Interventions for Prevention & Treatment

Interventions for Prevention & Treatment – Addressing tobacco control interventions to prevent tobacco use and to treat tobacco addiction

Over 80 studies were identified that have bearing on development and testing of interventions for prevention of and treatment for tobacco use and its negative health consequences. Most of the research efforts are involved in development and testing of interventions for treatment of smokers, particularly pregnant smokers, while few studies appear to be focused on smoking prevention.

Interventions for Prevention of Smoking and Related Health Risks

Researchers at the University of North Carolina Chapel Hill are testing the use of anti-smoking socialization to prevent children from smoking in households where parents smoke cigarettes. An effort at Colorado State University is examining the use of media campaigns to prevent rural 7^{th} and 8^{th} grade Mexican American and White non-Hispanic students from smoking. Information regarding the relationship between media exposure and cigarette smoking among teenage girls was recently collected by researchers at the University of Southern California. This information will enable health professionals to design more successful tobacco use prevention programs to reduce media influences on female adolescents. Research is being conducted to determine the developmental precursors to substance use in girls. Some efforts are focused on gaining an understanding of the health risks associated with smoking, e.g., cancer and fetal developmental disorders. This information can be used in educational information aimed at prevention and treatment of smoking.

Interventions for Treatment of Smokers

An effort at Louisiana State University is aimed at determining what types of interventions will be most successful in helping female students to quit smoking. Several studies are examining sex, menstrual cycle, and genetic influences on nicotine dependence and the ability of individuals to quit smoking. This information will aid in the development of more successful smoking cessation interventions. Information is being collected at the University of South Carolina to develop pharmacological interventions for correcting the behavioral problems associated with chronic tobacco use. Bupropion use, cognitive-behavioral therapy, and group therapy are being examined. Ongoing studies are testing the effectiveness of nicotine replacement therapy. One study examined the use of a nicotine patch to aid in smoking abstinence, and similarly examined the efficacy of the antidepressant fluoxetine. Other studies are comparing the effectiveness of nicotine replacement therapy combined with smoking cessation group therapy, and nicotine replacement therapy combined with aerobic exercise. Several studies are examining interventions that address postcessation weight gain. Researchers at the University of Wisconsin recently examined whether nicotine replacement therapy can help women who are concerned over postcessation weight gain. Moderate exercise with or without cognitive-behavioral smoking cessation therapy is being tested at Miriam Hospital in Providence, Rhode Island. Estrogen replacement therapy for postmenopausal women is being examined for its ability to help minimize weight gain and affect mood in women trying to quit smoking. Exercise is being examined as a treatment for depressed women attempting smoking cessation. The Center for Health Studies in Seattle recently tested the use of a motivational message from a pediatric health care provider, self-help materials, and several follow-up contacts to encourage mothers to quit smoking. Efforts are being made to incorporate tobacco treatment interventions into routine maternity case management and prenatal care services.

Interventions for Cessation Treatment of Pregnant Smokers

A focus of a number of studies is to develop and test interventions to aid in smoking cessation in pregnant mothers to prevent infant morbidity and mortality. Several studies are focused on gaining information that will aid in development of more effective interventions for treatment of pregnant smokers. Information is being collected at East Carolina University on the relationship between maternal depressive symptoms and other psychological factors and smoking cessation in pregnancy. A study by the Sequoia Foundation collected information on tobacco exposure levels during pregnancy. The Indigenous Peoples Task Force is collecting information on patterns of tobacco use among Minnesota's pregnant American Indian women.

A variety of interventions to promote smoking cessation in pregnant women are being compared and tested. These interventions include health education materials and programs, incentive programs, motivational enhancement therapy, telephone counseling, professional advice, nicotine replacement therapy, and bupropion treatment. Other interventions include testing the use of a reimbursement system for encouraging smoking cessation in Medicaid recipients. Research is being conducted at Duke University and the University of Connecticut to determine the efficacy of nicotine replacement therapy for treatment of pregnant smokers. At least three studies are testing the use of motivational enhancement therapy in reducing smoking during pregnancy. Researchers at the University of Alabama, Massachusetts General Hospital, the Kaiser Foundation, Duke University, and Brown University are testing multiple interventions, including various types of educational materials.

Interventions for Prevention of Smoking Relapse during Pregnancy and Postpartum

Several studies are focused on testing interventions for smoking relapse prevention during pregnancy and postpartum. Interventions being tested include bupropion treatment, self-help using a handheld computer, telephone counseling, motivational interviews, and educational booklets. Researchers at the University of California and at Brigham and Women's Hospital are testing the use of bupropion for preventing postpartum smoking relapse. Another effort is examining the use of a self-help smoking relapse prevention intervention using a small handheld computer that is individualized based on state-of-the art ecological momentary assessment techniques. An effort is ongoing to develop a series of cost-effective Stay Quit booklets based on theory and research on smoking relapse. A study at the University of Pittsburgh is collecting information on the effects of mood and weight concerns on postpartum smoking.

Other Related Activities

Several activities besides research studies that are contributing toward the development and testing of interventions for prevention and treatment of smoking include media campaigns, websites, and meetings. A national telephone Quitline is being offered and tested by the American Legacy Foundation. Several resources for smokers interested in quitting are provided by the National Women's Health Information Center on the "A Breath of Fresh Air" website. Topics discussed in the recent Annual Investigator Meeting 2002, Women and Smoking: Smoking Has No Glass Ceiling, included prevention and cessation strategies for women and girls and novel cessation approaches.

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: 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: 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: Mentored Investigator Award in Women's Health
Principal Investigator: Boardman, Lori A.
Institution: Women and Infants Hospital-Rhode Island, Providence, RI
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD001307
Project Funding Period: 25 September 2001 – 31 August 2006

Abstract: The purpose of this award is to provide support for Dr. Lori Boardman to pursue formal training in the fields of biostatistics, epidemiology and public health, thereby attaining the necessary theoretical and methodological background to further a career in patient- oriented research. The final three years of the award will be devoted to the design, implementation, analysis of data and preparation of the results of a randomized controlled trial of two smoking cessation interventions in a cohort of women referred for the evaluation of abnormal Papanicolaou smears. The primary aims of this study are to evaluate smoking cessation rates between the two groups and to confirm self-reports of cessation through measurement of cervical mucus cotinine. The secondary aims are to determine the regression rate of cervical neoplasia in women who quit smoking compared to those who continue and to assess the independent and combined contribution of human papillomavirus and smoking on the natural history of atypical or low-grade cervical neoplasia (includes cytology and/or histology). This trial will be conducted with the guidance of a multidisciplinary and experienced team including experienced women's health and behavioral health researchers, epidemiologists, an oncologist, and a statistician. Immediate Career Objectives: Pursue formal training in research design and analysis by obtaining a master's degree in public health; Improve abilities to design, perform, analyze and communicate research findings through the preparation of a master's thesis and formal presentations of ongoing research stemming from clinical work in cervical neoplasia; Implement and complete a randomized trial of two smoking cessation interventions in women with cervical neoplasia. Lone-Term Career Objectives: Become an independent and productive investigator in the field of women's health care; Secure independent grant funding for patient-oriented research; Become a leader in academic medicine and mentor more junior investigators interested in women's health.

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: TBA
Principal Investigator: Bowen, Margie
Institution: HealthPlus, New York, NY
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: A mini-grant proposal has been accepted to develop a prenatal smoking cessation incentive program for obstetric providers affiliated with HealthPlus, a not-for-profit health plan in New York City. Contract negotiations are still in progress.

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: Fetal Alcohol and Nicotine Induced Growth Retardation
Principal Investigator: Breese, Charles R.
Institution: Auburn University at Auburn, Auburn, AL
Funding Agency: National Institute on Alcohol Abuse and Alcoholism
Project ID: AA011164
Project Funding Period: 21 September 1998 – 31 August 2002

Abstract: Fetal alcohol syndrome is a constellation of birth defects caused by maternal alcohol use during pregnancy, and is characterized by intrauterine and postnatal growth deficits, and CNS dysfunctions in the offspring. Tobacco use during pregnancy is also an established cause of fetal growth deficiency, although the toxicological effects of prenatal nicotine exposure on the CNS are not clear. Since tobacco use is highly correlated in women that abuse alcohol during pregnancy, exposure to the combination of these substances may exacerbate the deficiencies associated with alcohol or tobacco use alone. While intrauterine and postnatal growth deficiencies are the most common symptoms of fetal alcohol or tobacco exposure, the cause of these deficiencies unknown. Studies have shown a consistent long-term reduction of insulin-like growth factor-1 (IGF-1), a major mediator of developmental growth, in prenatally ethanol-exposed offspring. The goal of this application is to investigate the actions of in utero ethanol, nicotine, and ethanol/nicotine co-exposure, on the regulation of the IGF and somatotropin gene families, and assess the relationship of changes in tissue and brain IGF and GH regulation, to that of the growth and CNS deficits observed in these offspring. The hypothesis is that fetal exposure to ethanol and nicotine inhibits fetal and neonatal IGF-1 gene expression, thereby reducing tissue availability to IGF-1, and causing or exacerbating the observed growth deficits observed in these offspring. The proposed studies to test this hypothesis include: 1) Examining the effect of fetal ethanol, nicotine and alcohol/nicotine co-exposure, on plasma and somatic tissue specific IGF and GH peptide and gene regulation; 2) Assessing the effect of fetal ethanol and nicotine exposure and co-exposure on changes on CNS neurotrophic expression, with particular emphasis on the IGF and neurotrophic gene families; 3) Examining the specific actions of ethanol and nicotine exposure on growth factor induced cellular function and second messenger systems, in organ culture systems of affected tissues; and 4) Assessing changes in gene expression by differential display PCR, to identify additional candidate genes in these disorders. These studies will provide valuable data which correlate with the endocrine and neuropathological changes seen in fetal alcohol syndrome and smoking in human populations.

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: Smoke-Free Connections: Helping Pregnant Women Build Support for Not Smoking
Principal Investigator: Carter Gaffney, Cecelia
Institution: Norris Cotton Cancer Center, Dartmouth Medical School, Hanover, NH
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040666
Project Funding Period: October 2000 – October 2002

Abstract: Determine whether home-based solution-focused smoking cessation counseling when combined with clinic-based best practice will increase the number of women who quit or significantly reduce cigarette smoking during pregnancy.

Research Design: Feasibility study in two phases. Phase one is natural history study to determine smoking prevalence, natural quit rates and levels of partner support with a Medicaid population. Phase two is an intervention study using a pre-posttest design to measure impact of combined clinic and home-based counseling on smoking during pregnancy.

Study Population: Low-income pregnant women receiving care through Medicaid-funded prenatal clinics in New Hampshire. All women who present for prenatal care at participating clinics who are currently smoking (a puff or more in the past 7 days), <20 weeks gestation, and married or living with a partner.

Intervention (if appropriate): All pregnant smokers will receive a brief counseling session at the first clinic visit based on best practice. A home visitor will provide two home-based counseling sessions based on solution-focused techniques. These sessions will be designed to increase the pregnant smokers' self-efficacy for quitting smoking, increase her partners' positive support for quitting smoking and to reduce her exposure to environmental tobacco smoke.

Outcome Measures (If cessation or reduction, how defined): Quit rate will be a ratio of a 7 day point prevalence smoking rate in third trimester of pregnancy compared to 7 day point prevalence smoking rate at intake. Women lost to follow-up will be considered smokers. Validated with NicAlert test. Number of cigarettes in past 7 days will be used to calculate reduction in smoking, measured at intake and during third trimester.

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: The Alabama Tobacco Free Families Program
Principal Investigator: Crawford, Myra
Institution: University of Alabama at Birmingham, Birmingham, AL
Funding Agency: National Cancer Institute
Project ID: CA86311
Project Funding Period: 4 August 2000 – 30 June 2004

Abstract: The objective of the Alabama Tobacco Free Families (ATOFF) Program, a multi-component, multi-channel health communications and policy change program, is to reduce the smoking prevalence rate among a representative sample of pregnant females whose maternity care is supported by Medicaid. This will be achieved by reducing the rate of females of childbearing age in eight targeted counties by changes in social norms. The proposed study is an extension of two decades of public health education studies conducted by the University of Alabama at Birmingham (UAB) tobacco research team in partnership with the ADPH's Bureau of Family Health Services (BFHS). ATOFF will expand this partnership to include the ADPH Bureau of Health Promotion and Information. It is designed to enhance the capacity of the state's Tobacco Use Prevention and Control Program (TUPC), funded by CDC in 1999. UAB and

ADPH will implement statewide and local partnerships targeting females of childbearing age to be tobacco-free prior to and during pregnancy. ATOFF will be evaluated using a time series design and analysis with multiple, quarterly baseline and follow-up measures of prevalence across the eight targeted counties. Process and behavioral impact evaluations will be conducted. The four specific aims to be accomplished by the proposed study will be to 1.) Identify and select a representative sample of patients from a randomly selected sample of Medicaid-supported maternity care sites to serve as the ATOFF clinic population, and to recruit a representative sample of females (14-44) to participate in a telephone-based survey to serve as the ATOFF community cohort; 2.) Develop and implement a multi-component, multi-channel program focused on females of childbearing age and their families in eight target counties and consisting of (a) a mass media-health communications component, (b) a community organization component, and (c) a professional practice component; 3.) Document the implementation success (process evaluation) of the media messages and community initiatives to change beliefs, behaviors, and social norms related to tobacco use among the samples of females in Aim number 1 by conducting clinical and community assessments in Years 01, 02, 03 and 04; and 4 Document, be self-reports and saliva continine tests, the effectiveness (impact evaluation) of ATOFF's program to reduce the prevalence among the clinic population at entry (first visit) into Medicaid maternity care, and by self-report via telephone of the females in the community population.

Title: A Computer-Based System of Adopting 5 A Guidelines into Obstetrical Practice
Principal Investigator: Cristiano, Lynda
Institution: Brigham and Women's Hospital, Boston, MA
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: A mini-grant proposal has been accepted to incorporate a tobacco treatment reminder system into the electronic medical record used by the OB/GYN Department of Brigham and Women's Hospital. Contract negotiations are still in progress.

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: Reducing Tobacco Abuse Among Pregnant American Indian Women
Principal Investigator: Day, Sharon
Institution: Indigenous Peoples Task Force, Minneapolis, MN
Funding Agency: Minnesota Partnership for Action Against Tobacco
Project ID: Not available
Project Funding Period: 1 May 2002 – 30 April 2004

Abstract: The Indigenous Peoples Task Force (IPTF) requests funds to conduct participatory action research with our community in Minnesota. The goal of this project is to deepen our understanding of why and how American Indian women smoke during pregnancy, to use the action research process to build community readiness to address this issue, and then to use our

critical inquiry to create intervention ideas to support and nurture pregnant women to reduce their commercial tobacco use and exposure to secondhand smoke.

How research fits funding priorities. This action research addresses the MPAAT priority funding areas 1) reduce tobacco (ab) use among communities of color and 2) reduce exposure to secondhand smoke.

Rationale, Design and Analysis Plan. To date, no research has been conducted to investigate patterns of tobacco use among Minnesota's pregnant American Indian women or effective culturally relevant programs to help them quit. While Minnesota's birth certificate data have not been published, our preliminary analysis of these data revealed alarmingly high prevalence of 40% smoking among pregnant American Indian women compared to 13% among European American women. We proposed a 3 stage participatory action research project: The first phase, "Learning," includes development of a community research team, then compilation and review of secondary data including underutilized data sets. We will develop a research plan with the community research team and train community researchers to collect data. The second phase of research will be "Listening." We will collaborate with community agencies to find participants. We will use creative, culturally appropriate data collection techniques, such as oral histories, talking circles, and Photovoice sessions with pregnant women who smoke or who have recently quit, and possibly elders, family members, or others as determined by the team. The third phase of research will be "Reflection and Sharing." The community research team will use collaborative, creative techniques to analyze the data, and then disseminate the results through community networks, news media, and cultural events. We will host a community feast/Vision Retreat to bring Native and non-Native groups together to begin the next phase of action--preparing an MPAAT intervention grant to nurture and support pregnant women to quit smoking and reduce exposure to secondhand smoke.

Title: Oregon Smoke-Free Mothers and Babies
Principal Investigator: Dodson, Donalda
Institution: Oregon Department of Human Resources, Salem, OR
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: The focus of the Oregon Smoke-Free Mothers and Babies project is to decrease tobacco use among pregnant women who are enrolled in Medicaid. Project staff are accomplishing this goal by incorporating the “5 A’s” into the state-funded maternity case management system, and by coordinating prenatal smoking cessation services among case managers, prenatal care providers, and the Oregon Quitline. The intervention is taking place in ten pilot counties, where systems level supports such as reminder systems, standardized data collection forms, and a fax referral system to the Oregon Quitline are being established. A quality improvement approach that emphasizes data-driven changes in the processes of care will help incorporate tobacco treatment interventions into routine maternity case management and prenatal care services.

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: Not available

Title: Maternal Interventions to Stop Smoking
Principal Investigator: Donatelle, Rebecca
Institution: Oregon State University, Corvallis, OR
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040669
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: Psychological Influences on Immune Responses to HPV
Principal Investigator: Fang, Carolyn
Institution: Fox Chase Cancer Center, Philadelphia, PA
Funding Agency: National Cancer Institute
Project ID: CA88307
Project Funding Period: 1 August 2000 – 31 July 2002

Abstract: The role of certain types of human papillomavirus (HPV) in the etiology of cervical cancer is well-established. However, the influence of psychosocial, behavioral and immunologic factors on cancer risk and development needs further exploration. The proposed project aims to elucidate the potential links between psychological (e.g., distress, coping processes) and behavioral (e.g., cigarette smoking) risk factors and novel immunologic measures (e.g., T-cell proliferative responses to HPV proteins) in women with mild dysplastic lesions of the cervix due to infection with highly oncogenic subtypes of HPV. Specifically, the proposed project is designed to identify potential behavioral and immunologic correlates of psychological distress and coping, with a particular emphasis on the effects of avoidant coping strategies on cancer risk and development. Sixty-two women referred for a follow-up colposcopy will complete baseline psychosocial assessments and provide a blood sample (for immune assays) prior to their colposcopy. In addition, HPV typing of cervicovaginal cells will be conducted at baseline. Follow-up assessments will be conducted at 6-months and 12-months post-baseline. Psychosocial assessments include measures of psychological distress, cancer-specific intrusive and avoidant ideation, and a variety of coping strategies. Relevant immune measures include numbers and percentages of circulating lymphocytes, as well as T-cell proliferative responses to synthetic peptides derived from HPV 16, a specific marker of immunocompentence and one that has been shown to be associated with viral clearance and cervical disease regression. In addition, medical outcome (regression, persistence, or progression of cervical lesions), demographic variables, and behavioral risk factors (e.g., smoking) will be assessed. The identification of potential interrelations among psychosocial, behavioral, and immunologic variables has important implications for cancer prevention and control, as this information can be used to guide the development of psychological and behavioral interventions aimed at reducing distress and avoidance, which may lead to improved behavioral, immunologic, and health outcomes.

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: Smoke-Free Families: National Research Office
Principal Investigators: Goldenberg, Robert, and Klerman, Lorraine
Institution: University of Alabama, Birmingham, Birmingham, AL, and Brandeis University Waltham, MA
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: The aim of this program is to reduce rates of smoking in families in the United States by supporting research to develop and evaluate effective new interventions to help women quit smoking before, during, and after pregnancy. Pregnancy, and the periods immediately preceding and following it, provide unique "teachable moments" to help women stop smoking. Women are highly motivated to stop smoking during these times, when they are concerned not only about their own health, but also about the health of their infants. Many women who do not otherwise seek or receive primary care or preventive services can be reached during family planning and prenatal care visits, with follow-up later in hospitals, pediatric offices, health clinics, day care programs, and during nursing visits to their homes. Providers and health care systems have especially compelling reasons to intervene during these periods given the many immediate health benefits of quitting.

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: Efficacy of Motivational Enhancement and Physiologic for Prenatal Smoking Cessation
Principal Investigator: Groff, Janet
Institution: Not available
Funding Agency: Robert Wood Johnson Foundation
Project ID: Not available
Project Funding Period: Not available

Abstract: This study proposes a randomized controlled trial to test the addictive effects of fetal ultrasound and motivational enhancement to best practice counseling for prenatal smoking cessation in low-income women. Biochemical validation of smoking will be measured at baseline, 34 weeks gestation, and six weeks postpartum.

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: Partnership for Smoke-Free Families Program
Principal Investigator: Hartigan, Phyllis
Institution: Children's Hospital and Health Center, San Diego, CA
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: In 1998, a trilateral partnership among three large not-for-profit healthcare systems was formed in 1998 to promote smoking cessation services for women during the preconceptional, prenatal, and post-partum periods. The intervention is a standardized program consisting of tobacco treatment resources, training, office support, and referrals to the California Smokers Quitline. The Smoke-Free Families mini-grant funds are being used to produce a technical assistance manual with sample materials and recommendations for other health care systems that want to implement similar activities.

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: Virtual Practicum for Counseling Tobacco Cessation in Pregnancy
Principal Investigator: Henderson, Joseph
Institution: Dartmouth Medical School, Hanover, NH
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: This project employs an educational model, the Virtual Practicum (a model that has sound basis in learning theory and has been shown to be easily used by and acceptable to health professionals), which can be disseminated via CD-ROM, via broadband Internet, or via CD-ROM + dial-up Internet. This project includes an evaluation to measure the impact in eight to ten communities in New England and Minnesota of the educational program on prenatal and primary care practices' implementation of the USPHS Tobacco Clinical Practice Guideline recommendations. The Agency for Healthcare Research and Quality (AHRQ), American College of Obstetrics and Gynecology (ACOG), Association for Maternal and Child Health Care Providers (AMCHCP), and the American College of Preventive Medicine are providing in-kind support to review program design and help to disseminate this program to students and practicing clinicians. Initial dissemination will be followed by expanded efforts to develop marketing relationships with relevant professional organizations representing the core audience.

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: Using Cotinine Feedback and Maternity Care Advocates to Assist Urban, Low-Income Pregnant Women Reduce Their Nicotine Exposure From Tobacco Smoke
Principal Investigator: Hock-Long, Linda
Institution: City of Philadelphia Department of Public Health, Philadelphia, PA
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: This study used a quasi-experimental pre-post comparison design to test the feasibility and effectiveness of an intervention that coupled routine biochemical screening at each prenatal visit with systematic advice and expanded counseling provided by clinicians, indigenous community health advisors, and maternity care advocates.

Title: Preventing Initiation of Smoking by Children
Principal Investigator: Jackson, Christine
Institution: University of North Carolina Chapel Hill, Chapel Hill, NC
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD036514
Project Funding Period: 30 September 1997 – 31 August 2003

Abstract: Children whose parents smoke cigarettes are at high risk for early initiation of smoking, and those who initiate smoking during childhood are at high risk for subsequent addiction to tobacco. Few programs are available that aim to prevent initiation of cigarette smoking during childhood, and none is available that aims to prevent early initiation by engaging parents who smoke in altering children's smoking-specific socialization. This project tests an innovative program to change smoking-specific socialization of children in households where parents smoke cigarettes. This continuation application requests one additional year of support for this research. Aim l: Develop an anti-smoking socialization program for parents who smoke. Through communication, modeling, rule setting, monitoring, and other socialization practices, parents influence their children's perceptions of the prevalence of smoking, the acceptability of smoking, the accessibility of cigarettes, and many other aspects of smoking. The premise of this research is that all parents, including parents who smoke, can engage in anti-smoking socialization, and that anti-smoking socialization can lower children's risk of smoking. Barriers to anti-smoking socialization include the misperception by parents that initiation of smoking is uncommon during childhood and the strong belief among parents who smoke that they lack credibility as sources of anti-smoking socialization. The program developed for this project addresses these and other barriers to involvement by parents who smoke in preventing their children from smoking. Aim 2: Using a 2-group randomized design, test the effects of anti-smoking socialization on children's susceptibility to and initiation of cigarette smoking. Sample: To date, this study has enrolled 813 mother-child pairs, where mothers were biological mothers, stepmothers, or other adult female guardians, from single- or 2-parent households, who reported smoking at baseline and whose children were in the 3rd grade at baseline. Design: Eligible participants who completed the baseline survey were randomly assigned to the treatment (n = 408) or control (n = 405) condition. Data on program implementation and impact have been obtained from mothers using telephone interviews administered 1 month post-treatment. Interviews administered to children 12, 24, and 36 months post-baseline will be used to assess program effects. Hypotheses: Children exposed to a program of anti-smoking socialization by mothers who smoke will be less susceptible to and report less initiation of smoking than unexposed peers. Analyses: A latent transition model will test the effects of anti-smoking socialization on children's susceptibility to cigarette smoking. Survival analysis will test the effects of anti-smoking socialization on children's initiation of smoking.

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: Prevention of Tobacco Use in Rural Ethnic American Youth
Principal Investigator: Kelly, Kathleen
Institution: Colorado State University, Fort Collins, CO
Funding Agency: National Institute on Drug Abuse
Project ID: DA007074
Project Funding Period: Not available

Abstract: Project IV: This project will determine whether localized media campaigns aimed at rural 7th and 8th grade Mexican American and White non-Hispanic students can influence their attitudes toward tobacco use and the subsequent use of tobacco (smoking cigarettes and smokeless tobacco). The primary target will be young women, where smoking produces potentially greater damage due to harmful effects to the fetus, newborn, and infant among pregnant smoking females. However, media messages will not be focused solely on females, and effects on males are expected such as reduction of smokeless tobacco. An effective and relatively low cost media campaign would be a valuable asset for rural communities that usually do not have the financial and technical resources for costly prevention efforts. However, typical media campaigns may not be useful for rural communities who may view their problems as more limited or unique compared to urban environments. The media campaigns that will be tested, therefore, will be localized to include local smoking data, identification with local situations, and images of local landmarks. There is evidence that prevention efforts may be enhanced by the use of peers; therefore, the effect of the media campaign alone (MEDIA) will be compared with the effect of the media campaign when local peers are added as an integral part of the media campaign (MEDIA+). In these MEDIA+ communities, a team of local peers (11th grade women) will be trained to present and monitor the media campaign. In addition, they will make radio spots, be names in news releases, and will be included in local visual references. The addition of this social influence from older females will be tested for its ability to reduce cigarette use and smokeless tobacco among younger females and males, over and above effects obtained in the MEDIA condition. Both experimental conditions will be compared to a control condition in which pre- and post assessments are obtained, with no intervention. Media components that can be localized to rural ethnic minority communities have been developed and tested, and the

training program for peer involvement in media campaigns has been tested by the investigators. The programs are designed so that, if successful, technology transfer through extension services or 4H organizations would be feasible.

Title: Ascertainment of Environmental Tobacco Exposure in Pregnancy
Principal Investigator: Kharrazi, Martin
Institution: Sequoia Foundation, Berkeley, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 8RT-0115
Project Funding Period: 1 July 1999 – 30 June 2002

Abstract: Even though it is well-known that the health of pregnant women and their newborn offspring is damaged be tobacco smoke, little is known about who in California is exposed to tobacco smoke during pregnancy, for how long and how much. One reason for this is that California is the only state that does not have a smoking question as part of its birth certificate. The objectives of this research project are to put together a source of information to answer these and other questions about smoking. We will work together with other programs of the California Department of Health Services, the National Centers for Disease Control and Prevention (CDC), the San Diego County Health Department, 20 delivery hospitals, area medical laboratories, and numerous community clinics and doctors to do this. We will collect information from pregnant women in San Diego County during 1999-2001. Blood and urine taken from pregnant women for non-study reasons and which is left over after analysis wil1 be collected by the study, stored and later used to measure how much tobacco smoke these women were exposed to. We will obtain the blood and urine at three points in the pregnancy: at the time each woman goes in for a pregnancy test at a lab or doctors' office, at 15 19 weeks gestation when she gives blood to be screened for certain birth defects, and at birth when umbilical cord blood is taken at the hospital. While at the hospital for delivery, the mother will be asked to answer a short questionnaire (in Spanish or English) about her smoking history and her exposure to others who were smoking during the pregnancy. Participation in the study is voluntary and necessary approvals from women will be obtained for all collection activities. Over a 19-month period, we plan to collect approximately 40,000 maternal urine or serum samples collected early in pregnancy, 60,000 maternal serum samples collected in the second trimester, and 50,000 umbilical cord blood samples, live birth records and questionnaires collected at the time of the birth. Approximately 6,000 blood and urine samples from over 2,000 women will be selected and sent to a special national lab for analysis. Levels of a tobacco metabolite (cotinine) in a woman's blood or urine will be measured to find out how much tobacco she and her baby were exposed to, either by smoking or by being around others who smoke. Once all of these data are linked together, we will be able to: 1) define the true pattern of tobacco smoke exposure across the nine months of pregnancy; 2) determine the characteristics of women who are most exposed to tobacco smoke; and 3) determine which of two smoking questions women most accurately respond to. If we can scientifically validate at least one of the smoking questions, then it will be recommended for use on future California birth certificates. The results of this study will be helpful in informing future research efforts as well as in shaping policies to prevent the health of pregnant women and their newborns from being damaged by tobacco smoke.

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: Nicotine Replacement and Oxidative Stress in Pregnancy
Principal Investigator: Klesges, Lisa M.
Institution: University of Tennessee Health Science Center, Memphis, TN
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD037225
Project Funding Period: 1 January 1999 – 31 December 2002

Abstract: This investigation seeks to answer to what extent 1) nicotine replacement therapy in pregnant women who quit smoking increases serum antioxidants and lowers levels of oxidative stress compared to their baseline levels while smoking, and 2) serum antioxidants and oxidative stress differ in pregnant smokers who a) are randomized to a behavioral smoking cessation program b) are randomized to a behavioral therapy plus nicotine replacement group and c) who relapse to cigarette smoking.

Title: A Planning Guide for OB/GYN Practice Sites
Principal Investigator: Krevor, Brad
Institution: Brandeis University, Waltham, MA
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: A previously developed manual, "Treating Tobacco Use and Dependence as a Chronic Disease: A Planning Guide for Practice Sites in Developing an Office-Based System of Care" will be modified for prenatal care providers to reflect the special needs of pregnant women who smoke. The Planning Guide will be reviewed by experts in prenatal smoking cessation, pilot tested with both public and private providers in Vermont, revised and made available for wide distribution.

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: 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: Oklahoma Smoke-Free Families Project
Principal Investigator: Leuthard, Joy
Institution: Oklahoma State Medical Association, Oklahoma City, OK
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: The Oklahoma Medical Association will develop a program to incorporate prenatal smoking cessation services into prenatal care practices that are members of the Oklahoma Physicians Resources/Research Network. Physician Enhancement Assistants will be used to provide on-site training and technical assistance to create office systems in support of the best-practice intervention. Contingent upon the results of the pilot, the Oklahoma State Medical Association will receive $400,000 to conduct a two-year demonstration of their academic detailing model.

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: Development of Substance Use in Girls
Principal Investigator: Loeber, Rolf
Institution: University of Pittsburgh at Pittsburgh, Pittsburgh, PA
Funding Agency: National Institute on Drug Abuse
Project ID: DA012237
Project Funding Period: 15 February 2000 – 31 January 2005

Abstract: The long-term development of substance use and abuse in girls and women are poorly understood. In at least two ways, females compared to males appear more vulnerable to substance abuse and dependence: a speedier development from onset of use to abuse, and a higher propensity to develop comorbid conditions. In addition, females and males with an early onset of substance use are more likely to become substance abusers. The main goal of the proposed research is to investigate the early phases in this development process. Specifically, we propose to study precursors to the onset of early substance use (i.e., mainly alcohol and tobacco use), the transition to onset of use, and the transition to regular use in an inner-city community sample of 2,484 preadolescent girls. The girls, together with their parent and school teacher, will be assessed yearly and will be followed up over a period of five years. The sample will be made up of approximately 50 percent African-American and 50 percent Caucasian girls. The proposed study will be a substudy linked to and benefitting from the NIMH-funded study on the same girls, which has as its main object the study of the development of antisocial and delinquent behavior. The present proposal has three foci: 1). To identify the developmental precursors to the onset and regular use of substances; 2). To examine behavior problems which interact with early substance use; and 3) To elucidate the risk and protective factors predictive of the precursors of early substance use and predictive of the early use. The proposed study will be the foundation upon which follow-ups beyond the current five-year period can be built in order to better understand the long-term antecedents, risk and protective factors for substance abuse and dependence in females.

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: Testing Pharmacological Therapies for Pregnant Smokers
Principal Investigator: McBride, Colleen
Institution: Duke University, Durham, NC
Funding Agency: National Cancer Institute
Project ID: CA089053
Project Funding Period: 1 May 2002 – 30 April 2007

Abstract: Smoking in pregnancy poses serious health risks to the fetus and the mother. About half of women smokers continue to smoke throughout pregnancy. Pregnant women who have the greatest difficulty quitting smoking even when provided with behavioral cessation interventions tend to be more dependent smokers who may requite nicotine replacement therapy to be successful at cessation. The proposed five-year study is designed to evaluate the effectiveness of providing over-the-counter (OTC) nicotine replacement therapy, choice of gum or patch, (NRT) to promote prepartum smoking cessation. Proposed is a two-arm design. Eligible pregnant women (N=300) will be randomized to either: Arm 1, Tailored Cognitive Behavioral Treatment (TCBT, n=150) that provides women with customized risk information about smoking and nicotine, the potential harms to the fetus and encouragement of appropriate behavioral skills building; or Arm 2, TCBT + NRT - the tailored intervention incorporating NRT information plus choice of patch or gum (n about150). The intervention will include 5 face-to-face contacts as part of prenatal visits and 2 telephone counseling sessions. Primary outcome measures will be biochemically validated 7-day prevalent abstinence rates at the 19-27th and 27-35th week of pregnancy. Secondary outcomes will include 7-day prevalent abstinence rates at 12 and 24 weeks postpartum, serious quit attempts, compliance with NRT, and use of materials. Saliva cotinine will be measured among all women at baseline, the 27-35th week of pregnancy, and 24 weeks postpartum. The significance of this project is that it relies on transdisciplinary collaborations to extend the science in nicotine replacement therapies to a population that could derive substantial health benefits. Moreover, the study results have immediate potential to inform clinical recommendations for integrating nicotine replacement into prenatal care.

Title: Smoke-Free Families: National Dissemination Office
Principal Investigator: Melvin, Cathy
Institution: Not available
Funding Agency: Robert Wood Johnson Foundation
Project ID: Not available
Project Funding Period: Not available

Abstract: This multi-component program has two aims: to promote the dissemination of existing best-practice treatments for pregnant smokers in prenatal care and to support innovative research to discover more powerful "breakthrough" treatments. The National Dissemination Office is funded to build capacity, demand and policy supports for proven interventions, and to conduct research on the systems changes needed to implement them. The National Program Office supports innovative research demonstrations with promise to produce the next generation of more effective treatments.

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 During Pregnancy and Breast Cancer
Principal Investigator: Mueller, Beth A.
Institution: Fred Hutchinson Cancer Research Center, Seattle, WA
Funding Agency: National Cancer Institute
Project ID: CA096434
Project Funding Period: 1 April 2002 – 31 March 2004

Abstract: Although cigarette smoking has been linked to the etiology of several cancers, the relationship between smoking and breast cancer remains unclear. A woman's first pregnancy represents a period of rapid breast cell growth and differentiation and thus, a period of vulnerability to the influences of smoking or other exposures. During pregnancy, tobacco mutagens and free radical formation caused by smoking may affect rapidly growing breast tissue or act synergistically with elevated estrogens to increase breast cancer risk. Because breast tissue is less differentiated at the onset of first pregnancy, it may be more susceptible to mutagenesis than in subsequent pregnancies. The proposed population-based case-control study will utilize linked vital statistics - cancer registry data to test the hypothesis that cigarette smoking during first pregnancy is related to the risk of breast cancer. The specific aims of this study are to: 1)measure the risk of breast cancer associated with smoking during a first pregnancy relative to not smoking during the first pregnancy, and 2)evaluate possible differences in the relation between smoking during first pregnancy and breast cancer by tumor estrogen receptor status. To the extent possible, the study will also evaluate a possible dose response relation between the average number of cigarettes smoked per day during first pregnancy and breast cancer risk, and measure possible differences in the relation between smoking during first pregnancy and breast cancer risk by subject characteristics such as parity at the time of diagnosis and pre-pregnancy weight. This study will be among the first to examine smoking during first pregnancy and breast cancer risk. The clarification of the role of smoking during first pregnancy in breast cancer development will aid in understanding the complex etiology of breast cancer, and may identify a specific preventive strategy to help reduce breast cancer incidence.

Title: Smoking Interventions for Low Income Pregnant Women
Principal Investigator: Ockene, Judith K.
Institution: Univ of Massachusetts Medical School Worcester, Worcester, MA
Funding Agency: National Heart, Lung, and Blood Institute
Project ID: HL051319
Project Funding Period: 1 March 1996 – 31 August 2001

Abstract: This five year Demonstration and Education project, the Provider-Delivered Smoking Intervention Project Plus (PDSIP+), will implement and evaluate the effect of a multicomponent intervention on the smoking cessation and maintenance rates of culturally-diverse, socioeconomically-disadvantaged, pregnant women (Hispanic, Black American and Caucasian) enrolled in the Women, Infants and Children (WIC) supplemental nutrition program. Three provider channels will deliver the interventions: l) WlC nutritionists during pregnancy and postpartum; 2) obstetricians (OB) and clinic staffs during pregnancy; and 3) pediatricians (PED) and clinic staffs during postpartum. A time-efficient yet intensive patient-centered intervention protocol will be used. This intervention has been previously demonstrated to be efficacious when used by general internists and family practitioners with a general population of smokers, and to be usable by WIC nutritionists. Three paired Massachusetts WIC sites and their related OB and PED clinics within Community Health Centers will be randomized to special intervention (SI) or usual care (UC). SI sites will receive training in the patient-Centered intervention, and establish an office practice management system to support intervention, which includes a system for linking the three channels of intervention delivery. UC sites will receive no intervention. In each of the three SI sites, an organizational assessment will be completed, a Health Center Operations

Board will be established to tailor implementation of the intervention in each site. Then each of the SI provider channels (WlC, OB and PED) will receive intervention training consisting of a structured group program with brief individual followup sessions. Written questionnaires will be done at baseline of SI and UC providers at post-training of SI providers, and at one year followup of both Sl and LC providers. Provider adherence to the intervention will be measured by patient exit interviews (WIC providers in SI and UC), chart audit (SI only) and retrospective patient report in patient interviews. Eligible pregnant women will have a baseline interview during their WlC enrollment visit. A brief assessment involving smoking status (with saliva cotinine validation of reported cessation), stage of change and report of provider intervention behavior will occur at ninth month of pregnancy, 3- and 9-months postpartum. A more comprehensive assessment will be conducted at l- and 6-months postpartum. Maintenance of cessation and overall non-smoking rates will be determined at each assessment point. The results of this study will demonstrate the effectiveness of a multicomponent program of linked providers, which is feasible and generalizable to other behaviors and other settings serving low-income, multicultural pregnant women.

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: Vaccine Effects on Fetal Nicotine Exposure in Rats
Principal Investigator: Pentel, Paul R.
Institution: Minneapolis Medical Research FDN, Inc., Minneapolis, MN
Funding Agency: National Institute on Drug Abuse
Project ID: DA015668
Project Funding Period: 30 September 2002 – 31 July 2006

Abstract: The aim of this proposal is to study the effects of maternal immunization with a nicotine vaccine on the pharmacokinetics, neurochemical consequences, and behavioral sequelae of gestationally administered nicotine in rats. Smoking during pregnancy is associated with a wide range adverse neonatal outcomes. Animal data strongly implicate nicotine as a teratogen and a contributor to these adverse outcomes. It has recently been shown that immunization of adult male rats with a nicotine vaccine can substantially reduce the distribution of acutely or chronically administered nicotine to brain and other organs. Preliminary data suggest that vaccination of female rats can also reduce the distribution of gestationally administered nicotine to fetal brain. The proposed study will address the mechanisms by which vaccination alters nicotine distribution to the fetus, and the magnitude and consequences of this effect under a variety of dosing conditions. The pharmacokinetics of nicotine in the pregnant rat will also be studied to better understand the determinants of fetal nicotine exposure. Specific hypotheses to be tested are that 1) Maternal vaccination reduces the distribution to fetal brain of nicotine administered during gestation using a variety of clinically relevant acute and chronic dosing regimens. 2) Protection of fetal brain from gestational nicotine exposure occurs via two complementary mechanisms; a reduction in unbound nicotine distribution to the fetus, and the transfer of maternal antibody to the fetus which then binds and sequesters nicotine in fetal serum, 3) Vaccination attenuates the increase in fetal brain c-fos mRNA expression associated with chronic gestational nicotine exposure, 4) Vaccination attenuates the increase in neonatal locomotor activity associated with gestational nicotine exposure, and 5) Nicotine clearance is lower in nonpregnant females than in males, but is increased in females during pregnancy. These immunologic, pharmacokinetic, neurochemical and behavioral data will be integrated to help understand the mechanisms by which vaccination alters fetal nicotine distribution, and the clinical potential of vaccination to reduce the teratogenic effects of gestational nicotine exposure.

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: Reducing Disease Risk in Low Income Postpartum Women
Principal Investigator: Peterson, Karen
Institution: Harvard University, Boston, MA
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD37368
Project Funding Period: 1 September 1999 – 30 June 2003

Abstract: The postpartum period is a window of opportunity to promote behaviors to reduce risk of chronic disease and benefit reproductive health, through interventions that address multiple levels of influence in the social context of low-income women. This study will test the efficacy of an education model delivered by community-based paraprofessionals from the Expanded Food and Nutrition Program (EFNEP). This educational program aims to improve dietary and activity patterns among low income, multi- ethnic women over a 12-mo postpartum period, followed by a 6-mo maintenance period. Women will be recruited through the Special Supplemental Food Program for Women, Infants, and Children (WIC) and randomized to l) Usual WIC Care, consisting of nutrition-risk appropriate and breastfeeding educational messages at the first postpartum and follow-up visits; 2) Enhanced EFNEP, consisting of Usual WIC Care plus a three-component intervention including 4 home visits and 4 group cooking and activity classes delivered by EFNEP paraprofessionals, and monthly motivational telephone calls made by project staff. During a 6-mo maintenance period, staff will make calls bi-monthly. Primary study Outcomes assessed at 4 time points (2-6 wk and 6, 12, 18 mo postpartum) include: a) fruit and vegetable intake; b) saturated fat intake; c) physical activity; secondary outcomes are Body Mass Index and indicators of fat mass and distribution. Statistical analysis will include explorations of mediating and modifying factors including social support and norms, perceived health status, smoking, television viewing, food insecurity, food/activity access, and utilization of federal programs and health care. Using existing federal programs for low income families as channels, intervention components specifically address influences that mediate adoption of healthy diet and activity behaviors among multi-ethnic, postpartum women. If efficacious, this

program can be readily disseminated through the existing community organizations in which it is being tested.

Title: Depression, HPA Function, & Smoking Abstinence in Women
Principal Investigator: Pomerleau, Ovide
Institution: University of Michigan at Ann Arbor, Ann Arbor, MI
Funding Agency: National Cancer Institute
Project ID: CA42730
Project Funding Period: 1 January 1998 – 31 December 2001

Abstract: There is evidence that smoking is becoming concentrated in populations who because of various risk factors, are more likely to initiate smoking or have greater difficulty quitting. One of the best documented of these cofactors is depression. Numerous observers have noted clear manifestations of depression and dysphoria in women with a history of Major Depressive Disorder (Hx+ MDD) when they attempt to quit smoking. The long-term objective is to characterize and possibly modify response patterns that constitute a diathesis for smoking. Based on the literature and our own pilot data, we postulate that the reinforcing value of nicotine self-administration is enhanced in Hx+ MDD by the drug's affect- normalizing properties and its ability to protect against the hypothalamic-pituitary-adrenal (HPA) axis dysregulation that often characterizes episodes of depression, as indicated by elevated cortisol and ACTH levels following dexamethasone administration, an effect that is most pronounced in postmenopausal women. The specific aims are to 1) trace the time course and severity of depressive symptomatology in Hx+ MDD and Hx- MDD women smokers across different age categories when they abstain from smoking; 2) determine susceptibility to induction of depressed mood in Hx+ MDD and Hx- MDD women smokers; 3) elucidate key biobehavioral mechanisms underlying the relationship between dysphoria and use of nicotine; and 4) determine the extent to which pharmacological manipulations can relieve abstinence- induced depression/dysphoria and concomitant HPA axis dysregulation. The research design employs both within-subject and between-group comparisons in two interlocking studies, involving within-subject and between-group comparisons of women smokers and carefully assessing both psychological distress and neuroendocrinological dysfunction. STUDY I will assess the effects of nicotine vs. placebo patch during a week of smoking abstinence on cognitive and neuroendocrinological variables. STUDY II will investigate the ability of the antidepressant fluoxetine vs. placebo to ameliorate depression/dysphoria and restore HPA-axis function during smoking abstinence. HEALTH IMPLICATIONS: Depression is a major women's public health problem in its own right, taking an enormous toll in terms of lost productivity and diminished quality of life. To the extent that it increases the likelihood of initiation and maintenance smoking, the health consequences are magnified---as underscored by the fact that lung cancer has now surpassed breast cancer as the leading cause of cancer death in women. A better understanding of the reinforcing effects of smoking, and the mechanisms underlying these effects in depression-prone smokers, may lead to the development of rational prevention and cessation strategies tailored to the special needs of this large at-risk population.

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: Telephone Counseling Program for Pregnant Smokers Enrolled in a Managed Care Organization
Principal Investigator: Rigotti, Nancy A.
Institution: Massachusetts General Hospital, Institute for Health Policy, Boston, MA
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040667
Project Funding Period: October 2000 – September 2004

Abstract: The purpose of this study is to test whether offering pregnant smokers a proactive telephone counseling program throughout pregnancy and for 2 months postpartum increases the rate of smoking cessation and of tobacco use reduction, at end of pregnancy and 3 months postpartum, compared to a "best practice" control.
Research Design: This study is a randomized controlled clinical trial to compare the effectiveness of an enhanced version of an existent smoking cessation telephone counseling program for pregnant women with a "best practice" control.

Study Population: The study population is pregnant women smokers enrolled in the Tufts Health Plan. The goal is to recruit 434 women over a 29-month enrollment period. Eligibility criteria include (1) being in the 1st or 2nd trimester of pregnancy, (2) having smoked >1 cigarette in the past week, (3) having access to a telephone and (4) the ability to speak English.

Intervention (if appropriate): The intervention condition will include:

1) A mailed pregnancy-tailored manual; 2) Proactive, stage-based telephone counseling by a trained smoking counselor on a standardized schedule for the remainder of pregnancy (an initial 15-20 minute call and up to 6 subsequent 10-15 minute calls). Counseling will incorporate motivational enhancement, skills training, problem-solving, and relapse-prevention strategies; 3) Mailings sent to the obstetrical provider (informing him/her of the patient's participation and reminding provider to advise nonsmoking at each visit). Chart stickers and self-help materials will also be provided. After delivery, similar letters will be sent to the obstetrician and the infant's pediatrician; 4) Stop-smoking advice from the obstetric provider.

Outcome Measures (If cessation or reduction, how defined): Smoking cessation at the end of pregnancy is the primary outcome. Smoking status outcomes will be assessed by telephone at the end of pregnancy (28-34 weeks) and 3 months postpartum. Saliva samples will be collected from self-reported nonsmokers at each follow-up point to verify nonsmoking status. Self-reported nonsmoking will be considered validated if saliva cotinine value is <20 ng/ml. Secondary outcome measures will include participant's health care utilization and costs (including those incurred during pregnancy and by the infant during months 0-3), which will be obtained from Tufts HP claims data. Intermediate outcomes will include number of quit attempts (defined as >24 hours of self-reported abstinence) and stage of readiness to quit smoking.

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: Not available

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: 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: Transplacental Pancreatic Carcinogenesis by NNK
Principal Investigator: Schuller, Hildegard
Institution: University of Tennessee, Knoxville, TN
Funding Agency: National Cancer Institute
Project ID: CA42829
Project Funding Period: 1 January 1998 – 31 July 2001

Abstract: This is a revised competing continuation proposal to study transplacental pancreatic carcinogenesis induced by coadministration of ethanol and the nitrosamine carcinogen NNK in a hamster model. Pregnant hamsters are administered 10% ethanol in drinking water from day 5 through day 15 of gestation and are then given a single intratracheal dose of 50 mg/kg NNK on day 15. The offspring develop adenocarcinomas of the exocrine pancreas with 50% incidence (males) and 77% incidence (females) as well as pancreatitis and marked acinar and ductular cell hyperplasia. Dr. Schuller proposes to investigate the mechanisms of carcinogenesis in this model. The general hypothesis to be tested appears to be that through a combination of b-adrenergic actions and in situ bioactivation to reactive intermediates, NNK initiates pancreatic tumorigenesis. The specific aims are 1) to investigate the role of the b-adrenergic receptor pathway in the initiation and development of pancreatic tumors; 2) to investigate the modulation of NNK metabolism and DNA adduction in fetal liver and pancreas by ethanol, 3) to identify mutations induced in K-ras and p53 genes in hamster pancreatic tumors; 4) to investigate the roles of individual cytochrome P450 enzymes in the bioactivation of NNK in fetal pancreas in vitro and in vivo; and 5) to investigate the ability of the nonsteroidal antiinflammatory agent sulindac to modulate pancreatic carcinogenesis. It is proposed that these studies will serve as the basis for developing effective strategies for prevention of cancer in the children of smokers.

Title: Adenocarinoma of the Lung in Women
Principal Investigator: Schwartz, Ann G.
Institution: Wayne State University, Detroit, MI
Funding Agency: National Cancer Institute
Project ID: CA087895
Project Funding Period: 13 June 2001 – 31 May 2006

Abstract: In 1998, 80,000 women in the US were diagnosed with lung cancer and incidence rates, particularly of adenocarcinoma, continue to increase among women. Many pieces of evidence suggest that there are gender differences in susceptibility to tobacco carcinogens. Several studies have shown that DNA adducts, p53 mutations, CYP1A1 expression in the lung, and GSTM1 null genotypes are more frequent in females than in males. Reasons for differential susceptibility by gender might be explained by variations in metabolic enzyme functioning or hormonal differences. Some of the same enzymes involved in the metabolism of carcinogens in tobacco smoke are involved in the metabolism of estrogen. The goals of the proposed study are two-fold. First, we will evaluate the role of tobacco smoke and estrogens in determining risk of adenocarcinoma of the lung among women. Secondly, we will evaluate the role of estrogen receptors and c-erbB-2 in lung tumors to further understand the pathways through which estrogen may be acting in the lung. The specific aims are: 1) To conduct a population-based case-control study of the contribution of tobacco exposure, estrogen use, and reproductive history in determining risk of adenocarcinoma of the lung in women. 716 cases will be identified through the Metropolitan Detroit Cancer Surveillance System of the Karmanos Cancer Institute (a SEER participant). An equal number of controls will be selected through random digit dialing. 2) To determine if genotype at the metabolic enzyme loci CYP1A1, CYP1B1, CYP17, CYP19, GSTM1, GSTP1, COMT, and NQO1 are associated with risk of adenocarcinoma of the lung in women. These enzymes are active in both the metabolism of tobacco smoke carcinogens and the synthesis and metabolism of estrogens. 3) To examine gene-gene and gene-environment interactions, focusing on tobacco and estrogen effects. 4) To determine estrogen receptor status (alpha and beta) and c-erbB-2 levels in the lung tumors of women with adenocarcinoma and evaluate risk associated with tobacco exposure, estrogen use, reproductive history, and genotype at metabolic enzyme loci by tumor characteristics. The proposed study represents a focused approach to defining the contribution of genes and environments in risk of adenocarcinoma of the lung in women. The interview component of the study will provide data about individually measured environmental risk factors. Genotypes have been chosen which impact on biologically effective dose of tobacco carcinogens and estrogens in the lung. The study of tumor characteristics will provide insight into mechanism of action. This large, population-based study should provide clues for important prevention and therapeutic strategies for lung cancer.

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: Progesterone Treatment on Effects of Stimulants in Females
Principal Investigator: Sofuoglu, Mehmet
Institution: University of Minnesota Twin Cities Minneapolis, MN
Funding Agency: National Center for Research Resources
Project ID: RR000400-320458
Project Funding Period: 1 December 1978 – 30 November 2004

Abstract: The main goals of these pilot studies are to obtain pharmacokinetic data for progesterone treatment in female nicotine and cocaine users and to investigate the safety and tolerability of progesterone treatment in conjunction with cocaine administration. The first study will be an open trial in which six female smokers who are in the early follicular phase of their menstrual cycle will be enrolled. Subjects will be given a single mg dose of micronized progesterone and multiple blood samples will be obtained to measure the plasma levels of progesterone. For the second study, cocaine dependent women who are in the early follicular phase of their menstrual cycle will have 2 experimental sessions. Subjects will be administered a single dose of micronized progesterone (200 mg), or placebo on each of two experimental sessions. Starting 2.5 hours after progesterone or placebo treatment, three doses of smoked cocaine (0.4 mg/kg) will be administered. We hypothesize that administration of 200 mg of progesterone will achieve plasma progesterone concentrations similar to those found in the luteal phase of the menstrual cycle, 3-30 ng/ml.

Title: Observational Study to Understand the Personal Meaning and Social Implications of Smoking
Principal Investigator: Stanton, Bonita
Institution: West Virginia University, Morgantown, WV
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: This is an observational study to understand the personal meaning and social implications of smoking and smoking cessation to a pregnant woman and her male partner experiencing the transition to parenthood.

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: Maine Prenatal Practice Collaborative
Principal Investigator: Swartz, Susan
Institution: Maine Medical Center, Portland, ME
Funding Agency: Not available
Project ID: Not available
Project Funding Period: Not available

Abstract: The Maine Prenatal Practice Collaborative proposes to improve tobacco treatment services among prenatal care providers who are members of MaineHealth, an integrated, not-for-profit healthcare delivery system. By using a collaborative learning process among participating office practices, the project aims to improve compliance with the best-practice intervention by raising clinician self-efficacy, promoting a team approach, improving delivery system design, and integrating decision support and patient self-management tools. In addition, social marketing techniques will be used to explore practices' needs and expectations regarding tobacco treatment for pregnant women, and to design appropriate project activities.

Title: Smoking Among LSU and SU Undergraduates: Causes and Elimination
Principal Investigator: Sylvester, Judith
Institution: Louisiana State University, Baton Rouge, Baton Rouge, LA
Funding Agency: Louisiana Health Excellence Fund
Project ID: Not available
Project Funding Period: June 2000 – May 2004

Abstract: This project will identify LSU/SU college students who smoke to determine why they smoke and what types of information and support will be necessary to help them to quit. Female smokers, who are putting their children at risk if they smoke during pregnancy, will be the main focus of these efforts. A second target will be minority students.

In 1996, the PI conducted a survey, based on a random sample of 400 LSU students, that found 30% of students smoke. Nearly a quarter of the females smoked. Sixty-five percent of the smokers said they had unsuccessfully tried to quit. This study will use a social marketing approach that first requires segmenting students into groups based on attitudes and behaviors.

This study will employ focus groups and Q methodology (factor analyzing subjects who sort a number if self-referent statements) to better describe smoking behaviors and explore possible strategies and support methods for students who wish to quit or reduce their amount of smoking.

Specific messages will be developed that target the segments identified in the first phase of the research. The best channels (media, support groups, posters, etc) for delivering the messages to the targeted segments will then be determined.

Finally, an evaluation of message salience and effect on behavior will be conducted. These findings can then be provided to other state centers that can then use this information to mount a large-scale campaign to reduce smoking behaviors among college students in Louisiana and at other campuses across the country.

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: Perinatal Depressive Symptoms and Smoking
Principal Investigator: Weismiller, David
Institution: Brody School of Medicine, East Carolina University, Greenville, NC
Funding Agency: Robert Wood Johnson Foundation
Project ID: 040679
Project Funding Period: 1 November 2000 – 31 January 2004

Abstract: To assess the relationship between maternal depressive symptoms and other psychosocial factors with smoking cessation and smoking intensity early and later in pregnancy.

Research Design: A prospective (observational) study. All women presenting for prenatal care at one of three prenatal sites are administered a short screening questionnaire to assess smoking status. All women who are current smokers (having smoked at least one cigarette during the past week) or who quit within the past year are then administered a questionnaire to assess maternal depressive symptoms, exposure to stressors, intendedness of pregnancy and smoking behavior. This questionnaire will be administered again at 30 weak gestation.

Study Population: Women are enrolled in the study at three care sites in the Greenville/Pitt County, North Carolina Area. These clinics all serve low-income women from the community of whom about 75 percent are Medicaid recipients and 70 percent are African American. The state of North Carolina has one of the highest rates in the state.

Intervention (if appropriate): N/A

Outcome Measures (If cessation or reduction, how defined): Relationships between maternal depressive symptoms and exposure to psychosocial stressors early and later (30 weeks #GA) in pregnancy with smoking behavior including cessation (defined as no smoking), relapse (defined

as having smoked at least one cigarette in the week prior to the interview), and smoking intensity.

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: Prenatal and Childhood Exposures and Age at Menarche
Principal Investigator: Windham, Gayle
Institution: Impact Assessment, Inc., San Diego, CA
Funding Agency: National Institute of Child Health and Human Development
Project ID: HD036762
Project Funding Period: 1 March 2000 – 28 February 2002

Abstract: Hazards posed to the developing fetus and child by exposure to chemical substances are receiving increasing attention. The developmental endpoints examined primarily have been adverse pregnancy outcomes, as well as some consideration of neurobehavioral development. Little is known about normal menstrual function and how it is initiated during adolescence. In this pilot study we propose to examine a measure of sexual development, namely, age at menarche, and its relationship to prenatal exposure to chemical substances including, tobacco smoke, alcohol and caffeine (TAC). Active smoking is a known reproductive hazard during pregnancy and has also been associated with infertility and alterations in hormone excretion levels. Prenatal alcohol exposure is associated with fetal growth retardation and neurologic impairment in offspring. Numerous studies have shown effects of alcohol on the endocrine system of adults and there is suggestive evidence it may effect sexual maturation. Known actions of caffeine present plausible mechanisms for alteration of hormonal profiles and an association with delayed time to conception has been reported. Thus all three exposures may possibly affect sexual development via actions on the prenatal hormonal milieu or the developing nervous system. The proposed pilot study would make use of a large data base of pregnancies ascertained in the early 1960's. Subjects of this study will be the 1000 daughters followed through childhood and adolescence, at which time age at menarche was ascertained. Extensive data was collected prospectively on prenatal exposures, as well as on potential confounders. A number of important exposures and conditions of childhood were also ascertained prospectively, including parental cigarette smoking, childhood behaviors, and growth. With these data we propose to examine whether in utero exposure to TAC or childhood exposure to parental smoking are related to perturbations in age at menarche. Early age at menarche has been associated with an increased risk of breast cancer, thus alteration in menarcheal age may serve as a sentinel of other adverse effects on children's and women's health. Such data will be valuable in designing further studies of the reproductive process and growth and development in relation to early life exposures.

Title: Smoking Cessation/Reduction In Pregnancy Trial (SCRIPT)
Principal Investigator: Woodby, Lisa
Institution: University of Alabama at Birmingham, Birmingham, AL
Funding Agency: National Heart, Lung, and Blood Institute
Funding ID: HL056010
Project Funding Period: 1 January 1997 – 31 December 2002

Abstract: Smoking among pregnant women, particularly public health maternity patients, is one of the most important risk factors in predicting infant and maternal morbidity and mortality. Smoking among pregnant women has been a national priority for our 1990 and Year 2000 health objectives. The objective of the proposed study-- Smoking Cessation and Reduction In Pregnancy Trial (SCRIPT) -- is to evaluate the EFFECTIVENESS of a smoking cessation intervention for pregnant smokers delivered as part of routine care by public health nurses in Alabama. Four aims will be completed 1) To randomly select a representative sample of public health maternity clinics and Medicaid-supported obstetrical care patients in Alabama; 2) To conduct, among patients and staff at Aim #1 sites, a three-phase formative evaluation of a multi-component smoking cessation and reduction intervention, including a patient education, counseling, skills training program for nursing staff; 3) To evaluate the behavioral impact of the multi-component health education intervention program among at least 2000 pregnant smokers, 1000+ randomly assigned to an Experimental (E) Group and 1000+ randomly assigned to a Control (C) Group at their first prenatal visit; and, 4) To conduct a process evaluation to document the degree of patient exposure to the intervention methods and evaluation procedures specified in Aim #3. SCRIPT will confirm the EFFECTIVENESS RATES AND EXTERNAL VALIDITY of the intervention. Very limited insight is available in the Public Health Practice literature about these two outcomes.

Title: Media and Smoking Among Adolescent Girls Across Ethnicity
Principal Investigator: Yang, Dongyun
Institution: University of Southern California, Los Angeles, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 8DT-0175
Project Funding Period: 1 January 2000 – 30 June 2002

Abstract: Smoking prevalence among adolescents has been increasing since the early 1990s in the United States and California. In California, more teenage girls reported smoking cigarettes in the past 30 days in 1996 than in 1990. More African-American, Hispanic and Asian female teenagers reported interest in trying a cigarette than their White counterparts. Tobacco advertising and promotion items appear to attract adolescents, especially girls who smoke to look "cool", to be mature, or to keep their weight down. Most current tobacco prevention programs are universal and do not consider the diverse cultural backgrounds of the targeted population. However, tobacco industry has employed ethnically specific marketing campaigns to attract young and/or female customers. More efforts are needed to improve the effectiveness of the current tobacco prevention programs by adding gender specific and culturally appropriate curricula. This project intends to study cigarette smoking behavior and media exposure among African-American, Asian, Hispanic, and White female teenagers. The proposed study also plans to investigate which ethnic groups are more vulnerable to tobacco advertising and promotion influences, and to determine whether the impact of tobacco marketing on female adolescent smoking differs across ethnicity among female teenagers. This study could provide better understanding of the relationship between media exposure and cigarette smoking among teenage girls. This study will use data already collected by the University of California, San Diego, and the California Department of Health Service. The two data sources were the California Tobacco Surveys (CTS) 1990-1991, 1992, 1993, and 1996, and the California Youth Tobacco Survey (CYTS) 1994-1997. The sample will be comprised of female adolescents with the following

selfidentified ethnicities: African-American, Asian, Hispanic, and White (total N = 13,250). Both conventional and advanced statistical approaches will be employed to study ethnic differences in media exposure and cigarette smoking. The findings in this study will enable the health professionals to design more successful tobacco use prevention programs to reduce media influences on female adolescents.

Title: Telephone Counseling for Pregnant Smokers
Principal Investigator: Zhu, Shu-hong
Institution: University of California, San Diego, CA
Funding Agency: California Tobacco-Related Disease Research Program
Project ID: 8RT-0103
Project Funding Period: 1 July 1999 – 30 June 2002

Abstract: Maternal smoking during pregnancy or shortly after childbirth has serious health consequences for the fetus or the developing infant. It is associated with an increased risk for spontaneous abortion, pregnancy complications, premature delivery, low birth weight, and prenatal and neonatal death. The increased risk can be reversed or minimized if women stop smoking soon after they become pregnant. However, it is estimated that 15% of pregnant women in the United States smoke cigarettes. Furthermore, of those who successfully quit during their pregnancy, 70% relapse soon after their baby is born. Thus, there is a pressing need to develop programs that can help these women quit smoking during pregnancy and prevent them from relapsing after childbirth. Unfortunately, few pregnant women have access to a suitable program, one designed to account for their distinctive circumstances and needs. Quitting smoking is difficult at any point in time, but stresses unique to pregnancy and to the postpartum period make it even more challenging for the women. This study will test the effectiveness of a telephone counseling helpline specifically designed for pregnant women. The counseling will be provided over the phone so that the pregnant women need not leave home to receive the help. The counseling will be tailored to individual needs as each woman will be assigned to a specific counselor who will work with her individually to come up with a quitting plan that suits her personally. The counselor will provide counseling over the phone to assist her to stop smoking (or to stay quit) throughout the pregnancy, and offer counseling and support up to six months postpartum. This study will recruit participants through the Partnership for Smokefree Families (PSF), a collaboration of three large and integrated health care systems in San Diego, which provide health care for about 20,000 pregnant women each year. It is estimated that about 80% of these pregnant women see their doctor during the first trimester for prenatal care. This provides a prime opportunity to intervene with this population. Physicians can ask their pregnant patients if they smoke. If they do, physicians can advise them to quit, provide written self-help materials, and refer them to the telephone counseling helpline (known as the PSF Helpline). The referral consists of two elements: 1) The smokers will be encouraged to call the helpline; 2) permission to have a counselor call them at home will also be requested. This study will use a proactive calling procedure to enroll these pregnant smokers into counseling if they fail to call the helpline after their visit with the physicians. The physicians can also provide support and a degree of accountability for pregnant smokers by asking about their smoking status at subsequent prenatal visits. As physicians may not have the time or training to offer smoking cessation counseling, the prenatal visit will be used as a springboard to enroll smokers into more extensive assistance, in this case the telephone counseling helpline. This would allow pregnant women to get the attention they need and would minimize the time drain on physicians. This study is designed to: 1) Determine how often pregnant smokers will call a free helpline for counseling after they are advised to do so in their first prenatal visit. 2) Determine how many pregnant smokers will participate in counseling if contacted proactively. 3) Test if telephone counseling can help pregnant smokers quit smoking and stay abstinent after the baby is born. This will be accomplished with a randomized design. Determine if quitting as

a result of doctors' advice and/or telephone counseling increases birth weights of babies born to participating women.

Activity Type: Media Campaign
Title: European Week against Cancer 2001: Women and Tobacco
Sponsor: Association of European Cancer Leagues
Date: September 5, 2001

Description/Agenda: (Press Release) Smoking - an increasing threat to womens´ health and well-being in Europe

The single most dangerous health habit among women in Europe is smoking. Tobacco use is one of the greatest burdens to the health and well-being of women around the world. At present it kills over half a million women each year, but this is expected to double by the year 2020. In some countries, lung cancer has already surpassed breast cancer as the main cause of cancer deaths among women.

It is especially young women who smoke more than men. Since 1970's, the number of smokers have decreased more among men than women. World wide, the smoking habit is spreading especially among women in lower social classes, who quit smoking less often than other women. Finding ways to make lower class girls adopt a smoke-free lifestyle is a great challenge to schools and health care professionals.

Lung cancer is rising more rapidly among women than among men in the European Union. Alarm bells are already ringing in some countries where lung cancer is currently more common among women under 45 years of age than men of the same age.

Tobacco free - it´s a beautiful thing

Women should not let themselves be fooled by the strong and persuasive messages of the tobacco industry, but realise that the best thing they can do themselves is to stop smoking. In addition to the indisputable and grave health effects, smoking has harmful effects on the appearance, skin, dental and oral hygiene. These effects appear relatively soon after smoking initiation. Most of them are fortunately reversible after stopping smoking. The damage on skin and the subsequent formation of wrinkles is irreversible, if smoking continues for decades. After 20 years of smoking the skin of a 40-year old woman has aged an additional 20 years.

It is never too late to stop smoking. Tens of thousands of women succeed in smoking cessation every year in Europe alone. During the European Week Against Cancer on October 8 - 14 women are encouraged to stop smoking and provided with advice and support on how to succeed in this.

The "Women and Tobacco" -campaign is targeted to women in the age of 20 - 35 years. During the week a variety of actions are taking place around Europe to promote reduction in womens´ smoking. The methods include conferences, advertising campaigns, media launches, press conferences, meetings and discussion groups, distribution of posters, leaflets and postcards, dissemination of cessation guidelines and advice on how to stop smoking. The campaign will be carried out in 20 European countries (Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Iceland, Ireland, Italy, Luxembourg, Norway, Poland, Portugal, Slovakia, Slovenia, Spain and UK). The European Week Against Cancer is an annual health promotion campaign which has been organised since 1989. It is a joint effort of non-profit cancer fighting organisations and their partners. On the pan-European level the action is co-ordinated by the Association of European Cancer Leagues (ECL).

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.

Activity Type: Media Campaign
Title: Women Statewide to Toss Their Tobacco Products
Sponsor: Colorado Department of Public Health and Environment
Date: May 13, 2001

Description/Agenda: (Press Release) DENVER – On Monday, May 13, the Colorado Women and Tobacco Coalition, which is comprised of 19 Colorado women's organizations, is kicking off National Women's Health Week with an invitation to women throughout the state to trade in their ashtrays, lighters and other tobacco paraphernalia for free cessation service information and t-shirts. Women's Health Week is being observed from Sunday, May 12, through Saturday, May 18.

The t-shirts list the "Top 10 Reasons Colorado Women Quit." The top 10 reasons were created by the winners of a coalition contest conducted earlier this year in which women from throughout Colorado participated. Monday's trade-in events will be held at venues throughout the state, listed at the end of this page.

The winning reasons for Colorado women to quit smoking are:

10. Ever try to accessorize with an oxygen tank?
9. Improved kissability.
8. High altitudes and low lung capacity don't mix.
7. Wrinkles, bad breath and yellow teeth are fine… for buffaloes.
6. Nicotine nixes the "Rocky Mountain High."
5. They've come a long way, baby.
4. They'd rather be skiing than dead.
3. Smoking around children = children smoking.
2. Because someone else needs them.
1. They CAN.

Sara Miller, the program manager for the Comprehensive Cancer Prevention Control Program at the Colorado Department of Public Health and Environment, said, "The purpose of the tobacco trade-in project is twofold. It is an effort to both raise awareness about the special dangers tobacco use poses for women and, at the same time, to offer support to those who want to quit.

"In Colorado, more women now die from lung cancer than those who die from breast cancer. In fact, tobacco use is the leading cause of preventable death for women in our state. In addition, smoking has damaging effects on women's reproductive health and is associated with pregnancy complications, reduced fertility and early menopause."

Miller said that, according to the Office of the Surgeon General, smoking is one of the most important preventable cause of poor pregnancy outcomes among women in the United States. Smoking is associated with an increased risk of miscarriage, stillbirth, pre-term delivery, low birth weight and infant death. As many as 10 percent of all infant deaths could be prevented if pregnant women did not smoke.

She said that smoking also can adversely affect children after they are born. For example, exposure to secondhand smoke increases the child's risk of pneumonia, bronchitis and fluid in the middle ear, Miller explained.

Women, and men, who want to quit smoking are encouraged to use Colorado's new, free, tobacco cessation services, the Colorado Quitline and QuitNet. Since its launch in late October 2001, the Quitline (1-800-639-QUIT) has received 4,771 calls. Its online counterpart, QuitNet (www.co.quitnet.com), has logged 22,175 visitors since it became operational on December 21.

Each is available 24 hours a day, seven days a week, and each offers personalized counseling services free of charge.

Activity Type: Meeting
Title: Annual Investigator Meeting 2002. Women and Smoking: Smoking Has No Glass Ceiling
Sponsor: California Tobacco-Related Disease Research Program
Date: December 4-5, 2002

Description/Agenda: (Information from Program) TRDRP focuses its 7th Annual Investigator Meeting on the theme of Women and Smoking to address what the U.S. Surgeon General describes as "an epidemic of tobacco-related diseases" for women. AIM's plenary session will examine: tobacco industry marketing aimed at women, health effects of tobacco use for women, sex and gender differences in tobacco-related disease mechanisms, and prevention and cessation strategies for women and girls. The conference will also include workshops on tobacco use and women's health and a Town Hall meeting exploring the issue of harm reduction. On Wednesday evening, a reception will be held at the nearby San Jose Art Museum. The conference will conclude with "TRDRP Listens"-an opportunity to tell us your views on TRDRP's research priorities and mission.

Poster sessions included: Cardio, Pulmonary & Other Tobacco-Related Diseases; Environmental Tobacco Smoke; Youth Cigarette Smoking; Economics & Policy; Novel Cessation Approaches; Women & Smoking; Smoking in Multiethnic Populations; Nicotine Receptors & Addiction; Lung Cancer; and Genetic Epidemiology.

Workshops included: Smoking and Breast Cancer, Cardiovascular Disease in Women, TCS Data on Women and Smoking in California, Tobacco Use Research Centers Panel Discussion, Cutting Edge Issues in COPD, and ETS and Adverse Pregnancy Outcomes.

Activity Type: Website
Title: A Breath of Fresh Air (http://www.4woman.gov/QuitSmoking/index.cfm)
Sponsor: The National Women's Health Information Center
Date: Last updated August, 2002

Description/Agenda: (Home Page Description) This specialty section will help you and the people you love to breathe clean**!** Along with information on the health effects of smoking, we provide you with resources to help you quit if you are a smoker. We encourage you to learn as much as you can about smoking and to share this information with the ones you love. Remember, it's best to never start smoking and if you do smoke, don't give up on quitting. We know how hard quitting can be, but you'll be glad you did! Being smoke-free will help you to live longer with better health.

We all need to be concerned about smoking. Today, about 1 out of every 5 women in America smokes, even though we know smoking is not good for our health. And, women are starting to smoke at younger and younger ages. Did you know that lung cancer kills more women every year than breast cancer? Did you also know that smoking could affect more than just your lungs? Smoking can increase your risk for heart disease, heart attack, stroke, osteoporosis (thinning or weakening of your bones), and cancers other than lung cancer. It can also affect your ability to get pregnant. Smoking when you are pregnant increases your chances of having problems with your pregnancy, including premature or early birth and having a baby with low birth weight.