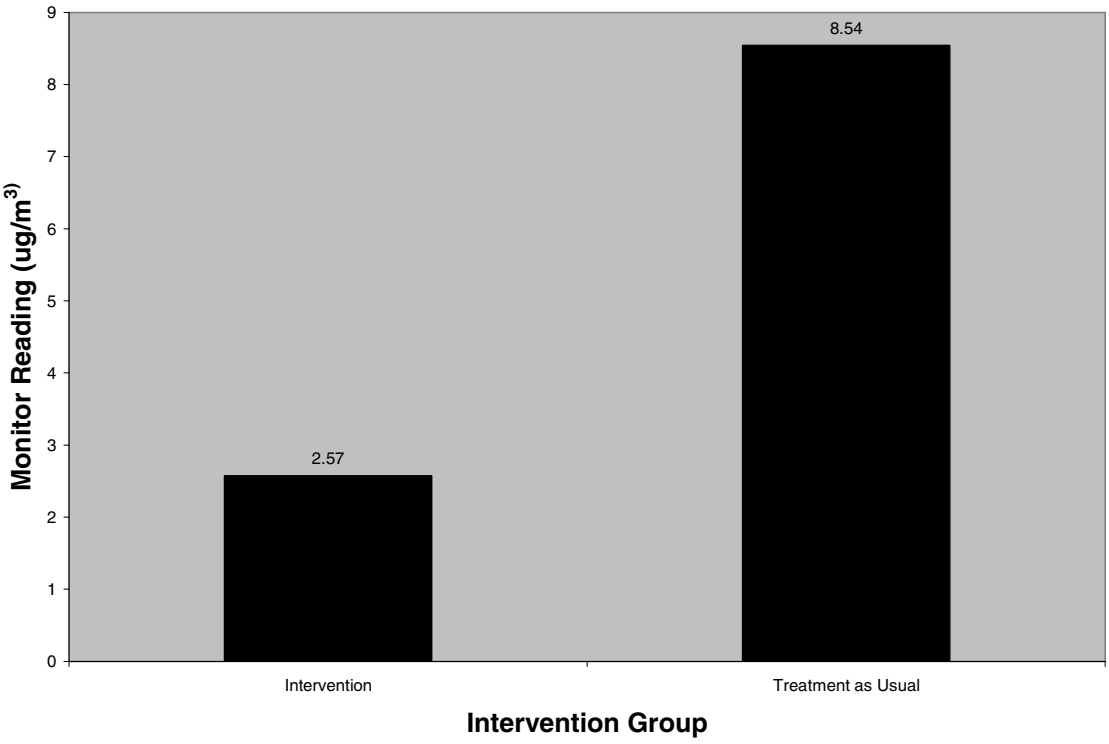


Figure 4. Readiness to Change to Have a Smoke-Free Home

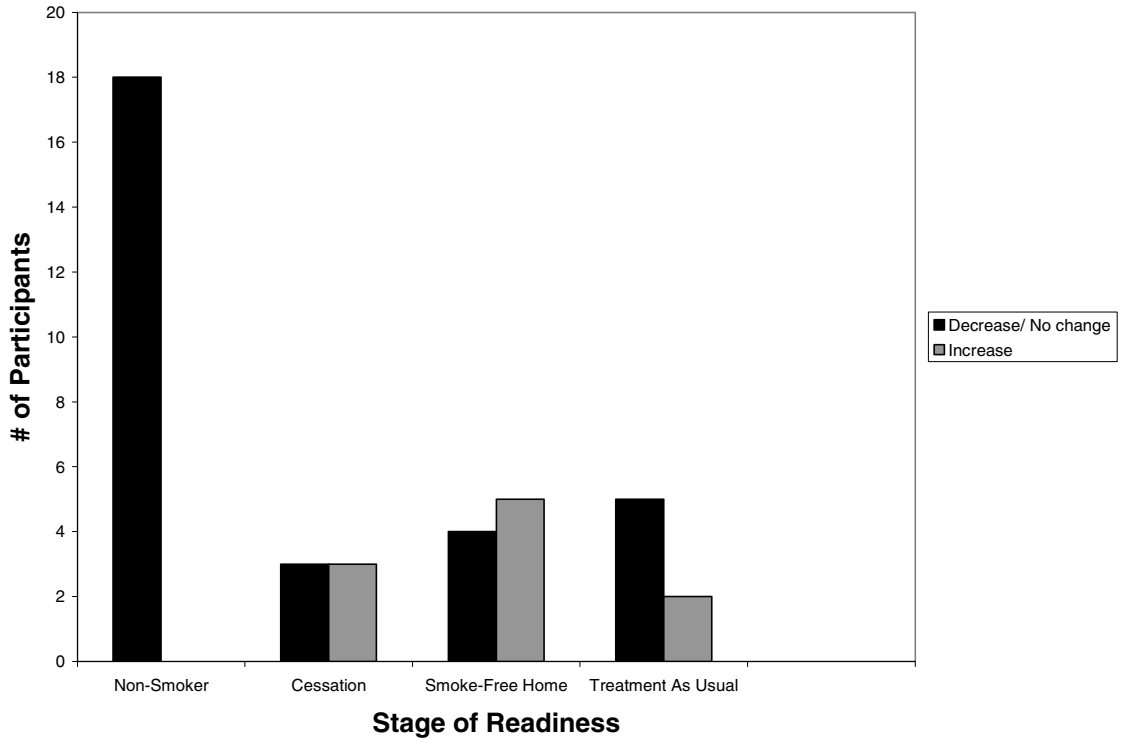
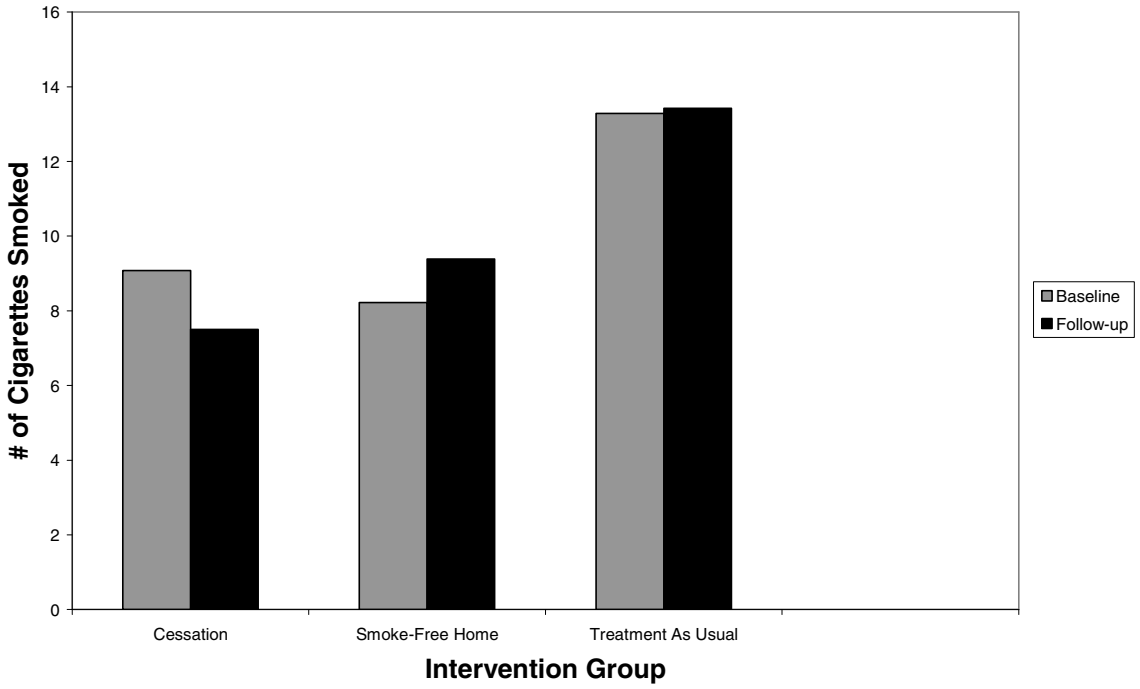


Figure 5. Reported Number of Cigarettes Smoked by Caregiver Group at Baseline and Follow-up



APPENDIX C

INSTITUTIONAL REVIEW BOARD FORM

Oklahoma State University
Institutional Review Board

Protocol Expires: 6/10/2005

Date: Friday, June 11, 2004 IRB Application No AS0491

Proposal Title: Addressing Environmental Tobacco Smoke Reduction in a Child Health Care Setting

Principal Investigator(s):

Ernestine Jennings
215 N. Murray
Stillwater, OK 74078

Frank L Collins
215 N Murray
Stillwater, OK 74078

Reviewed and Processed as: Expedited

Approval Status Recommended by Reviewer(s): Approved

Dear PI :

Your IRB application referenced above has been approved for one calendar year. Please make note of the expiration date indicated above. It is the judgment of the reviewers that the rights and welfare of individuals who may be asked to participate in this study will be respected, and that the research will be conducted in a manner consistent with the IRB requirements as outlined in section 45 CFR 46.

As Principal Investigator, it is your responsibility to do the following:

1. Conduct this study exactly as it has been approved. Any modifications to the research protocol must be submitted with the appropriate signatures for IRB approval.
2. Submit a request for continuation if the study extends beyond the approval period of one calendar year. This continuation must receive IRB review and approval before the research can continue.
3. Report any adverse events to the IRB Chair promptly. Adverse events are those which are unanticipated and impact the subjects during the course of this research; and
4. Notify the IRB office in writing when your research project is complete.

Please note that approved protocols are subject to monitoring by the IRB and that the IRB office has the authority to inspect research records associated with this protocol at any time. If you have questions about the IRB procedures or need any assistance from the Board, please contact me in 415 Whitehurst (phone: 405-744-5700, colson@okstate.edu).

Sincerely,

Carol Olson

Carol Olson, Chair
Institutional Review Board

The University of Oklahoma
Health Sciences Center
INSTITUTIONAL REVIEW BOARD

IRB Number: 11598
Approval Date: July 02, 2004

July 07, 2004

Mary Anne McCaffree, M.D.
Pediatrics Neonatology
940 N. E. 13th, CHO 2B2311
Oklahoma City, OK 73104-5066

RE: Addressing Environmental Tobacco Smoke Reduction in a Child Health Care Setting

Dear Dr. McCaffree:

The above-referenced research proposal was reviewed and granted expedited approval by the Chair of the Institutional Review Board (IRB). This proposal meets the criteria for expedited approval category 4 & 7. It is the judgment of the IRB Chair that the rights and welfare of individuals who may be asked to participate in this study will be respected; that the proposed research, including the process of obtaining informed consent, will be conducted in a manner consistent with the requirements of 45 CFR 46 or 21 CFR 50 & 56 as amended; and that the research involves no more than minimal risk to subjects.

This letter documents approval to conduct the research as described:

Public Affairs Review Dated: June 10, 2004
Consent form - Subject Dated: June 09, 2004
Other Dated: May 28, 2004 Educational Brochure
Survey Instrument Dated: May 28, 2004 Forms & Questionnaire
Advertisement Dated: May 28, 2004 Flyer
Protocol Dated: May 28, 2004
IRB Application Dated: May 28, 2004
Priv - Research Auth 1 Dated: June 02, 2003

As principal investigator of this protocol, it is your responsibility to insure that this study is conducted as approved. Any modifications to the protocol or consent form, initiated by you or by the sponsor, will require prior approval, which you may request by completing a protocol modification form. All study records, including copies of signed consent forms, must be retained for three (3) years after termination of the study.

It is a condition of this approval that you report promptly to the IRB any serious, unanticipated adverse events experienced by subjects in the course of this research, whether or not they are directly related to the study protocol. These adverse events include, but may not be limited to, any experience that is fatal or immediately life-threatening, is permanently disabling, requires (or prolongs) inpatient hospitalization, or is a congenital anomaly, cancer or overdose. For multi-site protocols, the IRB must be informed of serious adverse events at all sites.

The approval granted expires on June 30, 2005. Should you wish to maintain this protocol in an active status beyond that date, you will need to provide the IRB with an application for continuing review summarizing study results to date. IRB staff, Office of Research Administration, will request a progress report from you approximately two months before the anniversary date of your current approval.

If you have questions about these procedures, or need any additional assistance from the Board, please call the IRB office at (405) 271-2045 or send an email to irb@ouhsc.edu. Finally, please review your professional liability insurance to make sure your coverage includes the activities in this study.

Sincerely yours,

Karen J. Beckman, M.D.
Chair, Institutional Review Board

Ltr_Prot_Fappv_Exp

APPENDIX D

CONSENT FORM

Consent Form
University of Oklahoma Health Sciences Center & Oklahoma State University

Title: Smoke-Free Home Project
Investigators: Mary Anne McCaffree (OUHSC) and Ernestine Jennings, MS (OSU)

This is a research study to evaluate interventions being used on the NICU and in the Special Care Nursery to help decrease environmental tobacco smoke (ETS) exposure when your child goes home. We are asking your permission to use data that you provide to help us evaluate this project and hope that you will consent. Please take your time to make your decision. You may discuss this with your family and friends and ask any questions of the research staff.

Why is the study being done?

The purpose of this study is to examine the amount of tobacco smoke exposure in all families with infants in the NICU and Special Care Unit. This research is being done to determine the most efficient interventions to help people protect their children from ETS. To be in the study, you do not have to agree to quit smoking. You also do not have to agree to keep cigarettes away from your infant. You will be provided information on how to best have a smoke-free home even if you do not wish to participate in the research; however, we hope that you will participate to help determine the best way to address environmental tobacco smoke.

How many people will take part in the study?

Approximately 800 families of children admitted to the NICU and Special Care Nursery will be approached to participate in the study.

What is involved in the study and how long will I be in the study?

1. Baseline Questionnaires

You will be asked to answer several questions about yourself and to fill out some questionnaires that will take between 15-25 minutes of your time. These questionnaires will ask about tobacco use in your family; whether or not you are interested in quitting or cutting down smoking, if you are a smoker; and specific information about your willingness to keep your child free from ETS.

2. Carbon Monoxide (CO) measure

You will be asked to provide a CO measure which can telll whether you have been smoking. This measure will be used to determine current smoking status. This involves breathing into a machine.

3. Environmental Tobacco Smoke Exposure information

Non-smoking caregivers will be advised on the problems associated with environmental tobacco smoke and encouraged to continue keeping a smoke-free home.

Smoking care givers will be assigned to one of three groups. Smoking caregivers will not get to pick which condition they go through. It will be decided by chance, like the roll of the dice. The three conditions are "Usual Care Group", "Cessation Message Group" and "Smoke-Free Home Message Group". We believe all conditions are helpful, we want to know which one helps best. We will also audiotape the research assistant talking to you in the hospital.

4. Follow-up phone calls and visits

You will also be asked to participate in follow-up interviews after your child has been discharged from the unit. If you give permission we will obtain your phone number and call you at approximately one and three months after discharge. The follow-up phone interviews are expected to take 15-25 minutes.

5. Passive Nicotine Monitor

During the three-month call, you will be asked to place a small passive nicotine monitor in your home for one week. The nicotine monitor consists of a sodium-bisulfate-treated filter held in a 37-mm polystyrene cassette with a windscreen, and relies on passive diffusion of nicotine to the filter. A research assistant will deliver the monitor and in one week return to retrieve the monitor.

How Long Will I Be in This Study?

You will be in this study for three months. You can stop participating in this study at any time. There will be no penalty or negative consequences if you withdraw early from the study, and services at OU Medical Center, Children's Hospital for your infant will not be affected in any way by participation in this study.

What are the risks of the study?

The risks of this study are minimal and do not exceed those ordinarily encountered in everyday life. You do not have to quit smoking in order to participate in this study. If you are a smoker and you decide you would like to quit or cut down your smoking, you may experience nicotine withdrawal.

What are the benefits of the study?

By participating, you will have the indirect benefit of contributing to knowledge about ETS exposure for families. This knowledge may help us improve services for future patients. The benefit in learning about smoking and the importance of having a smoke-free home will occur with all families in the study.

What other options are there?

The only alternative is to not participate.

What about confidentiality?

All personal information will be kept confidential. You will not be identifiable by name or description in any reports or publications about this study. All information will remain in a locked cabinet at Oklahoma State University. Only the research staff will have access to this cabinet. As with any research study and/or agreement for treatment, research information may be disclosed if required by law. You will be asked to sign a separate authorization form for the use of sharing your protected health information.

There are organizations that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the Robert Wood Johnson Foundation and the OUHSC Institutional Review Board, and the OSU Institutional Review Board.

What are the costs?

There are no costs to you other than your time.

Will I be paid for participating in this study?

You will be paid $15.00 for your initial interview. You will be paid $50.00 after completing follow-up questionnaires and returning the passive nicotine monitor to the research assistant at the three-month follow-up period.

What are my rights as a participant?

Taking part in this study is voluntary. You may choose not take part or may leave the study at any time, even if you agree to take part in the study and then decide against it. Leaving the study will not result in any penalty, however, if you do not return the monitor there will be no final payment. We will tell you about any new information that may affect your health, welfare, and willingness to stay in this study. You understand that you have the right to access the medical information that has been collected about you as a part of this research study. However, you agree that you may not have access to this medical information until the entire research study has completely finished and you consent to this temporary restriction.

Whom do I call if I have questions or problems?

If you have questions about the study, contact Mary Anne McCaffree, MD at (405) 271-5215. For questions about your rights as a research subject, contact the OUHSC Director of Human Research Participant Protection at (405) 271-2045. You may also contact the OSU Director of University Research Compliance at (405) 744-5700.

Signature:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released and individual or institution from liability or negligence. You have been given opportunity to ask questions. You will be given a copy of the consent document.

I agree to participate in this study:

Printed Name: _____

Participant's Signature: _____Date:_____

Person Obtaining Informed Consent: _____Date: _____

Principal Investigator: _____Date: _____

APPENDIX E

HIPAA FORM

IRB No.:11598

AUTHORIZATION TO USE or DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH
An additional Informed Consent Document for Research Participation may also be required.
Form 2 must be used for research involving psychotherapy notes.

Title of Research Project: Addressing Environmental Tobacco Smoke Reduction in a Child Health Care Setting

Leader of Research Team: Mary Anne McCaffree, MD

Address: Pediatrics Neonatology, 940 NE 13th, CHO 2B 2311

Phone Number**: 271-5215**

If you decide to join this research project, University of Oklahoma Health Sciences Center (OUHSC) researchers may use or share (disclose) information about you that is considered to be protected health information for their research. Protected health information will be called private information in this Authorization.

Private Information To Be Used or Shared. Federal law requires that researchers get your permission (authorization) to use or share your private information. If you give permission, the researchers may use or share with the people identified in this Authorization any private information related to this research from your medical records and from any test results. Information, used or shared, may include all information relating to any tests, procedures, surveys, or interviews as outlined in the consent form, medical records and charts, name, address, telephone number, date of birth, race, and government-issued identification number.

Purposes for Using or Sharing Private Information. If you give permission, the researchers may use your private information to determine the effectiveness of interventions addressing environmental tobacco exposure in the Neonatal Intensive Care Unit and the Special Care Nursery.

Other Use and Sharing of Private Information. If you give permission, the researchers may also use your private information to develop new procedures or commercial products. They may share your private information with the research sponsor, the OUHSC Institutional Review Board, auditors and inspectors who check the research, and government agencies such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS). The researchers may also share your private information with Oklahoma State University and the Robert Wood Johnson Foundation Smoke-Free Families National Program Office.

Confidentiality. Although the researchers may report their findings in scientific journals or meetings, they will not identify you in their reports. The researchers will try to keep your information confidential, but confidentiality is not guaranteed. Any person or organization receiving the information based on this authorization could re-release the information to others and federal law would no longer protect it.

YOU MUST UNDERSTAND THAT YOUR PROTECTED HEALTH INFORMATION MAY INCLUDE INFORMATION REGARDING ANY CONDITIONS CONSIDERED AS A COMMUNICABLE OR VENEREAL DISEASE WHICH MAY INCLUDE, BUT ARE NOT LIMITED TO, DISEASES SUCH AS HEPATITIS, SYPHILIS, GONORRHEA, AND HUMAN IMMUNODEFICIENCY VIRUS ALSO KNOWN AS ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

Voluntary Choice. The choice to give OUHSC researchers permission to use or share your private information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for OUHSC researchers to use or share your private health information if you want to participate in the research and if you revoke your authorization, you can no longer participate in this study.

Refusing to give permission will not affect your ability to get routine treatment or health care from OUHSC.

Revoking Permission. If you give the OUHSC researchers permission to use or share your private information, you have a right to revoke your permission whenever you want. However, revoking your permission will not apply to information that the researchers have already used, relied on, or shared.

End of Permission. Unless you revoke it, permission for OUHSC researchers to use or share your private information for their research will never end. You may revoke your permission at any time by writing to:

Privacy Official
University of Oklahoma Health Sciences Center
PO Box 26901, Oklahoma City, OK 73190
If you have questions call: (405) 271-2511 or e-mail: ou-privacy@ouhsc.edu

Giving Permission. By signing this form, you give OUHSC and OUHSC's researchers led by Mary Anne McCaffree, M.D., permission to share your private information for the research project called Addressing Environmental Tobacco Smoke Reduction in a Child Health Care Setting.

Patient/Subject Name: _____

_____ _____
Signature of Patient-Subject or Parent if subject is a child — Date

Or

_____ _____
Signature of Legal Representative** — Date

**If signed by a Legal Representative of the Patient-Subject, provide a description of the relationship to the Patient-Subject and the Authority to Act as Legal Representative:

_____
OUHSC may ask you to produce evidence of your relationship.

A signed copy of this form must be given to the Patient-Subject or the Legal Representative at the time this signed form is provided to the researcher or his representative.

IRB No.: 11598

APPENDIX F

BASELINE INTERVIEW FORM

Smoke-Free Home Intervention-Baseline Interview		
I would like to talk with you about ETS in the home, May ask some questions about your family?		
Child's Name:	Child's DOB:	Sex: M F
Gestational Age:	Admit Date:	Int.Date:
Reason for Admit:	Team:	Dis. Date:
	CO monitor reading:	ppm
Caregiver Name:	Caregiver DOB:	Sex: M F
Caregiver Ethnicity: AA AI A/PI C H Multi O	Marital Status: M/P NM/P W/S/D NM/NP O	
Current Address:	City	Zip Code:
Phone Number:	Cell Phone:	
Annual Income: <14,000 14k-18k 18k-25k 25-41 42-65 >65K		Monthly:
Education:		
Have you ever smoked a cigarette? Y N If yes, when was your last cig:		
Have you smoked a cigarette in the last 30 days? Y N In the last 7 days? Y N		
During the last 7 days, how many cigarettes did you usually smoke each day?		
Did you smoke any time before or during the pregnancy? Y N		
When?: 1st tri 2nd tri 3rd tri After preg:		Other:
Caregiver smoking status: Smoker Non-Smoker	Pregnant NonSmk	Never Smoker
Cigarettes/day: Before Pregnant	While Pregnant:	
Currently considering quitting smoking: Y N	Readiness: **p c prp a m n/a**	
Currently considering keeping a smoke-free home: Y N	Readiness: **p c prp a m**	

Others in the home	**Age**	**Relationship**	**Smoker**	**# Cigarettes per day**
			Y / N	
			Y / N	
			Y / N	
			Y / N	
			Y / N	

Has anyone talked to you about smoking in the home? Y N If yes, Who?:										
Where allow smoking in the home?	No where	spec. gst.	certain areas	:	anywhere	Other:				
Importance:	1	2	3	4	5	6	7	8	9	10
Why not 1?										
Why not 10?										
Confidence:	1	2	3	4	5	6	7	8	9	10
Why not 1?										
Why not 10?										

Additional Questions

All	Barriers Questionnaire	Smokers:	Fagerström	Baseline Interview	Glover-Nilsson

APPENDIX G

FAGERSTRÖM TEST FOR NICOTINE DEPENDENCE

Fagerström Test for Nicotine Dependence (FTND)

Questions		Answers	Points
1.	How soon after you wake up do you smoke your first cigarette	Within 5 minutes 6 – 30 minutes 31 – 60 minutes After 60 minutes	3 2 1 0
2.	Do you find it difficult to refrain from smoking in places where it is forbidden e.g., in church, at the library, in cinema, etc.?	Yes No	1 0
3.	Which cigarette would you hate most to give up?	1st one in the morning All others	1 0
4.	How many cigarettes/day do you smoke?	10 or less 11—20 21 – 30 31 or more	0 1 2 3
5.	Do you smoke more frequently during the first hours after waking than during the rest of the day	Yes No	1 0
6.	Do you smoke if you are so ill that you are in bed most of the day?	Yes No	1 0

APPENDIX H

INTERVENTION SHEETS

Smoke-Free Home Intervention (C)				
Start time:	:		Initials:	
Intervention Date:	/ /			
ASK: *Smoker*. You have indicated that you are a smoker, Is it ok if we talk about your smoking? **Y / N**				
Non-Smoker: Will your child be exposed to any ETS when they leave the hospital?If No: Congratulate caregiver and give ETS pledge. If yes, where? (out of study if in the home).				
Smoker ADVISE: Quitting smoking is the best health behavior change you could make to reduce ETS exposure to your child.				
Assess: **We recognize that quitting smoking is challenging, would you be willing to attempt to quit smoking in the next 30 days?**				
Already doing so (Action)		Refer to Quitline, Address relapse		
Yes (Preparation)		Refer to Quitline, Set quit date		
If No, What about in the next 6 months?				
Yes (Contemplation)		Info. on areas of concern, Refer to quitline		
Not Ever (Precontemplation)		Move to contemplation. Identify:		
Relevance: Risks: Rewards: Roadblocks:				
ASSIST: Reflect stage, Based on what you have said, I would like to offer you a few things.				
Refer to quitline			**Con Prep Act**	
Set quit date (Quit sheet)	/ /		**Prep**	
Relapse prev. (problem solving etc.)			**Act**	
Information Brochure			**Pre** Con Prep Act	
Individual Information sheets 1-5			Pre **Con Prep** Act	
Identify Barriers/ Develop plan			**Pre** Con Prep Act	
Arrange Follow-Up: Discuss the one month follow-up and 3 month follow-up.(after discharge date on phone at 1; 3 in person)				
Date scheduled	/ /			Note # times rescheduled
Completion Time	:			
Notes:				

Smoke-Free Home Intervention				
Start time:	:			
Intervention Date:				
ASK: You have indicated that you are a smoker, Is it ok if we talk about smoking in the home? **Y / N**				
ADVISE: While quitting smoking is the best health behavior change you could make to reduce ETS exposure to your child, reducing the amount of environmental tobacco smoke (ETS) your baby is exposed to will also greatly reduce the health risks to your baby, and that is something I can help you with. **(Use info from Importance/ Confidence)**				
***Assess:* We recognize that reducing smoke in the home is challenging, would you be willing to adopt a smoke-free policy in the home to reduce your child's ETS exposure in the next 30 days?**				
Already doing so (Action)		Address relapse		
Yes (Preparation)		Set quit date		
If No, What about in the next 6 months?				
Yes (Contemplation)		Provide info. on concerned areas, Set quit date		
Not Ever (Precontemplation)		Move to contemplation. Identify:		
Relevance: Risks: Rewards: Roadblocks:				
ASSIST: Reflect stage, Based on what you have said, I would like to offer you a few things.				
Information Brochure			**Pre** Con Prep Act	
Individual Information sheets 1-5			Pre **Con** **Prep** Act	
No-smoking policy in the home	/ /		**Prep**	
SFH Relapse prev. (problem solving etc.)			**Act**	
Identify Barriers/ Develop plan			Pre **Con** **Prep** Act	
Cessation related **ASSIST** ***(Only if the caregiver specifically states they want to quit)***				
Refer to quitline			Con Prep Act	
If Cessation addressed: Reinforce Smoke-Free Home message: While we recognize you want to quit smoking, we also want to encourage you to keep your home free of smoke until you do quit.				
Arrange Follow-Up: Discuss the one month follow-up and 3 month follow-up.(after discharge date on phone at 1; 3 in person)				
Completion Time	:			
Notes:				

APPENDIX I

FOLLOW-UP INFORMATION FORM

Smoke-Free Home Intervention - Follow-Up				
Reintroduce study, CO monitor, questions about SFH, Nicotine monitor				
Child's Name:			Caregiver Name:	
Caregiver Ethnicity: AA AI A/PI C H Multi O			Marital Status: M/P NM/P W/S/D NM/NP O	
Current Address:			City	Zip Code:
Phone Number:			Cell Phone:	
CO Monitor reading ppm			Discharge Date:	
Caregiver smoking status:	Smoker	Non-Smoker	Pregnant NonSmk	Never Smoker
Change in smoking status:	Smoker	Non-Smoker	Pregnant NonSmk	Never Smoker
Have you ever smoked a cigarette? Y N If yes, when was your last cig:				
Have you smoked a cigarette in the last 30 days? Y N In the last 7 days? Y N				
During the last 7 days, how many cigarettes did you usually smoke each day?				
Did you smoke any time before or during the pregnancy? Y N				
When?: 1st tri 2nd tri 3rd tri After preg: Why restart?:				
Cigarettes/day: Before Pregnant While Pregnant:				
Allow smoking in the home? No One spec. gst. certain areas : anywhere Other:				
Currently considering quitting smoking: Y N Readiness:				
Currently considering keeping a smoke-free home: Y N Readiness:				
Did anyone other than the research team talk to you about smoking in the home? Y N				
If yes, Who?:				
Do you remember what you talked about with the research assistant in the hospital (condition)?				
Have you used any of the following to keep your home smoke-free				
Materials: Cess/ Helpline Family Other:				

Additional Others in the home	**Age**	**Relationship**	**Smoker**	**# Cigarettes per day**
			Y / N	
			Y / N	

Importance: 1 2 3 4 5 6 7 8 9 10
Why not 1?
Why not 10?
Confidence: 1 2 3 4 5 6 7 8 9 10
Why not 1?
Why not 10?

Additional Questions		**Monitor Placement**
Barriers Quest.		Time:
Smokers		Placement Description:
Fagerstrom		
Smoking Interview		
Glover Nilsson		Pick-up Date: Time:

VITA

Ernestine Gnobia Jennings

Candidate for the Degree of

Doctor of Philosophy

Dissertation: A RANDOMIZED CLINICAL TRIAL IN A CHILD HEALTH CARE SETTING COMPARING TWO BRIEF INTERVENTIONS TO REDUCE ENVIRONMENTAL TOBACCO SMOKE EXPOSURE

Major Field: Psychology, Clinical

Biographical:

Personal Data: Born in Fort Sill, Oklahoma, May 30, 1974, the daughter of Ernest and Lula Mae Green.

Education: Graduated from Norman High School, Norman, Oklahoma in May 1992; received Bachelor of Science degree in Social Work from the University of Oklahoma, Norman, Oklahoma in May 1997; received Master of Science degree in July 2003 from Oklahoma State University, Stillwater, Oklahoma in July 2003. Completed the requirements for the Doctor of Philosophy degree with a major in Psychology at Oklahoma State University in December, 2006.

Professional Memberships: Association for the Advancement of Behavior and Cognitive Therapy and Society of Behavioral Medicine.

Name: Ernestine Gnobia Jennings Date of Degree: December 2006

Institution: Oklahoma State University Location: Stillwater, Oklahoma

Title of Study: A RANDOMIZED CLINICAL TRIAL IN A CHILD HEALTH CARE SETTING COMPARING TWO BRIEF INTERVENTIONS TO REDUCE ENVIRONMENTAL TOBACCO SMOKE EXPOSURE

Pages in Study: 83 Candidate for the Degree of Doctor of Philosophy

Major Field: Psychology, Clinical

Scope: The present study tested whether a brief intervention emphasizing a Smoke-Free home message compared to an intervention emphasizing a Smoking Cessation message with smoking caregivers, would lead to lower levels of passive nicotine monitor readings in the home after discharge from an intensive care nursery. Given the likely importance of motivational variables in the successful initiation and maintenance of smoking behavior change, the present study also sought to examine the utility of a brief ETS reduction intervention for increasing intentions to change for having a Smoke-Free home. **Method:** Fifty-three smoking caregivers of infants admitted to a Neonatal Intensive Care Unit were randomly assigned to one of three groups. The **Usual Care Group (TAU)** received brief information about the hazards of ETS exposure routinely provided by nursing staff at discharge along with some advice from their physician. Both the **Smoking Cessation Group (CESS)** and the **Smoke-Free Group (SFH)** received a brief intervention following the *Clinical Practice Guideline for Treating Nicotine Dependence.* An additional 25 non-smoking caregivers were recruited as a comparison group. Initial measures of caregiver smoking were assessed using a carbon monoxide (CO) monitor and caregiver-report. Alternative measures of success (i.e., harm reduction) included progression along the stages of change model as measured by the Stages of Change Algorithm. Groups were compared on nicotine monitor levels in the home and parent report of smoking at three months post hospitalization. Additional analyses were run to determine the relationship of the Stage of Readiness to stop smoking on the rate of ETS exposure in the home. **Findings:** The results indicated passive nicotine monitor readings for smoking caregivers who did not receive any intervention had significantly different passive nicotine monitor readings at follow-up (8.54 ug/m^3) when compared to the intervention groups (2.57 ug/m^3) and the non-smoking control group (0.35 ug/m^3). No significant differences were found between the smoking caregivers in number of cigarettes smoked at follow-up. However, there were slight differences in Readiness to Change to have a Smoke-Free Home between the intervention groups and the Treatment as Usual control group at the three-month follow-up.

ADVISER'S APPROVAL: Frank Collins, Jr. Ph.D.