## PROPOSAL

### Overall Aim and Objectives

This multicenter study seeks to examine the effect of an educational intervention on emergency physicians' and surgeons' knowledge, attitudes and behaviors regarding screening for tobacco use on patients with traumatic injuries who present to the emergency department (ED) for treatment. The project consists of two components: (1) developing a curriculum containing didactic material, directed specifically at screening, brief intervention and referral of trauma patients (2) an ED- and hospital-based pilot study of screening, intervention, and referral of trauma patients that will include use of wallet cards containing the telephone number of the National Smokers' Quitline.

This study represents an extension of the work conducted by a consortium of emergency medicine organizations under a grant to the American College of Emergency Physicians from the Smoking Cessation Leadership Center, a national program office of the Robert Wood Johnson Foundation.

Numerous studies have documented an association between smoking and other risk taking behaviors, many of which lead to increased risk of preventable accidents, traumatic injury and resultant visits to the emergency department (ED), hospitalization, and surgery. [1-3] Critical illness, crisis, and hospitalizations due to trauma provide a prime opportunity for intervention, or a "teachable moment" on lifestyle and behavioral changes, such as smoking cessation. [4-6] Evidence demonstrates that behavioral counseling leads to increased rates of smoking cessation but the effect depends on the intensity of the intervention. [7] These interventions are particularly effective in trauma patients with unhealthy alcohol use. Intervention and education on smoking cessation while in the hospital, coupled with on-going professional support through referrals to local counseling services and smoking cessation treatment programs, can result in long-term healthy lifestyle changes not only related to smoking but also help reduce or eliminate future accidents and trauma injury events. [8] In addition, a recent analysis of elective operations on 393,794 patients from 2002 to 2008 in the Veterans Affairs Surgical Quality Improvement Program for all surgical specialties found that smokers had significantly more postoperative pneumonia, surgical–site infection and deaths than non-smokers. Several orthopedic studies have demonstrated delayed healing and increased post-operative infections among smokers. [9-12] Smoking cessation intervention among trauma patients has the potential to decrease hospital costs and length of stay as well as improve surgical outcomes among trauma patients requiring operative repair of their injuries.

The overall aim of this project is to improve the rate of smoking cessation interventions by healthcare providers treating trauma patients in the ED and in the inpatient trauma service.

The project consists of 2 components: (1) developing a didactic curriculum directed specifically at providers of care for trauma patients; (2) an ED and hospital trauma service study of screening, intervention, and referral of trauma patients that will include use of wallet cards containing the telephone number of the National Smokers' Quitline.

Aim 1: We aim to develop a didactic curriculum directed specifically at providers of care for trauma patients.

Aim 2: We aim to improve the confidence and knowledge base of smoking intervention techniques among the team of care-providers of trauma patients:

> We plan to engage 8 Level 1 Trauma Centers and enroll ED physicians and nurses, trauma surgeons and nurses in the ICU and on the hospital floor treating trauma patients, and orthopedic surgeons and ICU nurses on the hospital floor treating trauma patients with orthopedic injuries.

Aim 3: We aim to improve the rate of intervention among two subpopulations:

> 1. Patients who are awake and alert with minor traumatic injuries.
> 2. Patients with more significant injuries that require hospitalization and/or surgical intervention for their traumatic injuries.

## Current Assessment of Need in Target Area

Numerous studies of the epidemiology of tobacco use in emergency department patients have established the following: (1) the prevalence of tobacco use among trauma patients is higher than that of the general US population, as high as 50%; (2) ED patients typically have moderate levels of nicotine addiction and 61-79% are in the contemplation or preparation stage of change; (3) many trauma patients lack access to a primary care provider and are therefore unlikely to receive cessation messages from a another source of medical care. [13-17] The ED and trauma service screening and referral program for patients who smoke can provide a framework to help EDs and trauma services across the country to initiate smoking cessation efforts for these high risk patients.

To address the role of emergency medicine in tobacco control, the American College of Emergency Physicians (ACEP) convened a task force of representatives of major emergency medicine professional organizations in 2004. This work was funded by the Robert Wood Johnson Foundation through the Smoking Cessation Leadership Center (SCLC) at the University of California San Francisco and lead by Steven L. Bernstein, MD, FACEP. Recommendations on tobacco control practice, training and research from the task force were summarized in an article entitled "Tobacco Control Interventions in the Emergency Department: a Joint Statement of Emergency Medicine Organizations".[18] From these recommendations, a resultant study found that brief educational

intervention was able to increase ED-based tobacco screening and counseling by emergency physicians. Data from 1168 patient interviews and chart reviews showed that, post-intervention, providers were more likely to ask patients about smoking, make a referral, and document smoking counseling. [19,20] The proposed project expands on this prior project, targets a population with high risk-taking behaviors - smokers with traumatic injuries - and aims to continue brief intervention efforts during hospitalization for those requiring admission and/or surgical intervention by including other trauma care providers, such as trauma surgeons , orthopedic surgeons and nursing personnel in the effort.

## Technical Approach, Intervention Design and Methods

Settings: The study will be performed at eight trauma centers located throughout the United States. Sites will be chosen that have experience conducting ED-based clinical research, have emergency medicine, general surgery and orthopedic surgery residencies, located in urban areas, and generally serve a lower socioeconomic status patient population. The sites that will be invited to join the study will collectively treat roughly 700,000 ED patients annually. Of these, about 400,000 of the patients will be 18 or older, which will be the age criterion for patient inclusion. Patients with head injuries requiring operative intervention or resulting in demonstrable cognitive defects will be excluded. ED volume in each site will vary from 50,000 to 130,000. Patient inclusion criteria: must speak English or Spanish, current smoker (defined as >= 100 cigarettes/lifetime, and everyday use or some-day current use, able to give informed consent, and chief complaint traumatic in nature. Disposition status (admitted, discharged, etc.) will not be a criterion for inclusion or exclusion.

Subjects: Participation will be limited to those physician and nursing subjects who attend the protocol education and training session at each site. We expect about half of all eligible physicians and nurses to participate.

Intervention: Physicians

*Baseline assessment*. At baseline, each physician will complete a 20-item instrument assessing knowledge, attitudes, beliefs and practices about tobacco control. The physician will complete the instrument again one week after the completion of training. The survey instrument will be the survey used in our previous trial and was adapted from one administered by the Association of American Medical Colleges to a nationally representative sample of primary care physicians. All responses will be anonymized.

*Physician curriculum and training*. All resident and attending physicians and nurses in the study will receive a 60-minute lecture on the epidemiology of smoking, with a focus on the prevalence of tobacco use and tobacco-related illness among trauma patients. The lecture will also include an overview of the Public Health Service practice guideline, including principles of cessation and the brief negotiated interview form of the motivational interview and quitlines.

The training will be delivered by the site PI and Research Associates during the regular weekly conference program that each residency conducts and during organized nursing meetings. All educational materials will be prepared by Drs. Cydulka and Bernstein, and pilot tested on EM and surgical residents and nursing staff prior to study initiation.

*Post-intervention assessment*. One week after the training session, physicians will complete the same survey instrument.

Intervention: Emergency Department and Inpatient Units

*Baseline assessment*. Research associates (RAs) will interview 50 adult smoking trauma patients at each site – 25 patients who will be discharged home and 25 patients who have been admitted to the hospital for ongoing care. Based on an expected smoking prevalence rate of 30%, roughly 170 patients will need to be interviewed at each ED to yield 50 smokers. Basic demographic and clinical information will be recorded, including age, sex, race, ethnicity, insurance, source of usual medical care, and reason for visit. In addition, patients will receive the following instruments: Fagerstrom Test for Nicotine Tolerance, the Ladder of Contemplation, Importance-Readiness-Confidence Rulers, the Perceived Risk Assessment, and the Patient Smoking Intervention Opinion Survey. In addition, smokers' charts will be reviewed at the end of the clinical encounter to see if the physician documented smoking status, advice, or referral to a quitline or cessation program.

*Provision of smoking cessation literature and Quitline referral cards*. Within 48 hours of the educational intervention, each ED, surgical ICU, surgical floor, and orthopedics floor will be stocked with English and Spanish versions of an easy-to-read smoking cessation brochure prepared by the US Department of Health and Human Services ("Good Information for Smokers," and "Informacion Importante para Fumadores"). Both are available at no cost at www.ahrq.gov. Each ED will stock at least 200 copies of each brochure; they will be kept in a visible, accessible location, where other patient education materials are kept. In addition, each hospital will receive 1000 copies of a plastic wallet-sized card imprinted with the North American Quitline telephone number (1-800-QUIT NOW), for distribution to patients or their companions in the ED, surgical ICU, surgical floor, and orthopedic floor. Providers will not be told when or whether to distribute the brochures and wallet cards.

*Post-intervention assessment*. In the two weeks after the training session, RAs will again interview 50 adult smoking trauma patients at each site – 25 patients who will be discharged home and 25 patients who have been admitted to the hospital for ongoing care, recording the same demographic and clinical information as before. Charts will be reviewed to document whether ask-advise-refer interventions were performed.

*Research associate recruitment and training*: Each site will have one or more research associates (RAs) assigned to the study. The number of RAs per site will depend on availability of

local resources and ED volume. RAs may have a variety of backgrounds, but preferably will have some college education and prior experience in a health care setting. All RAs will receive a four-hour curriculum in tobacco control and study design, to be delivered by the site investigator. This curriculum will be prepared by the overall study PI and her associates. A manual of operations will be created for each site. At all sites, 10% of all charts reviewed by the RA will also be reviewed by the site investigator to check for fidelity to protocol. Kappa values will be calculated to measure interobserver for agreement for major outcome measures (e.g. whether smoking status was documented, advice given, quitcard provision and referral).

*Ethical Considerations*: The study will not begin until each site's Institutional Review Board has reviewed and approved the protocol. All study procedures will be conducted in compliance with provisions of the Health Insurance Portability and Accountability Act (HIPAA).

**Evaluation Design**

Prior to and following implementation of the education, surveys of providers and patient charts reviews pertaining to smoking interventions will be analyzed to measure the effectiveness of the education on increasing targeted providers confidence in counseling and documentation of smoking and tobacco use cessation counseling. Any necessary modifications to the curriculum will be made and then widely disseminated through the professional membership associations involved with this project.

*Biostatistical Considerations and Evaluation*: Data from physicians and patients will be entered into a web-based database and transferred to STATA 12 (StataCorp LP,College Station, Texas). Demographic information, clinical and behavioral data will be entered by study personnel Out of range data and logical inconsistencies in the electronic data file will be checked against the data collection forms and corrected as needed. Patterns of missing data will be examined. All tests will be two-sided, as appropriate, with $P < 0.05$ considered significant.

*Power analysis and sample size*: Our prior work indicates that interviewing 600 smokers, half before the intervention and half after, will provide a sufficient number of patients to generate accurate point estimates and confidence intervals.

Hypothesis 1. An educational intervention will increase the confidence and knowledge of emergency physicians, trauma surgeons and orthopedic surgeons to practice tobacco control in the emergency department and in the hospital setting.

The basic analysis will be a Wilcoxon-Mann-Whitney test of physician's responses to the appropriate questions. Generalized linear models will be fitted to determine the variables that are independently predictive of increasing physicians' confidence and knowledge to deliver tobacco interventions in the ED.

Hypothesis 2. An educational intervention and provision of Quitline referral cards in the ED will increase the delivery of ask-advise-refer interventions to ED patients who smoke.

The basic analysis will be a chi-squared test of the proportion of patients who smoke who received a cessation intervention, using a pre-/post-intervention format. Logistic models will be fitted to determine the variables that are independently predictive of physicians' delivering ask-advise-refer interventions. Regression diagnostics, including the Hosmer-Lemeshow goodness of fit test, will be performed.

**Dissemination of Smoking Cessation Education**

Data and results will be shared with the Smoking Cessation Leadership Center. Results from the trial will be submitted for presentation at meetings of relevant professional organizations, such as the annual Research Forum of the American College of Emergency Physicians (ACEP), the annual educational meetings of the American College of Surgeons, American Academy of Orthopaedic Surgeons, Emergency Nurses Association, American Academy of Nurse Practitioners, and Society of Emergency Physicians Assistants. Manuscripts will be submitted for publication in peer-reviewed journals such as *Annals of Emergency Medicine*, the official journal of ACEP. Study investigators will prepare an article for publication in ACEP's biweekly e-newsletter, *EM Today*, and ACEP's website (www.acep.org).

ACEP has a number of communication resources to disseminate this education, including: *Annals of Emergency Medicine*, a peer-reviewed leading journal in the specialty, ranking first among the 13 titles in the emergency medicine category of Thomson Scientific; *ACEP News* (printed monthly news magazine - 36,000 readers); *EM Today* (online news brief, five days a week - 22,000 emails – open rate is 34%); the *Weekend Review* (online Saturday news brief - 33,000 emails), *The Central Line* – ACEP's official blog (see http://thecentralline.org), and ACEP's website. ACEP also has an app where we will distribute the educational materials.

The intervention education resulting from this project will also be disseminated at ACEP's Scientific Assembly, a 5-day, 350 course educational conference for over 6,000 participants and at our Research Forum. ACEP will disseminate the smoking cessation intervention to our emergency physician members and encourage the stakeholders to disseminate to their memberships through their communication and educational avenues.

Surveys will be sent by ACEP and stakeholder organizations to gather data on the number of targeted learners utilizing the education to increase the smoking cessation interventions. The targeted measures of success will be determined by the association representatives attending the first meeting.

In addition to this education dissemination, the intervention may be sustained after the funding expires in several ways: modules may be posted on association and hospital websites in order

to further disseminate the information, buy-in of hospital administrators as smoking cessation counseling is a reimbursable activity and a CMS Quality measure tied to reimbursement.

## Summary

This multicenter pilot study of eight academic trauma centers seeks to establish the feasibility of training emergency physicians, trauma surgeons, orthopedic surgeons and nurses in tobacco control, and performing a simple ask-advise-refer intervention in the ED. If successful, the study will facilitate the adoption of ask-advise-refer interventions by the nation's trauma centers, thus providing the millions of patients who visit these EDs every year a new source of cessation screening and counseling. As this intervention will be performed by clinicians, not research personnel, its generalizability to all trauma centers is considerable.

## Literature Cited


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Appendices available upon request:

Survey instrument for physicians and nurses
Survey instrument for patients
Quitline card (prototype)

## Letters of Commitment

We have more than three letters of commitment but due to the RFP requirements, we are including only three in this proposal.

**Detailed Work Plan and Deliverable Schedule**

| Year 1 | Qtr |
|---|---|
| Assemble "task force" meeting of representatives from American College of Emergency Physicians American College of Surgeons, American Academy of Orthopaedic Surgeons, Emergency Nurses Association, American Academy of Nurse Practitioners, Society of Emergency Physicians Assistants in order to share each organization's understanding, approach and policy regarding existing smoking cessation intervention, develop consensus among the organizations regarding smoking cessation intervention in the treatment of trauma patients, develop consensus regarding each society members' practitioners' role in such intervention, develop consensus on optimal timing of approaching trauma patients (ED and inpatient) for intervention, and understand existing barriers to implementation of such interventions. | 1, 2 |
| Deliverable: A manuscript summarizing the outcomes of this meeting will be created and submitted for publication. | |
| 1. Recruit 8 sites for participation. | 2, 3 |
| 2. Design curriculum and draft educational materials. | 2, 3 |
| Deliverable: One hour Power Point presentation that includes generalize educational information about smoking and smoking cessation and curriculum tailored to specialty group ( i.e. emergency physicians, trauma surgeons, orthopedic surgeons, nurses, nurse practitioners and physician assistants). This Power Point presentation and talking points will be posted on the web for real-time reference. | |
| 3. Develop web based database. | 2, 3 |
| Deliverable: Web-based database that includes algorithm for entry error detection for use by all participating sites. | |
| 1. Assemble meeting of site investigators for review and training of protocol and operating manual. | 4 |
| 2. Pilot test in 2 of the 8 sites. | 4 |
| 3. Modify curriculum, educational materials and data entry system based on feedback. | 4 |
| Deliverable: Modified One hour Power Point presentation that includes generalize educational information about smoking and smoking cessation and curriculum tailored to specialty group ( i.e. emergency physicians, trauma surgeons, orthopedic surgeons, nurses, nurse practitioners and physician assistants). This Power Point presentation and talking points will be posted on the web for real-time reference. | |
| Year 2 | |
| 1. Disseminate education to participating healthcare providers at all 8 sites. | 1, 2 |
| 2. Test in remaining 6 sites (pilot sites excluded). | 1, 2 |
| Deliverable: Initial project database. | |

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|---|---|
| Post-intervention health care provider assessments via surveys of participants. | 3 |
| Deliverable: Complete database | |
| Final database clean up and data analysis. | 4 |
| Deliverable: Complete and clean database and analysis of variables and outcomes. | |
| 3. Report preparation and manuscript preparation. | 4 |
| Deliverable: Completed manuscript ready to submit for publication. | |

**Post Award – Sustainability and Dissemination and Education**

Following the grant period, ACEP will disseminate the intervention education through its many communication and education avenues.

ACEP has a number of communication resources to disseminate this education, including: Annals of Emergency Medicine, a peer-reviewed leading journal in the specialty, ranking first among the 13 titles in the emergency medicine category of Thomson Scientific; ACEP News (printed monthly news magazine - 36,000 readers); EM Today (online news brief, five days a week - 22,000 emails – open rate is 34%); the Weekend Review (online Saturday news brief - 33,000 emails), The Central Line – ACEP's official blog (see http://thecentralline.org), and ACEP's website. ACEP also has an app where we will distribute the educational materials.

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