1.0 Specific Aims

Cigarette smoking remains the largest preventable cause of death in this country, killing 443,000 people a year.[1] The US is a global leader in tobacco control efforts, and recent estimates indicate that the prevalence of current smoking has dropped below 20% for the first time on record.[1] However, pronounced health disparities exist in access to tobacco control resources and smoking cessation programs, resulting in fewer economically disadvantaged individuals successfully quitting smoking as compared with middle- and high-income individuals.[2] In addition, the tobacco industry aggressively markets its products to economically-disadvantaged, predominantly African American urban residents.[3] Nevertheless, most existing smoking cessation services do not meet the needs of low-income populations.[4]

The overarching goal of this study is to design, deliver, and evaluate a novel smoking cessation program targeted to low-income, uninsured, and underinsured individuals. "Delivering" in the context of this proposal means taking the program directly to neighborhoods where the target audience resides. Thus, our smoking cessation intervention research project will partner with Dr. Curtis Pettaway's existing Prostate Outreach Project in the Department of Urology at M. D. Anderson, which has served over 4,500 uninsured and underinsured individuals in the Houston area over the last five years. By utilizing a mobile unit and an established network of community sites, we will significantly increase the range of cancer prevention services for individuals with limited transportation abilities, and limited or no medical insurance who rarely or never use traditional health care facilities.

Specific Aim 1: Compare the efficacy of three smoking cessation interventions targeting community based low-income uninsured and underinsured individuals in a group-randomized trial. The interventions will include a Standard Care (SC) approach, consisting of brief advice to quit smoking, nicotine replace therapy (NRT), and self-help written materials; an Enhanced Care (EC) approach, consisting of the standard care components plus a cell phone-delivered text/graphical messaging component; and an Intensive Care (IC) approach, consisting of all SC and EC components plus a series of 11 cell phone-delivered proactive counseling sessions and a cell phone-delivered text/graphical messaging component.

Hypothesis 1.1. Participants randomized to the EC condition will have higher smoking abstinence rates at 12-month follow-up compared to participants randomized to the SC condition.

Hypothesis 1.2. Participants randomized to the IC condition will have higher smoking abstinence rates at 12-month follow-up compared to participants randomized to the EC condition.

Specific Aim 2: Evaluate the role of quit motivation, nicotine withdrawal, risk perception, self-efficacy, social support, and negative affect as potential mediators of smoking abstinence

Hypothesis 2.1: The EC's and IC's effects on abstinence will be mediated by quit motivation, nicotine withdrawal, risk perception, self-efficacy, social support, and negative affect.

Specific Aim 3: Compare the cost-effectiveness of the three treatment conditions.

Hypothesis 3.1*:* Compared to SC and EC, the IC is a cost-effective use of health care resources.

Although all three interventions will be made easily accessible to the target audience and are likely to have an impact, we believe that the IC will most successfully address the needs of low-income smokers. First, the IC program will be personalized and equipped with an intensive, extended

counseling and support module provided over the cell phone. Second, the program will combine three intervention components featuring high potential for maintaining support and motivation to quit and prevent relapse. Third, the IC intervention makes use of cell phone technology – an approach that has demonstrated efficacy and feasibility among low-income smokers (i.e., underserved HIV-positive smokers) in previous research conducted by the investigative team.[5] The proposed project offers a number of features (proximity of services to the place of residence, provision of cell phones, etc.) that are likely to reduce treatment barriers while enhancing participant recruitment and retention.

2.0 Background

Tobacco use among low-income populations. Data reveal that the initiation and maintenance of smoking is twice as likely for families living at the poverty level than for those living above the poverty level.[6] Comparisons of smoking prevalence using NHANES data for the past 25 years reveal a worsening gap between those at the lowest income levels and those at the highest.[7] Besides poverty, low education levels are associated with a higher prevalence of smoking. Surveys indicate that smoking rates are 33% among those who did not finish high school. In addition, smoking disproportionately affects low-income individuals who are members of racial/ethnic minority groups. For example, Delva and colleagues[4] conducted a cross-sectional survey of 1,021 adults assessing smoking rates in the poorest predominantly African American census tracts of Detroit using randomized sampling techniques. Using door-to-door interviews, 41% of females and 59% of males reported being smokers. Thus, expanding the reach of smoking cessation and treatment resources for population subsets with low levels of education and income is an urgent priority.

Smoking cessation studies among low-income populations. The majority of published studies targeting low-income smokers have used mostly Caucasian samples; quit rates have ranged from 6% to 16%.[8-11] The lack of focus on minority populations is surprising given the high prevalence of smoking among low-income adults. Further, this subpopulation has been less successful in achieving smoking cessation than groups with higher income and educational status.[2] Besides clinical trials, stop-smoking campaigns among low-income community groups using quasi-experimental designs have shown limited success.[12, 13] It is possible that living in tobacco-friendly environments and lacking access to resources for nicotine dependence treatment contributes to lower rates of success.[2]

Rates of smoking-related illness and mortality are highest among African Americans. African Americans are the racial/ethnic group with the largest proportion of indigent individuals.[6, 14] Despite bearing a disproportionate part of the suffering from tobacco-related conditions, few trials of smoking cessation among African Americans have been conducted.[15] In particular, an identified need exists for tailored smoking cessation interventions and treatment.[16] A feasibility smoking cessation intervention study with 100 African American smokers was conducted at three public health clinics.[17] Investigators used a stage-based computer expert system and tapes about stress reduction. The feasibility of the study was clearly supported. The quit rate at the 6-month follow-up was 16%, 80% of participants made a quit attempt, and 76% of participants were retained throughout the study. King and colleagues[15] conducted a single-group pilot study, recruiting 50 African American smokers. The intervention used a combination of nicotine replacement therapy and behavioral therapy techniques from national tobacco dependence and treatment guidelines. The study retention rate was 74% and carbon monoxide breath tests confirmed quit rates of 18% at the 6-month follow-up. These initial results support the feasibility of conducting studies with African American smokers. Considering that few studies exist, a pressing need exists to conduct controlled, randomized long-term smoking cessation studies that use nicotine replacement therapy and reach low-income minorities.

National statistics for health insurance coverage. Recent national estimates of Americans without health insurance revealed that 18% (54 million) had episodic coverage during the previous 12-month period and 10% (31 million) were not covered for more than a year.[18] This report indicated that Hispanics had the highest rate of uninsured at 30%, followed by African Americans at 15%. The state with the highest rate of uninsured (i.e., 30%) was Texas. An expansion of public investment to ensure universal access to health care and evidence-based preventive programs is a priority under the new administration.[19] As smoking is the leading cause of preventable morbidity and mortality in the US[20] and in consideration of the millions of uninsured and underinsured individuals, the new administration articulated plans to increase resources for reducing tobacco-related cancers including initiatives for evidence based smoking cessation treatments delivered through community-based programs.[19] Studies should be conducted to improve smoking cessation rates among low-income persons who are uninsured or underinsured and at high risk for tobacco-attributable morbidity and mortality.

Mobile health clinics. Mobile health clinics can be beneficial for providing care to underserved populations. Depending on needs, mobile units have provided the following outreach services: acute and chronic care treatment, immunizations, dental exams, post-disaster care, prenatal care, screenings for mental health, cervical and breast cancer screenings, hearing tests, and nutrition counseling.[21-29] Mobile units are gaining popularity, but there are few data on outcomes beyond utilization rates. Results of a case-control study examining outcomes for prenatal care among uninsured immigrants indicated that patients using the mobile clinic received prenatal care significantly earlier than participants using prenatal care from a stationary clinic. Prenatal care on the mobile unit was compared to stationary clinics and similar positive outcomes were found (e.g., gestational age at delivery, birth weight).[30] Post-test knowledge and skills for 777 participants were significantly increased after a breast cancer screening and awareness effort delivered by a mobile unit.[31] While no literature on providing smoking cessation treatments in a mobile unit was located, the evidence of favorable outcomes for other health conditions suggests that mobile units have potential for providing smoking cessation treatment. A clear need exists to test the efficacy, utilization and cost-effectiveness of using a mobile clinic to promote smoking cessation and access to low-income smokers.

Cell phone use. According to the Cellular Telecommunications & Internet Association, over 266 million people in the United States subscribed to cell phones as of October 2008, compared with approximately 4.3 million in 1990. The cell phone has become an integral and, for some, essential communication tool that has helped owners gain various kinds of assistance in daily life. For example, according to a 2008 Pew Report, 74% of the Americans who own cell phones say they have used them in an emergency and gained valuable help.[32] As cell phone use has become more widespread, its importance as a tool for preventive interventions has greatly increased. For many economically disadvantaged people, a cell phone will be the only technological device with computing capabilities that they may own. In response to this increasingly widespread cell phone availability, many health care studies utilizing cell phones have been initiated. Several recent smoking cessation studies utilizing cell phones and text messaging have shown feasible and promising results.[33-36] Studies in other areas like alcohol prevention, diabetes education, sexual health, diet and physical activity have also shown promising results.[37-41] Dr. Vidrine, one of the PIs on this project, has successfully utilized cell phones to deliver smoking cessation treatment to low-income HIV-positive smokers.[5, 42, 43]

Potential for dissemination. A major consideration in the design of the proposed study was the potential of the intervention delivery approach to have a significant public health impact. Compared to

higher-SES smokers, low-income smokers have limited resources for quitting smoking and are less likely to receive assistance through the health care system.[2] Therefore, it is critically important that these smokers be targeted directly. Thus, we chose to deliver and test our intervention approaches through utilizing a community network established by a mobile clinic supported by a well-developed infrastructure, the Prostate Outreach Project (POP). The POP provides care to a broad range of underserved patients who are representative of real-world, low-income individuals. This partnership with the POP is crucial to the success of the proposed study, and will facilitate broad and efficient dissemination of the interventions following the proposed study. If successful and cost-effective, this treatment delivery approach could be easily adopted by the POP and other mobile clinics. We believe that the interventions could also be incorporated within a variety of health-related outreach programs targeting low-income individuals. Indeed, dozens of outreach programs exist in the United States to address not only cancer but chronic obstructive pulmonary diseases, cardiovascular diseases, diabetes, and other health conditions. For example, according to the Office of Minority Health (personal communication), Texas alone features as many as 52 outreach programs; California has 48 programs. Many health care facilities, universities with medical schools, schools of public health, and other entities invest considerable efforts in reaching the underserved populations. We expect that the interventions and delivery approach would be highly appealing to these entities.

3.1 Preliminary studies

3.2 Experience with community-based low-income, multi-ethnic populations.

The University of Texas M. D. Anderson Cancer Center's Prostate Outreach Project (POP). The Prostate Outreach Project (POP) is a free community-based education and early prostate cancer detection program established initially in two undeserved primarily African American communities in Houston/Harris County, Texas in June 2003. The target communities were identified through information obtained from the 2001 Census. The original goals of the POP were to enhance African American men's knowledge of prostate cancer, promote early detection and follow up as a strategy for preventing the disease and reducing the high mortality rates associated with it. Since its inception, the target population has been expanded to include other underserved and racial/ethnic minority groups. The POP has provided education and prostate detection to 4,521 men of various ethnic backgrounds at a total of 240 events. The program is sponsored by a congressional allocation through the Centers for Disease Control and Prevention as well as funds from the University Cancer Foundation and the Prostate Cancer Research Program of M. D. Anderson. The POP operates under the direction of Dr. Curtis Pettaway, Professor in the Department of Urology at M. D. Anderson Cancer Center.

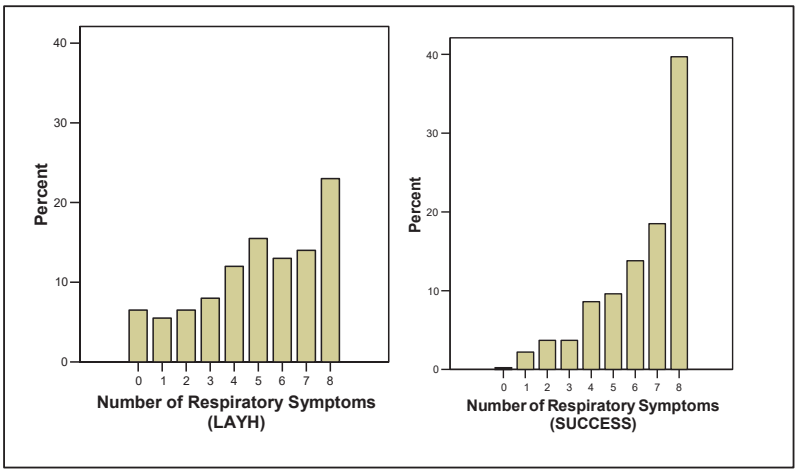
While the POP has been very successful, there are many more high-risk individuals in need of cancer prevention services. A critically important strength of the proposed trial will be to utilize the valuable network of community sites already established by the POP. Moreover, by providing smoking cessation treatment, we will increase the scope of cancer prevention services provided through the program, and greatly increase the target population from only men 40 to 70 years of age to all eligible adult men and women.

3.2. Experience with delivering smoking cessation programs.

Projects Look at Your Health and SUCCESS. These two separate projects (R01s, PI: Prokhorov), funded by the National Cancer Institute, were conducted to design innovative smoking cessation programs for community college students and university students. Project SUCCESS was designed

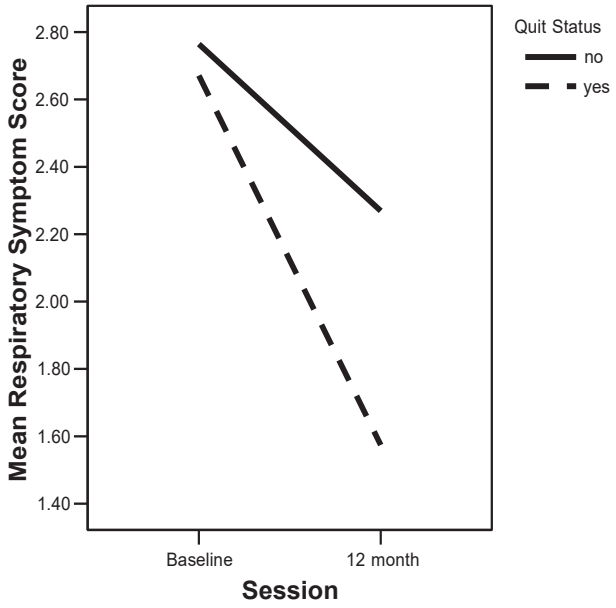
to develop and evaluate a computer-assisted, counselor-delivered smoking cessation program that addresses personal health issues and readiness to change smoking behavior among student smokers at The University of Houston. Project SUCCESS was a continuation of the original Look at Your Health (LAYH) study aimed at smoking cessation among community college students and using a similar intervention approach.

Figure1. Respiratory Symptoms among Smokers in Two Studies



Our experimental smoking cessation counseling strategy was heavily grounded in health feedback and correction of misconceptions regarding the impact of tobacco use on respiratory health. The majority (77%) of smokers reported not having any "symptoms, diseases, or illnesses caused by smoking" while Figure 1 demonstrates that less than 1% of the same sample of smokers reported no respiratory symptoms when completing the American Thoracic Society's inventory measuring eight symptoms: (1) morning cough, (2) daytime cough, (3) wheezing, (4) shortness of breath when walking, (5) shortness of breath during exercise, (6) phlegm or mucus production, (7) pain or tightness in the chest, and (8) getting very tired in a short period of time.[44] The rest of the respondents reported one or more of the aforementioned symptoms. In Project LAYH, a less pronounced but similar trend was observed (Figure 1).

Figure 2: Mean Respiratory Score by Session



Validation of Quit Status by Salivary Cotinine Values. Self-reported quitters must have had a cotinine value ≤ 5 ng/mL for validation of nonsmoking status. Self-reported smokers needed no validation. A total of 46 (58%) students who reported quitting provided a cotinine sample. Of these, 100% of quits reported by students were cotinine-validated. Hence, we used self-reported abstinence in our analysis.

Intent-to-Treat (ITT) Analysis. The ITT analysis was used to compare abstinence rates between groups where non-completers from both groups were considered to be smokers. This is a reasonable assumption since non-completers did not differ in important characteristics between the groups. Fifty-five (20%) students were quitters in the health feedback intervention group compared to 24 (10%) in the standard care (SC) group ($p<0.01$).

*Relapse (Smokers at 12-months)***.** Relapse was evaluated by responses to the following question "Have you quit smoking and then relapsed since your last session?" Out of 236 students who

completed the final assessment, 157 (67%) reported being smokers. The rate of relapse did not differ significantly between the health feedback intervention group and SC (51% vs. 59%, NS).

Changes in respiratory symptoms over time. The average baseline respiratory symptom scores were not significantly higher for quitters compared to smokers (2.8 vs. 2.7, NS). Respiratory symptoms declined in both smokers and quitters. However, the average rate of change from baseline to 12 months differed significantly between the two groups with quitters showing greater improvement than smokers (-1.1 vs. -0.5, $p<0.01$). The results are displayed in Figure 2. They underscore the importance of providing respiratory feedback during smoking cessation counseling.

*Health tests and computer software in smoking cessation counseling***.** A counselor delivered three sessions with each student: baseline, a 3-month follow-up, and a final assessment at 12 months.

Estimated "lung age." In Projects LAYH and SUCCESS, spirometry was performed among the participating college student smokers to examine the lung function and obtain feedback the estimated "lung age".[45] Significant differences were discovered in the mean "lung age" and chronological age in both studies at baseline. In both projects, the "lung age" has shown some but not significant improvements among quitters at the end of the study (likely because the restoration of lung function after quitting may take years while respiratory symptoms usually begin to subside in 2-3 months).

3.3. Experience with cellular telephones as smoking cessation intervention/assessment devices in low-income populations.

Feasibility of using a cellular telephone to deliver a proactive smoking cessation intervention to HIV-positive smokers. Dr. Damon Vidrine, the Associate Director for Research at the Oklahoma Tobacco Research Center, Co-Program Leader Cancer Health Disparities, Stephenson Cancer Center and Associate Professor in the Department of Family and Preventive Medicine, he and colleagues conducted a pilot feasibility study of a cell phone delivered intervention for medically indigent HIV-positive smokers. Twenty participants were recruited over a 6-day period at the time of their regularly scheduled medical care appointment. Smoking status was assessed for all patients during the vital signs assessment, which occurred prior to their physician visit. Patients who self-reported that they were current smokers were given a carbon monoxide breath test (CO test) to verify smoking status. Of the 20 participants who enrolled in the study, 19 (95%) completed the intervention. Of the 19 participants who received the intervention, 100% received four or more calls, with all participants maintaining contact through the 2-week intervention and completing the 6^{th} and final call. The overall contact rate was 93% (106 of 114 calls).[46]

A randomized trial of a proactive cellular telephone intervention for smokers living with HIV/AIDS. As a follow-up to the feasibility study, Dr. Vidrine performed an efficacy assessment of adding a proactive cellular phone-delivered intervention (CPI) to a recommended standard of care (RSOC) intervention consisting of brief physician advice to quit smoking and written materials. Participants randomized to the CPI group were given cellular telephones with prepaid minutes and received eight proactive phone-counseling sessions along with access to a smoking cessation hotline. The intervention was designed to reduce the barriers in access to care, provide an intensive level of support, and meet the special needs of a multiethnic, economically disadvantaged HIV-positive population. Ninety-five participants were enrolled and randomized in the trial.

At randomization, participants were stratified by cigarettes smoked per day, positive depression history, and level of nicotine dependence. We collected 3-month follow-up data on 77 participants, which reflects an 81% follow-up rate. As with the previous feasibility study, most counseling sessions were successfully completed on time. Of 384 calls, 311 were completed (81%). In addition, the vast majority of the CPI participants (81.1%) received six or more proactive calls. Finally, the hotline received 37 calls from CPI participants.

Unadjusted analyses based on available data indicated abstinence rates of 10.3% for the RSOC

group and 36.8% for the CPI group. Smokers in the CPI group were 3.6 times more likely to quit

smoking compared to smokers in the RSOC group (RR=3.6, 95%CI = [1.3–9.9], p=0.0059). Participants in the CPI group were 9.7 times more likely to make a successful quit attempt, defined as remaining abstinent for at least 24 hours, compared to participants in the RSOC group (RR=9.7, 95%CI = [1.3–72.5], p=0.0039). Finally, mean length (in days) of smoking abstinence was significantly longer for the CPI group compared to the RSOC group (CPI mean (SD)=30.8 days (31.1); RSOC mean (SD)=12.3 (19.7); t (72)=3.12, p=0.0026). In an attempt to identify the treatment's mechanisms, we examined change in levels of depressive symptoms, anxiety, self-efficacy, and perceived social support as mediators between the cell phone intervention and smoking status at the 3-month follow-up. Reductions in depression and anxiety levels and an increase in self-efficacy were identified as treatment mediators.[42]

3.4. Experience in research on the psychology of smoking and smoking cessation

The increasing recalcitrance of smokers. One focus of Dr. Jennifer Irvin Vidrine's (Co-Investigator) research has been on smokers who are heavily entrenched in their smoking behavior and are likely to have particular difficulty quitting. She has published two quantitative reviews supporting the hypothesis that the population of remaining smokers is progressively becoming harder to treat.[47, 48] Both reviews examined changes in abstinence rates following cessation treatment over time. Results indicated that behavioral and pharmacological cessation trials have progressively declined in efficacy over the past quarter-century, consistent with previous anecdotal and empirical evidence that smokers are becoming more heavily concentrated among individuals with the lowest levels of education, occupation, and income and are becoming increasingly difficult to treat. Findings highlight the need to expand the reach of evidence-based smoking cessation treatments to underserved and heavily dependent smokers likely to have particular difficulty quitting.

Health literacy and smoking risk communications. Dr. Irvin Vidrine is currently the PI on an NCI-funded R01 to examine how level of health literacy influences responses to smoking risk messages manipulated in terms of message framing and emotionality. In addition to traditional questionnaires, outcomes are assessed using "implicit" cognitive psychological measures. Thus, the study examines the immediate effects of different types of smoking risk messages on cognition in a laboratory setting. Findings will have important implications for the future development of smoking cessation interventions targeted at low literacy populations.

Mechanisms underlying changes in risk perceptions over time in the natural environment. Dr. Irvin Vidrine recently completed a K01 Mentored Research Development Award funded by the CDC. Recruitment yielded a racially/ethnically diverse and low socioeconomic status sample of smokers (N=200). Participants were 45% African American, 45% non-Latino white, 7.5% Latino, and 2.5% other or mixed race. Participants were 46 years of age on average (SD=9.7 years), had a mean 26-year smoking history (SD=11.1), and smoked an average of 21 cigarettes per day (SD=9.7). Nearly half the sample (46%) had an annual family income of less than $20,000 per year. In addition, 40% had private or group health insurance, 23% received Medicare, Medicaid, or medical assistance, and the remaining 37% had no health insurance of any kind. All participants received smoking cessation treatment consisting of nicotine patch therapy, in-person, minimal contact smoking cessation counseling, and self-help materials based on the PHS *Treating Tobacco Use and Dependence Clinical Practice Guideline*.[49] Biochemically-confirmed 7-day point prevalence abstinence was 32% three weeks after the quit day. Abstinence data were analyzed using an intent-to-treat approach. The goals of the project are to examine real-time, momentary changes in risk perceptions in the natural environment among smokers attempting cessation. Potential differences in perceptions of risk among smokers who achieve successful abstinence and those who relapse will be examined. It is expected

that factors including affective state, craving, and smoking behavior will influence perceptions of risk over time in the natural environment. Participants were tracked from one week prior to their quit date through three weeks after their quit date using state-of-the-science ecological momentary assessment (EMA) procedures.[50] All participants received smoking cessation treatment consisting of nicotine patch therapy, minimal contact smoking cessation counseling, and self-help materials based on the PHS *Treating Tobacco Use and Dependence Clinical Practice Guideline*. Risk perceptions were assessed using EMA, "implicit" cognitive psychological measures, and computer-administered questionnaires. Findings have the potential to shed light on important mechanisms that may influence the construction of risk perceptions and on how perceptions of risk and smoking behavior may be reciprocally related.

3.5. Summary of previous efforts

Several important lessons have been learned from these research experiences. First, despite the considerable health risks associated with smoking, the prevalence of smoking is high among low-income individuals. Second, this population has limited resources for quitting smoking. Third, innovative treatment approaches designed to overcome barriers to cessation can be efficacious. While cell phone-delivered treatments appear to be highly promising for individuals willing to enroll, less resource-intensive alternatives should also be explored. Thus, the proposed study reflects a logical, non-overlapping extension of the investigator team's previous research efforts. By targeting the general population of low-income smokers, we will be greatly increasing the potential target population beyond our previous work with HIV-positive smokers. An additional novel component of the proposed study is that we will be taking advantage of the non-voice capacities of the cell phone (i.e., text and pix [picture] messaging).

4.1 Participant eligibility

Inclusion criteria:

- Male or female, 18 years of age or older
- Smoked at least 100 cigarettes in lifetime
- English or Spanish speaking
- Currently smoking at least 5 cigarettes a day, on average
- Willing to set a quit smoking date within a week of the enrollment

Exclusion criteria include:

- Positive history of a medical condition that precludes use of the nicotine patch
- Current use of nicotine replacement therapy
- Current use of other smoking cessation medications (e.g., Chantix or Zyban)
- Pregnant or nursing
- Enrolled in another smoking cessation study

Target sample size N=756.

5.0 Study plan

5.1. Design overview. A group-randomized design will be used, with the community site as the sampling unit. We will stratify by site type (e.g. church, community center, supermarkets) and balance for racial/ethnic characteristics. Sites will be randomized to one of three intervention groups: Standard Care (SC), Enhanced Care (EC), or Intensive Care (IC). The rationale for having two intervention

groups (i.e., EC and IC) is to compare the effectiveness of the lower-cost text messaging intervention versus the higher-cost but more personal phone contacts. Figure 3 provides a description of the interventions.

5.2. Study sites and participants. *Case identification and recruitment*. An important strength of this proposal is our use of the M. D. Anderson Cancer Center's Prostate Outreach Project (POP) network to reach underserved smokers within various communities throughout the greater Houston metropolitan area. The POP has been very successful in establishing community contacts and delivering cancer screening services. Previously, with the use of a mobile unit, the POP has provided cancer screening services to individuals at approximately 150 different community sites (e.g., community centers, churches, and supermarkets). With the assistance of Dr. Pettaway (director of the POP), we will use this well-established community network and model of recruitment to reach a racially/ethnically diverse population of underserved smokers. We will open recruitment to family, friends and any other members of the community sites. Eligible study participants will be identified at each of the community sites previously visited by the mobile unit. Study participants will also be identified at other community centers and churches that are referred to our research team by contacts made at locations previously visited by the POP mobile unit. As was standard practice by the POP, a general information session will be held in which the smoking cessation study will be explained to potential participants. Research staff will be available to answer questions and then to individually obtain informed consent from individuals wanting to enroll in the smoking cessation trial. Research staff will also be available to assist community site staff in disseminating recruitment event information to community members if needed.

It should be noted that we have chosen to operationalize current smoking (smoke 5 or more cigarettes per day on average). Our previous efforts with indigent HIV-positive smokers indicate that a sizable proportion smoke at these lower levels but still have a high level of nicotine dependence. In addition, others have used similarly adjusted smoking eligibility criteria when targeting disadvantaged populations.[51]

5.3 Enrollment. We will restrict enrollment to the following three categories of sites: community centers, churches, and supermarkets. Other POP sites, including homeless shelters, barbershops, and fraternity organizations, are too few to be randomized across conditions. In addition, sites such as homeless shelters are likely to be so unique that including them in just one treatment condition (and not the others) could affect the internal and external validity of the results.

Between 2003 and 2008, the three categories of sites (community centers, churches, and supermarkets) comprised a total of 135 sites, and approximately 3,800 men from these sites were screened by the POP. Assuming 30% of these individuals were smokers (based on the most recent NHIS smoking prevalence estimates for low socioeconomic status populations[52]), this would provide a population of 1,140 smokers. In addition, assuming that two-thirds of the smokers would participate in a smoking cessation study (based on our previous work with medically indigent smokers living with HIV/AIDS[5]), this would yield a sample of 756 individuals. It should be stressed that these estimates are based only on the target population served by the POP – men aged 40 to 70 years. In the present study, a far larger population will be targeted - all smokers (men and women) over the age of 18 from these communities. This will likely double or triple the potential population of smokers at these sites. Thus, we anticipate no problem achieving our target sample size of 756 participants (252 participants in each of the three intervention groups).

5.4. Baseline assessment. Research staff will conduct an audio computer assisted self-interview (ACASI). The interview will take approximately 30-45 minutes to complete and answers will be recorded directly into a computerized database that will contain programmed logic checks and skip

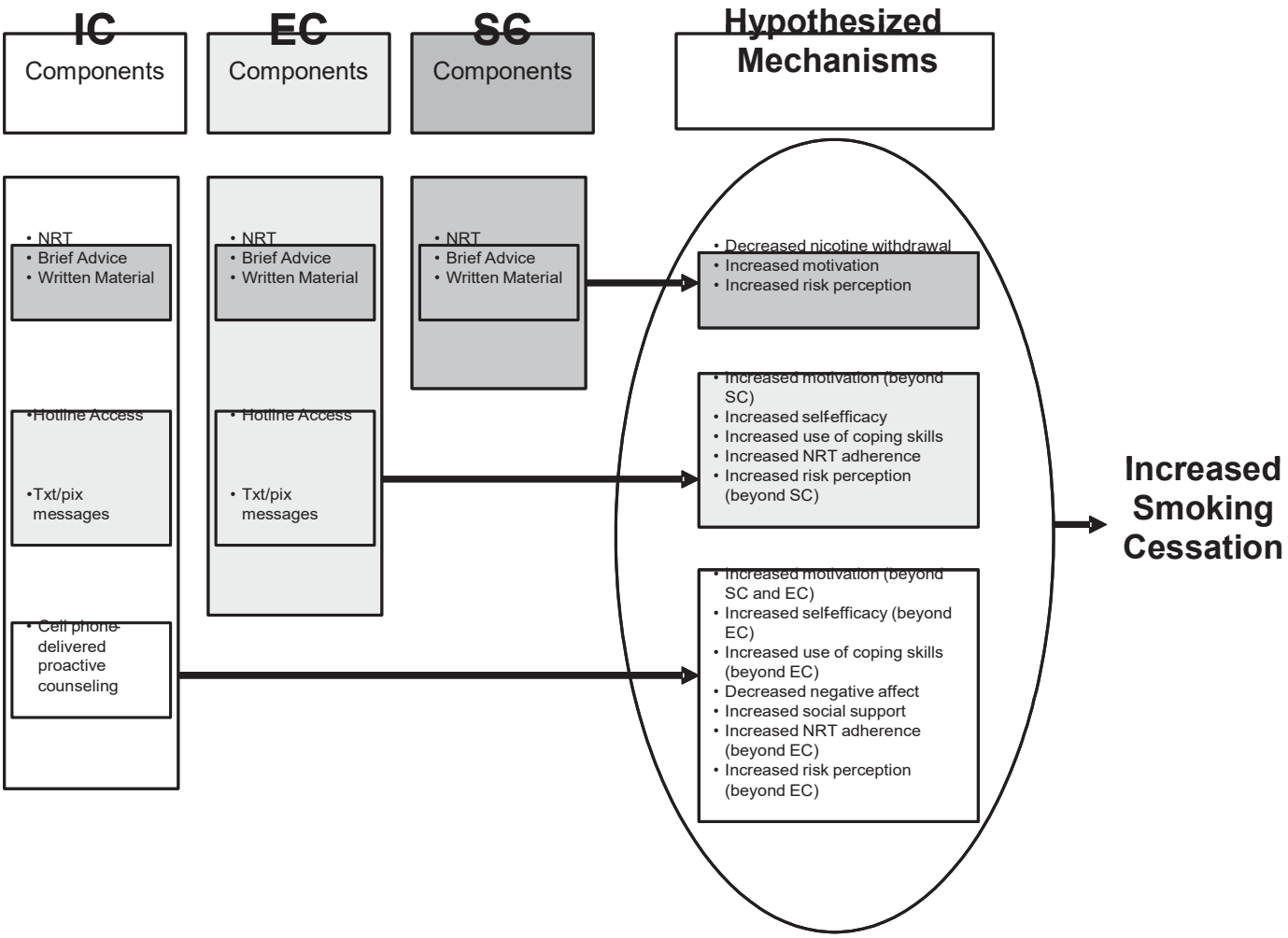
patterns. After completing the entire baseline assessment, participants will be given gift cards valued at $20. Following completion of this assessment, one of the three interventions will be delivered.

5.5. Cell phone assessments. Assessments will be performed monthly for the first 6-months post-study enrollment. These brief assessments will collect information on the participants' attitudes about smoking (i.e., quit motivation, risk perceptions/outcome expectancies, and self-efficacy), nicotine patch use, and smoking status (current status and quit attempts). To ensure the feasibility of this methodological approach, we will provide prepaid cell phones to all participants. The cell phones will be part of a phone plan that includes voice capabilities and minutes to complete the brief assessments. Following completion of the study, participants will be allowed to keep the phones. If a phone is lost, stolen, or damaged, it will not be replaced. Instead, participants will be given a phone number through which they can reach research staff. In previous studies, we have used this approach (providing prepaid cell phones to underserved participants) very effectively. In fact, in our previous cell phone counseling intervention study, we were able to complete more than 80% of scheduled cell phone counseling sessions. Because the brief assessment planned in the current proposal is far less burdensome, we expect a similar or higher completion rate. Participants who complete these assessments will receive additional gift cards ($10 gift card per completed monthly cell phone assessment). At the baseline visit, participants will be provided with the call schedule for the six cell-phone follow-up surveys, a copy of the survey questions, and a brief information sheet outlining the details of the phone plan.

5.6. 12-month follow-up. Our primary outcome will be smoking status at 12-month follow-up. Following a similar schedule previously used by the POP mobile unit, which previously returned to each community site on an annual basis, our research staff will return to each community site approximately 12-months after the initial visit to administer the 12-month follow-up assessment. The actual 12-month assessment will mirror the baseline assessment. Smoking status will be biochemically confirmed using saliva cotinine. Participants will receive a $40 gift card after completing this assessment.

5.7. Intervention approaches. We propose to assess the efficacy of three smoking cessation treatment approaches: Standard Care (SC), Enhanced Care (EC), and Intensive Care (IC). We have taken an additive approach in the design of these interventions, which will allow us to assess the benefit of adding novel components to a well-recognized SC approach. The true contribution of our proposed project will be assessing these interventions in the context of a mobile smoking cessation clinic, which targets underserved smokers in their own communities, greatly reducing important barriers to treatment. Figure 3 contains a brief overview of the treatment components associated with each of our intervention approaches.

Figure 3. Conceptual framework for hypothesized treatment mechanisms



***Conceptual framework*.** A conceptual framework illustrating hypothesized mechanisms through which our proposed interventions will increase smoking cessation is presented in Figure 3. This framework compares and contrasts the treatment components offered through the three treatment conditions: Standard Care (SC), Enhanced Care (EC), and Intensive Care (IC). The figure depicts the manner in which each treatment component exerts an effect on cessation. The treatment elements of the SC approach will serve as the minimal level of recommended care by the PHS *Guideline* and includes NRT, brief advice, and provision of self-help written materials.[53] The additional elements of the EC (i.e., cell phone delivered text/graphical messages, and access to a hotline) are proposed to offer unique pathways to increase smoking cessation, thereby significantly improving treatment outcomes over and above the effects of SC treatment components alone. Finally, the addition of the proactive counseling sessions in the IC approach is hypothesized to tap additional mechanisms, while strengthening the effect of other pathways. As a result of these additional effects, we hypothesize that the IC approach will result in significantly higher cessation rates than the EC condition. The individual treatment components are further described below.

***Nicotine replacement therapy (NRT)*:** NRT in the form of nicotine patches (Nicotine Transdermal System, manufactured by Novartis Consumer Health, Inc.) will be provided along with detailed instructions on proper use. The NRT will be provided to reduce nicotine withdrawal symptoms and enhance cessation outcomes. The provision of NRT is considered part of the minimum recommended level of acceptable care.[53] Studies have found that the use of the nicotine patch approximately doubles abstinence rates compared to placebo.[54] Although nicotine patches are available over-the-counter, in this study we will provide them in order to ensure proper monitoring of patch use and to

reduce potential economic barriers. All eligible participants will be provided with a 10-week supply of NRT patches at no cost. Participants will be provided with the 21 mg patch for 6 weeks, the 14 mg patch for 2 weeks, and the 7 mg patch for 2 weeks. The nicotine patches will be dispersed by trained research staff.

Brief advice to quit smoking. A research coordinator who has been trained to deliver smoking cessation counseling will administer brief advice to quit smoking. Brief provider advice to quit smoking is regarded as an effective and cost-efficient method to reduce smoking.[55] Even when the advice is limited to 3 minutes or less, a significant impact is seen.[53] As recommended by the PHS *Guideline*, brief advice to quit smoking will involve the provision of a clear, strong, and personalized message to quit and assistance in setting a quit date. Instructions on proper use of the nicotine patch will also be provided. This advice is proposed to exert effects on smoking behaviors by increasing motivation and knowledge. Motivation to change will be specifically enhanced through support and empathy, positive expectancies for the possibility of change, and emphasis on participant responsibility for behavioral change.

Self-help written materials. All participants will be provided with a manual. Written materials will reinforce the brief advice given by the research staff. Specifically, the materials will advise all patients to quit smoking, list adverse health effects of smoking, and recommend the use of social support and coping skills. Based on most major theories of health behavior, the information contained in the self-help materials is expected to increase risk perception and motivate participants to quit smoking. Meta-analyses indicate that self-help materials, when provided with other forms of cessation treatment, increase smoking abstinence rates.[53]

Access to a hotline. Individuals in the EC and IC groups will be provided a hotline number where they can reach the study counselors. To facilitate use, the hotline number will be programmed into each cell phone for easy use. Although past hotline studies have had limited success,[56, 57] the current hotline will have some additional benefits. Specifically, the hotline will be staffed by counselors who are familiar with the study, including the recruitment process and the text messaging component. The counselors will also be conducting the proactive counseling sessions with the participants randomized to the IC group. Participants will therefore be calling a familiar support person as opposed to making an anonymous call to a state or national quitline. In addition, the use of cellular phones will allow access to hotline support at the time of urge or following a lapse. Project counselors will carry cell phones in order to provide continuous hotline coverage during business hours. Counselors will record participants' use of the hotline, including the number of times each participant calls, reason for calls, length of calls, and topic areas discussed in calls.

Cell phone delivered text and pix messages. While introducing cessation treatment within the community sites established by the POP is an important step, the intensity of the treatment that can be provided at the time of a mobile unit's annual visit is limited. Time constraints associated with the community site visit will also limit the provision of support, teaching of coping skills, and general relapse prevention assistance. The literature indicates that most individuals who quit smoking relapse within the first week of abstinence,[58] and that increasing treatment intensity decreases relapse rates.[53] Therefore, when time limitations are combined with the infrequency of site visits, the need for an extension of treatment outside of annual visits is clear. We will attempt to address this concern by providing a text and pix messaging intervention to participants in the EC and IC groups.

Participants randomized to the interactive text messaging groups (EC & IC) will receive a series of text messages scheduled to begin shortly prior to their scheduled quit date, and continuing for a 3-month period. In the first week of treatment, participants will receive five messages per day. The

frequency will taper off to one message per day by week 4, and continue at this frequency until week 12.

The first step in this process will be to develop a bank of text messages. In general terms, the messages will be designed to utilize several hypothesized mechanisms leading to smoking cessation. That is, the text messages will be designed to increase knowledge/risk perception, maintain/increase quit motivation, promote coping skills use, increase social support, and enhance self-efficacy. The content of the messages will be designed to fit into one of four different categories: 1) Problem solving/coping skills; 2) Knowledge/risk perception; 3) Increasing and maintaining quit motivation; and 4) Increasing social support. Examples of text messages from each of these content categories are displayed in Table A.

The text messaging intervention is unique in that it has several levels of personalization for each participant (see Appendix F). First, the participant will receive texts based on their current smoking status (quit or relapse); smoking status information will be gathered from each participant in the EC and IC group on a weekly basis in order for them to receive appropriate text messages based on their current smoking status. Second, the participant will receive some Knowledge/Risk Perception texts that target 1) the participants' specific current health problems and 2) health problems that the participant may be concerned about developing in the future. Third, participants will also receive Problem Solving/Coping Skills text messages that specifically address coping skills that are preferred by the participant. The personalized coping skills text messages will be written by the research staff at the time of enrollment, when the staff learns of each participant's preferred coping skill. A participant will receive no more than 3 messages written at the time of enrollment. Lastly, the participant will receive at least one text message per week that addresses the participant by their first name within the message.

Table A. Examples of text messages from each of the four content categories

Message Category	**Potential examples of text messages**
Problem solving/ coping skills	• Make a list of things you can do instead of smoking. Keep the list handy. • Avoid tempting situations, like going to a smoke-filled bar.
Knowledge/ risk perception	• Quitting smoking helps prevent numerous cancers, such as lung, mouth, throat and liver cancer. • Quitting smoking is the single most important thing you can do to prevent heart disease. • Quitting smoking helps your body fight infection. It does this by strengthening your immune system.
Quit motivation	• Think about the strengths that you have that will help you stay away from cigarettes. • Quitting smoking is hard, but you've come this far. Stay motivated!
Increasing social support	• Remember to call a supportive friend if you need any extra encouragement! • Ask friends and family to support you by not smoking around you.

The content of the text messages is primarily drawn from cognitive-behavioral and MI techniques. Problem solving and skills training techniques, which are central components of cognitive-behavioral therapy, are empirically supported for smoking cessation. A substantial focus of the text messaging intervention is to facilitate the development of problem solving skills specific to smoking cessation. As a result, participants are expected to substantially increase their repertoire of coping skills for quitting smoking and maintaining abstinence. The acquisition and effective use of problem solving and coping

skills will further result in an increased sense of self-efficacy when participants are successful in quitting smoking.

In addition to text messages, we will also send pix messages to participants in the EC and IC groups. Some pix messages will actually be simple illustrations representing expected respiratory symptoms based on the scheduled quit date. Specifically, the illustrations will be used to display the typical range of respiratory symptoms following a quit attempt. Because respiratory symptoms often deteriorate for the first several weeks following a quit attempt before improving, we will use the pix messaging capacity of the cell phones to graphically display this trend to participants. We hypothesize that providing this information may reduce concern over increasing respiratory symptoms and may help to prevent smoking relapse.

Text message delivery. A crucial element to the text messaging component will be the development of a system to efficiently identify and send appropriate messages to the study participants. To do this, we will be developing an interactive database. In brief, this system will assist with the selection of appropriate text messages to be sent throughout the three-month treatment course. This selection will be based on the participants' current smoking status, content area covered, and areas of concerns voiced by participants. This selection methodology will also only select messages that have not been used in the previous 5 days, thus preventing the same messages from being repeatedly sent to a participant.

Cell phone delivered proactive counseling. The only distinction between the IC and EC treatment approach will be proactive counseling. As described in the preliminary studies section, we have successfully delivered proactive cell phone counseling to a multi-ethnic population of medically indigent persons living with HIV/AIDS. While the target population in the present proposal is not HIV-positive, we hypothesize that that a similar treatment approach will be efficacious. We will follow a similar treatment protocol in this project. Participants in the IC group will receive 11 proactive 15 minute phone calls over a 12-week period. Substantial evidence indicates a strong dose-response relationship between intensity of treatment and cessation success, with the first week after quitting being a critical period.[49, 58, 59] This relationship is hypothesized to be driven primarily by the concentrated and sustained social support provided to individuals. The establishment of a supportive clinical environment where participants are repeatedly encouraged and reinforced in their quit attempt further serves to increase and maintain motivation to quit. Counseling sessions will focus on topics such as coping with withdrawal and maintaining a commitment to continued abstinence. Five additional sessions are scheduled, with decreasing frequency, over the following 2.5 months. These sessions will focus on relapse prevention. The frequency of sessions will also allow for rapid intervention following lapses. Furthermore, each participant will be assigned a counselor (who will make all calls to that participant) in order to optimize rapport and familiarity with participants' unique concerns and smoking history. The number of calls completed, length of calls, and topic areas covered in each call will be recorded by the counselor.

Counseling content. Like the text message content, counseling session content of the IC (see Table B) is primarily drawn from cognitive-behavioral and motivational interviewing techniques and is meant to foster problem-solving skills. Counselors will use the call schedule in Table B; this schedule may be slightly modified such that a call session may be moved by one day or so to maximize study resources. At the time of enrollment, participants receiving counseling calls will be provided with a schedule of the counseling call sessions. If a session is moved to a different day, the participant will be notified by the study counselor of the modified schedule.

Table B. Schedule of calls and call content

Call	Time of Call	Content of Call

Call	Time of Call	Content of Call
1	1 day prior to quit date	Preparing to quit - why quit and making the commitment to quit
2	On quit date	Quitting Smoking – getting through the first day
3	2 days post quit date	Surviving Withdrawal - withdrawal facts and coping skills
4	4 days post quit date	Managing high risk situations
5	7 days post quit date	Stress, Negative Affect & Smoking
6	10 days post quit date	Improving Support and Asserting Yourself
7	2 weeks post quit date	Reviewing Problem Solving & Dealing with Lapses
8	4 weeks post quit date	Reinforcing Benefits of Being a Nonsmoker
9	6 weeks post quit date	Maintaining Commitment – Keeping Motivated
10	9 weeks post quit date	Successes and Challenges in Smoking Cessation
11	12 weeks post quit date	Long-Term Relapse Prevention

Additional cognitive-behavioral techniques incorporated into the intervention include behavioral activation strategies, assertiveness skills training, and stimulus control techniques. These strategies have been effectively used to treat a variety of clinical problems including depression and substance abuse.[60] While the primary focus of the intervention is to assist participants in quitting smoking, depression and substance abuse behaviors will be monitored throughout treatment as the prevalence of these conditions is greatly elevated in low-income populations. Any decreases in negative affect and substance use behaviors gained through the use of cognitive behavioral techniques are expected to further contribute to smoking cessation and improved health outcomes.

Motivational interviewing (MI) techniques will also be incorporated into the IC. The MI is a directive but client-centered therapeutic approach intended to enhance motivation for change through the exploration and resolution of ambivalence.[61] The MI's emphasis on the use of client-centered techniques to build trust and minimize resistance is based on Rogers' humanistic approach[62], while the focus on considering a person's readiness to change and exploring ambivalence draws from the Transtheoretical Model and Stages of Change.[63] Basic principles of MI include expressing empathy, developing discrepancy, avoiding argumentation, rolling with resistance, and supporting self-efficacy. These techniques will be used to enhance motivation for maintaining abstinence and increase self-efficacy and coping behavior in response to high-risk situations. Counselors will continuously seek to elicit self-motivational statements, reinforce positive steps toward change, and utilize empathic and reflective listening to supplement cognitive behavioral strategies.

5.8. Methodology rationale. All three treatments (SC, EC, and IC) are hypothesized to be effective and acceptable methods to increase smoking cessation in underserved populations. The SC serves as the minimal level of recommended care by the PHS *Guideline*.[53] Although a no-treatment control would offer a stricter test of efficacy, the provision of a minimal recommended standard of care intervention is considered a more ethical alternative. An alternative consideration includes mailing self-help information. While this approach has been effectively used to extend contact time and reduce relapse[56, 64], low literacy levels make written materials less acceptable and appealing to a lower SES population. Furthermore, our data show that the frequency of moving residences is extremely high in the low-income HIV-positive population and is likely high in the low-income population in general, making the receipt of mailed materials a significant barrier. The intensity and

personalization of proactive telephone counseling cannot be replicated with written materials in this population.

We considered using other types of technology, such as internet-based or PDA-delivered interventions. However, we were concerned that using an Internet-based approach would exclude a large proportion of the target population who may not have reliable access to the Internet. In addition, we decided to choose a cell phone-based intervention over a PDA intervention based on our successful experiences with cell phones, the affordability of cell phones, and the human contact made possible through cell phones.

5.9. Training. Counselors will receive extensive training in cognitive-behavioral and MI components of the CPI, and will be supervised in these activities by Drs. Prokhorov and Vidrine. At the outset, counselors will receive an intensive 2-day training workshop that reviews theories, principles, and skills of cognitive-behavioral counseling and motivational interviewing as well as the Transtheoretical Model's Stages of Change, upon which MI techniques are based. Counselors will be guided through a sequence of learning activities to develop and refine their counseling skills, which will include demonstrations, videotape examples, role-plays, group exercises, and supervised practice.

Procedural manuals will be developed by outlining schedules of calls and counseling techniques for both proactive calls and hotline calls. Extensive practicing and role-playing of each session as well as anticipated issues that might arise during those sessions will be conducted with all counselors. Counselors will meet with a clinical supervisor on a weekly basis throughout the study. Additional supervision sessions will be scheduled as needed to address particular concerns or difficulties encountered.

Ongoing monitoring and supervision of treatment delivery fidelity and therapist competence will ensure that the delivered treatment is of high quality and follows the protocol precisely. To monitor therapist adherence and competence, all phone counseling sessions will be recorded and Drs. Prokhorov and Vidrine will evaluate a random subset (10%) for compliance with treatment goals.

5.10. articipant tracking and retention procedures. In an effort to increase completion of follow-ups, we plan to use several approaches. First, intermediate monthly follow-ups throughout the 6 months post enrollment will be conducted via brief cell phone calls. This will eliminate the need for participants to arrange for transportation, schedule time off of work, arrange for childcare, etc. In addition, we will provide the cell phones on which the assessments will be conducted. This will eliminate the barriers that inconsistent phone service and/or numerous moves may pose to completing the follow-ups. In our previous studies with low-income HIV-positive populations, we have successfully completed 80% of proactive phone counseling sessions. In these same studies, we required in-person 3 and 6-month follow-ups and have achieved a follow-up rate of 70-80%. We expect the cell phone assessments planned in this study to pose far less burden than the counseling sessions. Therefore, we expect to achieve at least a 70% follow-up rate. In addition, we will provide the participants with gift cards for completing each assessment to further increase the likelihood of successful completion. In our experience, the inclusion of financial compensation increases compliance with study procedures for smoking cessation trials. The 12-month follow-up, our primary outcome, will take place at the same community site at which the participant was enrolled. By design, this site will be close to the participant's home, thus posing few transportation barriers. We will offer a larger gift card for completing this assessment since it will be associated with greater respondent burden compared to the cell phone assessments. Other procedures to reduce attrition include: 1) reminder phone calls (including calls on the cell phone that we will provide) and letters prior to scheduled follow-ups; 2) offering follow-up assessments on different days/times to accommodate different schedules; 3) collecting a phone number and home address so that participants can be contacted by telephone or mail as necessary; 4) obtaining the names, addresses, and phone

numbers of at least three collaterals (i.e., relatives/friends) who can provide information on the participant's whereabouts should the participant move during the study.

A primary mechanism for maintaining long-term follow-up of study participants is by maintaining personal contact between study personnel and participants. This can be achieved by (1) mailing reminder cards to each participant before a study assessment, (2) telephoning to encourage compliance with study assessments, and (3) assisting participants with obtaining appropriate transportation.

5.11. Data collection and management. Drs. Vidrine and Prokhorov will work with the other study investigators to develop and maintain quality assurance procedures for all data. A relational database will be created in Access to store all project related data. Access can accommodate complex relationships among tables, allowing large quantities of data to be integrated into a single database, as well as more powerful and flexible queries and reports. Access can be easily customized using Visual Basic to incorporate additional design features including more user-friendly interfaces, range checks for variables, and double-entry systems for data entry. Several procedures will be used to maintain the integrity of the data. All databases will be stored in a centralized location on one of the departmental servers, which is backed up daily, with access limited to specific users at the discretion of the PIs. Drs. Vidrine and Prokhorov will ensure that audits of selected subsets of data are performed and that appropriate safeguards of participant privacy are maintained. Privacy safeguards will include appropriate password protection and physical security for all computer systems. Personal names will not be stored in data files. The link between participant names and computer identifiers will be kept in a separate file and encrypted. Additional quality assurance procedures will include a data collection protocol documented in a protocol manual and regular meetings between Drs. Vidrine and Prokhorov and research staff to review problems and solutions, and discuss concerns. The Questionnaire Design System (QDS) data entry system will be used to conduct the baseline and 12-month audio computer-assisted structured interview (ACASI) assessments. The QDS will specifically provide field checks, range checks for continuous variables and valid value checks for categorical variables; checks for legitimate dates and times and logical consistency. A specific audit trail system that identifies the date, time, and individual making changes on the database will be part of the data management system. Preliminary analyses will be initiated shortly after data collection begins to allow monitoring of data quality.

Participants enrolled in this study may be approached by another research team to enroll in IRB-approved "Beyond Cue Reactivity: Event-Related Potentials and Smoking Cessation" (Protocol # 2011-1221). It is possible that participants in our study may enroll in this other study. Due to an overlap in the data collected in our study and Protocol 2011-1221, participant data may be shared between the studies to reduce participant burden and to conserve research resources. Participants will be notified during the informed consent process that their data may be shared with researchers from the other smoking-related study if they choose to enroll in that study.

6.0 Evaluation During Study

Study measures. Study data will be collected by ACASI (i.e., QDS), brief cell-phone assessments and medical/biological instruments (carbon monoxide monitor). The assessment schedule is provided in Table C.

Rationale for the assessment strategy and methodology Several major considerations guided our assessment procedures. First, assessment selection criteria included established reliability and validity of the measures. If measures with established psychometric properties were not available, the measures chosen were required to have at least face validity. Second, assessments had to either: a)

represent our hypothesized mechanisms (or be potentially related to the mechanisms); b) have been empirically demonstrated to predict smoking behavior; or c) describe the sample. All of the major assessments are based on the major models of health behavior, current theories of nicotine dependence, and/or existing data. Third, we have attempted to reduce the inconvenience associated with completing the assessment battery by providing financial compensation for participants' time.

Audio computer assisted self-interview (ACASI): The Questionnaire Design System (QDS)

The Questionnaire Design System (QDS) will be used to administer the questionnaires. The QDS utilizes a computer-administered interview format that includes audio scripts that accompany each item (i.e., each item is read to the participant by the computer). Our experience is that the time to complete an assessment battery is reduced substantially by using QDS versus paper and pencil versions, and particularly so among individuals with low education levels. The QDS administration will be conducted on a laptop computer in a private location at each community site.

Quit motivation. Quit motivation will be assessed with the *Reasons for Quitting* questionnaire. This 20-item scale assesses intrinsic (health concerns, self-control) and extrinsic (immediate reinforcement, social influence) motives for quitting smoking. Both intrinsic motives and the ratio of intrinsic to extrinsic motives have been demonstrated to predict successful smoking cessation.[65, 66]

Risk Perception. To assess risk perceptions and outcome expectancies, we developed a series of items based on recommendations by Brewer and colleagues.[67] Specifically, participants will respond to a series of four questions: 1) "If you don't quit or go back to smoking, what are your chances of ever developing a smoking-related health problem?"; 2) "If you quit smoking or remain quit, what are your chances of ever developing a smoking-related health problem?"; 3) Compared to other smokers, what are your chances of ever developing a smoking-related health problem if you continue or go back to smoking?"; 4) Compared to other smokers, what are your chances of ever developing a smoking-related health problem if you quit smoking or remain quit?"

Self-efficacy. The 9-item self-efficacy scale developed and validated by Velicer and colleagues will be administered.[68] This commonly used self-efficacy scale assesses an individual's confidence in his/her ability to not smoke in a variety of situations.

Intention to quit smoking. Intention to quit smoking will be assessed by asking participants whether or not they plan to quit smoking. Responses are entered on a 7-point scale, ranging from 1-definitely no to 7-definietely yes. An additional intention item will be developed to consider time frame (i.e., quitting within the next month - within the next year). Similar items will also be developed to assess intention to cut-back on the number of cigarettes smoked per day, and time frame for planned reduction.

Contemplation Ladder. The *Contemplation Ladder* is a single item that asks respondents to circle a number on an 10-rung ladder that represents their current level of readiness to consider smoking cessation.[69] Responses range from 0 (no thought of quitting) to 10 (taking action to quit smoking, e.g., cutting down enrolling in a cessation program).

Smoking Status. *The Smoking Status Questionnaire (SSQ)* is a 10-item questionnaire that assesses smoking behavior within the last 7 days, within the last 30 days, and since the time of last contact. Cigarettes smoked per day, longest period of abstinence since last contact, number of relapses, use of nicotine replacement, exposure to other types of tobacco, or use of any other cessation treatment (e.g., professional assistance and self-help) are also included.[70]

Demographic, Health, and Smoking Questionnaires. These items are designed to provide demographic data (e.g., age, race/ethnicity, education level, income, and occupation), current medications, current medical care (including number and type of healthcare visits), drug/alcohol use, history of depression, and smoking history (e.g., years smoked, amount smoked, age of initiation, previous quit attempts, and relapse history). These items have been used in several of our other smoking cessation trials as well as in our pilot study.[71-73]

Fagerström Test for Nicotine Dependence (FTND). The original items of the Fagerström Tolerance Questionnaire (FTQ) were derived from theoretical conceptualizations of reliance on nicotine.[74] The instrument is reliable and useful in a broad spectrum of populations.[75] The *FTND*, a modification of the FTQ, is a 6-item scale with solid psychometric properties.[76]

Center of Epidemiologic Studies Depression Scale (CES-D). The *CES-D* is a 20-item measure developed to assess depressive symptoms in community non-clinical populations.[77] This scale consists of four major factors: depressed affect, enervation, lack of positive affect and interpersonal problems. Good psychometric properties have been demonstrated across diverse populations.[78]

Positive and Negative Affect Schedule (PANAS). The *PANAS* is a 20-item adjective rating form that includes both positive and negative affect scales. Ratings are based on a 5-point Likert scale (1=very slightly or not at all to 5=extremely). The scales have demonstrated high reliabilities and intercorrelations between the scales are low.[79]

Interpersonal Support Evaluation List (ISEL). The *ISEL* will be used to measure social support. This 12-item measure assesses three constructs of social support: tangible, appraisal, and belonging.[80] Social support is a well-established predictor of successful smoking cessation.[53]

Wisconsin Smoking Withdrawal Scale (WSWS). The WSWS will be used to measure smoking withdrawal symptoms.[81] It includes subscales for anger, anxiety, sadness, concentration difficulty, craving, hunger, and sleep. All subscales have excellent internal consistency and demonstrate clear increases in withdrawal.[82]

Daily Coping Inventory. This is a 9-item scale that measures positive and negative aspects of cognitive and behavioral coping skills.

American Thoracic Society's Respiratory Symptoms Assessment. Respiratory symptoms are characterized by experience of specific symptoms (morning and daytime cough, phlegm production, wheezing, chest tightness and pain) scored on the standard American Thoracic Society's respiratory symptom assessment, and 8-item measurement tool. The overall respiratory symptom score and individual symptom scores will be compared with normative scores of each participant computed for nonsmokers.

Wisconsin Inventory of Smoking Dependence Motives (WISDM). The WISDM is a 37-item scale that measures smoking motivations and nicotine dependence across 11 subscales (Piper et al, 2004; Smith et al, 2010).

Minnesota Nicotine Withdrawal Scale (MNWS). The MNWS is a 15-item scale that measures smoking withdrawal symptoms including anger anxiety, cravings, depression, difficulty concentrating, hunger, impatience, insomnia, and restlessness (Hughes and Hatsukami, 1986).

Subjectively Measured Second-Hand Smoke Index. A subjective measure of reduction of in-home smoking will be assessed by self-report based on the Home Environmental Tobacco Smoke Index (Sockrider et al, 2003). The Home Environmental Tobacco Smoke Index has 9 items and asks informants if smoking is permitted in their home and how many people typically smoke in their home.

Subjective Social Status (SSS) Ladders (SES and Community). Each of the two ladders has 1 item. The SES SSS ladder assesses how the participant perceives his/her SES within the U.S. population; the Community SSS ladder assesses how the participant perceives his/her SES within his/her community.

Perceived General Health. The 1-item measure from the CDC's Behavioral Risk Factor Surveillance System (BRFSS) will be used to assess the participants' perception of their general overall health status.

Perceived Stress Scale (PSS). The 4-item Perceived Stress Scale will be used to assess the degree to which respondents find their lives to be stressful.

Assessment of Health Literacy. Participant health literacy will be assessed using the short version of the Test of Functional Health Literacy in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM) (or for Spanish speakers, the Short Assessment of Health Literacy for Spanish Adults (SAHLSA), which is based on the English REALM). Like many other health literacy instruments these assessments must be administered in-person by research staff, and therefore will not be part of the assessment that is delivered using the ACASI system described above. Health literacy will be assessed at the baseline visit.

Spanish translation. To help ensure that the proposed study is available to a representative sample of the underlying target population, we will hire bilingual research staff and recruit both English and Spanish speaking patients. Most of our proposed measures have been previously translated and validated for use in Spanish. For measures that have not yet been translated, we will follow the translation methodology recommended by the International Quality of Life Assessment (IQOLA) project, consisting of forward and backward translations, difficulty and quality ratings, pilot testing, and cross-sectional comparisons.[83] Psychometric assessment of the translated measures will mirror the approach we have used to assess other measures for use with underserved populations.[84] The M. D. Anderson Cancer Center provides professional Spanish translation services at no charge.

Table C. Assessment schedule (The assessments at Baseline and at the 12-month follow-up will take about 1 hour to complete; the monthly cell phone assessments will each take about 15 minutes to complete)

Measure	Baseline	Follow-up Assessments	
		Monthly for 6 months post-enrollment (cell phone)	12-month
Demographics and Health Behaviors	X		X*
Social Status Ladder (in U.S.)	X		X
Community Ladder	X		X
Perceived General Health	X	X	X
Perceived Stress Scale	X	X	X
Daily Coping Inventory	X	X	X
Reasons for Quitting	X		X
Risk Perceptions/Outcome Expectancies	X	X	X
Self-Efficacy	X	X	X
Intention to Quit Smoking	X	X	X
Contemplation Ladder	X	X	X
Smoking Status (self-report)		X*	X

Fagerström Test for Nicotine Dependence (FTND)	X	X*	X
Center of Epidemiologic Studies Depression Scale (CES-D)	X	X*	X
Positive and Negative Affect Schedule (PANAS)	X		X
Interpersonal Support Evaluation List (ISEL)	X		X
American Thoracic Society's Respiratory Symptom Assessment	X		X
Home Environmental Tobacco Smoke Index	X		
Wisconsin Smoking Withdrawal Scale (WSWS)			X
Wisconsin Inventory of Dependence Motives (WISDM)	X		
Minnesota Withdrawal Scale	X	X	X
Test of Functional Health Literacy in Adults - Short version (TOFHLA)	X		
Rapid Estimate of Adult Literacy in Medicine (REALM)	X		
Expired Carbon Monoxide			X
Saliva Cotinine		X (only those participants who report not smoking; saliva collected only at the 6-month time point)	X

* Brief version

Primary Outcome Variable. Salivary cotinine samples will be collected the final (12-months follow-up) assessment. This biochemical measure provides important *quantitative* information about smoking behaviors and is included as a secondary outcome measure. Salivary cotinine will be measured using the NicAlert™ test system manufactured by Nymox. This immunoassay uses monoclonal antibody-coated gold particles and a series of avidity traps that allow quantification. Counselors will guide participants through the process of saliva collection and use of the test strip; counselors also will interpret the results and enter them into the data collection program.

Detailed self-report of smoking status will also be assessed at the 12-month follow-up (as well as the monthly follow-ups). Smoking abstinence will be defined as a self-report of no smoking during the previous 7 days. We will also assess 30-day sustained abstinence. Continuous abstinence will be defined as a self-report of no smoking since the quit date. These are standard definitions of smoking abstinence. In addition, prolonged abstinence allowing for a 14-day grace period after the quit date as suggested by the Society for Research on Nicotine and Tobacco will be calculated.[85] We will use the intent-to-treat approach typically used in smoking cessation trials, thus those participants that are lost to follow-up will be classified as smokers in all outcome analyses (i.e., there is no “attrition” in the abstinence analyses). Seven-day smoking abstinence along with negative saliva cotinine will be the

primary definition of smoking abstinence for this study. However, the literature suggests that the relative efficacy of treatment (i.e., the magnitude of the treatment effect) is rarely affected by the choice of abstinence measure.[49]

In addition to the 12-month follow up, saliva samples will also be collected at the 6-month time point. While completing the 6-month cell phone survey, if a participant reports not smoking during the previous 7 days, then the participant will be asked to provide a saliva sample from which the cotinine level will be measured to verify smoking status. To collect the saliva, the collection materials including a collection tube and cotton swab will be mailed to the participant along with detailed instructions. Participants will also be asked to record other pertinent information on a short information sheet, such as the date and time the sample was deposited in the tube. After depositing the saliva sample into the tube, the participant will be asked to use a provided pre-paid envelope to mail the sample back to the research team along with the short information sheet. These procedures are commonly used in smoking cessation trials [86-90].

Process Evaluation. Following the completion of the 3-, 6-, and 12-month assessments, participants receiving the text message intervention will be asked a series of questions designed to assess their perceptions about the text messaging intervention they completed. Examples of the questions include attitudes about the program's effectiveness, ease of use, quality of the content, and level of burden involved (Appendix P).

7.0 Statistical Considerations

Specific Aim 1: Compare the efficacy of three smoking cessation interventions (SC, EC, and IC) targeting community based low-income uninsured and underinsured individuals in a group-randomized trial.

Hypothesis 1.1. Participants randomized to the EC condition will have higher smoking abstinence rates at 12-month follow-up compared to participants randomized to the SC condition.

Hypothesis 1.2. Participants randomized to the IC condition will have higher smoking abstinence rates at 12-month follow-up compared to participants randomized to the EC condition.

These two hypotheses will be evaluated independently with alpha levels of .017 (.05/3 ≈ .017) to adjust for the possible three pair-wise comparisons among the three conditions. As is traditional in smoking cessation studies, the primary abstinence analysis will be intent-to-treat with subjects lost to follow-up considered to be smokers. The primary smoking abstinence outcome will be defined as 7-day smoking abstinence along with negative saliva cotinine. Because abstinence is a binary variable (yes, no) the primary method of analysis will be a simple post-test analysis among smokers using mixed-model logistic regression. In these analyses, site will be modeled as a random effect nested within treatment condition, and condition will be modeled as a fixed effect. Important covariates that will be used to adjust for potential baseline differences include age, sex, ethnicity, baseline FTND score, depression history, and number of past quit attempts. The regression coefficient associated with the treatment group variable in this analysis will represent the overall log odds of being abstinent in the EC group relative to the SC group, or the IC group relative to the EC group at 12 month follow-up, controlling for the covariates. A limited number of pair wise interactions between selected covariates and treatment condition will also be examined in secondary exploratory analyses. This portion of the analyses will help us to determine whether the experimental intervention was more effective for certain groups of subjects than others. Results of these analyses, however, will be treated as hypothesis generating. In addition, we will examine more complex changes in cessation over time using repeated-measures analysis and low-order polynomials with the smoking data obtained at all four time points. A significant treatment-group-by-time interaction will indicate a

significant difference in the pattern of abstinence across time between the two treatment groups and will be tested by comparing the treatment-effect error against the time-by-condition error.

Our study will employ a number of strategies to improve retention rates and we hope to achieve at least 75% retention in all groups. In the event that we are not able to achieve this target, or if we find that attrition rates differ in some systematic way between the three groups being compared, multiple imputation methods proposed by Wayman[91], Rubin[92] and Schafer[93] will be explored to impute missing outcome data as a means of conducting sensitivity analysis.

Specific Aim 2: Evaluate the role of quit motivation, nicotine withdrawal, risk perception, self-efficacy, social support, and negative affect as potential mediators of smoking abstinence

Hypothesis 2.1: The EC's and IC's effects on abstinence will be mediated by quit motivation, nicotine withdrawal, risk perception, self-efficacy, social support, and negative affect.

In order to examine the mediating effect of the variables specified in the hypothesis, structural equation modeling will be used to develop a model of the patterns of association among the mediating variables, intervention method and abstinence. This will be done at individual time points as well as longitudinally across time. In order to establish mediation, the following criteria must be met: 1) the intervention condition must be significantly associated with abstinence, 2) the intervention condition must be significantly associated with the mediating variable, 3) the mediating variable must be significantly associated with abstinence, 4) the association between intervention condition and abstinence must decrease in the presence of the mediator.[94] The mediation effect estimate will be computed according to MacKinnon,[94] who describes mediation as the difference of the treatment condition with and without presence of the mediators, or alternatively, the product of the effect of the treatment on the mediators and the mediators on the outcome controlling for the treatment. In accordance with the methodology detailed by MacKinnon[94] and Brown,[95] the four criteria to assess mediation will be examined in simultaneous model and parameter tests using structural equation modeling software (EQS). The SEM (structural equation modeling) provides a flexible approach to modeling means, covariance, and correlation structures that yields relevant effect estimates (directional and non-directional; direct, indirect, and total) and standard errors for all of the parameters of interest in mediator analyses.[94, 96] The SEM also allows mediator and outcome measures obtained at each of the follow-up time points to be included in the same model. In addition, SEM provides estimates of each of the effects of several mediators, either individually or simultaneously. The stability of the patterns of association across time points can be tested in longitudinal structural equation models, and growth curve modeling will be used to characterize overall trajectories of the mediating variables, intervention method and abstinence over time. Beyond providing tests of model parameters, SEM also provides global measures of model fit[97] and permits the incorporation of latent variables into mediator models when appropriate.[98, 99] In addition, recent versions of software such as EQS permit robust model and parameter assessment under varied distributional conditions.[95, 100]

Specific Aim 3: Compare the cost-effectiveness of the three treatment conditions.

Hypothesis 3.1: Compared to SC and EC, the IC is a cost-effective use of health care resources.

The methodology that provides the foundation for cost-effectiveness analyses is clinical decision analysis, a quantitative approach for making clinical decisions under uncertainty.[101] Using a divide-and-conquer approach, decisions are broken down into components comprising clinical strategies, potential outcomes, and their probability of occurrence, and often involving the use of personal preferences or utilities. A mathematical model is then constructed based on these data, and the strategy with the greatest expected utility is the optimal decision. Sensitivity analysis then determines

whether changes in the parameters of the mathematical model lead to changes in the optimal decision.

For the smoking cessation interventions compared in the randomized clinical trial, we will perform an incremental cost-effectiveness analysis by comparing the expected economic costs and clinical benefits of the three strategies. The clinical strategies are as follows:

1) Brief physician advice + nicotine replacement therapy. This intervention is the Standard Care (SC) approach.
2) Brief physician advice + nicotine replacement therapy + one-time in-person counseling + cell-phone reminders. This intervention is the Enhanced Care (EC) approach.
3) Brief physician advice + nicotine replacement therapy + one-time in-person counseling + cell-phone reminders + cell-phone counseling. This intervention is the Intensive Care (IC) approach.

We will create a decision-analytic model using TreeAge Pro 2007 software (TreeAge Software, Inc., Williamstown, MA) to conduct the incremental cost-effectiveness analysis. The model begins with a decision node, indicating the three possible strategies, Standard Care, Enhanced Care, and Intensive Care approaches. After 12 months, patients will be determined to be quitters or smokers. At that point in the decision tree, there is a Markov model, used to calculate the life expectancy and quality-adjusted life expectancy of the cohorts. Patients are identified as smokers or quitters at the end of the 12-month period. Patients can die during the year; if they survive, they can either smoke (continuing to smoke or relapse, in the case of a quitter) or quit (continuing to quit or spontaneously quitting, in the case of a smoker from the earlier period). Long-term quitters are identified by those who quit smoking for 20 years.

The model will focus on the 12-month quit rate, the long-term probability of tobacco cessation relapse, and the mortality rates of persons who smoke and persons who have quit tobacco. The 12-month smoking cessation rate will be based on the data collected in the current study. Long-term tobacco cessation relapse rates and spontaneous will be based on a review of studies on the cost-effectiveness of tobacco cessation strategies.[102, 103] Spontaneous quit rates for years beyond the clinical trial will assumed to be 5.5%.[53] Using the decision-analytic model, we will determine the expected economic costs and health benefits of the 3 clinical strategies.

The cost-effectiveness analysis will be performed from the health care perspective. The health care perspective will include only the direct costs of health care and consist primarily of the costs associated with the tobacco cessation interventions. Ideally, the cost-effectiveness analysis would be done from the societal perspective; the societal perspective is an all-encompassing approach that includes the costs identified in the health care perspective as well those costs associated with time that may be incurred. However, the challenge of collecting data on time costs would be impractical and is likely to have little impact on the results. The analysis will be conducted using a descriptive, rather than a normative, approach. In the descriptive approach, the cost-effectiveness analysis is based on what we expect to happen with the use of the tobacco cessation interventions, and not necessarily on what should happen.

Effectiveness of the clinical strategies will be evaluated in terms of life expectancy and quality-adjusted life expectancy. From the decision-analytic model, we can calculate both life expectancy and quality-adjusted life expectancy for the various strategies. All-cause mortality will be determined from life tables adjusted by sex, age and smoking status. This was done in Fiscella and Franks[104] and later updated in Rogers[105]. To calculate quality-adjusted life expectancy, the model must incorporate appropriate adjustment weights for the mean quality of life of the cohort of participants that are in the mathematical model. The adjustment weights were also developed by Fiscella and Franks,[104] who calculated a mean quality-of-life measure for tobacco users and quitters. By incorporating this measure, an average quality-adjusted life expectancy for tobacco users and quitters

can be obtained; by incorporating the quit rate probabilities, the quality-adjusted life expectancy for the various tobacco cessation strategies can be computed.

We will identify the resources utilized by each of the tobacco cessation strategies. Resources of interest include physician-counseling time, nicotine replacement therapy, cell phone, and cell-phone counseling. We will have collected data on the estimated duration of counseling, and to determine this cost, will multiply the mean time spent on counseling by the health care professional by the average salary for a general internist in the Houston/Harris County area. The cost of nicotine replacement therapy will be determined by their average wholesale price. Lifetime health costs from tobacco use will be based on the estimates provided by previously published sources.[103, 106, 107] These studies have estimated that tobacco users have higher health-related costs in their lifetime compared to non-tobacco users. Future costs, as well as effectiveness, will be discounted at a rate of 3%, as recommended by the U.S. Panel on Cost-Effectiveness in Health and Medicine.[108] The tobacco cessation interventions occur over the first year and do not need to be discounted. However, future health care costs that occur in later years will need to be discounted, as well as the benefits of increased life expectancy. In the sensitivity analysis, we will also perform the cost-effectiveness analysis using alternative discount rates, ranging from 0% to 7%.

We will follow standard methodology for determining the incremental cost-effectiveness of the 3 clinical strategies.[109] We will rank strategies in order of increasing expected dollar costs. Strategies that are both more costly and less effective are said to be strongly dominated and not cost-effective. For strategies that are more costly and more effective, we will calculate incremental cost-effectiveness ratios computed as the difference in costs divided by difference in effectiveness. Given that there are three alternative strategies that are being compared, we will examine the possibility of strategies dominated in an extended sense. Extended (or weak) dominance exists when a strategy that has an incremental cost-effectiveness ratio greater than a more expensive alternative strategy; when this occurs, the weakly dominated strategy is also not considered cost-effective.[110]

We will analyze the incremental cost-effectiveness in terms of the dollars per quitter in order to compare our results with those of published analyses.[10, 111, 112] However, to be able to compare our results with the cost-effectiveness analyses of interventions that are not related to tobacco cessation, we will also express the results of the cost-effectiveness analysis in terms of dollars per life year and dollars per quality-adjusted life year gained.

Finally, in order to assess the robustness of our cost-effectiveness analyses, we will perform extensive sensitivity analyses on all major parameters of the decision-analytic models. We will determine how changes in the model parameters, especially the 12-months quit rate and the discount rate, would affect both the effectiveness of the tobacco cessation approaches as well as the incremental cost-effectiveness compared to that of usual care. We will compare our results to previously published interventions for tobacco cessation (when expressed in terms of dollars per quit) as well as interventions unrelated to tobacco cessation (when expressed in terms of dollars per life year or dollars per quality-adjusted life year).

Exploratory Analyses. Perceptions about ease of use and helpfulness in quitting and maintaining abstinence will be evaluated using feedback from participants randomized to these two conditions. Short surveys and structured interviews will record participants' perceptions about proactive individual counseling sessions provided via cell phone plus features that are added to the human counseling including visual components of the feedback, proactive messages and additional support elements designed to prevent relapse. Associations between ease of use and usefulness of the program in quitting and maintaining abstinence will be evaluated and compared between the two groups with bivariate statistical techniques. These outcomes will also be compared between subgroups categorized by selected socio-demographic and health related variables.

Power Considerations

The proposed study uses a group-randomized design with repeated observations at baseline and monthly for the first six months post intervention. A total of 126 centers will be stratified on type (e.g., community center, church, or supermarket), location, and ethnic composition, and randomly assigned from within strata to one of three treatment conditions: SC (Standard Care), EC (Enhanced Care), or IC (Intensive Care) conditions. This will yield a total of 42 centers per condition. Sample size is estimated using parameters obtained from the published literature and from our own research. All variables are in a 0/1 coding scheme, so that detectable differences are interpretable as absolute net differences in proportions.

*Detectable Difference in Smoking Cessation***.** Based on US national smoking prevalence data for underserved populations, we estimate that the baseline smoking prevalence at each community site will be 30%. In addition, based on the number of participants served previously by the POP (which was limited to men age 40-70), we estimate that we will easily be able to recruit 6 participants who are smokers from each site. This will result in 252 participants per condition, and a total sample size of 756 participants. Based on our previous work with low-income populations and the existing literature, [5, 52] we expect to achieve an effect corresponding to an 11% increase in abstinence in the EC group as compared to the SC group. This corresponds to a quit rate in the EC group of 18% and a quit rate of 7% in the control group. Using a Type I error rate of .017, an ICC (intraclass correlation coefficient) of .001, we will have 95% power to detect effect sizes corresponding to a net difference of 11% or larger. The use of a Type I error rate of .017 was based on a standard Bonferroni adjustment for multiple comparisons for the three possible pairwise comparisons among the three conditions. The ICC of .001 was chosen to reflect the likely low level of correlation among quit rates within the sites, consistent with other community site based interventions. It should also be noted that because of the low number of participants per group, the power calculations are not sensitive to this parameter. In comparing the two intervention groups, EC and IC, we again expect to achieve an effect corresponding to at least an 11% increase in abstinence in the IC group compared to EC, corresponding to a quit rate in the IC group of 29% and a quit rate of 18% in the control group. Using a Type I error rate of .017, an ICC of .001, we will have 79% power to detect effect sizes corresponding to a net difference of 11% or larger. The assumptions underlying the calculations project a worst-case scenario using a conservative Type I error and should provide sufficient power to achieve study goals. Because not all time points are used in this power calculation and no adjustments have been made for relevant covariates (including amount of treatment received), this power calculation is most likely conservative.

8.0 References

1. Collins, J. *Slightly Lower Adult Smoking Rates*. [Press Release] 2008 [cited 2008 Nov 13]; Available from: http://www.cdc.gov/media/pressrel/2008/r081113.htm.
2. Honjo, K., et al., *What accounts for the relationship between social class and smoking cessation? Results of a path analysis.* Soc Sci Med, 2006. **62**(2): p. 317-28.
3. Yerger, V.B., J. Przewoznik, and R.E. Malone, *Racialized geography, corporate activity, and health disparities: tobacco industry targeting of inner cities.* J Health Care Poor Underserved, 2007. **18**(4 Suppl): p. 10-38.
4. Delva, J., et al., *Cigarette smoking among low-income African Americans: a serious public health problem.* Am J Prev Med, 2005. **29**(3): p. 218-20.
5. Vidrine, D.J., et al., *A randomized trial of a proactive cellular telephone intervention for smokers living with HIV/AIDS.* AIDS, 2006. **20**(2): p. 253-60.

6. Thorne, S.L., et al., *Cigarette Smoking Among Adults --- United States, 2007.* MMWR, 2008. **57**(45): p. 1221-1226.
7. Kanjilal, S., et al., *Socioeconomic status and trends in disparities in 4 major risk factors for cardiovascular disease among US adults, 1971-2002.* Arch Intern Med, 2006. **166**(21): p. 2348-55.
8. McDaniel, A.M., et al., *Design and testing of an interactive smoking cessation intervention for inner-city women.* Health Educ Res, 2005. **20**(3): p. 379-84.
9. Parker, D.R., et al., *Feasibility, cost, and cost-effectiveness of a telephone-based motivational intervention for underserved pregnant smokers.* Nicotine Tob Res, 2007. **9**(10): p. 1043-51.
10. Ruger, J.P., et al., *Cost-effectiveness of motivational interviewing for smoking cessation and relapse prevention among low-income pregnant women: a randomized controlled trial.* Value Health, 2008. **11**(2): p. 191-8.
11. Solomon, L.J., et al., *Does extended proactive telephone support increase smoking cessation among low-income women using nicotine patches?* Prev Med, 2005. **40**(3): p. 306-13.
12. Fisher, E.B., et al., *Neighbors for a smoke free north side: evaluation of a community organization approach to promoting smoking cessation among African Americans.* Am J Public Health, 1998. **88**(11): p. 1658-63.
13. Hahn, E.J., et al., *Effectiveness of a quit and win contest with a low-income population.* Prev Med, 2004. **39**(3): p. 543-50.
14. Webb, M.S., *Focus groups as an intervention for low-income African American smokers to promote participation in subsequent intervention studies.* Res Nurs Health, 2008. **31**(2): p. 141-51.
15. King, A., et al., *A pilot community-based intensive smoking cessation intervention in African Americans: feasibility, acceptability and early outcome indicators.* J Natl Med Assoc, 2008. **100**(2): p. 208-17.
16. Lee, D., et al., *Tobacco use and low-income African Americans: policy implications.* Addict Behav, 2007. **32**(2): p. 332-41.
17. Hoffman, A.M., et al., *Computer expert systems for African-American smokers in physicians offices: a feasibility study.* Prev Med, 2006. **43**(3): p. 204-11.
18. Cohen, R.A. and D.M. Makuc, *State, regional, and national estimates of health insurance coverage for people under 65 years of age: National Health Interview Survey, 2004-2006.* Natl Health Stat Report, 2008(1): p. 1-23.
19. Obama, B., *Affordable health care for all Americans: the Obama-Biden plan.* JAMA, 2008. **300**(16): p. 1927-8.
20. Centers for Disease Control. *Adult cigarette smoking in the United States: current estimates*. Smoking & Tobacco Use Fact Sheet 2007 11/21/2008]; Available from: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/adult_cig_smoking.htm.
21. Douglass, J.M., *Mobile dental vans: planning considerations and productivity.* J Public Health Dent, 2005. **65**(2): p. 110-3.
22. Heller, B.R. and M.R. Goldwater, *The Governor's Wellmobile: Maryland's mobile primary care clinic.* J Nurs Educ, 2004. **43**(2): p. 92-4.
23. Jackson, D.M., et al., *Creating a successful school-based mobile dental program.* J Sch Health, 2007. **77**(1): p. 1-6.
24. Krol, D.M., et al., *A mobile medical care approach targeting underserved populations in post-Hurricane Katrina Mississippi.* J Health Care Poor Underserved, 2007. **18**(2): p. 331-40.
25. Miller, C.L., et al., *Risk-taking behaviors among injecting drug users who obtain syringes from pharmacies, fixed sites, and mobile van needle exchanges.* J Urban Health, 2002. **79**(2): p. 257-65.
26. Moulavi, D., et al., *Thinking about a mobile health unit to deliver services? Things to consider before buying.* Aust J Rural Health, 2000. **8**(1): p. 6-16.
27. Murphy, D.C., et al., *Mobile health units. Design and implementation considerations.* AAOHN J, 2000. **48**(11): p. 526-32.
28. Paris, N. and T. PorterO'Grady, *Health on Wheels.* Health Progress, 1994. **75**(9): p. 34-5.
29. Wiseman, R., *The Governor's Wellmobile program.* Am J Nurs, 2007. **107**(11): p. 30-1.
30. Edgerley, L.P., et al., *Use of a community mobile health van to increase early access to prenatal care.* Matern Child Health J, 2007. **11**(3): p. 235-9.
31. Chan, S.S., et al., *Using a community-based outreach program to improve breast health awareness among women in Hong Kong.* Public Health Nurs, 2007. **24**(3): p. 265-73.

32. Rainie, L. and S. Keeter. *How Americans use their cell phones*. Reports: Technology & Media Use 2006 11/21/2008]; Available from: http://www.pewinternet.org/ppf/r/179/report_display.asp.
33. Bramley, D., et al., *Smoking cessation using mobile phone text messaging is as effective in Maori as non-Maori.* N Z Med J, 2005. **118**(1216): p. U1494.
34. Haug, S., et al., *Continuous individual support of smoking cessation in socially deprived young adults via mobile phones--results of a pilot study.* Gesundheitswesen, 2008. **70**(6): p. 364-71.
35. Obermayer, J.L., et al., *College smoking-cessation using cell phone text messaging.* J Am Coll Health, 2004. **53**(2): p. 71-8.
36. Riley, W., J. Obermayer, and J. Jean-Mary, *Internet and mobile phone text messaging intervention for college smokers.* J Am Coll Health, 2008. **57**(2): p. 245-8.
37. Franklin, V.L., et al., *Patients' engagement with "Sweet Talk" - a text messaging support system for young people with diabetes.* J Med Internet Res, 2008. **10**(2): p. e20.
38. Hazelwood, A.J., *Using text messaging in the treatment of eating disorders.* Nurs Times, 2008. **104**(40): p. 28-9.
39. Lim, M.S., et al., *SMS STI: a review of the uses of mobile phone text messaging in sexual health.* Int J STD AIDS, 2008. **19**(5): p. 287-90.
40. Shapiro, J.R., et al., *Use of text messaging for monitoring sugar-sweetened beverages, physical activity, and screen time in children: a pilot study.* J Nutr Educ Behav, 2008. **40**(6): p. 385-91.
41. Wangberg, S.C., E. Arsand, and N. Andersson, *Diabetes education via mobile text messaging.* J Telemed Telecare, 2006. **12 Suppl 1**: p. 55-6.
42. Vidrine, D.J., R.C. Arduino, and E.R. Gritz, *Impact of a cell phone intervention on mediating mechanisms of smoking cessation in individuals living with HIV/AIDS.* Nicotine Tob Res, 2006. **8**(supplement 1): p. S103-S108.
43. Vidrine, D.J., R.C. Arduino, and E.R. Gritz, *The effects of smoking abstinence on symptom burden and quality of life among persons living with HIV/AIDS.* AIDS Patient Care STDS, 2007. **21**(9): p. 659-66.
44. Comstock, G.W., et al., *Standardized respiratory questionnaires: comparison of the old with the new.* Am Rev Respir Dis, 1979. **119**(1): p. 45-53.
45. Morris, J.F. and W. Temple, *Spirometric "lung age" estimation for motivating smoking cessation.* Prev Med, 1985. **14**(5): p. 655-62.
46. Lazev, A., et al., *Increasing access to smoking cessation treatment in a low-income, HIV-positive population: the feasibility of using cellular telephones.* Nicotine Tob Res, 2004. **6**(2): p. 281-6.
47. Irvin, J.E. and T.H. Brandon, *The increasing recalcitrance of smokers in clinical trials.* Nicotine Tob Res, 2000. **2**(1): p. 79-84.
48. Irvin, J.E., P.S. Hendricks, and T.H. Brandon, *The increasing recalcitrance of smokers in clinical trials II: Pharmacotherapy trials.* Nicotine Tob Res, 2003. **5**(1): p. 27-35.
49. Fiore, M.C., et al., *Treating Tobacco Use and Dependence*. Clinical Practice Guideline. 2000, Rockville, MD: U.S. Department of Health and Human Services. Public Health Services.
50. Vidrine, J.I. and D.W. Wetter, *Tobacco-relevant risk perceptions: an alternative measurement approach.* Nicotine Tob Res, 2005. **7**(5): p. 815-6.
51. Solomon, L.J., et al., *Free nicotine patches plus proactive telephone peer support to help low-income women stop smoking.* Prev Med, 2000. **31**(1): p. 68-74.
52. Centers for Disease Control, *Cigarette Smoking Among Adults --- United States, 2007.* MMWR Morb Mortal Wkly Rep, 2008. **57**(45): p. 1221-1226.
53. Fiore, M.C., et al., *Treating Tobacco Use and Dependence:2008 Update. Clinical Practice Guideline*. 2008, U.S. Department of Health and Human Services. Public Health Service: Rockville, MD.
54. Fiore, M.C., et al., *The effectiveness of the nicotine patch for smoking cessation. A meta-analysis.* JAMA, 1994. **271**(24): p. 1940-7.
55. Cummings, S.R., S.M. Rubin, and G. Oster, *The cost-effectiveness of counseling smokers to quit.* JAMA, 1989. **261**(1): p. 75-9.
56. Brandon, T.H., et al., *Preventing relapse among former smokers: a comparison of minimal interventions through telephone and mail.* J Consult Clin Psychol, 2000. **68**(1): p. 103-13.
57. Glasgow, R.E., et al., *A stop-smoking telephone help line that nobody called.* Am J Public Health, 1993. **83**(2): p. 252-3.

58. Zhu, S.H., et al., *Telephone counseling for smoking cessation: effects of single-session and multiple-session interventions.* J Consult Clin Psychol, 1996. **64**(1): p. 202-11.
59. Zhu, S.H., et al., *Evidence of real-world effectiveness of a telephone quitline for smokers.* N Engl J Med, 2002. **347**(14): p. 1087-93.
60. O'Donahue, W., J.E. Fisher, and S.C. Hayes, eds. *Cognitive Behavior Therapy: Applying Empirically Supported Techniques in Your Practice*. 2003, John Wiley & Sons, Inc.: Hoboken, New Jersey.
61. Miller, W.R. and S. Rollnick, *Motivational Interviewing: preparing people to change addictive behavior*. 1991, New York: Guilford Press.
62. Rogers, C.R., *Client-centered therapy*. 1951, Boston: Houghton-Mifflin.
63. Prochaska, J.O. and C.C. DiClemente, *Stages and processes of self-change of smoking: Toward an integrative model of change.* Journal of Consulting & Clinical Psychology, 1983. **51**(3): p. 390-395.
64. Owen, N., A.L. Ewins, and C. Lee, *Smoking cessation by mail: a comparison of standard and personalized correspondence course formats.* Addict Behav, 1989. **14**(4): p. 355-63.
65. Curry, S., E.H. Wagner, and L.C. Grothaus, *Intrinsic and extrinsic motivation for smoking cessation.* J Consult Clin Psychol, 1990. **58**(3): p. 310-6.
66. Curry, S.J., L. Grothaus, and C. McBride, *Reasons for quitting: intrinsic and extrinsic motivation for smoking cessation in a population-based sample of smokers.* Addict Behav, 1997. **22**(6): p. 727-39.
67. Brewer, N.T., et al., *Risk perceptions and their relation to risk behavior.* Ann Behav Med, 2004. **27**(2): p. 125-30.
68. Velicer, W.F., et al., *Relapse situations and self-efficacy: an integrative model.* Addict Behav, 1990. **15**(3): p. 271-83.
69. Biener, L. and D.B. Abrams, *The Contemplation Ladder: validation of a measure of readiness to consider smoking cessation.* Health Psychol, 1991. **10**(5): p. 360-5.
70. Cinciripini, P.M., et al., *The effects of smoking schedules on cessation outcome: can we improve on common methods of gradual and abrupt nicotine withdrawal?* J Consult Clin Psychol, 1995. **63**(3): p. 388-99.
71. Cinciripini, P.M. and C. Gray, *Development and validation of a coping skills scale for smoking cessation*. 1996, Society for Research on Nicotine and Tobacco: Washington, DC.
72. Cinciripini, P.M., et al., *A placebo-controlled evaluation of the effects of buspirone on smoking cessation: differences between high- and low-anxiety smokers.* J Clin Psychopharmacol, 1995. **15**(3): p. 182-91.
73. Gritz, E.R., et al., *Predictors of long-term smoking cessation in head and neck cancer patients.* Cancer Epidemiol Biomarkers Prev, 1993. **2**(3): p. 261-70.
74. Fagerstrom, K.O. and N.G. Schneider, *Measuring nicotine dependence: A review of the Fagerstrom Tolerance Questionnaire.* Journal of Behavioral Medicine, 1989. **12**(2): p. 159-182.
75. Pomerleau, C.S., et al., *Reliability of the Fagerstrom Tolerance Questionnaire and the Fagerstrom Test for Nicotine Dependence.* Addict Behav, 1994. **19**(1): p. 33-9.
76. Heatherton, T.F., et al., *The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire.* Br J Addict, 1991. **86**(9): p. 1119-27.
77. Radloff, L.S., *The CES-D scale: A self-report depression scale for research in the general population.* Applied Psychological Measurement, 1977. **1**(3): p. 385-401.
78. Breslau, N. and E.O. Johnson, *Predicting smoking cessation and major depression in nicotine-dependent smokers.* Am J Public Health, 2000. **90**(7): p. 1122-7.
79. Watson, D., L.A. Clark, and A. Tellegen, *Development and validation of brief measures of positive and negative affect: the PANAS scales.* J Pers Soc Psychol, 1988. **54**(6): p. 1063-70.
80. Cohen, S., et al., *Measuring the functional components of social support*, in *Social support: Theory, research, and applications*, I.G. Sarason and B.R. Sarason, Editors. 1985, Martinus Nijhoff: The Hague, The Netherlands. p. 73-94.
81. Welsch, S.K., et al., *Development and validation of the Wisconsin Smoking Withdrawal Scale.* Exp Clin Psychopharmacol, 1999. **7**(4): p. 354-61.
82. Wetter, D.W., et al., *Tobacco withdrawal signs and symptoms among women with and without a history of depression.* Exp Clin Psychopharmacol, 2000. **8**(1): p. 88-96.
83. Bullinger, M., et al., *Translating health status questionnaires and evaluating their quality: the IQOLA Project approach. International Quality of Life Assessment.* J Clin Epidemiol, 1998. **51**(11): p. 913-23.

84. Vidrine, D.J., et al., *Validity of the Household and Leisure Time Activities questionnaire (HLTA) in a multiethnic HIV-positive population.* AIDS Care, 2004. **16**(2): p. 187-97.
85. Hughes, J.R., et al., *Measures of abstinence in clinical trials: issues and recommendations.* Nicotine Tob Res, 2003. **5**(1): p. 13-25.
86. Greeley, D.A., R.F. Valois, and D.A. Bernstein, *Stability of salivary cotinine sent through the U.S. mail for verification of smoking status.* Addict Behav, 1992. **17**(3): p. 291-6.
87. Etter, J.F., T. Vu Duc, and T.V. Perneger, *Saliva cotinine levels in smokers and nonsmokers.* Am J Epidemiol, 2000. **151**(3): p. 251-8.
88. Foulds, J., et al., *The stability of cotinine in unfrozen saliva mailed to the laboratory.* Am J Public Health, 1994. **84**(7): p. 1182-3.
89. Walker, N., et al., *Does improved access and greater choice of nicotine replacement therapy affect smoking cessation success? Findings from a randomized controlled trial.* Addiction, 2011. **106**(6): p. 1176-85.
90. Whittaker, R., et al., *A theory-based video messaging mobile phone intervention for smoking cessation: randomized controlled trial.* J Med Internet Res, 2011. **13**(1): p. e10.
91. Wayman, J.C., *Multiple imputation for missing data: what is it and how can I use it?*, in *2003 Annual Meeting of the American Educational Research Association*. 2003: Chicago, IL.
92. Rubin, D.B., *Multiple Imputation for Nonresponse in Surveys*. 1987, New York: John Wiley & Sons, Inc.
93. Schafer, J.L., *Analysis of Incomplete Multivariate Data*. 1997, New York: Chapman and Hall.
94. MacKinnon, D.P., *Analysis of mediating variables in prevention and intervention research*, in *NIDA Series Monographs*. 1994. p. 127-153.
95. Brown, R.L., *Assessing specific mediational effects in complex theoretical models.* Structural Equation Modeling, 1997. **4**: p. 142-156.
96. Bollen, K.A., *Total, direct, and indirect effects in structural equation models*, in *Sociological Methodology*, C.C. Clogg, Editor. 1987, American Sociological Association: Washington, D.C. p. 37-39.
97. Hu, L.-H. and P.M. Bentler, *Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives.* Structural Equation Modeling, 1999. **6**: p. 1-55.
98. Bollen, K.A., *Structural Equations with Latent Variables*. 1989, New York: Wiley.
99. Finch, J.F., S.G. West, and D.P. MacKinnon, *Effects of sample size and nonnormality on the estimation of mediated effects in latent variable models.* Structural Equation Modeling, 1997. **4**: p. 87-107.
100. West, S.G., J.F. Finch, and P.J. Curran, *Structural equations with non-normal variables: problems and remedies*, in *Structural Equation Modeling: Issues and Applications*, R. Hoyle, Editor. 1995, Sage: Newbury Park, CA. p. 56-75.
101. Cantor, S.B., *Decision analysis: theory and application to medicine.* Prim Care, 1995. **22**(2): p. 261-70.
102. Cohen, D.R. and G.H. Fowler, *Economic implications of smoking cessation therapies: a review of economic appraisals.* Pharmacoeconomics, 1993. **4**(5): p. 331-44.
103. Parrot, S., et al., *Guidance for commissioners on the cost effectiveness of smoking cessation interventions.* Thorax, 1998. **53**: p. S1-S38.
104. Fiscella, K. and P. Franks, *Cost-effectiveness of the transdermal nicotine patch as an adjunct to physicians' smoking cessation counseling.* JAMA, 1996. **275**(16): p. 1247-51.
105. Rogers, R.G., et al., *Mortality attributable to cigarette smoking in the United States.* Population and Development Review, 2005. **31**: p. 259-292.
106. Hodgson, T.A., *Cigarette smoking and lifetime medical expenditures.* Milbank Q, 1992. **70**(1): p. 81-125.
107. Wagner, E.H., et al., *The impact of smoking and quitting on health care use.* Arch Intern Med, 1995. **155**(16): p. 1789-95.
108. Gold, M.R., et al., *Cost-effectiveness in Health and Medicine: Report of the Panel on Cost-Effectiveness in Health and Medicine*. 1996: New York.
109. Kamlet, M.S., *The Comparative Benefits Modeling Project: A framework for cost-utility analysis of government health care programs*. 1992, U.S. Department of Health and Human Services,.
110. Cantor, S.B., *Cost-effectiveness analysis, extended dominance, and ethics: a quantitative assessment.* Med Decis Making, 1994. **14**(3): p. 259-65.
111. Altman, D.G., et al., *The cost-effectiveness of three smoking cessation programs.* Am J Public Health, 1987. **77**(2): p. 162-5.

112. Davis, A.L., R. Faust, and M. Ordentlich, *Self-help smoking cessation and maintenance programs: a comparative study with 12-month follow-up by the American Lung Association.* Am J Public Health, 1984. **74**(11): p. 1212-7.