

Smoking Intervention with Trauma Patients

Rita K. Cydulka, MD, MS, FACEP
Professor and Vice Chair, Department of Emergency Medicine
Case Western Reserve University School of Medicine
MetroHealth Medical Center

Steven L. Bernstein, MD, FACEP
Professor and Vice Chair for Academic Affairs, Department of Emergency
Medicine
Yale University School of Medicine

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Please read this manual carefully before enrolling patients or providers. Refer to it if questions arise during the course of patient/provider enrollment. If you have problems/ideas/suggestions, please discuss them with your Site Principal Investigator. Call Drs. Cydulka or Bernstein if you have any unresolved questions. Thank you.

STUDY TEAM ROSTER

Rita K Cydulka, MD
Co-PI
216-778-3577
rcydulka@metrohealth.org

Steven Bernstein, MD
Co-PI
Steven.bernstein@yale.edu

Jeff Claridge, MD
Trauma Surgery PI

Brendan Patterson, MD
Orthopedic Surgery PI

Michelle Fakler
Research Assistant
330-819-2224
Michelle.Fakler@case.edu

Charles (Todd) Sarbach
Webmaster
Steven Lewis
Statistician

Kathy Kriedler
Grant Manager

Julie Nichols, RN
Project Coordinator
216-957-6488
jnichols@metrohealth.org

PARTICIPATING STUDY SITES

Denver Health
Christopher Colwell, MD
Christopher.Colwell@dhha.org

Emory
Hany Atallah, MD
404-616-7496
Hatalla@emory.edu

MetroHealth Medical Center
Rita K Cydulka, MD
216-778-3577
rcydulka@metrohealth.org

University of Pennsylvania
Karin Rhodes, MD
215-746-6824
Karin.Rhodes@uphs.upenn.edu

University of Texas
Mandy Hill, need to get her initials
713-500-7661
Mandy.J.Roberts@uth.tmc.edu

Smoking Intervention with Trauma Patients

Objectives

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

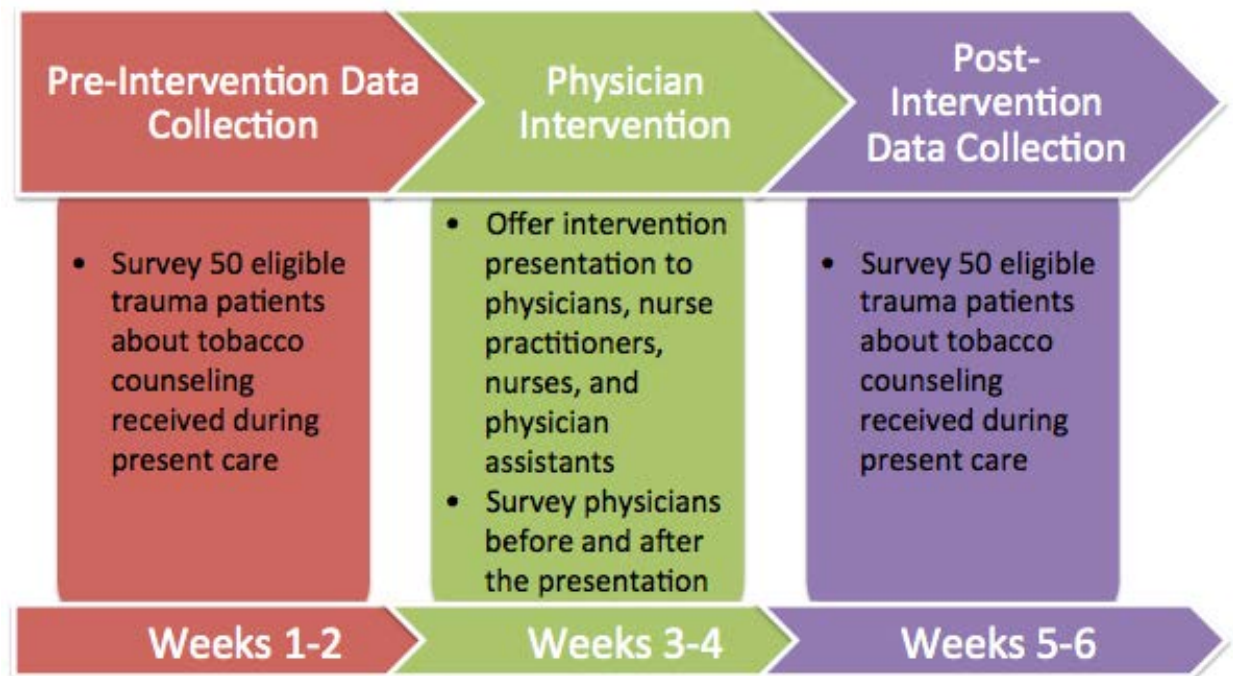
Aim 2: We aim to improve the confidence and knowledge base of smoking intervention techniques among the team of care-providers of trauma patients:

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.

Design: Interventions and Duration



Intervention: Care providers

Baseline assessment. At baseline, each physician will complete a data collection instrument assessing knowledge, attitudes, beliefs and practices about tobacco

control. The physician will complete the instrument again one week after the completion of training.

Physician curriculum and training. All resident and attending physicians and nurses in the study will receive a lecture on the epidemiology of smoking, with a focus on the prevalence of tobacco use and tobacco-related illness among trauma patients.

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

Intervention: Trauma patients

Baseline assessment population. Research associates (RAs) will interview trauma patients until 50 adult smoking trauma patients have been identified at each site – 25 patients who will be discharged home and 25 patients who have been admitted to the hospital for ongoing care.

The healthcare provider educational intervention will occur after 50 baseline smoking trauma patients have been assessed. 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.

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.

Sample Size and Population

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.

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. To assess the efficacy of the intervention, a population of trauma patients to yield 50 eligible subjects will be surveyed pre- and post-intervention.

1. STUDY OBJECTIVES

1.1 Primary Objective

The educational intervention will improve the confidence and knowledge base of

smoking intervention techniques among the team of care-providers of trauma patients

1.2 Secondary Objectives

The educational intervention among the team of care-providers of trauma patients will 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.

2. BACKGROUND AND RATIONALE

2.1 Background

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.

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.

2.2 Study Rationale

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.

In 2004, the American College of Emergency Physicians (ACEP) convened a task force of representatives of major emergency medicine professional organizations to address the role of emergency medicine in tobacco control. 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.

3. STUDY DESIGN

Data Collection: Patient Baseline

- Research assistants consent eligible trauma patients and administer survey at a single time point. This survey assesses rate and quality of provider tobacco counseling provided to this patient.
- Research assistants populate database with de-identified information from survey tools daily

Data Collection: Care-provider baseline

- Prior to the intervention, participating care-providers consent to participate in the educational intervention and to provide baseline and post-intervention data concerning knowledge, attitudes, beliefs and practices about tobacco control

Intervention

- Care-providers participate in a classroom-based or web-based educational seminar on tobacco counseling

Data Collection: Care-provider post-intervention

- Care-providers complete the same survey tool that was presented at baseline. These data are used to assess the primary objective of this study.

Data Collection: Patient post-intervention

- Research assistants consent eligible trauma patients and administer survey at a single time point. As with the baseline population, this survey assesses rate and quality of provider tobacco counseling provided to this patient.
- Research assistants populate database with de-identified information from survey tools daily
- These data are used to assess the secondary objectives of this study

4. SELECTION AND ENROLLMENT OF PATIENT PARTICIPANTS

4.1 Inclusion Criteria

- Age greater than 18 years
- English or Spanish speaker
- Current daily or some days smoker

4.2 Exclusion Criteria

All candidates meeting any of the exclusion criteria at baseline will be excluded from study participation.

Exclusion criteria:

- Individuals deemed too ill to consent
- Individuals who have sustained a brain injury during the most recent incident
- Cognitive impairment
- Leaving Emergency department against medical advice
- Inability or unwillingness of individual or legal guardian/representative to give written informed consent.

4.3 Study Enrollment Procedures

4.3.1 Determining Eligibility

- Research Assistants should approach all adult trauma patients eligible for participation.
 - Trauma Patient: Patients presenting to the emergency department who require trauma team evaluation
- RA's should ask Q1-Q9 (Exclusion and Inclusion criteria) to determine eligibility
- **All** Inclusion Criteria must be checked to enroll patient.
- If **any** Exclusion Criteria are checked, patient is excluded.
 - **Thank** patient.

4.3.2 If patient is **eligible** for the study

- **Ask** if s/he would be willing to participate.
- If yes, then obtain written informed consent
 - Obtain consent in the language (English/Spanish) preferred by patient
- Have patient **sign** consent and HIPAA forms
- Provide a copy of the consent form to the patient
- Signed consent forms will be stored in a locked cabinet in the research office at each site.

4.3.3 Completing the data collection instrument

- **IMPORTANT: Do not leave blank spaces on the DCI. Check each page after completion, and again upon the conclusion of the survey**
 - *Ask enrolled patients Q10 – Q51*
 - *Review chart for Q52 – Q64*
- 4.3.4 Completing data collection at a site
- **Target:** 50 enrolled patients before the intervention, and 50 enrolled patients after the intervention who have received care from providers who have undergone the intervention
 - In order to account for patients with providers who have not undergone the intervention, *it is estimated that 60-70 eligible patients must actually be enrolled.*
 - **IMPORTANT:** If you enroll patients who were treated primarily by residents rotating from other services, or patients treated by providers who were not trained, these data will be excluded from the primary analysis. We will analyze them separately.

5. SELECTION AND ENROLLMENT OF PROVIDER PARTICIPANTS

5.1 Eligible Participants

- Attendings and residents in orthopedic surgery and trauma/general surgery
- Emergency medicine Nurse Practitioners
- Emergency medicine Physician Assistants
- **IMPORTANT:** House officers temporarily rotating through from other services are welcome to listen to the lecture, but are not the subjects of this study.

5.2 Intervention Timeline

- The estimated timeline for data collection period 1, the intervention, and data collection period 2 is approximately 5-6 weeks.
- **IMPORTANT:** Select an appropriate 5-6 week window
- **Weeks 1-2:** Data collection period 1
- **Week 3:** Intervention with providers
- **Weeks 4-5:** Data collection period 2

5.3 Intervention Description

5.3.1 Intervention/Lecture

- Deliver the presentation according to accompanying script
- Conclude presentation by handing Outline card to each member of the audience

5.3.2 Pre-Intervention (Baseline) Provider Survey

- Record each provider's name on the provider roster

- The number to the left of the provider's name should appear in the 'Study sticker' box on the top right of each page of the Provider survey instrument
- **IMPORTANT:** Make sure that each provider uses the same number for the pre- and post-intervention surveys.

5.3.3 Post-Intervention Provider Survey

- Distribute the provider post-intervention survey *one-two weeks after lecture*.
- Again record each provider's name on the Provider Roster.
- The number to the left of the provider's name should appear in the 'Study sticker' box on the top right of each page of the Provider survey instrument.
- **IMPORTANT:** Make sure that each provider uses the same number for the pre- and post-intervention surveys.

5.3.4 Abbreviated Provider Training

- Providers who missed the formal lecture may receive an abbreviated training, using a shortened PowerPoint presentation. If a computer presentation is not feasible, print the lecture as a handout (fits on 3 pages using Handouts view). This may be done in about 10 minutes.
- **IMPORTANT:** It is essential to train all providers in as narrow a time frame as possible (2-3 days is ideal), and NOT to begin post-intervention data collection until most trauma care providers have been trained.
- **IMPORTANT:** Providers who receive the abbreviated training also need to complete the pre- and post-intervention surveys, and have study numbers assigned using the method described earlier.
- **IMPORTANT:** Please record on the Provider Roster which providers receive the abbreviated training, so we may report the proportion of providers who received this intervention.

5.3.5 Wallet Cards

- On the day of the resident lecture, place the Quitline wallet card in the various places in the ED where providers sit and complete charts. You may place the cards in specially designed holders, or the drawers, cubbies, and slots where materials are routinely kept. Do not place the cards in publicly accessible places, like the waiting area or examination rooms (because of their limited supply.)
- Check the ED daily to make sure that the cards (and holders) are still present. Replenish the cards as needed. Keep track of how many cards are used. (Best done by rubber-banding the cards in packs of 50, and counting the number of packs used.)

- Make sure that nursing is aware of the cards; they may distribute them too, if they wish.
- Cards unused at study completion may be distributed as you see fit.
- **IMPORTANT:** If a patient who was not offered a Quitline card asks the research assistant for one, please do so (but record the patient as not having received a wallet card from the provider).

6. DATA COLLECTION AND QUALITY ASSURANCE

6.1 Data Collection Forms

- 10.1.1 Trained research assistants at each site will administer survey tools to patients and providers.
- 10.1.2 Trained research assistants will input the information from the data collection instrument into a secure database for storage

6.2 Data Management

- 10.2.1 The data collection instrument and consent forms will be stored separately.
- 10.2.2 All data collection instruments and consent forms must be kept in locked, secure cabinets
- 10.2.3 Upon completion of each phase of the study, please mail all patient and provider forms using next-day service to:

Rita K Cydulka, MD, MS
 Department of Emergency Medicine
 MetroHealth Medical Center
 Room BG3-70
 2500 MetroHealth Drive
 Cleveland, Ohio 44109

IMPORTANT: Keep a photocopy of all materials, including data forms, for yourself.

IMPORTANT: Do not mail the provider roster to the coordinating site. Keep the roster in a locked, secure cabinet.

6.3 Quality Assurance

10.3.1 Training

Dr. Cydulka will be available for all questions regarding training and scripts.

7. PARTICIPANT RIGHTS AND CONFIDENTIALITY

7.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document (see Appendix) and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

7.2 Informed Consent Forms

A signed consent form will be obtained from each patient and provider participant. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant or legal guardian and this fact will be documented in the participant's record.

7.3 Participant Confidentiality

All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using a participant identification number (Participant ID, PID) only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB.

8. REFERENCES

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9. SUPPLEMENTS/APPENDICES