Addiction

Addiction – Addressing the biology and behavior of addiction

Over 60 studies were identified that are examining either the biological or behavioral aspects of addiction, or identifying methods to overcome addiction. Most of the studies focus on nicotine addiction, although a few are examining addiction to other drugs. While studies associated with the biological aspects of addiction largely have application to all smokers, much of the research on interventions to overcome addiction is focused on pregnant mothers.

Biological Aspects of Addiction

Several research efforts are being conducted that focus on gaining an understanding of the biological basis of nicotine addiction. One study is examining the effects of gender and menstrual cycle on the neuropharmacology of nicotine addiction. Pain-reduction effects of nicotine are being examined across gender and phases of the menstrual cycle. Several studies use animal models to examine the neural receptors involved in nicotine addiction and the gestational effects of nicotine exposure. The acute and chronic effects of nicotine on dopaminergic function at various stages of development are being investigated. Investigators plan to identify the nicotine acetylcholine receptor involved in dopaminergic regulation. The long-term effects of nicotine on the number and function of receptors in the brain are being examined. A study is in progress at the University of South Carolina to determine the role of the dopamine neurochemical system in gender differences following repeated intravenous nicotine administration. Investigators will test the ability of gonadal hormones to modulate dopamine receptor responsiveness. At the Fred Hutchinson Cancer Research Center and at Washington University, researchers are examining genetic influences on nicotine dependence. Genes involved in dopaminergic neurotransmission in the mesolimbic pathway of the brain will be examined. A recent effort studied the effect of nicotine withdrawal on attention and right/left brain balance. Increased understanding of genetic influences on the ability of individuals to quit smoking may lead to improvements in success rates of smoking cessation efforts. Researchers at Ohio State University are examining the effects of differences in plasma cotinine levels, body composition, and menthol preference on nicotine dependence in African Americans. A rat model is being used to examine sex differences in the influence of nicotine self-administration. Nicotine withdrawal symptoms are being examined in adolescents, in smokers with depressive symptoms, and in heavy and light drinkers.

Behavioral Aspects of Addiction

Differences between smokers' and nonsmokers' behavior, as well as reasons for differences in smoking behavior across races, are being studied. It is anticipated that a better understanding of the psychological aspects of addiction will lead to more successful interventions to overcome addiction. Coping behaviors, self-efficacy, perceived stress, and processes of change are being examined as predictors of relapse. Researchers are testing whether instilling coping skills will aid in relapse prevention. Several studies are looking at the concern of women over postcessation weight gain. Information regarding pre- and postcessation energy expenditure is being collected at the University of Wisconsin. Researchers at Miriam Hospital in Rhode Island are testing the effect of moderate-intensity exercise to enhance the achievement and maintenance of smoking cessation among healthy female smokers. The effects of cognitive behavior treatment for weight concerns, standard smoking cessation, the use of bupropion, and placebo effects are being compared. A researcher at Harvard is examining therapeutic use of aerobic exercise combined with nicotine polacrilex gum therapy to minimize postcessation weight gain. Estrogen replacement therapy was recently tested in postmenopausal women attempting to quit smoking to minimize weight gain and affect mood. The University of Pennsylvania is developing a program to encourage training in several areas including biobehavioral mechanisms of tobacco addiction.

A variety of behavior modification and pharmacological interventions are being tested for effectiveness in overcoming addiction. One study is examining the effectiveness of cognitive-behavioral techniques to aid in smoking cessation for women at risk for cervical cancer. Cognitive-behavioral strategies, nicotine replacement therapy, and motivational intervention are being examined to enable smoking cessation and thereby reduce cervical cancer risk. Mood Management group smoking intervention, social support, and behavior therapy to aid in smoking cessation are being examined to overcome nicotine addiction. Efforts are ongoing at the University of Texas to compare relapse prevention treatment and bupropion treatment.

Methods for Overcoming Addiction in Pregnant Women

Researchers are studying methods to overcome nicotine and drug addiction in pregnant women. The benefits of overcoming smoking addiction during pregnancy have long-range impact not only on the mother but on the overall health of the family. Information regarding the patterns of maternal smoking during pregnancy is being collected to enable development of targeted interventions. Many studies are examining the use of educational materials, incentives, counseling, therapy, and telephone social support to encourage cessation of smoking in pregnant women. Studies are ongoing on the possible use of bupropion to reduce smoking during pregnancy: one is comparing nicotine replacement therapy versus bupropion usage, and another is determining the adverse events and adverse effects of bupropion. In a separate study, researchers are comparing the effectiveness of nicotine gum versus placebo in aiding smoking cessation during pregnancy. A voucher-based incentive program for promoting smoking cessation and preventing relapse during pregnancy and postpartum is being tested at the University of Vermont. The level of cotinine in the saliva is often used to measure the success of these interventions. A study at Virginia Commonwealth University is examining the ability of pregnant women to discontinue illicit drug use.

Preventing Relapse in Women During or After Pregnancy

Several studies seek to understand coping strategies used by pregnant women who are successful in overcoming addiction, and the behavior of pregnant women unable to overcome addiction. Information on the behavior of these mothers, largely obtained through interviews and focus groups, will aid in the development of interventions that help to reduce smoking relapse postpartum. Efforts are being conducted to determine the effect of mood, weight concerns, and the menstrual cycle on postpartum relapse. The use of bupropion, educational materials, home-visiting nurse contact, and counseling are being examined as methods to permanently overcome nicotine addiction.

Title: Biobehavioral Nicotine Dependence in Black Women
Principal Investigator: Ahijevych, Karen L.
Institution: Ohio State University, Columbus, OH
Funding Agency: National Institute on Drug Abuse
Project ID: DA010809
Project Funding Period: 1 February 1997 – 31 January 2002

Abstract: More African Americans die from diseases caused by cigarette smoking than from AIDS, homicide, drugs and accidents combined. In addition, smoking intensifies a number of serious health problems that disproportionately affect African Americans including heart disease, cancer, stroke, low birth weight, and infant mortality. African Americans report smoking fewer cigarettes per day, prefer high nicotine, mentholated brands, and are noted to be highly dependent on nicotine. Higher cotinine levels, the major metabolite of nicotine, have been described in black women, in comparison to other race-gender groups, in spite of smoking fewer cigarettes per day. Furthermore, there is a lower smoking cessation quit rate among African American women compared to Caucasian women. Alternative explanations for increased exposure as indicated by elevated cotinine levels in African American women are warranted. The overall aim of the FIRST award proposal is to examine effects of selected biobehavioral and contextual factors on smoke constituent exposure and nicotine dependence in African American and Caucasian women. Three separate studies to be conducted in the General Clinical Research Center (GCRC) with black and white women are proposed. 1) To characterize cotinine elimination trends, subjects will be admitted for a 7-day inpatient study of smoking abstinence during which plasma cotinine levels will be obtained. The effect of race, body composition, and menthol preference on cotinine trends will be analyzed. 2) During a 4 hr study, the effects of smoking topography (e.g. puff duration and volume and lung retention time), race, menthol preference, and body composition on plasma nicotine trends post-cigarette will be analyzed. Menthol exposure will be examined. 3) During a 6-day inpatient study with a counterbalanced design, smoke constituent exposure as measured by plasma nicotine and carbon monoxide increases pre to post-cigarette, as well as puff duration and volume, and lung retention time, will be contrasted across three conditions of nicotine availability of usual, increased and restricted smoking rates. Information about metabolic and behavioral issues concerning nicotine will add to a limited knowledge base about nicotine dependence in African American women and provide scientific support for specific targeted smoking cessation interventions, in conjunction with or separate from nicotine replacement.

Title: Cigarette Smoking Topography Among Women Smoking Menthol/Nonmenthol Cigarettes
Principal Investigator: Ahijevych, Karen L.
Institution: Ohio State University, Columbus, OH
Funding Agency: National Center for Research Resources
Project ID: RR000034-40S10633
Project Funding Period: 1 December 1976 – 30 November 2001

Abstract: To examine the pharmacokinetics of menthol in venous plasma following dosing via cigarette smoking women cigarette smokers.

Title: Tobacco Cessation in Postmenopausal Women
Principal Investigator: Allen, Sharon S.
Institution: University of Minnesota Twin Cities, Minneapolis, MN
Funding Agency: National Institute on Drug Abuse
Project ID: DA008075
Project Funding Period: 1 March 1993 – 31 July 2002

Abstract: In spite of the negative health effects of cigarette smoking, if current trends continue, smoking rates for women will surpass men by the year 2000. Studies show that women have a greater fear of weight gain after quitting, as well as, they tend to gain more weight to suggest gender specific cessation strategies are needed. Animal and clinical studies suggest that estrogen could decrease appetite behavior and minimize weight gain, as well as, affect mood and therefore could attenuate withdrawal symptoms. However, no study has systematically and comprehensively investigated the different effects of estrogen replacement therapy (ERT) in smoking cessation in postmenopause where the estrogen level is low. This renewal application will address this area in a randomized double blind nontreatment study conducted in 2 parts over 4 years. Part I investigates if there is a differential effect of ERT on appetitive behavior and withdrawal symptoms in postmenopausal women during short term smoking cessation, i.e., to decrease appetite behavior and minimize weight gain, and affect mood and attenuate withdrawal symptoms. Eligible subjects are randomized to smoking and non-smoking status, and enter a 3-week period of scheduled measurements. Week 1 is baseline with smoking ad lib, and in weeks 2 and 3 some subjects stop smoking while others continue smoking. During these 3 weeks weight, caloric intake, RMR and tobacco withdrawal symptom measurements will be done. Part II is also a short term nontreatment study investigating the additive effects of ERT on the same parameters in postmenopausal women on nicotine replacement. Subjects are randomized to ERT and placebo and monitored for 1 month, then randomized to placebo or active patch. The study design and measurements are identical to Part I. The results of this research will increase our understanding of the functional relationships between ERT and appetitive behavior and withdrawal symptoms in smoking cessation in postmenopausal women. This research will provide new information which will be important and useful in assessing direction for specific and more effective treatment strategies for smoking cessation in women during the postmenopausal years.

Title: Sister to Sister: Helping Low-Income Women Quit Smoking
Principal Investigator: Andrews, Jeannette O.
Institution: University of South Carolina at Columbia, Columbia, SC
Funding Agency: National Institute of Nursing Research
Project ID: NR008065
Project Funding Period: Not available

Abstract: Tobacco use is strongly linked to coronary heart disease (CHD), the leading cause of death in women. African American women of lower socioeconomic status are known to have high smoking rates, disparities in smoking related diseases, and difficulty with cessation. Despite these inequities, sparse data exist describing effective interventions targeted to this population. Although not evaluated in African American women, research supports that intensive group tobacco cessation interventions produce the highest quit rates (24 - 48 percent) over self help (7 - 11 percent) and brief interventions (13 - 16 percent) with other populations. Social support and informal extended kin network, particularly with lay health advisors (LHA), are beneficial in targeted behavioral interventions to African American women for other risk reduction measures such as breast cancer screening; however this approach has not been effectively evaluated with tobacco cessation. With further exploration and knowledge, the investigator's goal is to develop and implement a nurse/LHA-managed smoking cessation

intervention tentatively entitled, Sister To Sister: Helping Low-Income Women Quit Smoking. The proposed intervention will target mediating variables of social support, self-efficacy, and adaptive coping mechanisms utilizing an intensive group intervention managed by a nurse and LHA. A community advisory group consisting of informal and formal community leaders will be formed to assist with the recruitment and retention of LHAs. Community partnership(s) with businesses, health agencies, churches, and other organizations will provide a representative to the advisory group and resources such as physical space and incentives for LHA. A mid-range theory of self care behaviors in low-income African American women will be developed to provide a framework the study, and Prochaska's Transtheoretical Model of Change will be used to guide the development and implementation of the nurse/LHA intervention.

Title: Biobehavioral Markers of Risk for Nicotine Addiction
Principal Investigator: Anokhin, Andrey P.
Institution: Washington University, St. Louis, MO
Funding Agency: National Institute on Drug Abuse
Project ID: DA000421
Project Funding Period: 1 July 2001 – 30 June 2006

Abstract: This Mentored Research Scientist Development award (KO1) resubmission requests 5 years of support for research and advanced research training on the genetic and biobehavioral etiology of substance use disorders, using nicotine addiction as a model system. Although a strong genetic contribution to smoking behavior has been well documented by recent studies, little is known about biobehavioral mechanisms that might mediate increased genetic risk. The overall goal of the proposed research is to identify electrophysiological trait markers of genetic susceptibility to nicotine addiction and to differentiate them from the long-term impact of smoking on brain function. This goal will be achieved through the integration of genetic and experimental psychophysiological methods. Epidemiological and behavioral research strongly implicates disinhibition (deficits of inhibitory selfregulation of behavior) as a potential mediator of susceptibility to smoking and other substance use behaviors. The proposed study will use an extended co-twin control design to delineate genetic and environmental causes of differences between smokers and nonsmokers on psychophysiological traits pertinent to disinhibition. Young adult MZ female twins and their siblings (total n=300) concordant and discordant for lifetime regular smoking will be recruited from an ongoing study of 3000 female twins and their parents. Assessments will include a diagnostic interview, questionnaires, and a battery of laboratory psychophysiological tests. The focus will be on electrophysiological traits theoretically and empirically linked to cognitive and behavioral disinhibition: ERPs elicited in classical oddball and Go-No Go tasks and prepulse inhibition of startle response (PPI). Specific aims are to identify genetically transmitted characteristics of CNS functioning indicative of increased vulnerability to nicotine addiction and to assess the long-term impact of smoking on brain function. Significantly elevated MZ compared to full sib correlations will lead to a future ROI proposal to study DZ pairs, to confirm genetic etiology. It is expected that the proposed study will advance our understanding of biobehavioral mechanisms mediating vulnerability to nicotine addiction and provide useful end phenotypes for future genetic linkage or association studies of smoking and other substance use disorders. The training component will include supervised research, formal course work and tutorials in advanced methods of genetic analysis, and lab training in experimental psychopharmacology. The acquired expertise will allow the candidate to better integrate genetic and psychophysiological approaches in order to establish a program of interdisciplinary research in the neurobehavioral genetics of addiction.

Title: Smoking Cessation in Mothers and Other Household Members of Babies Being Treated in a Special Care Nursery
Principal Investigator: Becker, Bruce
Institution: Rhode Island Hospital, Providence, RI
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040671
Project Funding Period: 1 October 2000 – 30 September 2003

Abstract: The major goals of this project are to define the natural history of smoking and smoking cessation for mothers and other household members of babies being treated in the Special Care Nursery and to test a smoking cessation intervention in this milieu.

Title: Human Neurophysiology of Nicotine Analgesia: Sex Differences
Principal Investigator: Becker, David
Institution: University of California, San Francisco, San Francisco, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 9RT-0142
Project Funding Period: 1 July 2000 – 30 June 2003

Abstract: Nicotine addiction is a powerful process that is not well understood. The ability of nicotine to reduce pain and discomfort has been proposed as a mechanism underlying smoking addiction. The majority of human studies have found pain-reducing effects, while others, especially those using women subjects, have not. Furthermore, a recent study found that nicotine reduced pain for men, but not women. These findings suggest an important gender difference in the mechanisms of smoking that lead to addiction.

We will use state-of-the-art techniques for assessing pain and pain-reduction to test for the reality and magnitude of nicotine's pain-reducing effects in both smokers and nonsmokers; their possible dependence on gender; and their possible dependence on menstrual cycle phase in women. These techniques will include the use of an objective, neurophysiological measure of pain. Measures of the electrical activity of the brain that can be recorded with electrodes placed on the head have been shown to be sensitive to a number of different pain-reducing treatments. We have developed a measure that can differentiate pain from other, non-pain aspects of sensory processing. In addition, we will assess pain-reduction from nicotine with three other pain measures: the amount of painful electrical current needed to produce a just painful sensation; the amount of heat needed to produce a just painful sensation; and subject's ratings of the painfulness of electrical pulses across a range of pain intensities.

Nicotine will be administered using a computer controlled intravenous infusion to produce and maintain stable target blood levels of nicotine. This will allow us to exert precise control over nicotine levels in both smokers and nonsmokers. In contrast to other methods of providing nicotine that involve multiple, small amounts of drug and rapidly changing blood levels (smoking, nasal spray) or more slowly changing blood levels (skin patch, gum), computer controlled infusions will provide the stable blood concentrations necessary for the approximately 45 minute set of tests of pain-reduction.

Each subject will participate in two infusion sessions: one for nicotine and one for a non-active substance. Each session will include two sets of pain measures: a pre-drug baseline set and a drug infusion set. Procedures will be identical in each set.

Specifically, we hypothesize that, using a procedure where neither the subject nor the technician running the session knows whether the drug given is nicotine or a non-active substance, intravenous nicotine will provide more pain reduction for men than for women. We will test this

hypothesis separately in groups of 60 smokers and 60 nonsmokers. Furthermore, we will relate the degree of pain-reduction produced in each smoking subject to his or her own patterns of smoking behavior (using the Smoking Occasions Questionnaire) in order to evaluate whether the pain-reduction effect is associated with the use of smoking to relieve physical and emotional discomfort. In a second study, 20 women subjects will participate in nicotine sessions during each of three different phases of the menstrual cycle. We hypothesize that the pain-reducing effects of nicotine will vary across the menstrual cycle.

Title: Designing a Provider Incentive System to Increase Adherence to Maternity Tobacco Cessation Guidelines
Principal Investigator: Bentz, Charles
Institution: Providence Health Systems, Oregon Region, Portland, OR
Funding Agency: Robert Wood Johnson Foundation
Project ID: 043969
Project Funding Period: 1 December 2001 – 30 November 2003

Abstract: To significantly increase adherence with the 5 A's Tobacco Cessation guidelines for pregnant smokers in Oregon through development of a comprehensive reimbursement system for obstetrical providers.

Objectives:
Develop a comprehensive reimbursement system for obstetrical providers. Develop a strong implementation strategy for the reimbursement system. Develop the capacity to conduct future systems-level tobacco research by establishing relationships between key Oregon entities engaged in maternity tobacco cessation. This project will significantly advance the state of the art of maternity tobacco cessation within Oregon. Since Providence hospitals have the largest volume of deliveries in Oregon, this reimbursement system applied within Providence has the potential to significantly decrease smoking rates during pregnancy in this state. The collaboration with Care Oregon will potentially extend the reimbursement system to all Medicaid pregnant smokers in Oregon, which could lead to significant reductions in the Medicaid smoking rate. The comprehensive implementation strategy will provide a compelling rationale for managed care organizations (MCOs) to adopt the reimbursement system. The implementation strategy will include a variety of tools to assist MCOs in efficiently implementing the new reimbursement system. Financial modeling is a key component of this strategy, so that MCOs can easily predict the costs of implementing the reimbursement system and can demonstrate the cost-effectiveness of the system in achieving tobacco cessation among pregnant smokers, including avoided negative outcomes for the baby. The implementation strategy will also include recommendations for reducing barriers to provider adherence with 5 A's guidelines, and materials that will aid dissemination once reimbursement is adopted (e.g., suggestions for clinic-based training materials on implementing the 5 A's with pregnant smokers, and information about how to use the new reimbursement billing codes). The statewide coalition developed during this planning project will help direct the adoption of the reimbursement system by Oregon MCOs. A successful working partnership will be established between Providence, Care Oregon, the various Oregon agencies focusing on maternity tobacco cessation (TOFCO and the Oregon Health Division), and Oregon State University tobacco researchers who are currently studying the efficacy of patient incentives in maternity tobacco cessation. This partnership will enhance future research opportunities by creating relationships that encourage collaboration on additional shared research goals beyond the reimbursement system.

Title: Neurodevelopmental Basis(es) of Nicotine Sensitization
Principal Investigator: Booze, Rosemarie M.
Institution: University of South Carolina at Columbia, Columbia, SC
Funding Agency: National Institute on Drug Abuse
Project ID: DA013712
Project Funding Period: 28 September 2002 – 30 June 2007

Abstract: Gender differences in response to psychostimulants have been reported both in animals and humans; however, the biological mechanisms which underlie these gender differences to psychostimulants remain for the most part, unexplained. The common observation is that females are more sensitive to psychostimulants, such as nicotine. Our hypothesis is: Gonadal hormones in adulthood and development act on dopaminergic systems, providing the underlying basis for the gender differences in behavioral sensitization produced by repeated IV nicotine administration. First, we will determine whether pharmacokinetic differences between the sexes result in higher levels of nicotine in the female brain. We have successfully developed a technically simple, economical and practical non-tethered technique for repeatedly administering IV nicotine to freely moving, group-housed rats. Detailed pharmacokinetic analysis has demonstrated rapidly peaking nicotine levels following IV dosing in rats, which is similar to that observed in humans, as opposed to SC or PO dosing. Using this clinically relevant IV rodent dosing model, we will determine whether pharmacokinetic factors contribute to the increased sensitivity of female animals to the effects of nicotine. Second, we will determine whether gonadal hormones regulate the expression of gender differences in response to nicotine in adulthood. We will test the ability of gonadal hormones to modulate dopamine receptor responsiveness to chronic nicotine administration. Third, we will determine whether the brain organizational (neurodevelopmental) effect of the perinatal hormonal milieu mediates the gender differences in nicotine responsiveness. We have pharmacologically characterized a recently discovered unique dopamine receptor subtype (D3) which is localized to the striatum/nucleus accumbens region of the brain. We hypothesize that alterations in dopaminergic systems underlie the gender differences produced by repeated IV nicotine administration. Our long-term goal is to determine the role of the dopamine neurochemical system in gender differences following repeated IV nicotine administration. The ultimate goal of this research is to develop pharmacological interventions to assist in correcting the behavioral problems associated with chronic tobacco use in humans, and specifically to provide potential insight into effective gender-specific treatment strategies for smoking cessation.

Title: Preventing Smoking Relapse During Pregnancy and Beyond
Principal Investigator: Brandon, Thomas H.
Institution: University of South Florida, Tampa, FL
Funding Agency: National Cancer Institute
Project ID: CA094256
Project Funding Period: 1 August 2002 – 31 July 2007

Abstract: The prenatal risks of tobacco smoking motivate many women to quit smoking during pregnancy and to maintain abstinence for several months. Unfortunately, the majority of these women relapse to smoking either during their pregnancy or within the first six months postpartum. Resumption of smoking is associated with cancer and other health risks to the smokers themselves and to those exposed to their environmental tobacco smoke, including the infant and other members of the family. Because so many women are able to achieve at least short-term abstinence during their pregnancy, the pregnancy and postpartum periods are collectively viewed as a "window of opportunity for interventions designed to prevent smoking relapse. Although modest success has been achieved at aiding women in smoking cessation during pregnancy, attempts to prevent subsequent smoking relapse have been unsuccessful to date. The goal of Study I is to develop the key materials for a cost-effective minimal

intervention preventing smoking relapse among pregnant/postpartum women. The intervention will be modeled after one developed by the research team that has been found to reduce smoking relapse by approximately two-thirds among a general population of recent quitters. This intervention comprises a series of eight Stay Quit booklets mailed to former smokers over a year. The booklets were developed based on theory and research on smoking relapse, and were found to be extremely cost-effective. However, because pregnant and postpartum women differ in many ways from the general population of ex-smokers, it cannot be assumed that the existing intervention would adequately meet their unique needs. The end product of Study I will be a series often Forever Free for Baby and Me booklets designed to be provided to women between their sixth month of pregnancy and eight months postpartum. The content of the booklets will be based on three sources of information: (1) the existing, validated Stay Quit booklets, (2) theory and research on smoking relapse during and after pregnancy, and (3) systematic formative research comprising focus groups, in-depth interviews, and learner verification interviews. Subjects will include pregnant and postpartum women who have maintained tobacco abstinence, as well as those who have relapsed; their partners; and relevant health professionals in the community. Study II will be a randomized, controlled trial of the intervention developed in Study I. Women who have quit smoking during pregnancy will be recruited via childbirth education classes and randomly assigned to receive the series of Forever Free booklets versus a usual care control condition. Follow up will be conducted through 12 months postpartum, and a format cost-effectiveness analysis wilt be conducted. If shown to be effective, this minimal intervention would be easy and inexpensive to disseminate to women via a variety of channels and settings.

Title: Nursing Smoking Cessation Intervention During Pregnancy
Principal Investigator: Bullock, Linda F.
Institution: University of Missouri Columbia, Columbia, MO
Funding Agency: National Institute of Nursing Research
Project ID: NR005313
Project Funding Period: 1 August 2001 – 30 April 2005

Abstract: Problems related to smoking during pregnancy are entirely preventable. The imminent danger of smoking to mothers (i.e. abruptio placentae) and unborn children (i.e. low birthweight) calls for prompt and intensive intervention. Reasons for continued smoking during pregnancy vary by age and income. In this proposed study's low-income population, the most likely group to smoke throughout pregnancy, women suffer from stressful events in their lives, which they cite as difficult barriers to smoking cessation. Social support has been shown to be beneficial in general for coping with problems. AHCPR smoking guidelines call for a social support component in cessation programs that is delivered by healthcare providers. Unfortunately, the guidelines' recommendations for social support focus narrowly on smoking related problems alone. For low-income pregnant women, this tight focus means healthcare providers may not touch on the very topics that are key to their quitting smoking. Nurses' skills in assessment and providing support are extremely well matched to delivering the help women need to quit smoking during pregnancy. This study's primary aim is to determine whether a combination of an established smoking cessation educational program for pregnant women and a nurse- delivered telephone social support intervention (weekly telephone calls as well as having 24-hour pager access to research nurses) will increase pregnant womens' smoking cessation or smoking reduction rates. A sample of pregnant women who smoke will be recruited from WIC clinics in central Missouri. The outcome measure will be saliva cotinine values collected repeatedly every month from enrollment in the study until the last month of pregnancy. A secondary aim of the study will be to determine the prevalence of relapse among the women who quit smoking, when the relapse occurs, and associated stressors. A randomized controlled trial of four groups will be conducted using a repeated measures 2x2 factorial design with two levels of education (Present or Absent) and two levels of nurse-delivered telephone social support

(Present or Absent). To determine significant group differences in quit rates, Chi-square analysis for each month will be used. A fixed-effects repeated measure ANOVA will be used to determine significant group differences in reduction in smoking and survival analysis will detect if there are significant group differences in time to relapse.

Title: Postpartum Smoking and Infant ETS Reduction Trial
Principal Investigator: Collins, Bradley H.
Institution: University of Pennsylvania, Philadelphia, PA
Funding Agency: National Cancer Institute
Project ID: CA093756
Project Funding Period: 27 March 2002 – 31 December 2006

Abstract: The purpose of this proposal is to build a mentored, clinical research training experience to foster independent professional development in cancer control research. This application is being submitted from the University of Pennsylvania Cancer Center, which provides a setting with excellent opportunities to work with Dr. Caryn Lerman, the Transdisciplinary Tobacco Use Research Center (TTURC), and my co-sponsors, Drs. Charles O'Brien and J. Sanford Schwartz. Sound career development in cancer control research requires broad exposure to research methodologies and intensive research training in order to make significant, independent contributions to this field. Therefore, this K07 Career Development Award application seeks to achieve these goals in the area of tobacco control and maternal and child health. General plans for the career development program include: (a) expanding working knowledge of areas relevant to cancer/tobacco control research; (b) refining skills in the application of behavioral science to cancer/tobacco control; (c) increasing knowledge of maternal health issues related to cancer/tobacco control; (d) expanding understanding of the biobehavioral mechanisms of tobacco addiction; (e) improving skills in designing, implementing, and analyzing cancer/tobacco control interventions; and (f) learning effective ways to disseminate research findings to impact upon public health practices. Specifically, the research project aims to develop a low-cost, primary-care intervention to reduce children's Environmental Tobacco Smoke exposure and maternal smoking rates targeting under- served mothers with children ages 0-2. The effectiveness of this intervention will be tested by comparing it with a standard care control-group intervention using a two-group, repeated measures randomized design. The intervention will be modeled after more intensive, home-based counseling programs, the feasibility of which has been demonstrated. However, as these interventions were labor intensive and costly, the proposed intervention presents an innovative, comprehensive, albeit streamlined primary-care approach to an emerging issue in the tobacco control field. This intervention will also set the groundwork for an eventual R01 that will test the treatment and prevention efficacy of this intervention on other populations (e.g., adolescent smokers and their younger, nonsmoking siblings).

Title: Determinants and Trajectories of Smoking Cessation, Maintenance, and Relapse Among Pregnant and Postpartum Adolescents: A Naturalistic Qualitative Study
Principal Investigator: Constantine, Norm
Institution: Public Health Institute, Berkeley, CA
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040675
Project Funding Period: March 2001 – November 2002

Abstract: There are several compelling reasons to study pregnant and postpartum adolescents as a distinct subpopulation with regard to smoking cessation and relapse. First, there are few published studies focused on smoking cessation and relapse among pregnant and postpartum

adolescents. Second, smoking rates for pregnant adolescents are higher than for all other age groups of pregnant women. Third, pregnant adolescents typically differ from adult pregnant women on many characteristics potentially related to smoking cessation, therefore, we do not know the extent to which smoking cessation research on pregnant adults can be generalized to adolescents.

PHI's Center for Research on Adolescent Health and Development is conducting a naturalistic qualitative study to address key knowledge gaps related to smoking cessation and relapse among pregnant and postpartum adolescents. We employ the methods of grounded theory, a general methodology for developing theory that is deeply grounded in data systematically gathered and analyzed. This approach has special utility in studies to create new and theoretically expressed understandings of an understudied phenomenon, such as adolescent pregnancy and smoking cessation.

The study has two specific aims: (1) to develop a theoretical framework that explains the processes and experiences of smoking cessation, maintenance, and relapse by pregnant and postpartum adolescents, and (2) to provide a theoretical foundation for potential intervention approaches and strategies specifically targeted to this group. The study addresses the following research questions: (1) for pregnant and postpartum adolescents, what are the key processes and experiences of smoking cessation, maintenance, and relapse during pregnancy and through six months postpartum? and (2) for pregnant and postpartum adolescents, which individual and environmental factors and interactions of factors, influence smoking cessation, maintenance and relapse, during pregnancy and through six months postpartum?

Our target population comprises low-income pregnant and postpartum adolescents, predominately white, Hispanic, and African American, between the ages of 14 and 19, who: (1) have had lifetime use of 100 or more cigarettes; (2) have smoked at least 10 cigarettes during the three months prior to discovery of pregnancy; and (3) have abstained from smoking for at least 30 consecutive days during the pregnancy. Interviews are being conducted with a total of 60 adolescent participants, with some participants selected for follow-up interviews. Participants are selected based on evolving theoretical sampling considerations, but all will fall within the birth status range of three months pre-delivery to twelve months postpartum. We also will conduct four focus groups, two with adolescents and two with adult professionals. We will share our developing theory with these participants and facilitate constructive conversations in which they respond to and critique our work, and offer confirming or differing interpretations of our data.

Data management and analysis occur in coordination with data collection throughout the course of the study, and are enhanced by the use of ATLAS/ti qualitative analysis software. Our primary analytic activities consist of: (1) interview transcription, (2) open coding, (3) axial and selective coding, (4) process analysis, and (5) validation of the theoretical scheme. The specialized tools of microanalysis and memos and diagrams are used extensively.

We expect the proposed study to provide a key component of the inceptive theory development and knowledge-building needed in the understudied area of smoking cessation, maintenance, and relapse among pregnant and postpartum adolescents. The resulting knowledge should stimulate further research, as well as development and evaluation of interventions.

Title: Smoking Research with Incarcerated Females
Principal Investigator: Cropsey, Karen L.
Institution: Virginia Commonwealth University, Richmond, VA
Funding Agency: National Institute on Drug Abuse
Project ID: DA015774
Project Funding Period: 30 September 2002 – 31 August 2007

Abstract: The purpose of this application for a 5-year Mentored Patient-Oriented Research Career Development Award (K23) on smoking among incarcerated females is to conduct research and training activities to advance the candidate's development as an independent clinical researcher. This includes formal classwork pertaining to research design, biostatistics, and ethics along with conference attendance and meetings with mentors. The proposed research plan includes two studies that build upon each other in the area of smoking among female prisoners. The first study is cross-sectional and is designed to investigate the smoking behavior of incarcerated females. In addition, this study will examine differences between smokers, ex-smokers, and non-smokers on measures of substance abuse and personality, with consideration to other key covariables such as criminal history, medical problems, readiness to change, and Axis I pathology as possibly differentiating between the three groups. The second study will be a clinical trial using Hall et al. 's (1994) Mood Management group smoking cessation intervention combined with nicotine patch (or no patch). The intervention group will be compared to a wait-list control group who will receive the treatment six months later. It is expected that women who successfully complete the intervention will have higher smoking cessation rates than wait-list controls. Further, it is hypothesized that women with substance abuse and psychiatric comorbidity will have poorer outcomes than those without comorbidity. These projects should add significant information to the literature which is currently devoid of research related to smoking and female prisoners. This is particularly relevant now as it has been shown that women may have more difficulty with quitting smoking than men and may also have additional concerns related to smoking (e.g., smoking as weight management) that influence their success. Testing effective smoking cessation interventions with this underserved and understudied population is urgently needed as the medical costs associated with treating prisoners currently accounts for 11% of the Department of Corrections' budget and is expected to double over the next 10 years. Overall, these projects will provide experiences necessary for the candidate to develop an independent research program focusing on effective smoking interventions for incarcerated individuals.

Title: Pediatric Smoking Cessation Study
Principal Investigator: Curry, Susan J.
Institution: Center for Health Studies, Seattle, WA
Funding Agency: National Heart, Lung, and Blood Institute
Project ID: HL056772
Project Funding Period: 1 July 1997 – 30 June 2001

Abstract: In this revised application the investigators propose to recruit 500 female smokers from two low-income urban pediatric clinics. The first aim of the study is to conduct a randomized trial comparing usual care to a smoking cessation intervention consisting of a brief motivational message from a pediatric health care provider; self-help materials developed specifically for low literacy, low income populations; a 10 to 15 minute motivational interview with a specially-trained nurse at the pediatric clinic; and three personal follow-up contacts. The primary endpoint is smoking prevalence at a 12 month follow-up. Secondary endpoints include use of the self-help materials, serious quit attempts, and short and long-term abstinence. A second aim is to conduct a prospective, longitudinal assessment of factors associated with smoking cessation in the target population. For this aim, at baseline and at three and 12 months, a

variety of process variables are to be measured, including knowledge and attitudes about smoking and health, expectations and concerns about weight and weight gain following smoking cessation, motivation regarding smoking cessation, alcohol and other drug use, stress, depression, partner and household-member smoking status, and health events of the child. The investigators plan to examine the degree to which these variables predict changes in smoking status, whether time-related changes in these variables are associated with change in smoking status, and the extent to which these variables moderate the intervention effects.

Title: Biochemical Feedback and Benefits Expansion for Smoking Cessation: Sustained Treatments Over the Prenatal Period (STOPP)
Principal Investigator: Doescher, Mark
Institution: Not available
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040664
Project Funding Period: October 2000 – September 2004

Abstract: This is a four-year randomized controlled trial that will assess whether a package of interventions will reduce the rate of smoking in pregnant women and new mothers enrolled in the Medicaid-sponsored Community Health Plan of Washington (CHPW). The objective is to test whether cessation rates, including end-of-pregnancy and 12-month postpartum cessation rates, will improve in women who attend clinics receiving the CHPW-sponsored package of perinatal cessation benefits compared with those who attend control clinics.

Title: Maternal Interventions to Stop Smoking
Principal Investigator: Donatelle, Rebecca
Institution: Oregon State University, Corvallis, OR
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040699
Project Funding Period: October 2000 – September 2004

Abstract: Tobacco use is widely recognized as the single, most important public health issue today, causing nearly half a million deaths per year, over $50 billion in smoking-related illnesses, and contributing significantly to the total US burden of disease. The economic burden to Oregon from smoking, based on 1996 data, is $1.5 billion. Of that, $800 million is for medical expenditures (direct costs) and $700 million is for loss of productivity due to illness or premature death (indirect costs). Recent (1998) Oregon Health Division data indicate that over 22% of Oregonians smoke and that 82% of these smokers initiate their smoking behavior before the age of 21. For Pregnant Smokers Smoking has remained the single most important modifiable cause of poor pregnancy outcome in the USA. Smoking accounts for 20% of low birth weight deliveries, 8% of preterm births, and 5% of all perinatal deaths, contributes to Sudden Infant Death Syndrome (SIDS) and may cause important changes in fetal brain and nervous system development. In the US quitting smoking can prevent 40,000 low-birthweight (small for age) babies and can prevent 4,600 perinatal deaths (estimated cost of $69,542 for each perinatal death).

New economic estimates indicate that the direct medical costs of a complicated birth for a smoker are 66% higher than for nonsmokers which reflects the intensive medical care required. 28% of the high-risk, low-income, Oregon Health Plan pregnant population smoke, as reported by Oregon Health Division (1999 data).

Study Design

Four-year, randomized controlled trial of a theory-based, motivational intervention using patient incentives and clinic supports combined with a core “best practice” intervention delivered by OB/GYN practitioners.

Purpose

To significantly increase smoking cessation behavior among low-income, high risk (Medicaid/Oregon Health Plan eligible) pregnant women who access private practice managed care prenatal clinics in heavily populated areas of Oregon.

Expected Outcomes

(1) Establish whether incentives are more effective than Best Practice in motivating smoking cessation/reduction, (2) Examine feasibility of delivering the intervention in managed care prenatal clinics on a national basis.

Title: Pilot—Prenatal Nicotine Exposure and the Dopaminergic System
Principal Investigator: Garcia-Davila, Martha I.
Institution: Georgetown University, Washington, DC
Funding Agency: National Cancer Institute
Project ID: CA084718-050004
Project Funding Period: Not available

Abstract: The mesolimbic system has been implicated in the addictive properties of most drugs of abuse and dependence including cocaine, heroin, amphetamines and nicotine from tobacco. Nicotine affects the dopaminergic system in multiple ways including increasing both the firing rate and bursting activity of dopaminergic cells and by enhancing synthesis, metabolism and release of dopamine. In these studies we propose to examine, using an animal model, the acute and chronic effects of nicotine of dopaminergic function (dopamine release and dopamine uptake) at various developmental ages. The relationship between the nicotine-induced change in nicotine acetylcholine receptor (nAChR) numbers following chronic prenatal nicotine and the number of dopamine transports will also be assessed. Finally, the identify of the nAChR involved in the dopaminergic regulation will be determined by labeling the receptors with [125I]epibatidine, a high affinity radioligand for a variety of nAChRs, and immunoprecipitation of the receptors with subunit-specific antibodies. To determine the identify of these nAChRs involved in regulating dopaminergic function may lead us to a better understanding of nicotine's effects in brain and in addictive properties during various developmental stages. This knowledge will also help in the development of specific therapeutics, as well as in assessing the validity of using nicotine as a therapeutic agent in developmental disorders or during pregnancy as an aid to quit smoking.

Title: Obesity Prevention After Smoking Cessation in Menopause
Principal Investigator: Geiselman, Paula J.
Institution: LSU Pennington Biomedical Research Center, Baton Rouge, LA
Funding Agency: National Institute on Aging
Project ID: AG018239
Project Funding Period: 1 March 2000 – 28 February 2003

Abstract: The present proposal is an obesity prevention pilot study that addresses the high risk of weight gain associated with smoking cessation in postmenopausal women, especially African Americans. This proposal is innovative and unique in its analysis of at and other macronutrient

intake as a target for individually tailored, weight control intervention following smoking cessation in women. This treatment program is designed for the primary prevention of weight gain that can lead to overweight in normal- weight women, that can progress to obesity in women who are already overweight (BMI=25.0-29.9), and for the prevention of additional weight gain in obese women with BMI's greater than or equal to 30.0. Postmenopausal African-American and Caucasian women aged 45-59 years will undergo the same standard two-week smoking cessation program followed by a 20-month, experimental or control follow-up intervention. Specific aim 1; To compare the relative effectiveness of following an empirically validated smoking cessation program with either 1) a group cessation maintenance program with standard exercise advice and food pyramid instructions for healthy eating or 2) a novel, individually tailored dietary-control and exercise, weight-management and cessation program in Caucasian and African-American postmenopausal women as assessed by weight change from baseline to post-cessation months 6, 12, and 20. It is hypothesized that our individually tailored, long-term, experimental intervention will effectively control dietary intake, particularly fat intake, thereby preventing weight gain post-cessation. Specific Aim 3: To assess whether there is differential responsiveness on the above measures in postmenopausal Caucasian versus African-American women. It is hypothesized that African-American women may respond differently from Caucasian women on the above measures. This pilot study is an extension of our research program with the long-term objective of developing individualized, multi-disciplinary, long-term interventions for the prevention of weight gain following smoking cessation in various subsets of women throughout the American population.

Title: Smoking Cessation to Reduce Cervical Cancer Risk
Principal Investigator: Greene, Paul
Institution: University of Alabama at Birmingham, Birmingham, AL
Funding Agency: National Cancer Institute
Project ID: CA75455
Project Funding Period: 30 September 1997 – 30 June 2002

Abstract: Cervical cancer is a major source of morbidity and mortality among women, with a particularly high burden evidenced among women in Alabama. Although HPV has been identified as the major causative agent for cervical cancer, most women with HPV do not develop cervical neoplasia, suggesting that progression to cervical cancer may be influenced by other factors. Smoking has consistently been associated with increased risk for cervical cancer, even among women already at elevated risk due to cervical dysplasia and HPV infection. Further, available data suggest that smoking cessation may decrease cervical cancer risk. These data justify a prospective, controlled study, examining the efficacy of smoking cessation in halting the progression of cervical dysplasia. The proposed 5-year clinical trial will evaluate the effect of a theory-based smoking cessation intervention on progression from low-grade squamous intraepithelial lesions (LSIL) to high-grade squamous intraepithelial lesions (HSIL) in female smokers with HPV. The plan is to recruit 220 current smokers ((10 cigarettes/day) with oncogenic HPV from the University of Alabama at Birmingham Colposcopy Clinic and randomly assign them to one of two treatment conditions: 1)usual care (UC); or 2) smoking cessation intervention (SCI). Patients in both groups will receive standard conservative management for LSIL, biannual pap smears and more aggressive treatment, as needed. Additionally, patients in the SCI group will also participate in an intensive smoking cessation intervention which will include: 1) cognitive-behavioral strategies to facilitate changes in smoking behavior; 2) short-term nicotine replacement therapy to minimize discomfort associated with nicotine withdrawal; and 3) a motivational intervention to promote the optimal use of cognitive-behavioral strategies and nicotine replacement therapy. The primary outcome will be rate of biopsy-confirmed progression to HSIL over 18-month follow-up. The investigators also propose to collect self-report and biochemical measures of smoking status and dysplasia

progression. Finally, perceptions about cancer risk and cancer control practices will be assessed to examine relationships with smoking cessation program participation and changes in smoking.

Title: Staying Smoke Free: A Role for Visiting Nurses in Preventing Postpartum Relapse
Principal Investigator: Groner, Judith
Institution: Columbus Children's Hospital, Columbus, OH
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040678
Project Funding Period: October 2000 – September 2002

Abstract: To refine and pilot an intervention incorporated into home health visits to new mothers who quit smoking during pregnancy, to prevent relapse to smoking and quickly intervene with mothers who resume smoking within 6 months after delivery.

Research Design: Quasi-experimental with non-concurrent, non-randomized samples. The smoking relapse rate of the intervention group will be compared with baseline relapse rate of a natural history sample established prior to the intervention.

Study Population: Women who quit smoking during pregnancy, and who remain smoke free for at lest 7 days prior to delivery. The population will be enrolled at the Ohio State University Hospital Post-Partum Service.

Intervention (if appropriate): The intervention has four components over time, and is based on cognitive-behavioral theory. The components occur at the following times: at the postpartum recruitment contact (Component 1), first home visiting Nurse contact within 1 week of delivery, (Component 2), within 1 month of delivery, by home visit or telephone call (Component 3), and within 3 months after delivery by home visit or by telephone call (Component 4). Home visits or phone calls will be determined by the usual Home Visiting Nurse criteria -- if mother/infant dyad warrants home visits 3 or 4, then intervention will occur at that visit; if they don't require home visits, then intervention will occur by phone from the Home Health Nurse.

Outcome Measures (If cessation or reduction, how defined): Maintenance of smoke-free status will be measured at 3 and 6 months post intervention. Maintenance is defined as self-report of not resuming smoking since quit date during pregnancy. Participants who report not resuming smoking will have their saliva tested for cotinine to confirm recent smoke-free status. The other main outcome measure is the cost of the intervention, to be measured by personnel time in successfully completing the intervention.

Title: Innovation to Prevent Post-Partum Relapse
Principal Investigator: Haas, Jennifer
Institution: University of California, San Francisco, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 9IT-0192
Project Funding Period: 1 July 2000 – 30 June 2002

Abstract: Cigarette smoking is the leading cause of preventable morbidity and mortality for women in the United States. Pregnancy is a pivotal event of young adulthood for many women. This is confirmed by the observation that women are much more likely to quit smoking around the time of pregnancy than at any other. Unfortunately, women who quit during pregnancy have extremely high rates of relapse during the months immediately following delivery. There are several reasons why post-partum women are at high risk of relapse including: decreased motivation, depression, stress, sleep deprivation, and concerns about the loss of weight gained

during pregnancy. Conversely, there are many reasons to think that the perinatal period is an important opportunity to influence a woman's lifetime smoking behavior including: parenthood and a growing sense of responsibility, more frequent contact with the health care system, and less severe nicotine cravings because a woman has already been smoke-free for several months. Behavioral intervention during pregnancy has not been associated with an increase in post-partum tobacco abstinence. Recent studies suggest that bupropion is effective therapy for smoking cessation. There are several reasons that bupropion may be an effective therapy to prevent relapse post-partum, including mood stabilization, decreased fatigue, decreased tobacco craving, and increased weight loss. To date, there is no literature examining the use of bupropion or other anti-depressants as part of an intervention to prevent post-partum relapse. In the proposed IDEA Award program, we will conduct a series of exploratory studies to examine the feasibility of incorporating bupropion into an innovative treatment program to prevent post-partum smoking relapse. The results of this work will be used to design a randomized controlled clinical trial to prevent post-partum smoking relapse that will incorporate pharmacotherapy in addition to a behavioral intervention. The proposed project will address the following Specific Aims: (1) To define an appropriate target population for a pharmacologic intervention to prevent post-partum relapse to tobacco use, we will quantify the amount of bupropion in breastmilk of 20 women who are lactating but not breastfeeding. The results of this Aim will determine whether it is safe to administer bupropion to post-partum women who are still breastfeeding or contemplating breastfeeding or whether it is necessary to wait until a woman is no longer breastfeeding. (2) To inventory, categorize and evaluate behavioral smoking cessation and relapse prevention interventions for pregnant and post-partum women. (3) To obtain explicit information about how best to target a multi-faceted intervention to prevent post-partum smoking relapse, we will conduct interviews with a multi-ethnic sample of 50 women. Each woman will be surveyed twice: once during pregnancy and the then again 6 – 8 weeks postpartum. These surveys will examine: (a) The prevalence and duration of breastfeeding among a multi-ethnic sample of women who have quit smoking during pregnancy. (b) A woman's perception of her risk of relapse. (c) The acceptability of a pharmacologic intervention during the post-partum period. (d) The acceptability of a variety of behavioral interventions (e.g., content, format, intensity) for these women and their household members. Pregnancy is an important opportunity in young adulthood to reduce a woman's lifetime exposure to tobacco. If women can be converted from pregnancy-quitters to long-term quitters this would significantly reduce their lifetime exposure to tobacco as well as reducing the exposure of their children to environmental tobacco smoke. The results of the proposed research will lead directly to an innovative, multi-faceted, targeted intervention to prevent post-partum relapse in a multi-ethnic cohort of women.

Title: Smoking Cessation for Pregnant Substance-Dependent Women
Principal Investigator: Haug, Nancy A.
Institution: University of Maryland Baltimore County, Catonsville, MD
Funding Agency: National Institute on Drug Abuse
Project ID: DA05980
Project Funding Period: Not available

Abstract: Pregnant drug-dependent smokers are a subgroup of substance abusers at especially high risk for health complications. Due to documented deleterious effects of drug use and smoking on both mother and neonate, effective smoking cessation interventions are warranted. The proposed research will systematically examine smoking topography, attitudes, and behaviors among substance-dependent women. The effectiveness of smoking cessation Motivational Enhancement Therapy (MET) in increasing quit rates and reducing smoking throughout pregnancy will be evaluated. The Transtheoretical Model will be incorporated as a conceptual framework for describing and predicting the change process involved in pregnancy smoking cessation. Since MET can be individually tailored to stage of change for smoking, this alternative strategy for pregnancy smoking cessation will be compared with standard care

(practitioner advice) in a two-group experimental design. Data will be collected on factors related to quitting prenatal tobacco use, as well as on the interactions that occur with illicit substance use. Participants will be primarily lower socioeconomic status (SES) and minority (African-American) pregnant women from urban areas, seeking drug treatment as well as prenatal care at a comprehensive, specialized program. The specific aims of the research are: 1) To characterize smoking patterns and nicotine dependence in a sample of pregnant, treatment-seeking drug-dependent women; 2) To establish pretreatment stages of change for quitting smoking during this pregnancy and their relationship to other smoking and drug use variables; 3) To determine the clinical effectiveness of a specialized intervention (MET) for increasing smoking cessation rates and impacting stage movement; and 4) To identify factors associated with quitting smoking during pregnancy.

Title: Voucher-Based Incentives to Treat Pregnant Smokers
Principal Investigator: Higgins, Stephen T.
Institution: University of Vermont & State Agricultural College, Burlington, VT
Funding Agency: National Institute on Drug Abuse
Project ID: DA014028
Project Funding Period: 30 April 2001 – 31 March 2006

Abstract: Maternal cigarette smoking is the most important preventable cause of poor pregnancy outcomes in the U.S. and a leading cause of pediatric morbidity and mortality. Approximately 30% of women in the U.S. are cigarette smokers when they become pregnant and the prevalence is greater still among less educated women. About 80% of these women smoke throughout their pregnancy. Even among those who quit, 25-30% relapse during the pregnancy and 70% within 6 months of delivery. Efficacious interventions have been developed for promoting smoking cessation during pregnancy, but cessation rates are low, especially among low-income and highly nicotine-dependent women (< 15%). Efficacious interventions to prevent relapse during the postpartum period remain to be developed. We propose to examine the efficacy of a voucher-based incentive program for promoting smoking cessation and preventing relapse during pregnancy and postpartum. This incentive program is efficacious in promoting and sustaining abstinence in cocaine and other illicit drug abusers. A recent trial suggested that vouchers may be efficacious for increasing smoking cessation among pregnant smokers. The proposed studies are designed to rigorously evaluate the efficacy of voucher-based incentives for promoting cessation and extend them to preventing relapse among pregnant women and new mothers. Two randomized trials are proposed. First, we will examine the efficacy of vouchers delivered contingent on smoking abstinence for increasing cessation rates during pregnancy and postpartum among 226 women who are still smoking at their first prenatal visit. Second, we will examine the efficacy of contingent vouchers for preventing relapse during pregnancy and postpartum among 96 women who have already quit smoking prior to the first prenatal visit. Women for both trials will be recruited from Vermont's largest obstetrical practice, which serves a large population of uninsured, low-income women. In both trials, the voucher-based intervention will be added to brief smoking advice delivered by physicians/midwives and compared against control conditions wherein brief advice is combined with vouchers delivered independent of smoking status. Overall, the proposed studies have the potential to contribute important new scientific and practical information on effective treatment for one of our nation's most daunting drug abuse problems.

Title: Pilot: Nicotine and Exercise Related Energy Expenditure in Women
Principal Investigator: Jorenby, Douglas E.
Institution: University of Wisconsin Madison, Madison, WI
Funding Agency: National Cancer Institute
Project ID: CA084724-04S10004
Project Funding Period: 30 September 1999 – 31 August 2004

Abstract: On average, smokers weigh less than nonsmokers, and most smokers gain 2-3 kg of weight in the first six months of a cessation attempt. Fear of weight gain is a significant barrier to cessation attempts, particularly among women who smoke as a weight control strategy. For all its clinical relevance, little is known about the metabolic mechanisms of post-cessation weight gain or strategies to prevent it, esp. in women. This study will utilize a human indirect calorimetry chamber to assess exercise-related energy expenditure in 20 pre-menopausal women who are regular smokers. Each will participate in a pre-cessation assessment of resting energy expenditure, response to 20 minutes of standardized light exercise, and recovery time from exercise. The entire sample will then quit smoking for 72 hours, half using a 21 mg patch, half without nicotine replacement, and repeat the calorimetry assessment. The results should indicate the degree to which nicotine replacement therapy can increase exercise-related energy expenditure and/or prolong metabolic recovery time. Providing women with an active intervention to address weight gain may increase the number of successful cessation attempts, and may aid those who relapse due to fear of weight gain.

Title: Exercise and Nicotine Replacement for Female Smokers
Principal Investigator: Kinnunen, Taru
Institution: Harvard University Medical School, Boston, MA
Funding Agency: National Institute on Drug Abuse
Project ID: DA012503
Project Funding Period: 15 April 1999 – 31 March 2002

Abstract: Each year nicotine addiction is responsible for more than 125,000 deaths of American women. In 1987, cigarette smoking related lung cancer surpassed breast cancer as the leading cause of death by cancer among women. The prevalence of smoking has declined more slowly for women than for men, suggesting that quitting smoking is more difficult for women. Factors that may contribute to the gender difference in cessation rates include women's greater tendency to smoke as a means of coping with negative affect, and their greater concern about postcessation weight gain. It seems clear that special interventions are needed to address these unique concerns of female smokers. Nicotine replacement therapy has shown some success in improving smoking cessation rates, reducing the severity of negative affect usually experienced during cessation, and, in the case of nicotine gum, minimizing postcessation weight gain. Aerobic exercise has also been found to improve mood and control weight. In combination, nicotine replacement therapy and aerobic exercise should be a powerful smoking cessation treatment for women. The proposed study will investigate the effects of an aerobic exercise intervention as an adjunct to nicotine polacrilex gum therapy. Three hundred female smokers will receive nicotine gum therapy and will be randomly assigned to an exercise intervention, an equal contact control condition, or a gum alone control condition. The exercise intervention will consist of three 45-minute sessions of aerobic exercise per week from 3 weeks precessation through 16 weeks postcessation. All participants will be followed for one year after cessation. In addition to determining the effectiveness of the adjunct exercise intervention on cessation rates, the mechanisms (e.g., relief of negative moods, suppression of cessation-related weight concerns, relief of premenstrual distress) by which exercise affects cessation will be examined. The proposed study will provide the first large-scale test of a very promising intervention to aid women in smoking cessation. The combination of an exercise intervention with nicotine replacement, which has not yet been investigated, should provide a particularly effective

treatment program for female smokers. Intensive focus on the mechanisms by which exercise affects cessation will provide information essential both for understanding the nature of the relationship between exercise and smoking cessation, and for later refinement and enhancement of the exercise intervention.

Title: Acute Nicotine Abstinence in Adolescents
Principal Investigator: Krishnan-Sarin, Suchitra
Institution: Yale University, New Haven, CT
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD037688
Project Funding Period: 30 September 1998 – 31 May 2003

Abstract: The applicants will conduct a detailed, prospective examination of tobacco withdrawal symptoms of male and female adolescents who are either heavy users, light users or nonusers of tobacco products (including cigarettes and smokeless tobacco). In adults, physical dependence as documented by the presence of withdrawal symptoms, is known to be an important factor in the maintenance of cigarette smoking, and the intensity of nicotine withdrawal has been shown to be directly correlated to the intensity of nicotine use. It has been suggested that like adults, adolescents may also be physically dependent on nicotine. However, all the studies examining incidence of nicotine withdrawal in adolescents have been retrospective in nature, but they suggest that self-reports from adolescents indicate that they also experience withdrawal during abstinence from nicotine. The specific aims of this proposal are (1) to conduct a prospective and systematic study of nicotine withdrawal symptomatology in adolescents who differ in amount of tobacco use (heavy users, light users, nonusers) using standard nicotine withdrawal measures as well as the Clinical Institute for Narcotic Assessment (CINA) scale-(2) to evaluate gender differences in the incidence of nicotine withdrawal in adolescents, (3) to determine if adolescents experience cognitive performance deficits during nicotine withdrawal and if these deficits are greater in heavy users compared with light users of tobacco products, (4) to evaluate alterations in responsivity to both physical and mental stress during nicotine withdrawal, in heavy and light users of tobacco products, compared with nonusers of tobacco and (5) to document alterations in responsivity of the hypothalamo-pituitary-adrenal (HPA) axis and sympathetic system during nicotine withdrawal and exposure to stress. The results of this study would have substantial implications for the use of nicotine substitution and other treatments in adolescents for the pharmacological management of withdrawal, and could also help elucidate the role of cognitive deficits and stress in maintaining cigarette smoking in adolescents. Determining physical dependence and related changes in adolescent tobacco users may also provide valuable information regarding the process of development and maintenance of nicotine dependence.

Title: Early Tobacco Abstinence in High Risk Smokers
Principal Investigator: Krishnan-Sarin, Suchitra
Institution: Yale University, New Haven, CT
Funding Agency: National Institute on Drug Abuse
Project ID: DA013334
Project Funding Period: Not available

Abstract: This proposal is composed of two sequential studies; the study will examine male and female smokers with and without current depressive symptoms on the clinical course (intensity, content and duration) of cigarette abstinence effects, and responses to cigarette-related cues during acute and prolonged nicotine abstinence; the second study will conduct a similar examination in male and female smoker who are either heavy or light drinkers. Alcohol

dependence, major depression/current depressive symptoms and female gender have also been associated with high rates of cigarette smoking and poor smoking-treatment outcomes. In adult smokers without psychiatric comorbidity, development of nicotine withdrawal is an important factor in the maintenance of cigarette smoking (USDHHS, 1988), and the intensity of withdrawal is directly correlated with the degree of nicotine use. Retrospective studies report that smokers with a history of major depression disorder and/or alcohol dependence experience more current depressive symptoms (without current MDD) and heavy drinkers (without alcohol dependence) has not been examined. This is particularly important considering a significant percentage of smokers have depressive symptoms and are also heavy drinkers but may not meet criteria for MDD or alcohol dependence. Detailed understanding of the nicotine abstinence syndrome in these high-risk smoker could lead to strategies (behavioral and pharmacological) for effective management of withdrawal symptoms which may prevent relapse to smoking. The following specific aims will be tested 1) To compare male and female smokers, with and without current depressive symptoms, in a prospective study of the intensity, content & duration of nicotine abstinence effects during an eight-day abstinence period, and responses to cure exposure (in vivo cigarette cues, alcohol and negative affect- inducing imagery cues) during acute versus prolonged abstinence and, 2) To compare male and female smokers, who are either heavy alcohol drinkers or light alcohol drinkers, in a prospective study of the intensity, content & duration of nicotine abstinence effects during an eight-day abstinence period, and responses to cure exposure (in vivo cigarette cues, alcohol and negative affect-inducing imagery cues) during acute versus prolonged abstinence.

Title: Explaining Racial Differences in Smoking
Principal Investigator: Landrine, Hope
Institution: San Diego State University Foundation, San Diego, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 8RT-0013A
Project Funding Period: 1 July 1999 – 30 June 2002

Abstract: Studies indicate that the prevalence of cigarette smoking among Black adults (30-56%) far exceeds that of White adults (20-27%) even when controlling for income and education (socioeconomic status, SES). Blacks also have lower rates of quitting smoking and higher levels of nicotine dependence than Whites, with these also transcending SES. Consequently, Blacks continue to suffer smoking-related diseases and death at a significantly higher rate than Whites. In addition, Blacks have the lowest rate of smoking as adolescents but the highest rate of smoking as adults. This pattern is not an artifact of differences in smoking among Blacks born in different generations but instead suggests that something happens to Blacks at ages 18-24 that leads many to initiate smoking at those late ages, and to then be unable to quit. Although these racial differences are well-known, the explanation for them remains unknown and unexamined. Understanding the factors underlying these differences is crucial to tobacco control for the state's ethnically diverse population however, and so investigating Black smoking and racial differences in smoking is one of the five challenges ahead for TRDRP. This project responds to that challenge by examining one variable that might explain these differences racial discrimination. Our preliminary studies revealed that racial discrimination is a stronger predictor of smoking among Black adults than all SES variables, and revealed that only Blacks who experience high discrimination have higher smoking prevalence rates than Whites. These initial data suggest that racial discrimination may be a sociocultural stressor unique to Blacks that many Blacks cope with by smoking. What happens to Blacks at ages 18-24 that leads many to initiate smoking may be the onset of racial discrimination when they become adults and enter a hostile White work-world. Hence, this project entails a survey on smoking and racial discrimination mailed to a random sample of 4,000 Black and 2,000 White California adults. We will test the hypothesis that racial discrimination accounts for Black-White differences in

1) smoking prevalence; 2) age of initiation of smoking; 3) degree of nicotine addiction, 4) difficulty quitting smoking; and 5) stage of readiness to quit smoking. We theorize that Blacks who experience frequent discrimination will differ from Whites on all five variables, whereas Blacks who experience infrequent discrimination will not. We further hypothesize that the age at which Blacks began their first full-time job will be a strong predictor of the age at which they initiated smoking. Our data then can be used to design new, culturally-tailored smoking prevention and cessation programs for Blacks that might reduce the high cost of Black tobacco use in the state. Simultaneously, we will examine the effects of various incentives and survey manipulations on response rates from Blacks and Whites, and provide data on the best procedures for getting Blacks to return surveys about their tobacco use.

Title: Smoking Cessation Program for Low Income Pregnant Women
Principal Investigator: Lasater, Thomas M.
Institution: Brown University, Providence, RI
Funding Agency: National Heart, Lung, and Blood Institute
Project ID: HL057457
Project Funding Period: 30 September 1997 – 31 July 2003

Abstract: This project is a collaborative effort of physicians with experience in providing prenatal care to low income participants and researchers who have developed and refined three different program components to reduce cigarette smoking. The design is a prospective randomized pretest/posttest design with biochemically confirmed smoking status as the outcome. Posttests will be carried out at 37 weeks of gestation, six weeks postpartum and six months postpartum. Participants will be randomized to three groups. Group 1 will use an adapted version of a Quit Kit called "A Pregnant Woman's Guide to Quit Smoking" developed by Dr. Richard Windsor; Group 2 adds a Quit and Win contest used by the Principal Investigator; and Group 3 adds the use of telephone counseling based upon motivational interviewing. These materials will be made culturally appropriate for African-Americans and Hispanics.

Title: Initial Subjective Reactions to Nicotine in Young Adults
Principal Investigator: Lessov, Christina N.
Institution: Washington University, St. Louis, MO
Funding Agency: National Institute on Drug Abuse
Project ID: DA015268
Project Funding Period: Not available

Abstract: This 12-month project is motivated by the hypothesis that individual differences in initial nicotine sensitivity in humans are associated with nicotine dependence vulnerability and are an important mediator of genetic influences on risk of nicotine dependence. This application combines (1) characterization of existing data on self-report reactions to first cigarette assessed retrospectively in a large adolescent female twin sample (Missouri Adolescent Female Twin Study, MOAFTS) and on subjective reactions to nicotine versus placebo administered by nasal spray to smoking experimenters (smoked fewer than 100 cigarettes lifetime) and measured in the laboratory (Nicotine Challenge Study); and (2) collection of new self-report data on subjective reactions to first cigarette and recalled reactions to nicotine nasal spray in order to assess validity of proposed measures of nicotine sensitivity data and the feasibility of collecting such data from genetically informative samples. If measures can be shown to have acceptable reliability and validity, to be strongly familial and to be associated with nicotine dependence vulnerability, this will lay the groundwork for including such measures in gene-mapping and other genetic studies of nicotine dependence vulnerability and will help identify potential key targets for smoking prevention and intervention. A series of individualized tutorials and formal coursework will

provide necessary advanced research training in human behavior genetic of addiction to support this research plan.

Title: Treating Postpartum Nicotine Dependence
Principal Investigator: Levine, Michele D.
Institution: University of Pittsburgh at Pittsburgh, Pittsburgh, PA
Funding Agency: National Institute on Drug Abuse
Project ID: DA015396
Project Funding Period: 30 September 2002 – 31 May 2007

Abstract: This Mentored Research Scientist Development Award describes a training and research plan designed to qualify the candidate to design and conduct research on the prevention of smoking relapse during the postpartum period. Although many women quit smoking during pregnancy, approximately 70% will resume smoking within a year of giving birth. Because smoking during the postpartum period has negative effects on the health of both women and children, preventing postpartum relapses to smoking can have important public health benefits. To date, however, little is known about the causes or prevention of postpartum smoking. Changes in mood and increases in concerns about weight are common during the postpartum period, and these factors also have been related to women's smoking behavior. Thus, it is hypothesized that mood and weight concerns increase women's vulnerability to postpartum smoking relapse. To elucidate the effects of mood and weight concerns on postpartum smoking, the candidate proposes a research plan designed to: (1) assess factors theoretically related to postpartum smoking relapse; (2) develop a postpartum-specific relapse prevention program addressing factors found to relate to postpartum relapse; and (3) test the feasibility, acceptability and initial efficacy of this postpartum-specific relapse prevention program. This research plan is combined with a training plan designed to establish a strong knowledge base in the following areas: (1) the physiologic effects of nicotine and tobacco on women, (2) factors in the postpartum period that affect mood and weight, and (3) advanced longitudinal data analytic techniques. The background and skills developed during through this research and training plan will provide a cohesive framework for the candidate's future career as an independent investigator in the area of clinical research on approaches to women's smoking cessation.

Title: Safe Babies: The Determinants of Postpartum Smoke-Free States and Relapse During Pregnancy and Postpartum
Principal Investigator: Lohr, Jacob A.
Institution: Governor's Institute on Alcohol and Substance Abuse, Inc.,
Research Triangle, Park NC
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040668
Project Funding Period: October 2000 – December 2002

Abstract: To examine the determinants of relapse and relapse prevention among women who quit smoking during their pregnancy.

Research Design: We will enroll a cohort of pregnant women who have successfully quit smoking during pregnancy and follow this cohort for four months postpartum. All women will participate in individual interviews to verify smoking status, and to complete screening and assessment forms. We will conduct focus groups with new mothers who do not resume smoking and focus groups with mothers who relapse. Focus groups will examine determinants of relapse prevention and successful cessation such as social support, clinical support and education, internal and external factors, incentives, addiction, and employment.

Study Population: The target population will be white and African American women whose prenatal charts indicate that they were smokers at the start of their current pregnancy and who quit smoking by the end of the second trimester.

Outcome Measures (If cessation or reduction, how defined): Expected outcomes include an understanding of (1) interventions that may improve successful maintenance of smoking cessation and (2) a theoretical model for postpartum relapse and maintenance. This model will describe the relapse process, identifying stages of relapse and factors that contribute to postpartum relapse and maintenance.

Title: Moderate Exercise to Aid Smoking Cessation in Women
Principal Investigator: Marcus, Bess
Institution: Miriam Hospital, Providence, RI
Funding Agency: National Cancer Institute
Project ID: CA77249
Project Funding Period: 17 April 1998 – 31 January 2003

Abstract: Lung cancer rates now exceed breast cancer rates as the leading cause of death by cancer among women. Furthermore, smoking prevalence rates among women are declining at a slower rate than men and approximately 23% of women still smoke. One important reason why women do not attempt and/or succeed at smoking cessation may be fear of post-cessation weight gain. However, combined smoking cessation and weight control treatments have not been successful at decreasing post-cessation weight gain or enhancing achievement of smoking cessation. Exercise offers a healthful alternative to smoking, which may allay women's fear of weight gain. Exercise facilitates regulation of body weight, moderates mood changes, aids in decreasing responses to stress, and is incompatible with smoking. The proposed study will test the hypothesis that moderate intensity exercise enhances the achievement and maintenance of smoking cessation among healthy adult female smokers. This is a randomized controlled clinical trial comparing two conditions: (a) cognitive-behavioral smoking cessation plus moderate exercise and (b) cognitive-behavioral smoking cessation with equal contact time. The treatment is delivered over 12 weeks. A sample of 224 subjects will be recruited, treated for twelve weeks and followed for 12 months. This design permits separation of the effects of physical activity from the effects of frequent contact with staff and other subjects. Smoking cessation outcome (7 day point-prevalence) will be verified by saliva cotinine. Exercise adherence will be validated by attendance at supervised sessions, exercise monitors, and maximal exercise testing. Secondary analyses of hypothesized mediators (weight and/or weight concerns, negative affect, withdrawal symptoms, self-efficacy, motivation) of the effect of moderate exercise on smoking cessation will also be examined. Successful smoking cessation in women could significantly reduce chronic disease mortality in this group. Although intensive, this kind of program could have advantages over pharmacologic treatments and/or could be made more disseminable and cost-effective, but only if the initial results of this rigorous trial are promising.

Title: Bupropion and Weight Control for Smoking Cessation
Principal Investigator: Marcus, Marsha D.
Institution: University of Pittsburgh at Pittsburgh, Pittsburgh, PA
Funding Agency: National Institute on Drug Abuse
Project ID: DA004174
Project Funding Period: 1 July 1986 – 30 November 2004

Abstract: Although rates of smoking have declined, the decrease in prevalence has been much less pronounced in women than in men, and women are particularly vulnerable to ongoing

smoking-related morbidity and mortality. One reason for gender differences in smoking cessation is concern about cessation-related weight gain among women. In the previous grant period, we tested the efficacy of two adjuncts to a standard cessation program for weight concerned women, behavioral weight control (WEIGHT) and cognitive behavior therapy to reduce weight concerns (CBT). Results of this trial have shown that CBT is a promising adjunctive treatment for weight concerned women. Specifically, 59.7% of known in the CBT condition were abstinent from smoking in post- treatment. Further, CBT yielded significantly higher abstinence rates in 3- month follow-up when compared to standard cessation only or the WEIGHT adjunct, with cessation rates of 39.4%, 23.6%, and 22.6% for the three groups, respectively. Nevertheless, abstinence rates decreased significantly during follow-up for all groups, and in the present study, we propose a randomized, double-blind, controlled trial to determine whether the addition of bupropion (Zyban) to CBT treatment for weight- concerned women will enhance longer-term abstinence. Four hundred fifty weight-concerned women smokers will be randomized to either cognitive behavioral treatment for weight concerns plus standard cessation (CBT) or standard smoking cessation only (STANDARD), and six months of either bupropion (Zyban) or placebo. Primary outcome will be rates of smoking abstinence and time to relapse across the four treatment conditions. In addition, we will determine the effects of these treatments on tobacco withdrawal, mood, and weight. Results of this investigation will provide information on the relative efficacy of CBT and bupropion alone and in combination, and the utility of drug and counseling strategies that are specifically tailored for a high- risk population. This is a competing continuation of 2-R01-DA04174-13.

Title: Partner Assisted Interventions for Pregnant Smokers
Principal Investigator: McBride, Colleen
Institution: Duke University, Durham, NC
Funding Agency: National Cancer Institute
Project ID: CA76945
Project Funding Period: 26 September 1997 – 30 June 2002

Abstract: Smoking during pregnancy increases women's risk of complications of pregnancy and numerous birth outcomes. Two-thirds of women smokers continue to smoke during pregnancy, with particularly high rates of smoking among low income and less educated women. For the majority of women, pregnancy occurs in the context of an intimate relationship that pregnant women report as their primary source of support. However, naturally occurring partner support may not be enough to assist pregnant smokers with cessation, particularly when the partner is a smoker. The proposed study is a five year randomized trial to evaluate the incremental improvement of providing a part-assisted support adjunct to state-of-the-science self-help smoking cessation interventions for pregnant smokers. Ft. Bragg military base located in Fayetteville, NC was selected as the study site because of high smoking rates, high birth rates and the majority of women who receive prenatal care are married to military personnel. Three intervention conditions will be tested in an additive design. Eligible couples who are receiving prenatal care at Ft. Bragg/Womack Army Medical Center will be identified from automated appointment logs and recruited to participate. Couples who agree (n=700) will be randomized to (1) provide advice and a self-help booklet (usual care prototype, n=233); (2) self-help guide and relapse prevention kit plus pre-and postpartum telephone counseling (enhanced self-help, n=233); or (3) enhanced self-help plus a partner-assisted support intervention that includes a couple contact session and tailored serialized written materials plus cessation materials for partner smokers (partner-assisted, n=233). Participants will be surveyed at baseline, 32 weeks of pregnancy, and 8 weeks, 6 and 12 months postpartum. Self reported smoking status will be biochemically validated late in pregnancy and at the 12 month follow-up. The primary outcomes of interest will be rates of smoking cessation among pregnant women and levels of perceived partner support for cessation at all follow-ups.

Title: Smoke-Free Families: National Partnership to Help Pregnant Smokers Quit
Principal Investigator: Melvin, Cathy, and Kahler, Kay
Institution: Sheps Center for Health Services at the University of North Carolina at Chapel Hill, Chapel Hill, NC and Vose, Porter Novelli, Inc.
Funding Agency: Robert Wood Johnson Foundation
Project ID: Not available
Project Funding Period: Not available

Abstract: The National Partnership to Help Pregnant Smokers Quit is a coalition of diverse organizations that have joined forces to improve the health of this and future generations by increasing the number of pregnant smokers who quit smoking. Through a nationwide effort to reach women, providers and communities, the National Partnership hopes to ensure that all pregnant women in the Unites States are screened for tobacco use, and receive best-practice cessation counseling as part of their prenatal care.

Title: Bupropion for Smoking Cessation in Pregnancy
Principal Investigator: Miller, Hugh S.
Institution: University of Arizona, Tucson, AZ
Funding Agency: National Cancer Institute
Project ID: CA089510
Project Funding Period: 5 September 2002 – 31 August 2004

Abstract: Smoking in pregnancy is associated with a variety of complications, including low birth weight (LBW), intrauterine growth restriction (IUGR), antenatal bleeding and pre-term birth (PTB). These significant health hazards could largely be prevented with successful antepartum smoking cessation. In recognizing both the success and the limitations of counseling based smoking cessation programs, we are interested in piloting the use of pharmacologic agents for reduced smoking during pregnancy. The first objective of the proposed research is to evaluate the efficacy of a pharmacologic aid for successful smoking cessation in pregnancy. The specific aims include evaluating bupropion SR's efficacy for both cessation and reduction of antenatal smoking by comparing pregnant women receiving smoking cessation counseling combined with placebo to those pregnant women who receive smoking cessation counseling combined with bupropion SR. The second objective of the proposed research is to evaluate the safety of bupropion SR used for smoking cessation in pregnancy. The specific aims include determining the adverse events and adverse effects associated with antenatal bupropion administration. Secondarily, the pilot seeks to evaluate the impact of bupropion SR on maternal well being, anxiety, depression, psychosocial variables and neonatal outcome (birth weight, Apgar scores, and neonatal intensive care unit admission rate). This research will consist of a pilot double blind placebo controlled randomized trial in which pregnant women who self-report continued smoking at the inception of prenatal care, will be randomized to one of two groups. The interventions will consist of brief smoking cessation counseling in combination with either placebo or bupropion SR. Participants will be surveyed to determine important demographic factors, psychosocial variables, and intercurrent medical illnesses, including measures of psychiatric disease, particularly concurrent depression. Maternal outcome measures will include cessation and smoking reduction rates by self-report and biochemical analysis (urinary cotinine and breath carbon monoxide analysis). The proposed research seeks to evaluate whether a pharmacologic aid (bupropion SR) administered antenatally can achieve higher rates of smoking cessation and smoking reduction without imposing serious adverse outcome.

Title: Smoking Cessation for Women at Risk for Cervical Cancer
Principal Investigator: Miller, Suzanne
Institution: Fox Chase Cancer Center, Philadelphia, PA
Funding Agency: National Cancer Institute
Project ID: CA76644
Project Funding Period: 1 April 1999 – 31 January 2004

Abstract: Smoking accounts for approximately one in every five deaths in the United States, totaling more than 419,000 deaths each year. Cigarette smoking is associated with a number of adverse health effects, including an increased risk of cervical dysplasia. Minority women not only suffer from disproportionately higher rates of cervical cancer mortality, but they are also significantly more likely to smoke. Emerging guidelines recommended that patients with smoking-related prenoplastic conditions be identified as candidates for smoking cessation, at all medical visits, particularly low-income, ethnic minorities. Toward this end, the proposed study will assess the utility of a theory-driven smoking cessation intervention, based on well-established cognitive-behavioral techniques, presented at a teachable medical moment (i.e., around diagnostic follow-up for an abnormal Pap smear result). Low-income inner city women (N=502) will be randomized to either a 7-session enhanced smoking cessation protocol, delivered over a 13-week period, or to a matched control condition that equates for time, attention, and format. Both groups will receive advice and tips for quitting, along with nicotine replacement therapy. In addition, the intervention group will receive a cognitive-affective smoking program, systematically tailored to the individual's attentional style (i.e., high vs. low monitoring). The control group will receive general health behavior recommendations (e.g., diet, exercise), tailored to high vs. low monitors. Participants will be assessed at baseline (prior to the diagnostic follow-up visit), on the day of the visit, and at 6- and 12-months post-visit. Assessments will include background variables (e.g. demographics), process variables (e.g., stage of change, disease status), and outcome variables (e.g., biochemical and self-reported smoking status). The proposed study will bring together two key strengths: 1) expertise in the individualized assessment and management of cervical cancer risk feedback; and 2) expertise in the development and implementation of smoking cessation interventions. It will apply these strengths to the delivery and evaluation of a highly transportable, readily implemented, intervention, focusing on a traditionally underserved population.

Title: Mapping the Natural History of Smoking and Smoking Cessation Among Pregnant Women
Principal Investigator: Muramoto, Myra
Institution: The University of Arizona, College of Medicine, AZ
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040672
Project Funding Period: 1 October 2000 – 30 September 2003

Abstract: Purpose: (1) To document the natural history of smoking cessation and relapse as a dynamic process influenced by differing sets of variables over time and in response to life transitions or events, e.g. delivery, motherhood, stress, depression. (2) To examine the harm reduction goals, strategies, and practices of pregnant and postpartum women who reduce their smoking intensity but not quit, and how this changes over time. (3) To gain a better understanding of how social support networks affect a woman's ability to quit or reduce smoking during pregnancy and postpartum, with a particular focus on the extent to which patient characteristics such as age, ethnicity, gravity and parity, and breastfeeding status influence provider attitudes and characteristics. (4) To document the cessation treatment practices of prenatal and maternal child health providers.

Research Design: A longitudinal ethnographic study of smoking and quitting behavior among pregnant/postpartum women who currently smoke or have quit during pregnancy. The study will apply both qualitative and quantitative methods. Subjects will be interviewed a total of nine times from the time of the study entry until six months postpartum. Each pregnant woman will be interviewed three times prior to delivery and monthly for six months postpartum. Prepartum interviews will be in-person and postpartum interviews will consist of three in-person interviews and three telephone interviews. At the completion of the interviews, some subjects will participate in focus group sessions. In addition, this study will conduct focus groups with prenatal and maternal child health care practitioners.

Study Population: Sixty low-income pregnant women from WIC clinics in Tucson and in Pima, Pinal and Santa Cruz counties will be enrolled. Forty of the sixty women enrolled will be Caucasians and twenty will be Hispanics. A second target population (for focus groups) is prenatal and maternal child healthcare providers.

Outcome Measures: Self reported abstinence will be verified by salivary cotinine.

Title: Nicotine Replacement Treatment for Pregnant Smokers
Principal Investigator: Oncken, Cheryl
Institution: University of Connecticut School of Medicine and Dentistry, Farmington, CT
Funding Agency: National Institute on Drug Abuse
Project ID: DA015167
Project Funding Period: 1 July 2002 – 31 March 2007

Abstract: Smoking during pregnancy is one of the most important modifiable causes of poor pregnancy outcomes in the United States. Unfortunately, the majority of women who smoke prior to pregnancy continue to smoke during pregnancy. Even with augmented behavioral interventions, smoking cessation rates in pregnancy trials rarely exceed 20 percent. These low quit rates may be due to inadequate treatment of the physical addiction to nicotine. Indeed, medications are first-line treatment for smoking treatment in non-pregnant smokers. However, little information is available on the safety or efficacy of medications to treat pregnant smokers. This proposal will examine the utility of one first-line medication, nicotine gum, as an aid to smoking cessation during pregnancy. The specific research aims of this project are: 1. To compare smoking cessation rates and smoking reduction among pregnant smokers who are randomized to receive 2 mg nicotine gum or a matching placebo; 2. To compare nicotine gum versus placebo on surrogate measures of maternal and fetal safety (i.e., overall nicotine and tobacco exposure), and birth weight at the time of delivery; 3. To examine which subjects benefit the most from the use of nicotine gum for smoking cessation during pregnancy. Subjects will be recruited from a prenatal clinic that serves primarily a low-income, minority population. Two hundred sixty-six pregnant smokers who smoke at least 5 cigarettes per day will be randomly assigned to receive a behavioral counseling intervention and either a 6-week course of 2 mg nicotine gum or placebo for smoking cessation followed by a 6-week taper. Primary outcome measures will be 7-day point prevalence cigarette abstinence, number of cigarettes smoked per day, saliva cotinine concentrations, and measures of tobacco exposure (i.e., carbon monoxide in exhaled air, and urine anabasine and anatabine) at 6 weeks after the quit date and at 32-34 weeks gestation. Birth weight will be obtained at the time of delivery. We hypothesize that 1. Pregnant smokers who are randomized to nicotine gum will have double the quit rates, and will reduce their smoking to a greater degree than subjects randomized to placebo; 2. Nicotine gum compared to placebo will reduce maternal cotinine levels, carboxyhemoglobin levels, and urine anabasine and anatabine levels. Birth weights will be higher in the offspring of subjects randomized to nicotine gum compared to placebo and will be negatively correlated with carbon monoxide and urinary alkaloids at 32-34 weeks gestation; 3. The odds of cigarette abstinence will be increased primarily in subjects who smoke at least 15 cigarettes per day.

Title: Research on Maternal Depressive Symptoms and Postpartum Smoking
Principal Investigator: Orr, Suezanne
Institution: East Carolina University School of Health and Human Performance, Greenville, NC
Funding Agency: Robert Wood Johnson Foundation
Project ID: 043281
Project Funding Period: 1 March 2002 – 29 February 2004

Abstract: This grant provides supplemental funding for research focused on the relationships between maternal prenatal depressive symptoms (and other psychosocial factors) and maternal prenatal smoking cessation and intensity (i.e., number of cigarettes smoked). During the current study, data are being collected on psychosocial factors and smoking status at the first prenatal visit and at 30 weeks gestation. During this study, the research team will collect follow-up data at the 6- or 12-week postpartum visit and again at 6 to 12 months postpartum. The purpose of this further research is allowing the team to thoroughly measure smoking status during the postpartum period, which will greatly aid the team's findings. The findings from this research will lead to future new treatments of depressive symptoms as a way to prevent smoking relapse and facilitate smoking cessation.

Title: Sex Differences in Nicotine Reinforcement: Human/Animal
Principal Investigator: Perkins, Kenneth A.
Institution: University of Pittsburgh at Pittsburgh, Pittsburgh, PA
Funding Agency: National Institute on Drug Abuse
Project ID: DA012655
Project Funding Period: 1 September 2000 – 31 July 2004

Abstract: Men and women may differ in factors that reinforce smoking behavior: self-administration of nicotine per se is often less robust in women, women are less sensitive to many effects of nicotine, and nicotine replacement is less effective for smoking cessation in women. Nicotine therefore may be a less reinforcing consequence of tobacco smoking in women vs. men. Other results suggest that non-nicotine aspects of smoking (e.g. sensory effects) may be more reinforcing in women. In this revision of "Sex Differences in Nicotine Reinforcement: Human/Animal" (DA 12655), we will examine sex differences in the influence of nicotine and non-nicotine factors on self-administration (SA) behavior. A unique feature of this proposal is a parallel series of studies exploring these questions using an animal (rat) model of nicotine self-administration. Procedures in the human and animal lines of research will allow independent manipulation of nicotine and non-nicotine factors. Our specific aims are to: 1) Examine differences in smoking (human) or i.v. nicotine (rat) self-administration in females as a function of menstrual/estrus cycle phase and compare this SA behavior to males. Results will determine the influence of cycle phase on SA, which may help explain observed sex differences, and critically inform the design of all subsequent research in this project as to whether cycle phase must be controlled. 2) Examine sex differences in the influence of nicotine dose on SA behavior in humans and animals. Nicotine clearly is the primary psychoactive ingredient reinforcing smoking behavior. However, nicotine may be less important in regulating this behavior in females. We will explore this possibility by determining whether self-administration behavior is less affected by manipulations of nicotine dose in females. 3) Examine sex differences in the influence of non-nicotine, drug-related stimuli on SA in humans and animals. Males' behavior may be more tightly controlled by nicotine and females' relatively more influenced by non-nicotine cues accompanying drug. Results will determine the reinforcing effect of smoking stimuli that have been largely ignored in past human research and provide directions for future

study of conditioned reinforcement of smoking. Findings will clarify whether, and to what extent, nicotine and non-nicotine factors differentially reinforce SA behavior in females versus males. Similarities between species would bolster the relevance of the animal findings for human smoking reinforcement and allow an animal model by which to subsequently (and more invasively) investigate mechanisms for these sex differences. Results will increase our understanding of tobacco dependence in women and suggest approaches to developing improved smoking cessation treatments for women, among other future directions. This program may also provide directions for the study of sex differences in pharmacological and non-pharmacological reinforcement from other abused drugs, with potential relevance for broadly improving substance abuse treatment in women.

Title: Patterns of Maternal Smoking During Pregnancy
Principal Investigator: Pickett, Kate E.
Institution: University of Chicago, Chicago, IL
Funding Agency: National Institute on Drug Abuse
Project ID: DA014334
Project Funding Period: 1 September 2001 – 31 May 2003

Abstract: Studies of maternal smoking during pregnancy have traditionally conceptualized it as a relatively stable behavior, based on the assumption that few changes will occur after the transition to pregnancy. Those few studies that have examined changes over the course of the pregnancy have examined them categorically (e.g., third trimester smoking or not). In contrast, we present preliminary evidence of substantial fluctuation in maternal smoking over the course of the pregnancy, including repeated changes in overall status (i.e., smoking or not) and in categorical status (e.g., light to moderate). While these data provide evidence of individual fluctuation, group patterns of maternal smoking during pregnancy have not been empirically identified. Lack ; of empirical knowledge about patterns of maternal smoking seriously impedes scientific progress for two reasons. First, prenatal exposure to cigarettes has serious consequences, including accruing evidence of long term consequences such as increased risk of disruptive behavior disorders. Identifying the role that maternal smoking plays in the etiology of complex, multifactorial child outcomes will require more precise specification of exposure. Second, prevailing methods of prenatal cessation intervention are frequently limited to the first prenatal visit. Classification of specific patterns of smoking behavior may inform the development of targeted interventions. The proposed project is designed to classify patterns of maternal smoking during pregnancy utilizing sophisticated methods of trajectory analysis. We propose to conduct secondary data analysis of the Maternal-Infant Smoking Study of East Boston (MISSEB), a prospective population-based study with repeated measures of maternal smoking throughout the course of the pregnancy (n=873). Group patterns of maternal smoking trajectories (e.g., late pregnancy relapse, cycling between cessation and relapse) will be modeled using a semi-parametric mixed-model approach. Specific aims of the project are to: (1) characterize patterns of maternal smoking during pregnancy, using both self-reported and biochemical measures of maternal smoking and, (2) examine the explanatory power of these patterns for predicting adverse perinatal outcomes.

Title: Developmental Exposure to Nicotine
Principal Investigator: Poland, Russell E.
Institution: Cedars Sinai Medical Center, Los Angeles, CA
Funding Agency: National Institute on Drug Abuse
Project ID: DA014680
Project Funding Period: 30 September 2001 – 31 July 2004

Abstract: This is an R21 application to explore the development of an animal model to study the effects of parental and peripuberal exposure to nicotine. Nicotine remains an important drug of abuse worldwide. In the United States (U.S.), tobacco use is the single leading preventable cause of death. However, despite considerable negative publicity and health warnings, approximately 25 percent of the U.S. population still smoke. Aside from producing profound behavioral effects in the adult organism, nicotine also disrupts developmental processes in many species. Recent epidemiologic data suggest that fetal exposure to nicotine increases the risk for tobacco use during adolescence and adulthood, particularly in females. In addition, 75 percent of adult tobacco users report their first tobacco use occurred when they were "youngsters" (childhood or adolescence). In order to study this issue further, as well as to develop an animal model to elucidate potential underlying mechanisms, the effects of nicotine exposure during gestation on nicotine self-administration in adult male and female rat offspring will be studied. In addition, the effects of nicotine exposure during the periadolescent period on nicotine self-administration in adult offspring will be ascertained. It is hypothesized that nicotine exposure in utero will increase nicotine self-administration in adult offspring. Similarly, peripuberal exposure to nicotine also will increase nicotine self-administration during adulthood. The proposed studies will characterize the relationships between exposure to nicotine during critical periods of development and the acquisition, maintenance, extinction and re-initiation phases of nicotine self-administration. The results of these experiments should provide new and important insights on the relationships between prior nicotine exposure and nicotine-seeking behavior. In addition, since nicotine is considered as a "gateway" drug for the subsequent use of alcohol and other illicit drugs, the results of the proposed studies will lay the groundwork to further understand the factors which might increase vulnerability to drug addictions in general, and to nicotine abuse, in particular.

Title: Motivational Intervention for Pregnant Women Who Continue to Smoke After Receipt of Best Practice Cessation Services
Principal Investigator: Quinn, Virginia
Institution: Kaiser Foundation Research Institute, Oakland, CA
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040539
Project Funding Period: 1 October 2000 – 30 September 2003

Abstract: Purpose: To develop and test a brief, multi-component, motivational intervention for delivery by ultrasound technicians to smokers presenting for their routine mid-pregnancy ultrasound. Research Design: The proposed intervention will be tested using a historical usual care control group design. The control group will be impaneled in the first 7 months of recruitment. The intervention group will be impaneled in the 7 months following implementation of the cessation program. Data from baseline and postpartum interviews will be used to adjust for confounding influences and to identify the predictors of cessation.

Study Population: 284 adult pregnant smokers will be recruited from the diverse membership of a large multi-specialty group model HMO.

Intervention (if appropriate): The intervention consists of 10 to 15 minutes of counseling and written materials tailored to smokers' stage of change and characteristics that put them at risk for

continued smoking. Additionally, women will receive smoking-related health messages when presented with an ultrasound scan of their developing fetus. The intervention will be structured by the principles and techniques of motivational interviewing and provide cognitive/behavioral strategies for cessation. It will include previously identified elements of effective brief interventions.

Outcome Measures (If cessation or reduction, how defined): The primary dependent variable is biochemically confirmed abstinence in the 8th month of pregnancy.

Title: Motivational Interviewing to Prevent Postpartum Relapse
Principal Investigator: Quinn, Virginia
Institution: Kaiser Foundation Research Institute, Oakland, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 6KT-0206
Project Funding Period: 1 July 1997 – 30 June 2001

Abstract: The goal of this study is to develop and test an innovative relapse prevention program for women who stop smoking during pregnancy. Pregnancy offers women one of the best opportunities to stop smoking. Nearly half of the women who were smoking prior to pregnancy take advantage of this time of change and quit smoking, mainly to protect the health of their unborn child. Unfortunately, rates of relapse after delivery are high with as many as 70% of the quitters returning to smoking within 6 months of delivery.

Cigarette smoking is associated with many serious illnesses, especially those related to heart and lung disease. Although smoking carries additional risks for women of reproductive age, more than 25% of US women between the ages of 18 and 44 continue to smoke. Postpartum relapse re-exposes women to the health dangers of smoking. Further harm is done by exposing infants and children to passive smoke. Numerous studies have documented increased rates of respiratory infections, including pneumonia, bronchitis, and ear infections. More recently, passive smoke has been implicated in Sudden Infant Death Syndrome.

To develop an effective program we will adapt the principles and techniques of motivational interviewing to the context of postpartum relapse. Motivational interviewing is a supportive, non-judgmental counseling style that appears to be especially useful with behaviors that are difficult to change. It helps clients weigh the benefits and costs of their behaviors. The counseling will be delivered over the telephone by trained health educators in 4 to 6 brief calls. The literature identifies the influence of powerful barriers to maintenance such as being around other smokers, having a partner who smokes, and lack of confidence in the ability to stay off cigarettes. Counselors will help women identify their personal threats to maintenance, including lack of motivation to stay off cigarettes, and will assist women in developing effective coping strategies. The content of the program will be developed from telephone interviews and focus groups conducted among white, black, and Latino women who quit smoking during pregnancy. Subjects will be recruited from the diverse population of Southern California Kaiser Permanente. The effectiveness of the motivational interviewing program will be measured by comparing the bio-chemically confirmed 6-month postpartum abstinence rates among women who received the counseling program and women who did not. An effective postpartum relapse prevention program would make a significant contribution to the health of young women, their newborn infants, and other family members.

Title: Prenatal Smoking Cessation Relapse Prevention Trial
Principal Investigator: Quinn, Virginia
Institution: Kaiser Foundation Research Institute, Oakland, CA
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD036719
Project Funding Period: 1 May 1999 – 30 April 2003

Abstract: Smoking during pregnancy exerts an independent, adverse effect upon numerous reproductive outcomes, and thus the reduction in the prevalence of prenatal smoking has been a national priority for the past decade. Approximately a quarter of US women smoke prior to becoming pregnant, with a third of these smokers quitting prior to the start of prenatal care - and are referred to as Spontaneous Quitters (SQs). Several studies have documented that at least 25 percent of SQs relapse prior to delivery, and therefore the health of the mother and fetus is once again jeopardized due to tobacco exposure during pregnancy. To date, randomized trials testing various interventions have failed to reduce prenatal relapse with this group. This study proposes to develop a telephone counseling relapse prevention program based on the principles of motivational interviewing to address the needs of this unique group of recent quitters. The theoretically-grounded program will be developed during a formative assessment period consisting of in-depth interviews and focus groups with a representative sample of SQs. The effectiveness of the intervention will be tested under conditions of typical clinical practice among a diverse population of prenatal patients who are members of a large HMO (Southern California Kaiser- Permanente). A total of 480 SQs will be randomly assigned to either a) usual care -- consisting of provider advice which may be offered during prenatal visits and a self-help smoking cessation/maintenance booklet; or b) usual care + the experimental telephone-based counseling intervention. The principal dependent variable will be biochemically confirmed maintenance of cessation for the duration of pregnancy. If effective, the proposed intervention offers the opportunity to decrease the prevalence of prenatal smoking among the approximate 1 million US women who annually initiate prenatal care as prepregnancy smokers. Finally, as more than 75 percent of the women who stop smoking during pregnancy are SQs and given the high rate of postpartum relapse, learning about successful maintenance during pregnancy may aid intervention efforts to prevent the return to smoking after delivery.

Title: Epidemiology of Smoking Cessation--Genetic Influences
Principal Investigator: Rossing, Mary
Institution: Fred Hutchinson Cancer Research Center, Seattle, WA
Funding Agency: National Cancer Institute
Project ID: CA78784
Project Funding Period: 21 February 2000 – 31 December 2002

Abstract: Cigarette smoking remains the single most preventable cause of cancer mortality in the United States. However, although most current smokers report a desire to quit, the decline in adult use of tobacco has slowed in recent years. These observations highlight the need for new insights into determinants of smoking cessation. Available data support a role of genetic influences on smoking behavior; these effects may be most evident in populations, such as the United States, with relatively strong social pressures against smoking. The goal of the proposed study is to examine genetic influences on smoking cessation. Among 700 female participants in a smoking cessation trial, we will assess the relation of polymorphisms of genes involved in the neurologic activity or metabolism of tobacco and nicotine with the likelihood of being a non-smoker at the end of the trial and when re-contacted several years later. Of particular interest are genes involved in dopaminergic neurotransmission in the mesolimbic "reward" pathway of the brain, as the addictive effects of tobacco and nicotine operate primarily through this system. Blood specimens collected in the proposed study will, in addition to enabling the work currently proposed, form a resource for future genetic studies of smoking cessation as new

and relevant polymorphisms are identified and characterized. Increased understanding of genetic influences on the ability of motivated, healthy individuals to quit smoking may lead to improvements in success rates of smoking cessation efforts. In the future, such knowledge may allow the identification of subgroups of individuals who are most likely to benefit from particular pharmacologic interventions.

Title: Accelerating Progress of Smoking Cessation in Pregnancy
Principal Investigator: Ruggiero, Laurie
Institution: University of Rhode Island, Kingston, RI
Funding Agency: National Cancer Institute
Project ID: CA71098
Project Funding Period: 1 January 1998 – 31 July 2002

Abstract: Smoking continues to be the most preventable cause of death and disability in the United States. As many as 87 percent of lung cancer deaths are secondary to smoking, as well as 30 percent of all cancer deaths. The mortality trends in lung cancer rates for women are rising more rapidly than for men and lung cancer is the leading cause of death from cancers in women. Given the mortality trends in lung cancer for women and the link to their smoking patterns, cancer prevention efforts should focus on targeting high risk female mothers as well as take advantage of teachable moments to best accelerate progress toward smoking cessation in women. Economically disadvantaged pregnant women are both more likely to smoke prior to becoming pregnant and less likely to quit during pregnancy than other women of childbearing age. Even when they do quit during pregnancy, they are likely to relapse postpartum. Therefore, pregnancy and the postpartum period is an important window of opportunity for interventions to motivate these women and accelerate their progress toward smoking cessation. Reducing smoking in pregnancy and postpartum would serve to reduce health risks for two individuals, mother and child, thereby, promote the cancer prevention objectives set forth in Healthy People 2000. The proposed project is a collaborative effort of the Cancer Prevention Research Consortium at the University of Rhode Island and the Women and Infants Hospital of Rhode Island, a teaching hospital of Brown University Medical School. The proposed study is designed to evaluate the impact of an innovative stage-based individualized, interactive intervention (Individualized Intervention) on smoking cessation compared with a stage-matched self-help approach (self-help Intervention) and a standard care condition. The Individualized and self-help Interventions will be based on existing theoretical concepts and behavior change techniques of the Transtheoretical Model. The target population will be low-income culturally diverse pregnant women attending public maternity clinics.

The proposed study will involve a prospective randomized, three-group, repeated measures design. Information gained from the project data will help determine the efficacy of this innovative smoking cessation intervention, identify the impact of the intervention on intermediate or process variables, and provide insight into the influence of pregnancy and delivery on readiness for changing smoking behaviors. The benefits of promoting smoking cessation programs during pregnancy will not only have a long-range impact on the individual, but also on the overall health of the family.

Title: Stage-Based, Expert System-Driven, Smoking Cessation Program for Low-Income Pregnant Women
Principal Investigator: Ruggiero, Laurie
Institution: University of Illinois at Chicago School of Public Health, Chicago, IL
Funding Agency: Robert Wood Johnson Foundation
Project ID: 047472
Project Funding Period: 1 December 2002 – 31 August 2003

Abstract: Specific aims of this project are to develop motivational enhancements and conduct formative evaluations based on the use of fetal ultrasound assessment, carbon monoxide measurement, and urine cotinine measurement in ethnically diverse, low-income pregnant women attending public maternity clinics.

Title: A Randomized Controlled Trial of Sustained Release Bupropion for Prevention of Relapse in Women Who Quit Smoking During Pregnancy
Principal Investigator: Samelson, Renee
Institution: Brigham and Women's Hospital/Harvard Medical School, Boston, MA
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040665
Project Funding Period: 1 October 2000 – 30 September 2005

Abstract: To evaluate whether bupropion given to women who have quit smoking during pregnancy is effective in decreasing postpartum relapse. Research Design. We propose a randomized placebo controlled trial of 300 women to determine whether women treated with bupropion have lower rates of smoking relapse than women receiving placebo. Study Population. Subjects will be recruited from the clinical practices at Brigham and Women's Hospital. Pregnant women at least 18 years of age, who have quit smoking within the year prior to delivery and have not resumed smoking will be eligible to participate. Patients with contraindications to treatment with bupropion and breastfeeding women will be excluded. Intervention (if appropriate). Subjects will be randomized to receive bupropion or placebo. Those randomized to bupropion will be receive 150 mg by mouth twice a day for 9 weeks. Outcome Measures (If cessation or reduction, how defined). The primary outcome measured is smoking cessation at 3 and 6 months. This will be measured using a urine cotinine to creatinine ratio.

Note: The abstract information was obtained from data associated with Dr. Diana Rodriguez-Thompson, at Brigham and Women's Hospital.

Title: Effects of Prenatal Nicotine Exposure on Nicotinic Receptors
Principal Investigator: Sargent, Peter
Institution: University of California, San Francisco, San Francisco, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 9RT-0101
Project Funding Period: 1 July 2000 – 30 June 2003

Abstract: Cigarette smoking is a highly addictive behavior. The chemical in cigarettes that gives tobacco users their "kick" is nicotine, and this chemical has a number of effects on the brain. The target of nicotine is a family of protein molecules called "nicotinic receptors." The real purpose of these molecules isn't to respond to nicotine but rather to respond to a chemical "transmitter" that some nerve cells in the brain use to communicate with each other. Nicotine interferes with this communication, enhancing some connections between nerve cells and depressing others. Nicotine has both rapidly-acting and long term effects on its receptors; it is the long term effects that probably lead to our becoming addicted to nicotine. To understand

these effects, it is important to study the receptor molecules with which nicotine interacts. I am doing this by looking at whether long-term exposure to nicotine changes the number of receptors in the brain and whether it alters the way those receptors work. I will expose rats at around the time of birth to low levels of nicotine for a few weeks, to mimic the exposure they might have received if their mother had "smoked." I will then examine the nicotinic receptors in these rats to learn how they have been affected by this long-term exposure to nicotine. This research will hopefully tell us more about the effects of maternal smoking on the unborn child.

Title: Coping During Spontaneous Smoking Cessation in Pregnancy
Principal Investigator: Scheibmeir, Monica
Institution: University of Kansas Medical Center, Kansas City, KS
Funding Agency: National Institute of Nursing Research
Project ID: NR007735
Project Funding Period: 1 September 2001 – 31 August 2003

Abstract: Up to 30 percent of pregnant smokers spontaneously quit smoking during pregnancy. Unfortunately, the effects of cessation are short-lived with relapse rates reaching up to 70 percent within three to six months following delivery. In spite of established behavioral interventions and pharmacotherapies discovered in the past ten years, the prevalence of smoking in pregnant women, as well as relapse in the postpartum period, remains very high. Gaps in our knowledge exist about the efficacy of coping strategies used by pregnant women to successfully quit smoking. This exploratory study will assess the smoking cessation strategies used by low-income women attending publicly funded prenatal clinics who spontaneously quit smoking during pregnancy and after delivery using quantitative and qualitative methods. The specific aims are to: (1) Describe the coping strategies that low-income spontaneous quitters use during pregnancy and the early postpartum period, (2) Compare the self-efficacy to quit smoking of low-income spontaneous quitters with that of low-income pregnant smokers, and (3) Clarify the relationship between coping strategies and self-efficacy among low-income spontaneous quitters during pregnancy and the early postpartum period. Two county health prenatal clinics will be used to recruit 30 participants for the sample of spontaneous quitters and 150 women will be recruited for the sample of continuous smokers. Data collection for the sample of spontaneous quitters will include face-to-face interviews with participants and questionnaire data collected twice during the pregnancy and once at six-weeks postpartum. For participants who continue to smoke during pregnancy, data collection will be done once and include written questionnaire information. Data analysis methods will include descriptive statistics, Pearson Product Moment correlations, mixed linear modeling and qualitative content analysis. Triangulation of the qualitative and quantitative data will enhance the validity of the findings. This study will address a critical gap in our knowledge of the primary strategies used by women to remain abstinent from cigarettes. New insights on the key factors associated with successful abstinence will be used to enhance this window of opportunity that pregnancy provides for women smokers.

Title: Prevention of Smoking Relapse in Women
Principal Investigator: Schmitz, Joy M.
Institution: University of Texas Health Science Center, Houston, TX
Funding Agency: National Institute on Drug Abuse
Project ID: 1DA008888
Project Funding Period: 1 June 1994 – 30 June 2003

Abstract: Cigarette smoking is a prototypic case of drug dependence and a dominant cause of coronary artery disease (CAD). In the past several decades, women's rates of CAD and other smoking-related diseases have increased in proportion to their increased exposure to tobacco smoking. Effective smoking cessation interventions have the enormous potential of reducing

smoking prevalence and improving women's health. The proposed studies provide a direct and logical extension of our previous research evaluating smoking cessation and relapse prevention (RP) treatments in health-compromised women. Our ongoing work fails to provide strong evidence of RP's superiority over a comparison treatment, and underscores the need to develop more potent interventions to prevent relapse in this refractory population. We propose to do this by combining RP with a new effective and safe pharmacologic intervention. Two parallel, double-blind, placebo-controlled studies will be conducted, each employing a 2 X 2 factorial design that crosses medication (bupropion 300 mg/d vs. placebo) and therapy (RP vs. Discussion Support). Women who smoke will be randomized into one of the four treatment combinations. The 7-week trial will involve weekly clinic visits at which time participants will receive medication doses and individual therapy. The integrated treatment of RP and bupropion 300 mg/d is expected to increase significantly the probability of abstinence and produce improvements in other relevant domains, including self-efficacy, coping, craving, and depressive symptomatology. Study 1 will enroll 104 women with stable CAD. Study 2 will enroll 104 women with significant CAD risk factors, but without diagnosis. The studies are technically rigorous and scientifically innovative. An analogue role-play test will be used to examine coping skills acquisition as a function of treatment and as a predictor of outcome. To verity treatment fidelity we will use written therapy manuals, trained therapists, and adherence checking systems. Appropriate procedures to safeguard against adverse events will include initial medical evaluation, baseline ECG, daily recording of pill taking and cardiac symptoms using an electronic medication dispensing and diary unit, weekly measurement of vital signs and side effects, and regular contact with the study psychiatrist and cardiologist. The primary dependent measure will be smoking status, validated by saliva cotinine. Assessments at 3-, 6-, 9-, and 12-months following maintenance treatment will be used to evaluate the relative durability of treatment effects. In summary, this research will contribute new theoretical and empirical information concerning the independent and interactive effects of two proven interventions, and shed light on the processes by which these interventions work. We expect that this study will result in the development of an efficacious treatment for smoking in medically at-risk women, and will therefore have major implications for health and health care costs related to drug dependence and medical disorders.

Title: Behavioral Genetics of Nicotine Dependence
Principal Investigator: Sirevaag, Erik J.
Institution: Washington University, St. Louis, MO
Funding Agency: National Institute on Drug Abuse
Project ID: DA014374
Project Funding Period: 5 August 2001 – 31 May 2006

Abstract: This proposed project, which is submitted by a new investigator, will examine genetic influences on biological responses to nicotine in women using a pharmacogenetic paradigm. Specifically, this project will: (i) determine whether there are substantial genetic influences upon reactivity to nicotine in non-smokers, and (ii) examine the relationship between level of reactivity, progression to regular smoking and risk for dependence. Genetic influences upon nicotine reactivity will be determined within the context of a laboratory nicotine challenge protocol which will provide subjective, physiological and performance-based measures of nicotine responsivity in twin pairs stratified by smoking status. Monozygotic (MZ) and dizygotic (DZ) correlations in twin pairs concordant for non-smoking will be used to estimate the contributions of genes, shared environment and within-family environmental differences in experience to variability in measures of nicotine reactivity. Twin pairs can also be observed in smokers. The relationship between nicotine reactivity and risk for dependence will be evaluated by estimating the correlations, stratified by zygosity, of the responses to nicotine in non-smoking twins drawn from smoking-discordant twin pairs with the level of dependence evidenced by the

smoking co-twin. Dependence will be defines as score on the modified Fagerstrom FTND Dependence scale. To enhance statistical power, same-sex full siblings of smoking twins will also be tested whenever available. Previous epidemiological studies have indicated that at least some factors influencing smoking dependence appear to be substantially heritable. Data obtained from the proposed project may facilitate the elucidation of critical (phenotypic) differences in biological responses to nicotine. These results could subsequently be used to inform future studies examining the genetics of smoking dependence and persistence and may also impact the development of appropriately targeted smoking prevention and cessation interventions.

Title: Motivational Enhancement Therapy for Pregnant Smokers
Principal Investigator: Stotts, Angela
Institution: University of Texas Health Science Center, Houston, TX
Funding Agency: National Cancer Institute
Project ID: CA84805
Project Funding Period: 30 September 1999 – 29 September 2002

Abstract: Adverse health effects of cigarette smoking on pregnancy outcomes are significant and costly. Despite the well-publicized risks, almost one-quarter of women continue to smoke throughout pregnancy. Further, women from disadvantaged backgrounds are over-represented among pregnant smokers. Innovative smoking cessation interventions are needed to increase quit rates in pregnant smokers, particularly in low socioeconomic populations. The proposed study evaluates the feasibility and efficacy of theoretically innovative prenatal smoking cessation intervention based on Motivational Enhancement Therapy (MET). A randomized, controlled, pretest/posttest, between groups design will be employed to compare MET with usual care for reducing smoking rates among pregnant women. Sixty-seven pregnant smokers, at least 16 years of age and attending a university-based, public clinical will be assigned to each of the two groups. In addition to achieving higher abstinence rates, we expect that the MET intervention will produce significant changes in several domains of function (e.g. coping, self-efficacy, readiness to change). Smoking outcomes will be assessed via objective (saliva cotinine analyses) and self-report measures. Logistic regression procedures will be used to examine posttreatment smoking group differences. Repeated measures analysis of variance will be used to evaluate treatment related changes in other domains of functioning. MET strategies and techniques are implemented using an empathic, non- confrontational yet directive counseling style to enhance motivation and reduce ambivalence about change. The MET intervention consists of four counseling sessions and one stages of change based, personalized feedback letter delivered over 8-weeks. The first counseling session will occur at the clinic during a woman's first prenatal visit with the three subsequent sessions being conducted by telephone. Therapy manuals, trained counselors, competency checks, and adherence rating scales will be used to verify treatment fidelity. This research will contribute important theoretical and empirical information concerning the efficacy of a new and innovative intervention for pregnant smokers and will provide the basis for larger effectiveness trials.

Title: Brief Intervention for Drug Use in Pregnant Women
Principal Investigator: Svikis, Dace S.
Institution: Virginia Commonwealth University, Richmond, VA
Funding Agency: National Institute on Drug Abuse
Project ID: DA011476
Project Funding Period: 1 February 1998 – 31 January 2004

Abstract: Prenatal drug use is associated with a variety of medical and developmental consequences. Although many women spontaneously quit substance use on learning they are pregnant, others continue to use throughout pregnancy. Compared to alcohol and tobacco, little

is known about prenatal quitting rates for illicit drug use. Also, little is known about the influence of alcohol and tobacco use on prenatal illicit drug use, and about psychological and other factors that account for the differences in ability of pregnant women to quit illicit drug use. Finally, better interventions are needed to enhance prenatal substance use quitting rates. Currently, the most common intervention is brief professional advice (BPA), which has only limited clinical effectiveness. To address these issues, a random-assignment clinical trial will be conducted to assess the effectiveness of two promising interventions of increasing clinical intensity on reducing prenatal opiate and/or cocaine use. Subjects will be pregnant women of lower socioeconomic status with less than a high school education (estimated gestational age at admission 20 weeks). Subjects with pre-pregnancy/prior prenatal opiate and/or cocaine use will be randomly assigned to one of three intervention groups (N=237/group): (1) BPA only (standard medical practice); (2) BPA in combination with behavioral incentives (BI); and (3) BPA in combination with BI and Motivational Enhancement Therapy (MET). Subjects will be followed prospectively throughout pregnancy and into the post partum period to determine changes that occur in substance use. Both self-report and objective measures of substance use will be employed. The study will also identify psychological and other factors (e.g., depression, maternal-infant interactions, drug use by significant other) that influence quitting and relapse to prenatal substance use. A comparison group of non-opiate/cocaine users (N=237) will be included to assess effects of prenatal opiate and/or cocaine use on maternal and infant outcomes. The study will also determine the influence of pre-pregnancy substance use on within-pregnancy quitting rates of illicit drug use, and the impact of quitting on maternal and infant health.

Title: Gender, Menstrual Cycle and Smoking Cue Reactivity
Principal Investigator: Upadhyaya, Himanshu P.
Institution: Medical University of South Carolina, Charleston, SC
Funding Agency: National Institute on Drug Abuse
Project ID: DA016511-010003
Project Funding Period: 1 September 2002 – 31 August 2007

Abstract: Cigarette smoking is common; approximately 25% of adults over 18 years of age are regular smokers. Craving is an important component of the symptoms experienced during smoking cessation and it considered a crucial factor in relapse. There is some evidence that menstrual cycle may impact smoking and relapse for women, but this has not been well explored. Hence, menstrual cycle phase may be an important modulator of craving and may contribute in relapse among women attempting smoking cessation. There is also data suggesting that there are different subjective and physiological responses to nicotine during different phases of the menstrual cycle, but little work has been done in exploring the effect of menstrual cycle phases on smoking cue-reactivity. Research on the effect of menstrual cycle phase on smoking cue-reactivity may be especially important for smoking cessation treatment as it is common practice in smoking cessation programs to set a quit date prior to the quit attempt. Knowledge about the menstrual cycle phase differences in cue-reactivity may help in setting an optimal quit date for women in order to maximize the chances of successful smoking cessation The specific aims of the proposed project are: 1. To examine the effect of menstrual cycle phase on reactivity to "in vivo" cigarette smoking cues and negative affect-inducing cues in nicotine-dependent women. 2. To examine gender differences in the reactivity to "in vivo" cigarette smoking cues and negative-affect inducing cues in nicotine-dependent men and women. The proposed project will use both in vivo smoking cues, as well as negative affect/stress cues to explore smoking cue-reactivity in female smokers during four biologically verified menstrual phases. Female cigarette smokers' reactivity will also be compared to the reactivity of male cigarette smokers who will be tested in a similar protocol. Both subjective craving and mood responses, as well as physiological responses (e.g., real-time heart rate, galvanic skin conductance) will be measured

during the study. This information may help in designing specific smoking-cessation approaches for nicotine-dependent women.

Title: Exercise Intervention for Depressed Smokers
Principal Investigator: Vickers, Kristin S.
Institution: Mayo Clinic Rochester, Rochester, MN
Funding Agency: National Cancer Institute
Project ID: CA094760
Project Funding Period: 1 September – 31 August 2004

Abstract: This application will serve as the foundation on which the Principal Investigator will build a line of research dedicated to the area of nicotine dependence treatment for depressed smokers. Cigarette smoking is the single most important preventable cause of morbidity, mortality, and excess health costs in the United States. Depressive symptoms have been identified as a major barrier to smoking abstinence, and depressed women attempting smoking cessation may be particularly vulnerable to relapse related to negative affect. Consequently, researchers have identified the need for smoking interventions specifically targeting depressed women. Mood management interventions have been shown to increase the smoking abstinence rates for depressed smokers. Exercise is effective in the treatment of depression and is an aid for smoking cessation among women, but has not been studied in depressed smokers. Further, exercise interventions for smoking cessation have not included pharmacotherapy (e.g., nicotine patch). The proposed project addresses the current lack of effective smoking interventions specifically targeting depressed women. The specific aims of this pilot study are: 1) to evaluate the feasibility of an individually-tailored exercise intervention for depressed smokers, 2) to evaluate in a pilot randomized trial the effect of the exercise intervention compared to a health education intervention on the smoking abstinence rates at the end of treatment (week ten) and at week 24, 3) to examine the effect of the exercise intervention on depressive symptoms, and 4) to examine the relationship between baseline depressive symptoms, exercise adherence, and change in exercise levels among those assigned to the exercise intervention. We hypothesize that the exercise intervention will be feasible and associated with higher seven-day point-prevalence smoking abstinence rates than the health education intervention at weeks 10 and 24. Sixty women between the ages of 18 and 50 who are classified as depressed, based on a Center for Epidemiologic Studies - Depression Scale (CES-D) score of greater than or equal too $16, will be randomly assigned to a ten week individual program of: 1) individually-tailored, moderate-intensity exercise or 2) health education. Participants in both conditions will receive nicotine patch therapy and nicotine dependence counseling. Data collected will provide feasibility and effect size estimates to be used for an R01 submission. The ultimate goal of this work is to develop effective interventions that will reduce future tobacco-related morbidity and mortality among depressed smokers.

Title: Individualized Relapse Prevention Among Women Smokers
Principal Investigator: Wetter, David
Institution: Center for Health Studies, Seattle, WA
Funding Agency: National Cancer Institute
Project ID: CA74517
Project Funding Period: 1 September 1997 – 30 June 2002

Abstract: Among women, the epidemic of smoking related cancers continues to grow and lung cancer recently surpassed breast cancer as the leading cause of cancer mortality. Smoking cessation is a cornerstone of cancer prevention and control because cancer risk declines following smoking cessation. Unfortunately, relapse is the "rule rather than the exception"

among smokers attempting to quit and relapse remains the most refractory aspect of nicotine dependence. Women appear to have higher relapse rates than men and relapse prevention has been identified as a priority in reducing smoking prevalence among women. Basic and clinical research on the precipitants of smoking relapse have demonstrated that coping behaviors are powerful determinants of relapse. The most influential model of smoking relapse, "relapse prevention" (Marlatt & Gordon, 1985), proposes that self-efficacy and outcome expectations are causal determinants of coping behaviors, and in fact, these variables have been among the better predictors of relapse. Moreover, there is evidence that interventions based on relapse prevention theory are effective, that they instill coping skills, and that coping skill acquisition mediates intervention effects on abstinence. The specific aims of this proposal are to l) Develop and evaluate the efficacy of a unique, self-help smoking relapse prevention intervention among women. The intervention will be administered via a small hand-held computer. The general content of the intervention will be tailored specifically for women and each participant's intervention will be individualized prior to delivery based on state-of-the-art "ecological momentary assessment" techniques; and, 2) Examine the effects of the relapse prevention intervention on hypothesized treatment mechanisms (coping behaviors, self-efficacy, processes of change, negative affect, perceived stress) and the impact of those mechanisms on relapse, i.e. test for mediation effects. The proposal translates basic and clinical behavioral science research into a novel, theoretically-based treatment that provides individualized, situation-specific coping strategies, motivational and supportive messages, and other relapse prevention information. Moreover, unlike conventional relapse prevention treatments, participants have access to the intervention at an time and in any place, i.e. the intervention occurs in real-time in naturally occurring settings. The intervention has the potential to produce significant advances in the prevention of smoking relapse.

Title: Smoking Relapse Prevention Among Postpartum Women
Principal Investigator: Wetter, David W.
Institution: University of Texas MD Anderson Cancer Center, Houston, TX
Funding Agency: National Cancer Institute
Project ID: CA089350-01A1S1
Project Funding Period: 1 February 2002 – 31 January 2007

Abstract: Postpartum relapse rates among women who quit smoking during pregnancy are exceedingly high (i.e., approximately 45 percent at 2-3 months postpartum, 60-70 percent at 6 months, and up to 80 percent at one year). These high rates of postpartum relapse are surprising because they occur in a population where the majority of women have been abstinent for 7-9 months prior to giving birth. Thus, the tremendous public health opportunity to facilitate long-term abstinence from tobacco among mothers as well as reduce the detrimental effects on smoking on their children is not being fully realized. The overall aim of this project is to develop and evaluate a "Motivational Relapse Prevention" (MRP) treatment for reducing postpartum smoking relapse among women who quit during pregnancy. MRP will utilize a motivational enhancement approach that specifically targets increasing commitment and intrinsic motives for maintaining postpartum abstinence, relapse prevention theory constructs (i.e., self-efficacy, outcome expectancies, coping behavior), and issues of particular relevance to postpartum women (e.g., negative affect, stress, social support, weight concerns). Treatment will be telephone-based and is designed to be easily disseminated to population-based settings for tobacco control (e.g., state quitlines, health care systems). In addition, the project will assess the cost-effectiveness of MRP. Participants (N=400) will be randomly assigned to one of two groups: 1) Standard Relapse Prevention, or 2) MRP. MRP will consist of six telephone counseling calls, and relapse prevention self-help materials designed specifically for the postpartum period. Postpartum assessments will occur at weeks 8, 26, and 52.

Title: Smoking, Gender, Hormones and the Brain
Principal Investigator: Zaidel, Eran
Institution: University of California Los Angeles, Los Angeles, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 8IT-0112
Project Funding Period: 1 July 1999 – 30 June 2001

Abstract: Despite steady progress in the fight against nicotine addiction over the past 25 years, the percentage of female smokers is increasing. The United States may soon become the first society in history in which more women than men smoke. In part, this is because women are less likely to be able to quit, whether they try on their own or with the help of smoking cessation programs. This appears to be especially true for nicotine replacement therapies (such as nicotine patches or gum), which have helped a greater percentage of men than women in almost every study. There is thus a clear need for new forms of treatment which are tailored especially for women.

Nicotine is an addictive drug, and the primary reason people use cigarettes is to get nicotine. However, other aspects such as the taste of smoke also become pleasurable to the smoker. These other aspects may be more important for women, and this could be one reason that nicotine in the patch and gum may be less likely to help them give up cigarettes. To test this theory, we will study the differences in men and women's reaction to nicotine alone, or to smoking a cigarette which contains very little nicotine.

Smokers often feel that cigarettes help them stay focused, and one of the symptoms of nicotine withdrawal is difficulty paying attention. In women, withdrawal symptoms and attentional ability may change at different points of the menstrual cycle. Our research will use a measure of attention to study the effect of smoking and withdrawal across the menstrual cycle. Our test is also able to determine differences between the right and left sides of the brain, and the effectiveness of the connections between the two sides. This is useful since gender, menstrual hormones, and withdrawal may be associated with changes in right/left balance. The brain controls smoking, as it does any other behavior. Knowledge of which brain areas are responsible will let new treatments to help smokers quit become more effective, by specifically targeting those areas. Our research will help provide this knowledge, with special emphasis on factors (attention, menstrual cycle, and right/left brain function) that are believed to be important to female smokers.

Activity Type: Media Campaign
Title: Great Start
Sponsor: American Legacy Foundation
Date: December 4, 2001 (Launched)

Description/Agenda: (Press Release) The American Legacy Foundation announced today the launch of its "Great Start" campaign to help the hundreds of thousands of women who smoke during their pregnancy to quit. Great Start is the first national campaign of its kind in the United States. The campaign includes:
The first national telephone "Quitline" offering pregnant smokers free counseling sessions. Quitline operations, managed by the American Cancer Society, are available 24 hours a day, beginning today. The toll-free number to call is 1-866-66-START. A national television advertising campaign in all 50 states and the District of Columbia. Utah First Lady Jacalyn S. Leavitt and the wives of governors of 15 other states appear in ads that run in their home states. "About 426,000 women smoke during pregnancy each year in America," said Dr. Cheryl Healton, Legacy president and CEO. "That includes 13 percent of all pregnant women, and 18

percent of pregnant young women aged 15-19. We know that many of these expectant mothers want to stop smoking and would stop if they received assistance. We hope that Great Start will provide tens of thousands of women with the help they need to quit smoking during their pregnancy, and quit for good." American Cancer Society Chief Executive Officer John R. Seffrin, Ph.D., said, "The American Cancer Society takes care of more than a million telephone callers annually. We are the only organization in the nation with the capacity and the capably trained smoking cessation counseling resources to support Great Start. We are delighted to support our colleagues in the American Legacy Foundation in this important new campaign to positively influence the health of these expectant mothers and their babies." Healton said that smoking during or after pregnancy has been linked to one in 10 infant deaths. Smoking dramatically increases the risk for a wide range of reproductive health problems including miscarriage, stillbirth, and premature delivery. Women who smoke are also nearly 70 percent more likely to have a low birth weight baby. Smoking during pregnancy, or smoking by a mother or father around babies or young children (secondhand smoke exposure), can cause common children's health problems including asthma, pneumonia, bronchitis, hearing problems, and learning and behavioral problems. Smoking also causes about 1,000 cases of sudden infant death syndrome each year nationwide. "The U. S. ranks 26th in the world in infant mortality," Healton said. "Effective smoking cessation programs for pregnant women can help save many children." Starting today, pregnant smokers can call the toll-free Great Start Quitline to receive telephone counseling sessions with a counselor who is specially trained to help pregnant smokers quit. Spanish-language counseling is also available. Healton said, "The Quitline allows any expectant mother who smokes, anywhere in America, to get help quitting just by reaching for a telephone." Great Start has the support of a coalition of women state leaders organized and led by Utah First Lady Jacalyn S. Leavitt. The coalition includes representatives from the following states: Alaska, Arkansas, California, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Michigan, Montana, Ohio, Oklahoma, Tennessee, Texas, and Washington. "The Great Start campaign is vitally important," Mrs. Leavitt said. "It will bring new visibility to a serious health problem that hasn't received the attention it deserves. We believe we can motivate pregnant women to take the first step toward a healthier family." The television ads deliver the inspiring message that smokers can make a difference in their health and the health of their babies if they quit smoking, and encourage pregnant women to call the toll-free Quitline for assistance. The national television campaign in all 50 states and the District of Columbia begins on Dec. 18. Ads begin running today in the states which are part of the coalition.