Name of Project: Maintaining Nonsmoking

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)

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Research question(s):

This research is designed to study the treatment of smoking as a chronic addiction and determine if the positive findings for our long-term relapse prevention treatment model can be reproduced in a medical outpatient setting. The specific aims of this study are:

1. To determine if an extended behavioral treatment protocol increases smoking abstinence rates over those found with a brief monitoring intervention.
2. To determine if an extended cognitive-behavioral intervention is more efficacious for smoking cessation than a non-specific behavioral intervention that is matched for frequency of contact and treatment duration.
3. To determine if combining extended cognitive behavioral intervention with pharmacological treatment increases abstinence rates over those found with extended cognitive behavioral abstinence alone.

Brief Background/Significance:

Cigarette smoking is a widespread and costly addiction, costing over $50 billion annually in direct and indirect health care costs. Like other addictions, tolerance and dependence have been shown to be characteristics of nicotine. Similarly, chronicity and relapsing course of nicotine dependence are well documented in studies, indicating that most smokers have tried to quit many times, that most of these attempts to quit fail, and that relapse is the norm. For the most part, smoking cessation treatment models have been either inexpensive or time limited and have used brief courses of medications or behavioral treatments. In contrast, this research is designed to study the treatment of smoking as a chronic addiction, based on a chronic disorder model, and apply the positive results we found in our clinical research setting to the medical outpatient setting.

Inclusion/exclusion criteria (list)

Inclusion criteria: Smokers over the age of 18 who smoke at least 10 cigarettes per day and who are patients of UCSF general medical practices at either the Parnassus or Mt. Zion campuses.
Exclusion criteria:

- Acutely life threatening diseases
- Evidence of alcohol or other drug abuse so severe that the patient is judged to be potentially unable to comply with the protocol
- Leaving the Bay Area within the study period
- Non-English speaking
- Pregnancy or lactation
- Any psychological disturbance so severe that their primary care provider thinks they shouldn’t participate or a disturbance that is not stabilized
- Currently on dialysis
- Any condition that prohibits moderate physical activity
- Schizophrenia or Bipolar Disorder indicated in the medical record, or in the case of Bipolar Disorder, diagnosed as part of the mood disorders section of the MINI. Individuals with Depressive Disorders can participate, so long as they do not report suicidal ideation within the last year, and have providers’ permission.

Method of contact/recruitment (be specific)

1) **Recruitment:** The logistics of implementing the following options are being discussed with key players in the outpatient clinics, including Drs. Eliseo Perez-Stable and Pam Ling, to ensure minimal impact on patient flow and provider workload. The following options are being developed:
   
a. LVN/MA assesses smoking status as part of the check-in process. If patients indicate active smoking status, the LVN/MA then gives the patient a Study Info card; interested patients can fill out name/contact info section of card and drop in box at the front desk. The Research staff will pick up box contents regularly and send the following text via Secure email to providers, providing advance notice before contact by Research staff:

   “We are recruiting patients to participate in the Maintaining Nonsmoking study, which compares varenicline and four versions of supportive counseling to aid smoking cessation. The following list of patients under your care have expressed interest in enrolling in the trial. Please contact the study’s Nurse Practitioner, Leah Juhle at leah.juhle@ucsf.edu within the next week if you have any concerns about our staff conducting an initial Telephone Screening. If you do not respond to this message, we will proceed with our initial screening and notify you prior to enrollment of any of the patients under your care.”

   b. Providers write “Smoking Cessation Study” or apply “Smoking Cessation Study” sticker to pink Check-Out sheet for patients who indicate active smoking status. Pink sheets are saved by front desk staff for research staff review.

2) **Advertisement**
   
a. Posters and study information cards will be displayed in the outpatient medical offices in accordance with the rules and regulations of the clinic.
   b. Research staff will send an email describing the study to all providers.
c. Research staff will attend pre-clinic conferences and team meetings periodically to promote awareness of the study and answer questions.

d. Research staff periodically will do Smoking Cessation education sessions that include study information at pre-clinic conferences.

3) Notification of providers prior to enrollment

a. If a patient meets enrollment criteria, the study’s Nurse Practitioner will send the following email to the patient’s provider via Secure email:

“Patient X meets criteria to enroll in the Maintaining Nonsmoking study after completion of medical record review and a history and physical exam. This study includes a course of varenicline and supportive counseling. If you have any questions or concerns, please contact the study's Nurse Practitioner, Leah Juhle, at 415-502-8437.”

b. If the Nurse Practitioner has any concerns about a subject's enrollment she will discuss the issue with the study physicians first and contact the PCP for clarification when required to ensure patient safety.

Benefits/burden for participants (clearly identify potential for harm)

Benefits: A major benefit of participating in this study is that the participant may quit smoking, which can lead to improvements in overall health and reduce the risk for smoking-related illness. Also, the treatment the participant receives may prove to be more effective than other available treatments.

Burdens: There are some risks associated with participation in this study. Varenicline has known side effects. The most frequent side effects of varenicline are nausea (30% of people) described as mild or moderate by 95% of these and usually transient but occasionally enduring, insomnia (14%), abnormal dreams (increased frequency or vividness or nightmares) (13%) and vomiting (5%). None of these are serious. The product information also reports constipation (1%) and flatulence (0.7%) occurred more often than with placebo.

The Food and Drug Administration (FDA) has issued an alert on varenicline, citing concerns about suicidal thoughts, suicidality and aggression, and case reports of potential adverse effects in bipolar disorder. Patients will be screened at each visit and at interval phone calls and any evidence of serious adverse events will be managed via medical staff advice.

Varenicline should not be taken by women who are pregnant since the potential risks to the fetus are unknown. There are also some risks associated with completion of interviews and questionnaires. These may be stressful for some participants. Smoking cessation itself may be stressful and often results in unpleasant withdrawal symptoms. A final risk is loss of confidentiality.

Any benefits or burden to DGIM practitioners?

This study provides a potential resource for DGIM practitioners who are treating patients that desire smoking cessation support. The burden of the study on DGIM
practitioners would be limited to the time required to refer potential subjects. In a small number of cases, the study nurse practitioner may contact the DGIM practitioner if there is a question regarding a patient’s eligibility after the study staff has reviewed the patient’s medical records and completed a physical exam.

**Timeline for recruitment (projected start and stop dates)**

Recruitment for this study is planned for a 30 month period, beginning approximately April 2010 and ending approximately October 2012.

**Funding source**

National Institute on Drug Abuse (NIDA)

**Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)**

Drs. Pam Ling and Eliseo Perez-Stable are co-investigators on the study.

**Do you agree to notify us when recruitment is completed?**

Yes, we will notify the DGIM when recruitment is completed.

**Date form completed:** 3/18/2010