Sample Research Proposal

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I. Title of Proposed Research Project Medical Students as Mediators of Change in Tobacco Use

II. Specific Aims

In conducting this study, we will accomplish the following specific aims:

Specific Aim 1. Compare the effectiveness of the stage specific smoking cessation counseling intervention with the control intervention by evaluating the impact on the following patient outcomes at 1, 3, 6 and 12 months: a) quit rate, b) stage of change, c) desire to quit, d) motivation to quit, e) confidence in quitting (self-efficacy), and f) nicotine dependence.

Hypothesis 1. Patients counseled by students initially trained in stage specific smoking cessation counseling will have higher quit rates, improve their stage of change, increase their desire to quit, be more motivated to quit, have higher confidence in quitting, and have less nicotine dependence at 12 months.

Specific Aim 2. Compare the effectiveness of the stage specific smoking cessation counseling intervention with the control intervention by evaluating the impact on the following processes of care rated by patients at 1, 3, 6 and 12 months: a) satisfaction with the quality of care in general, and b) satisfaction with the quality of care related to smoking cessation counseling.

Hypothesis 2. Patients counseled by students initially trained in smoking-specific behavioral counseling will have greater satisfaction with both measures of quality of care at 12 months.

III. Background

Tobacco is the only legally sold product known to cause death in one half of its regular users.(1) Thus, of the estimated 1.3 billion people in the world who smoke, nearly 650 million will die prematurely as a consequence.(1) In the United States, approximately 25% of men and 20% of women, or 46 million adults, smoke.(2) The financial toll of tobacco use in the U.S. is substantial. Estimated costs include $75 billon per year in medical expenditures and $80 billion from lost productivity.(3) The personal health risks of smoking are even more significant with respect to morbidity and mortality. Although the role of physicians in cessation efforts has been

demonstrated, many physicians fail to counsel patients. The most common reasons cited for lack of counseling include inadequate training and time pressures. Our intervention will target medical students in the early stages of training. The proposed intervention will provide a foundation for medical learners in stage specific counseling and will aid physicians in primary practice to help their patients stop smoking. The rationale for this program is that providing education early and allowing students to use these skills with patients in the community can help: 1) future physicians with confidence in smoking cessation counseling, 2) physicians in the community who may not have adequate time to counsel patients, and 3) patients whose health may be at risk from smoking.

IV. Research Methods

Study Design: Randomized cross-over trial consisting of two smoking cessation counseling interventions: 1) counseling intervention including patient education, written material and follow-up by students who have been trained in stage specific tobacco cessation techniques, and 2) counseling intervention that includes patient education, written material and follow-up by students who have been trained in non-smoking cessation techniques (exercise counseling).

Setting: Community practice sites in internal medicine, family medicine and pediatrics throughout Connecticut where medial students attend weekly continuity sessions with physician preceptors.

Study Subjects: 80 first-year medical students and 308-350 patients aged 16 years or older in the students' community practice sites who are seeing the students' physician preceptor for any reason and meet criteria of smoking one or more cigarette daily in the previous week.

Randomization: Students will be randomized by the day they attend their Principles of Clinical Medicine Course and trained in stage specific tobacco cessation counseling or exercise counseling. After 6 months, students will receive training in the other behavioral counseling technique.

Main Outcome Measures: patients' quit rate, stage of change, desire to quit, motivation to quit, confidence in quitting (self-efficacy), and nicotine dependence at 1, 3, 6, and 12 months.

Process Measures: patient satisfaction with the quality of care in general, and satisfaction with the quality of care related to smoking cessation counseling.

Analyses: patient level analyses of main outcome and process measures comparing patients who received counseling from students trained in smoking cessation counseling and patients who received counseling from students trained in exercise counseling adjusting for potential confounding factors. We will use logistic regression for dichotomous outcomes and linear regression for continuous outcomes. We will use generalized estimating equations (GEE) and random effects modeling to allow us to adjust for time-dependent covariates

V. Timeline of Research Project

Activity	1	2	3-4	5	6-9	10-12	13-14
Student randomization	X						
Train standardized patient		X					
Assess student behavioral counseling skills			X				
Train student in smoking or exercise counseling				X			
Assessment of office practice sites				X			
Train medical assistants to recruit patients				X			
Recruit patients				X	X		
Patient counseling in-person				X	X		
Patient counseling by phone				X	X		
Data collection				X	X		
Data analysis						X	X
Prepare publication(s)							X
Present research at scientific meetings							X

VI. Literature Cited

1. World Health Organization Website: WHO tobacco Treaty set to become law, making global public health history.   WHO . 2005. 1-17-2005.

2. Cigarette smoking among adults--United States, 2001. MMWR Morb Mortal Wkly Rep 2003; 52(40):953-956.

3. Centers for Disease Control. Targeting Tobacco Use, the Nation's Leading Cause of Death 2004. CDC. 2005. 1-19-2005.