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Disseminating Organizational Screening and Brief Intervention Services (DO-SBIS) for Alcohol at Trauma Centers Study Design

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Abstract

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Objective—In 2005 the American College of Surgeons passed a mandate requiring that Level I trauma centers have a mechanism to identify patients who are problem drinkers and have the capacity to provide an intervention for patients who screen positive. The aim of the Disseminating Organizational Screening and Brief Intervention Services (DO-SBIS) cluster randomized trial is to test a multilevel intervention targeting the implementation of high quality alcohol screening and brief intervention (SBI) services at trauma centers.

Method—Twenty sites selected from all US Level I trauma centers were randomized to participate in the trial. Intervention site providers receive a combination of workshop training in evidence-based motivational interviewing (MI) interventions and organizational development activities prior to conducting trauma center-based alcohol SBI with blood alcohol positive injured patients. Control sites implement care as usual. Provider MI skills, patient alcohol consumption, and organizational acceptance of SBI implementation outcomes are assessed.

Results—The investigation has successfully recruited provider, patient, and trauma center staff samples into the study and outcomes are being followed longitudinally.

Conclusion—When completed, the DO-SBIS trial will inform future American College of Surgeons' policy targeting the sustained integration of high quality alcohol SBI at trauma centers nationwide.

Keywords

Acute care medical trauma centers; Injury; Alcohol; Screening and brief intervention; American College of Surgeons

1. Introduction

Physical injury with and without traumatic brain injury constitutes a major public health problem for both civilian and veteran trauma-exposed patient populations. Each year in the United States (US), approximately 1.5-2.5 million Americans are so severely injured that they require inpatient surgical hospitalization.

Epidemiological investigations have documented that alcohol use problems are endemic among US trauma center inpatients. A body of evidence derived from efficacy and effectiveness spectrum randomized clinical trials now suggests that alcohol screening and brief intervention (SBI) programs derived from motivational interviewing (MI) principles may reduce alcohol consumption among patients presenting to acute care medical, trauma center settings. Thus, the widespread integration of high quality alcohol SBI into acute injury care has the potential to markedly increase the population impact of injury prevention efforts and has been a longstanding public health objective.

In 2005, the American College of Surgeons, the primary agency responsible for developing United States' trauma center regulatory requirements, passed a resolution mandating that Level I trauma centers must have a mechanism to identify patients who are problem drinkers and have the capacity to provide an intervention for patients who screen positive. Trauma centers that are found not to be performing alcohol SBI during American College of Surgeons' verification site visits risk losing College accreditation and associated federal funding. This represents the first ever nationwide United States policy mandate for the integrated treatment of alcohol use problems in a general medical setting (i.e., hospital inpatient, emergency department, or primary care outpatient setting). Although an enormous first step, specific alcohol screening and brief intervention methodology is being left to the discretion of each trauma center. There is a substantial risk that the mandate will be implemented with marked variability and that lower quality alcohol SBI procedures could

become the default standard of trauma center care nationwide. The overarching goal of this research program is to harness the opportunity afforded by the American College of Surgeons' mandate by taking investigative steps to test the delivery of high quality, evidence-based alcohol SBI procedures.

2. Conceptual frameworks informing the DO-SBIS study protocol

A number of conceptual frameworks inform the development and implementation of the Disseminating Organizational Screening and Brief Intervention Services (DO-SBIS) study protocol (Figure 1). Just as readiness has given a model for individual level change , organizational behavior and implementation science frameworks can be incorporated into a program readiness for change model that can guide integration of high quality alcohol SBI services into routine trauma center practice (Figure 1). The model outlines three key stages in the transfer of new alcohol SBI : 1) *Adoption*, an initial leadership decision to allow new screening and brief intervention procedure provision at a trauma center, 2) *Implementation*, the preliminary use of a new method, and 3) *Integration*, the maintenance into routine provider and patient level targets for organizational development activities. The model suggests that organizational and provider readiness for change are key attributes for initial assessment. Multiple trauma center provider, patient, and organizational level targets for institutional development activities are also identified by the model.

Diffusion of innovation research suggests that trauma centers may be classified into adopter categories with regard to institutional readiness to implement evidence-based alcohol SBI procedures (Figure 1). Adopter categories range from innovators or early adopters (i.e., groups likely to rapidly take up an innovative technology), through middle majority adopters (i.e., medium uptake), and laggards (i.e., slow to adopt or no uptake). Diffusion of innovation research also suggests that trauma centers in the middle majority adopter category that are neither innovators nor laggards may be best suited for intervention. These centers are anticipated to be receptive to implementing high quality screening and brief intervention procedures in the wake of the American College of Surgeons' mandate, yet are unlikely to do so without evidence-based intervention training and organizational development activities. Literature suggests that innovators and early adopters may already be implementing high quality SBI services and may not require intervention, and that laggards may be unresponsive to intervention.

3. Methods

3.1. Design overview

The specific aim of the DO-SBIS investigation is to test, in a cluster randomized clinical trial design, the effects of a multilevel intervention on the delivery of high quality alcohol SBI services at 20 United States Level I trauma centers (Figure 2). The 10 Level I trauma center sites randomized to the intervention receive a combination of workshop training, as well as feedback and coaching in evidence-based MI interventions. Intervention sites also receive organizational development intervention activity delivered by the interdisciplinary study team members. Control sites implement usual care alcohol SBI. Trauma center provider, patient, and organizational level outcomes are collected and followed longitudinally.

3.2. Selection of trauma center sites and providers

A nationwide readiness assessment was conducted prior to the implementation of the clinical trial in order to classify US Level I trauma centers into adopter categories (Figure 2). The nationwide readiness survey included interviews with trauma program coordinators at

each US Level I trauma center site. Survey items assessed current alcohol SBI practices, previous trauma center training in alcohol SBI, and willingness to receive additional provider, patient, and organizational level trainings. Hospital and national websites were used to characterize centers with regard to hospital beds, training programs, and National Institute of Health (NIH) alcohol protocol grant funding. Sites classified as innovators and early adopters demonstrated well developed alcohol SBI services and had established trauma surgical and SBI provider champions; innovator sites often demonstrated prior NIH or other extramural funding for alcohol SBI protocols. Laggard sites endorsed little training or service development, had no champions, and displayed little or no future interest in SBI organizational development. Middle majority sites fell between these two extremes, demonstrating interest in SBI related organizational development, but with fewer established champions and prior training/service development.

Middle majority adopter sites were retained in the study as they were anticipated to be receptive to implementing a screening and brief intervention procedure, yet unlikely to do so without externally prompted evidence-based intervention training and organizational development activities (Figure 2). The middle majority adopter sites received further indepth evaluations performed by the study's principal investigator and trauma surgical co-investigators that included rated discussions with potential trauma surgery opinion leaders and alcohol SBI provider champions. Site motivation and readiness to participate in the study were reassessed during these evaluations. This readiness assessment was used to select 20 American College of Surgeons verified middle majority centers for randomization in the clinical trial. Prior to randomization, a single trauma surgeon opinion leader and alcohol SBI provider champion(s) were identified at each site. Also prior to randomization, organizational process mapping was applied to each of the 20 sites in order to identify 10 staff affiliated with trauma center alcohol screening and brief intervention work units.

3.3. Randomization

The unit of randomization was the individual trauma center. Randomization occurred in a 1:1 ratio according to a computer-generated random assignment sequence.

3.4. Blinding

Research assistants conducting all assessments and follow-up interviews are blinded to trauma center intervention and control group assignments. Similarly, patients recruited from intervention and control group sites are not aware of trauma center group assignments.

3.5. Multilevel intervention procedures

The 10 intervention trauma center alcohol SBI providers were randomized to receive evidence-based MI workshop training, telephone coaching, and written feedback via email in conjunction with organizational development activities targeting the delivery of high quality alcohol SBI services. The MI intervention component has been successfully developed and implemented by the study team over the past decade in clinical trials and subsequently in routine clinical practice.

To initiate the intervention training, a one-day MI workshop is conducted at each intervention trauma center. During the site visit, the alcohol SBI champion provider(s) at each intervention trauma center receives training in the delivery of MI interventions targeting changes in post-injury alcohol consumption and related behaviors. Motivational interviewing approaches encourage movement in the direction of reductions in at-risk drinking behaviors by empathically exploring ambivalent feelings about alcohol use after an injury. The core intervention is a 20-30 minute motivational interview that can be delivered at bedside to injured inpatients by the full spectrum of trauma center providers (e.g., masters)

in social work and nursing providers). The acute care MI protocol developed for the intervention consisted of a graded sequence of the following clinical tasks: 1) Eliciting from patients their views on the importance of changing, as well as their confidence in being able to change, 2) giving patients personalized feedback on alcohol use, and 3) clarifying the patient's goals (e.g., to quit or cut down) and action plans. Each patient's motivation for counseling and readiness for change determined when and how many of these tasks will be discussed. The earlier tasks were emphasized with patients in the pre-contemplation or contemplation stages of change, and the later tasks were emphasized with those in the preparation or action stages. Previous investigation suggests that training workshops, plus feedback and coaching are the optimal procedures for teaching evidence-based alcohol intervention. For six months after the site visit, alcohol SBI provider champions at intervention sites receive expert telephone coaching and written feedback in motivational interviewing.

At intervention sites, training in MI is embedded within ongoing organizational development intervention activities (Figure 1). The organizational development intervention components are distilled from evidence-based organizational interventions including the Availability, Responsiveness, and Continuity (ARC) intervention. Organizational development interventions such as ARC aim to improve human service organizations' delivery of health services by facilitating personal relationships with members of an organization, enhancing network development among providers, team building, enabling collaborative participatory decision making, providing information and feedback, facilitating conflict resolution when necessary, enhancing continuous quality improvement efforts, and aiding with job redesign. For the purposes of the current investigation, the organizational development intervention procedure has been adapted to fit the stages of the program change model (Figure 1). Study team intervention logs are used to document the timing and delivery of organizational development intervention activities.

3.6. Control trauma centers

Control trauma centers implement SBI care as usual. Preliminary studies suggest that there may be marked variation in SBI implementation at usual care control sites. As an incentive for study participation, both control and intervention sites receive a waiver on the American College of Surgeons alcohol SBI requirement during study participation. As a further incentive for participation, control sites receive a MI site visit training at the termination of the study protocol after recruitment and outcome assessments are complete.

3.7. Patient eligibility and enrollment

Patients included in the trial are male and female survivors of motor vehicle crashes, assaults, and other intentional and unintentional injuries, ages 18, who are so severely injured that they require inpatient hospital admission. Injured participants recruited into the trial are consecutively admitted patients who test positive for blood alcohol. Patients with self-inflicted injuries, monolingual non-English speaking injury survivors, and prisoners are excluded from the trial. Patients with Alcohol Use Disorders Identification Test (AUDIT) scores 20 are also excluded from the trial as these patients are less likely to benefit from brief interventions. After patients consent to the protocol and have received their baseline assessment from trauma center providers, SBI provider champions at intervention and control sites are instructed to deliver brief interventions targeting alcohol use reductions.

3.8. Outcome assessments: Overview

Provider, patient, and organizational level outcomes are collected in order to assess the impact of the multilevel intervention (Table 1). To assess sustained intervention effects over

time, all outcome assessments extend longitudinally beyond the six months of active intervention site training.

3.9. Provider assessments of MI fidelity

The DO-SBIS investigators sought to advance the field of randomized MI training trials by deploying multiple measures of MI skill over a greatly extended time period. Therefore, the study design compares the natural development of MI skill over time (control group) with the development of formally-trained clinicians (intervention group) during both the training period and for nearly two years after the end of formal training. An accurate time series of real-world trauma clinicians' skill development enhances current and future training and supervision efforts at trauma centers.

Intervention and control alcohol SBI providers participate in a total of seven 20-minute standardized patient actor telephone interviews. Baseline standardized patient interviews with providers took place at all 20 sites prior to randomization (Table 1). Intervention sites were scheduled for standardized patient interviews one week after workshop training and then again at 1-, 4-, 7-, 17-, and 27-months after the intervention workshop training; control site practitioners undergo a comparable sequencing of baseline, as well as 7-, 17-, and 27-month follow-up assessments. Frequent early longitudinal assessments are required in order to measure the impact of initial intensive workshop training, written feedback, and telephone coaching. Multiple longitudinal assessments may also allow for discrimination between transient training effects of the standardized patient interviews anticipated to occur in both intervention and control site providers, versus sustained gains in MI proficiency anticipated to occur only in intervention group providers as a result of workshop training, feedback and coaching.

For each assessment point, telephone appointments are made by the study standardized patients, who are blinded to SBI provider intervention and control group status. Each standardized patient interview lasted approximately 20 minutes and is audio-recorded. Standardized patient interviews incorporate a graded sequence of clinical difficulty ranging from early interviews, in which actors role-play patients ready and willing to change, to final interviews, in which actors role-play more challenging patients who are in the precontemplation stage of change.

Each interview is coded with the Motivational Interviewing Treatment Integrity coding system. Trained coders apply MITI coding rules to derive scores while listening to audiotaped standardized MI interviews. Global scores evaluating the entire session rate each counselor's MI Spirit, Evocation, and Collaboration. Also, the frequencies of individual provider behaviors are counted by coders during the interview. These behavioral scores include open and closed questions, simple and complex reflections, giving information, and MI-adherent and -nonadherent behaviors. The MITI has established reliability and validity, and MITI coding procedures have been manualized and applied in over 20 published studies.

3.10. Patient outcomes

All patient level outcomes, including the primary outcome of interest post-injury alcohol consumption, are assessed via patient self-reports (Table 1). Investigation of standardized assessments of patient self-reported alcohol consumption across clinical populations including injured trauma survivors suggests that while some variation in the accuracy of self-reports exists, self-reports have established reliability and validity and can be used with confidence.

The AUDIT is being used to assess alcohol use at baseline in the inpatient ward and again 6and 12-months after each patient's hospital admission. The AUDIT is a 10-item screening instrument for the early identification of problem drinkers. In addition to the AUDIT, Form 90 will be used to augment the assessment of alcohol consumption at the 6- and 12-month time points. Form 90 is an optimal assessment for the investigation as it can be flexibly employed in telephone evaluations and the brief interviews required in general medical setting follow-ups. Form 90 has established reliability and convergent validity. The 6- and 12-month follow-up telephone interviews will also include selected Form 90 items assessing the use of drugs, the use of substance-related health services, recurrent injury events, episodes of driving under the influence of alcohol, and substance-related legal encounters (Table 1). These Form 90 items will be augmented with the Short Inventory of Problems in order to enhance the assessment of alcohol and drug-related problem behaviors. Additional trauma center patient level assessments derived from previous acute care study protocols by the investigative team included posttraumatic stress disorder symptoms, depression, and

3.11. Trauma center staff organizational outcomes

functional outcomes (Table 1).

The investigation uses the Organizational Social Context (OSC) and Organizational Readiness for Change (ORC) measures to assess and compare acceptance of SBI services for intervention and control site staff (Table 1). The OSC assesses domains of organizational climate and culture, including emphasis on emotional support, job satisfaction, hierarchy of authority, motivation, and service quality. The ORC assesses four domains of organizational readiness for the implementation of trauma center alcohol programs, including motivational readiness, institutional resources, staff attributes, and institutional climate. These organizational assessments have established reliability and validity when used across diverse institutional contexts. Ten staff members, identified by the institutional process mapping procedure, constituted the trauma center organizational alcohol SBI work unit for each assessment. Intervention sites receive assessments at baseline pre-randomization, and 7-, 17-, and 27-month follow-up. Control sites undergo a comparable sequencing of baseline pre-randomization, and 7-, 17-, and 27-month follow-up assessments (Table 1).

3.12. Other DO-SBIS study protocol assessments

Each patient enrolled consents to the release of trauma center medical record data; deidentified trauma registry data for all trauma patients admitted during the time period of each site's patient recruitment is also obtained. The characteristics of patients recruited into the investigation will be compared to the population of patients admitted at the individual site during the time period of recruitment (Table 1). The nature and duration of all intervention contacts is documented and used to assess elements of the organizational development intervention activities. Study logs will also document when providers either discontinue delivering SBI (attrition), or are terminated from trauma center employment (turnover). After the completion of the clinical trial, study investigators will conduct semistructured qualitative interviews with each site's SBI provider champion(s).

3.13. Analysis plan

The purpose of the DO-SBIS statistical analyses is to compare trends in the primary outcomes for the 20 trauma centers assigned to intervention and control conditions. All primary statistical analyses will be conducted with the intent-to-treat sample. The investigation will use mixed effects, hierarchical regression models to test the primary provider, patient, and organizational level hypotheses for both continuous and discrete outcome variables.

A particular strength of mixed effects, hierarchical regression models is the ability to model patients, providers, and treatment nested within trauma center sites. A key consideration for the trial is this nesting and the ascertainment of associated intraclass correlations (ICC). All sample size estimates are therefore adjusted for the clustering of patients and providers within trauma center sites, using appropriate ICCs derived from the investigative group's previous multisite trauma center studies.

3.14. Sample size and power

The primary outcome variables are intervention and control group: 1) Ratings of provider proficiency in the delivery of evidence-based MI intervention derived from the MITI, 2) Patient self-reported alcohol consumption 6- and 12-months post-injury, and 3) Staff ratings of organizational climate, culture, and readiness derived from the OSC and ORC. Power analyses were conducted to determine the appropriate number of patients for the study using the Power Analysis and Sample Size Software. Sample size estimates were inflated to account for any anticipated ICC using previously described methods.

Hypothesis 1—SBI providers at intervention sites will demonstrate greater proficiency in MI interventions over time as evidenced by improved MITI scores. Estimates of evidencebased MI workshop training on MI proficiency were derived from published reports on evaluations of MI workshop participants. For power analyses we used pre-training and follow-up assessment of a specific MI behavior, the percentage of open-ended questions asked. Previous investigation with community substance abuse counselors suggests that at baseline, untrained providers will ask between 25-30% (SD = 16%) open-ended questions. Follow-up assessments suggest that MI proficient providers will ask 41% (SD = 23%) openended questions, while untrained providers should remain in the 25-30% range. With α = 0.05 and 0.75 correlation of scores across assessment points, the investigation will require 20 providers (i.e., at least 1 provider at each site) to attain >80% power. The investigation anticipates having at least one SBI provider at each site. Of note, the anticipated ICC for providers nested within sites is negligible.

Hypothesis 2—Patients who receive SBI services at intervention trauma centers will demonstrate significant reductions in alcohol consumption over time compared to patients at control trauma centers. Estimates for the effect size in the current investigation are derived from previous studies across Level I trauma center sites. Previous MI interventions conducted by highly trained Ph.D. and M.S.W. level providers were associated with 12-month effect sizes of 0.30. We conservatively estimate that in this nationwide trial, routine trauma center SBI providers will be 60% as effective in delivery of MI, yielding a 12-month effect size of 0.18. Comparisons of blood alcohol concentrations from our previous studies that have randomly sampled injured patients suggest an ICC = 0.00028 across trauma center sites. Assuming a linearly increasing effect size culminating at 0.18, a constant correlation of 0.70 across assessments, an ICC = 0.00028, $\alpha = 0.05$, and 30% 12-month attrition, to attain 80% power the investigation will require recruitment of 800 patients (40 patients * 20 sites) in order to retain 520 patients at the 12-month post-injury follow-up.

Hypothesis 3—Providers at intervention sites will demonstrate significantly improved scores on organizational climate, culture, and readiness inventories over time. Estimates of the impact of the MI training and organizational development activities on organizational climate, culture, and readiness are derived from previous acute care medical organizational assessments. Intervention sites are hypothesized to demonstrate scores on organizational culture-emphasis emotional support subscales reflective of high quality acute care environments, while control sites will be hypothesized to demonstrate scores reflective of lower quality acute care environments. Of particular note, organizational climate, culture,

and readiness inventories are anticipated to demonstrate a high ICC. With an ICC = 0.53, α = 0.05, the investigation will require 200 providers (i.e., 10 providers at each site) to attain 80% power.

3.15 Study Design Considerations and Limitations

The trauma surgical study context influenced a number of important investigative design considerations and study limitations. The investigation used an AUDIT 20 cutoff to exclude heavy drinkers, because World Health Organization guidelines strongly recommend that patients with AUDIT scores 20 receive referral to a specialist for a diagnostic evaluation. The American College of Surgeons' Alcohol mandate only requires that patients receive screening and intervention. Thus in order to comply with both the College mandate and the WHO guidelines, patients included in the study had AUDIT scores 20 were excluded from the study, yet continued to receive trauma center alcohol care that could include screening, intervention, and referral to treatment. A limitation of this approach may have been to exclude the most highly symptomatic drinkers and thus diminish the likelihood of finding an intervention treatment effect.

Also, in this implementation spectrum cluster randomized trial, we did not have the flexibility to require an extensive training period for providers, or train alternate providers beyond those selected by the trauma center as SBI champions. Therefore, we were not able to train providers to proficiency in motivational interviewing as might occur in efficacy or even effectiveness spectrum trials.

Another design consideration was that any of the five MITI global indices including: Global Spirit, Percentage Complex Reflections, Reflection to Question Ratio, Percent MI Adherence, and Percent Open Questions could have been selected for use inthe power and sample size estimations. Percent Open Questions was a MITI indice that had been used as a primary training outcome in previous investigations by members of the investigative group, thus providing preliminary data for power analyses; This indice also had the greatest "face validity" for pragmatically oriented trauma surgical co-investigators. Finally, human subjects' considerations including the complexity of orchestrating IRB approvals across the 20 trauma center sites pragmatically influenced the decision to assess MI fidelity through audio recorded standardized patients interviews rather than audio recorded sessions with actual injured trauma center patients.

4. Results

A total of 40 SBI providers (16 intervention and 24 control) are undergoing serial assessments of MI skills with standardized patient assessments. Providers are predominantly female (95%) and from White backgrounds (88%). On average, providers have been employed at their respective trauma centers for 7 years and graduated from college or other educational programs 16 years prior to study participation. There were no significant differences between intervention and control group providers with regard to demographic, trauma center, or educational characteristics.

A total of 878 blood alcohol positive injured patients have been recruited from the 20 trauma center sites; 409 or 47% of patients were recruited from intervention sites and 469 or 53% were recruited from control sites. The average age of patients is 36.9 years old, 24% of patients are female, and 38% are from non-White backgrounds. The mean AUDIT score for patients is 10.1 (SD = 5.0). There were no significant differences between intervention and control group patients with regard to demographic or clinical characteristics.

A total of 219 (109 intervention and 110 control) trauma center staff are participating in the longitudinal organizational climate, culture, and readiness assessments. Providers are predominantly female (71%) and from White backgrounds (87%). On average, providers have been employed at their respective trauma centers for 9 years and graduated from college or other educational programs 16 years prior to study participation. There were no significant differences between intervention and control group staff with regard to demographic, trauma center, or educational characteristics.

5. Conclusion

The aims, design, and time trajectory of the DO-SBIS investigation derive from the opportunity presented by the American College of Surgeons' policy mandate for SBI services as a requisite for Level I trauma center accreditation. A novel aim of the investigation is to conduct a definitive multisite randomized clinical trial that will inform future American College of Surgeons' policy mandates for high quality evidence-based alcohol SBI services at Level I trauma centers. The American College of Surgeons' commitment to review the empiric literature and mandate procedures derived from this evidence provides a unique "make it happen" regulatory context in which to conduct this general medical setting cluster randomized trial. Thus, findings from the study will be used to directly inform the development of performance standards and quality indicators that will be incorporated into future mandates and clinical practice guidelines targeting the sustainable delivery of high quality alcohol SBI procedures for trauma centers throughout the US.

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Fig. 2. DO-SBIS study protocol.

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Timing	Assessment	Z	Mode	Measures	Outcome
Pre-randomization	All United States Level I trauma center program coordinators	204	Phone	Alcohol SBI Readiness Survey	Classification/selection of RCT middle majority adopter sites
Pre-randomization	Middle majority adopter trauma centers	40	Phone	Early adopter status interview assessment	Selection of site trauma surgeon and SBI provider interventionist(s)
Pre-randomization baseline, 1-week, 1-, 4-, 7-, 17-, and 27-month follow- up	Alcohol SBI champion(s)	20+	Phone	MITI-coded standardized patient actor interviews [34]	Motivational interviewing intervention fidelity and skill level
Pre-randomization baseline, 7-, 17-, and 27-month follow-up	Trauma center staff comprising alcohol SBI work unit	10*20	Web	Organizational Social Context and Readiness [44, 45]	Organizational climate, culture, and readiness for change
Pre-intervention, 6-, and 12-month post-hospital admission	Patient self-report of primary alcohol outcomes	800	In-person/ Phone	AUDIT, Form 90, and SIP [33, 34]	Alcohol consumption and alcohol use problems
Pre-intervention, 6-, and 12-month post-hospital admission	Patient self-report of secondary outcomes including PTSD, depression, drug use & function	800	In-person/ Phone	Multiple (PCL-C, PHQ- 9, Form 90 drug, MOS SF-12) [41-43]	Trauma center secondary outcomes
RCT recruitment period	Patient trauma registry data	800	CONSORT	Diagram of patient flow through protocol at 20 sites	Estimation of target population and intervention reach
RCT development and implementation	Study intervention team members' records	S	Computer entry	Logs and field notes	Intervention activity documentation
Study end-point	Trauma center SBI champion(s)	20	In-person/ Phone	Semi-structured qualitative interviews	Facilitators and barriers to SBI implementation and maintenance