Abstract

Chronic obstructive pulmonary disease (COPD) is the 12th most prevalent disease worldwide and the sixth most common cause of death. Emerging evidence from epidemiological studies points to cigarette smoking as the major cause of COPD. The Corsicana-Navarro Health Department primary care clinic is an ideal setting for the implementation of a smoking cessation program consisting of pharmacotherapy, educational materials, and nurse telephone support. Efficacy of the 12 week intervention will be measured by compliance, quality of life, and reduction of the age-related decline in FEV1 of middle-aged smokers with COPD at pre- and post-intervention. Participants will be self-selected from adult tobacco abusers who self-disclose cigarette smoking of one pack per day (1ppd) or more for at least five years history and who have a desire to quit smoking. The enrollees will be randomly sorted into three groups of twelve by order of enrollment. Group one will receive only one intervention with the remaining groups adding at least one additional intervention. The Transtheoretical Model of Change, an intentional change model that focuses on the individual, serves as the underlying theoretical foundation for the interventional study and evaluation. If successful, this pilot program could be expanded to other rural health districts in an effort to reduce the economic and social burden of COPD.
COPD: Primary Prevention In Public Health

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide and results in an economic and social burden that is substantial and increasing (Wagena, Zeegers, van Schayck, & Wouters, 2003). The disease is a common chronic lung disorder, which causes substantial disability, impaired quality of life, and increased risk of premature death (Bellamy & Smith, 2007). The diagnosis can be defined as a disease state characterized by progressive air flow limitation that is not fully reversible (Wagena et al., 2003). The disease encompasses both chronic bronchitis and emphysema and is associated with abnormal inflammatory response of the lungs to noxious particles or gases (Bellamy & Smith, 2007).

Statement of the Problem

Tobacco smoke has been indicated by a growing body of evidence as the most important risk factor for COPD; although, other environmental, occupational, and genetic factors may be involved (Bellamy & Smith, 2007). It was not until 1984 that sufficient data became available from epidemiological and annual studies to recognize that cigarette smoking is the major cause of COPD (Wagena et al., 2003). The United States (US) Surgeon General subsequently acknowledged that the contribution of smoking cigarettes to COPD morbidity and mortality far outweighs other factors. Approximately one in 20 deaths in the US cited COPD as the underlying cause in 2005 (Centers for Disease Control [CDC], 2008). During 2000-2005, COPD was the cause of death for 718,077 US citizens aged 25 years and older. Moreover, COPD is the 12th most prevalent disease worldwide and the sixth most common cause of death (Wagena
Smoking cessation is the most effective way to reduce the risk of developing COPD (Bellamy & Smith, 2007). Quitting smoking can prevent or delay the development of airflow limitations (Wagena et al., 2003). After smoking cessation, the annual decline in lung function is usually reduced, sometimes to nonsmoking levels. The risk of developing COPD has been reported as inversely related to socioeconomic status while nutrition, smoking, overcrowding, air pollutants, and genetic determinants have been hypothesized as risk factors (Kara, 2005). Many community health departments offer an indigent primary healthcare clinic. Such settings would be ideal for smoking cessation programs that could include teaching interventions and selected pharmacotherapeutics that could be obtained through pharmaceutical drug assistance partnerships at no cost.

The purpose of this project proposal is to describe the research and development of a smoking cessation program designed for patients with COPD in a selected rural healthcare community. The Corsicana-Navarro County Health Department provides an indigent primary healthcare clinic. This would be an ideal setting for a smoking cessation project designed to prevent or delay the development of airflow obstruction through selected interventions.

**Objectives**

Smoking cessation is integral in the management of the patient with COPD. Because COPD is a growing health problem and primarily a smoker’s disease, it is necessary to implement intensive smoking cessation programs. Smoking cessation is currently the only intervention that has been most efficacious in slowing the progression
of COPD and is therefore one of the most cost-effective healthcare strategies available to healthcare providers (Howard, Knight, Boler, & Baker, 2008). The aim of this proposed smoking cessation program is to determine the impact of the program on long-term survival of smokers with COPD within a selected rural community.

Implementation of a smoking cessation program would primarily consist of developing a model for prevention, evaluation of efficacy, and cost-benefit analysis. The proposed program would include smoking cessation counseling, reduction of social and economic burden, and screening for early COPD. Effectiveness of the model would be measured by non-compliance, relapse rates, quality of life, and varying degrees of withdrawal symptoms. According to Schofield, Kerr, and Tolson (2007), smoking cessation is an incremental process in which identification of individual health beliefs is prerequisite to supporting behavior change. The purpose of early COPD detection is therefore not to offer medical treatment, but to promote smoking cessation. The objectives of the program are to evaluate the cost-effectiveness of smoking cessation interventions and the benefits of smoking cessation outcomes. In order for prevention to be effective, increased awareness is necessary secondary to some measure of early disease identification (Vestbo, 2007).

Abstinence outcomes in a group of COPD patients who participate in this 12-week smoking cessation program will be followed for 6-months post-intervention. The smoking cessation program may include Nicotine Replacement Therapy (NRT), selected pharmacotherapies, unaided cessation, and/or physical exercise along with teaching intervention in group sessions. The major impact of the proposed program would be evaluated in terms of the following outcomes:
1. Increased peak exercise capacity/and or peak oxygen uptake (typically exertional dyspnea) as it correlates with degree of airflow.

2. Quality-adjusted life expectancy and healthcare cost savings (i.e. hospitalizations, primary care office visits) as evidenced by selected variables such as cost-effectiveness and resource allocation.

3. Significant reduction of age-related decline in FEV1, and in numbers of middle-age smokers with COPD.

Moreover, secondary implications of the proposed program would address the impact on other people of smoking cessation such as occurs through decreased exposure to environmental.

The benefits of a smoking cessation project for participants who already have a diagnosis of COPD has been noted in research by Jiménez-Ruiz, García, and Guadrado (2007). It is expected that participants in the proposed project might experience improvement in exercise tolerance, decrease in healthcare expenditures, reduction in morbidity and mortality rates, and an increase in selected health and economic benefits. Finally, any “at risk” group should be identified for the purposes of further prevention and early intervention strategies. Intensive smoking cessation programs can improve long term survival, even when successful in only a minority of patients.

**Theoretical Foundation**

The smoking cessation program will be based on the Transtheoretical Model of Change (Prochaska & Velicer, 1997), an empirical model distinguishing various stages of behavioral change. Smokers in the intervention program will regularly complete
questionnaires about their smoking habits, attitudes, and progress during the smoking cessation process. The individual questionnaires will then be analyzed by a computerized expert system that creates letters with comments on the smoking cessation process with suggestions for further steps from a pool of feedback paragraphs (Martin-Diener, Gehring, & Somaini, 1997). Tailored communications are one of the most promising approaches to smoking cessation interventions in rural and middle-aged populations. Assessments based on the Transtheoretical Model of Change are processed by computer-based expert systems that generate feedback reports tailored to each individual to accelerate their progress through the stages of change for smoking cessation (Velicer, Prochaska, & Redding, 2006). According to these researchers, a series of just three tailored communications were found to produce long-term point prevalence abstinence rates within a narrow range of 22-26% abstinence.

Another expert system intervention for smoking cessation to be used will be the Pathways to Change system (Velicer, & Prochaska, 1999). These assessments will be performed either by mail or by telephone interview by which each smoker receives a three-to-four page report that provides individualized recommendations matched to the individual’s needs and readiness-to-change. The literature states that expert system interventions have the potential to produce a high impact on the smoking population.

The Transtheoretical Model posits that health behavior change involves progress through six stages of change: (a) precontemplation, (b) contemplation, (c) preparation, (d) action, (e) maintenance, and (f) termination (Prochaska & Velicer, 1997). The authors state that basic research has generated a rule of thumb for at-risk populations: (a) 40% in precontemplation, (b) 40% in contemplation, and (c) 20% in preparation. The
key organizing construct of the model is the stages of change construct. The authors believe that the most promising data outcomes have been shown in computer-based individualized and interactive interventions. Previous studies suggest that a motivational smoking cessation intervention could be successful for young adult smokers. Combining motivational interviewing session with personalized health feedback is likely to increase participant motivation to quit and movement through the stages of change (Prokhorov et al., 2008). In addition, the investigators will assess the rural population of smokers via a computer-assisted, counselor-delivered smoking cessation program that addresses personal health risks and readiness to change smoking behavior within the targeted population.

The Transtheoretical Model of Change is a model of intentional change that focuses on decision-making of the individual (Velicer, Prochaska, Fava, Norman, & Redding, 1998). Velicer et al postulates that the Transtheoretical Model construes change as a process involving progress through sequential stages. Precontemplation is the stage in which people have no intention of changing and lack complete awareness of their bad habit health risks. This stage is usually measured over six months. People tend to freeze in this stage when they are uninformed or under-informed about the consequences of their behavior. Contemplation is the stage in which people develop a sense of awareness of their problem behavior and begin to desire change. In this stage, people are intending to change in the next six months. In the preparation stage, the person plans to take action within one month. The person may start to develop a plan that is unique to his/her circumstance. These individuals engage a plan of action, such as joining a health education class, consulting a counselor, teacher, coach, mentor, etc.
Action is the stage in which the person actually makes the change in behavior, experiences, and/or environment. The individual must attain a criterion that scientists and professionals have agreed is sufficient to reduce risk for their potential disease state. Maintenance is the stage in which individuals are working on ways to prevent relapse. In this stage, the goal is to maintain all of the progress made in the action stage. The person usually realizes that he/she must be committed for the remainder of their life to kick the habit and not just for the initial change stage. This stage is recognized as a lifestyle change and not just a quick fix. During the termination stage, the problem is no longer tempting and the person becomes confident the habit will not return.

The Transtheoretical Model of Change will serve as the underlying theoretical foundation for both intervention and evaluation. The proposed project will incorporate constructs of perceived risks and benefits with the goal of heightening perceived benefits of quitting smoking and by increasing participant perceptions of smoking risks. Intervention participants will receive individual, motivational counseling and complete computerized questionnaires. Feedback will be provided on their carbon monoxide levels and their lung function, which will be tested via spirometry.

**Methods and Rationale**

A number of smoking cessation interventional designs have been published through Randomized Controlled Trials (RCTs), quasi-experimental studies, and pre-post test designs (Luker, Chalmers, Caress, & Salmon, 2007). The researchers noted that many designs, including qualitative, assisted more in uncovering the subjective experiences of the participants than the details of intervention. For the purposes of this
project, an interventional study is proposed since smoking cessation has been encouraged by previous providers without success (Oleske, 2001). Specifically, the descriptive approach will be utilized to obtain information about the variability of smoking cessation through selected measures. Further, it has not been determined from previous research whether smoking cessation utilizing Varenicline (Chantix) is efficacious. Informal anecdotal reports by patients utilizing pharmacotherapeutics alone have suggested minimal efficacy.

Study participants will be adults (18 years and older) of both gender and have received a medical diagnosis of tobacco abuse. For inclusion purposes, the study will incorporate a non-pharmacological smoking cessation intervention, including psychological, supportive, or educational initiatives as defined by Luker et al. (2007). The pharmacologic agent intervention will be Varenicline (Chantix), which has been shown to be more effective than sustained release bupropion or placebo (Tobin, 2007). According to Tobin, Varenicline, a partial agonist selective for nicotinic acetylcholine receptor subtypes, reduces nicotine cravings as the drug binds with neuronal nicotinic acetylcholine receptors, which produces agonist activity and simultaneously prevents nicotine binding to the receptor.

The study participants will be drawn from a population of indigent patients seen at the Corsicana-Navarro County Health Department primary care clinic. The adults will be selected from self-disclosed reports of cigarette smoking of one pack per day (1ppd) or greater for at least five years with a desire to quit smoking. The patients will be randomly assigned to one of three groups of twelve following enrollment. Group one will have pharmacotherapy only. Group two will have pharmacotherapy and psychological
intervention with educational handouts. Group three will have pharmacotherapy, psychological intervention with educational handouts, and weekly telephone support by the nurse.

Research shows that a combination of patient counseling and pharmacological therapies has been found to be most effective in successful smoking cessation helping (Schiller & Ni, 2006; Tobin, 2007). A benefit and risk review of pharmacological smoking cessation therapeutics has been documented by Wagena et al. (2003). According to the researchers, “the combination of pharmacotherapy (to reduce craving and withdrawal) and a relapse-prevention program in which attention is focused on the behavioral aspects of smoking and smoking cessation, seems to increase abstinence, especially when the psychosocial intervention is prolonged for a longer period (p. 382).

**Budget**

The proposed project will involve five phases. The first phase will be to develop a proposed budget. The second phase will be to develop a comprehensive timeline. The third phase will be to develop the teaching intervention and related measurements. The fourth phase will include implementation followed by the fifth phase of evaluation. The proposed budget for the project will include the hiring of a consultant to provide expert information technology necessary for successful implementation of the project. The cost to retain an informatics nurse specialist is $500.00 USD to build the computer platform necessary to host the various measurements and to build the links between the elements of the teaching intervention and the survey instrumentation. The next line item in the budget involves the purchasing of project equipment such as spirometry, and intervention workbooks. The proposed cost for these items is budgeted at $8,500 USD
although in-kind contributions for additional items such as blood pressure cuffs, scales, and related equipment as well as the time contribution of the project investigators will not represent additional out-of-pocket expense. Marketing consultant fees will be budgeted at $500 USD for the purpose of recruitment and retention of project participants. Finally, a statistical consultant will be retained at a cost of $500.00 USD to provide the statistical analysis for the project evaluation. In sum, a $10,000 USD grant application will be developed for the implementation and evaluation costs of the project.

Evaluation

Sources of data from the project will be evaluated using an adult tobacco survey, state-specific surveys, state and/or local progress reports, and a behavioral risk factor surveillance system. Efficacy data will determine intervention effects of both short-term and long-term outcomes. Smoking cessation interventions will be measured by a tool adapted from research by Abdullah, Mak, Loke, and Lam (2005). The outcome of interest will be the seven day point prevalence quit rate at six months (defined as not smoking during the seven days preceding the six month follow-up). Other secondary outcomes will include a 24 hour point prevalence quit rate and self-reported continuous quit rate with a biochemically validated quit rate at 6 months. It is expected that the smoking cessation program will show that at 6 months follow-up, the 7 day point prevalence quit rate will be significantly greater in the intervention group by 15-20% than in that of the control group. These findings should support the premise that proactive telephone counseling and tailored communications based on the Transtheoretical Model of Change is an effective aid to promote smoking cessation in a rural population of patients with COPD.
Summary

Patients with COPD are at risk for significant morbidity and mortality worldwide in addition to an economic and social burden that is substantial (Wagena, et al., 2003). The disease is a common chronic lung disorder, which causes substantial disability, impaired quality of life, and increased risk of premature death (Bellamy & Smith, 2007) in the US and worldwide. Tobacco smoke has been indicated in best evidence as the most important risk factor for COPD while smoking cessation has been shown to be the most effective way to reduce COPD sequelae (Bellamy & Smith, 2007). A 12-week computerized smoking cessation program is planned for implementation in a rural population of patients with COPD. The smoking cessation program may include Nicotine Replacement Therapy (NRT), selected pharmacotherapies, unaided cessation, and/or physical exercise along with the teaching intervention for each group session. While grant funding is desired for the consultative and computer elements of the program, sustainability of the program is anticipated through dissemination of findings.
References


