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The Emergency Department Safety Assessment and Follow-up Evaluation (ED-SAFE): Method and Design Considerations

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Abstract

Background—Due to the concentration of individuals at-risk for suicide, an emergency department visit represents an opportune time for suicide risk screening and intervention.

Purpose—The Emergency Department Safety Assessment and Follow-up Evaluation (ED-SAFE) uses a quasi-experimental, interrupted time series design to evaluate whether (1) a practical approach to universally screening ED patients for suicide risk leads to improved detection of suicide risk and (2) a multi-component intervention delivered during and after the ED visit improves suicide-related outcomes.

Methods—This paper summarizes the ED-SAFE's study design and methods within the context of considerations relevant to effectiveness research in suicide prevention and pertinent human participants concerns. 1,440 suicidal individuals, from 8 general ED's nationally will be enrolled during three sequential phases of data collection (480 individuals/phase): (1) Treatment as Usual; (2) Universal Screening; and (3) Intervention. Data from the three phases will inform two separate

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evaluations: Screening Outcome (Phases 1 and 2) and Intervention (Phases 2 and 3). Individuals will be followed for 12 months. The primary study outcome is a composite reflecting completed suicide, attempted suicide, aborted or interrupted attempts, and implementation of rescue procedures during an outcome assessment.

Conclusions—While 'classic' randomized control trials (RCT) are typically selected over quasi-experimental designs, ethical and methodological issues may make an RCT a poor fit for complex interventions in an applied setting, such as the ED. ED-SAFE represents an innovative approach to examining the complex public health issue of suicide prevention through a multiphase, quasi-experimental design embedded in 'real world' clinical settings.

Keywords

suicide; research methods; mental health; emergency department

1. Background

Suicide is the 10th leading cause of death in the United States. [1] Considerable federal effort has been directed towards reducing the national suicide rate. An emergency department (ED) visit may represent an opportune time to initiate suicide prevention efforts because a significant concentration of individuals at risk for suicide present to the ED for care.[2] The average annual number of ED visits for attempted suicide and self-inflicted injury more than doubled from approximately 244,000 in 1993–1996 to 538,000 in 2005–2008.[3] Studies conducted outside of the United States (U.S.) have found that nineteen percent of suicide attempters treated in the ED will re-attempt within the 6 months after the visit[4], and 39% of completed suicides are by people who had been seen in an ED within the year before their death.[5] When prospectively queried, rates of suicidal ideation among adult ED patients presenting with *non-psychiatric chief complaints* have ranged from 3 to 12%.[6–10]

Despite the likely density of at-risk individuals, most ED clinicians do not routinely screen for suicide risk. This is, in part, due to the paucity of evidence to support such screening. The human participants' protections needs associated with managing such high risk individuals and the need for large sample sizes to test suicide reduction strategies due to the relative rarity of the event has discouraged research in this area. As a result, there are no suicide risk screeners validated for primary risk detection among adult ED patients. Despite the barriers to doing such research, the public health impact of preventing suicide argues for expanded efforts to develop and test feasible approaches to universal ED-based screening for suicide risk and effective interventions that can be initiated during or shortly after the ED visit. In response to this need, the National Institute of Mental Health (NIMH) issued a Request for Applications, RFA-MH-09-150, and "Suicide Prevention in Emergency Departments." Detailed information regarding the background leading up to the issuance of the RFA, as well as specific application requirements may be found on the National Institutes of Health website (http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-09-150.html).

The Emergency Department Safety Assessment and Follow-up Evaluation (ED-SAFE) was funded as a result of the RFA. ED-SAFE study has two primary objectives: (1) to develop and test the feasibility and effectiveness of a standardized approach to screening adult ED patients for suicide risk using a tool suitable for systematic use in general medical EDs; and (2) to refine and test an ED-initiated intervention to reduce suicidal behavior among people who screen positive for suicide risk. ED-SAFE attempts to examine both of these components (screening *and* intervention) in a single study. Studying both screening and intervention, the practical constraints of working within a 'real world' clinical setting, the methodological issues associated with studying rare events, and the high-risk nature of the

patient population led to several important design considerations. The goal of this paper is to summarize ED-SAFE methodology, with a focus on design considerations, human participants' protections, and intervention fidelity.[i]

2. Study design and procedures

The study team decided to use a three phase, interrupted time series design to achieve the study's dual objectives. The overall study approach is presented in Figure 1. It consists of three sequential phases of data collection Across all three phases, data collection will be standardized but suicide-related clinical protocols applied during routine care in the EDs will change. This is consistent with systems-based change and effectiveness research principles. Specifically, after the Treatment as Usual phase, all sites will implement universal suicide risk screening for adults as a standing clinical protocol. All adults treated in the EDs will be screened regardless of their reason for presentation or recruitment into the prospective subcomponent of the study. Data will then be collected for the Universal Screening Phase. After data collection for the Universal Screening Phase is complete, all sites will modify their clinical protocols to add enhanced secondary screening and discharge with outpatient suicide prevention resources, including a personalized safety plan and outpatient mental health resource guide. In addition, the post-visit telephone intervention, Coping Long-term with Active Suicide Program – Emergency Department (CLASP-ED), will be initiated. Data will then be collected for the Intervention Phase.

Data from these three phases will be used for two primary evaluations. Phases 1 and 2 (Treatment as Usual, Universal Screening) will be used to determine the feasibility and effectiveness of universal suicide risk screening (the Screening Outcome Evaluation). Phases 2 and 3 (Universal Screening, Intervention) will be used to determine the feasibility and effectiveness of the enhanced intervention combining improved ED safety planning and a postED telephone intervention in decreasing future suicidal behavior (Intervention Evaluation).

2.1 Study sites and participants

ED-SAFE has eight participating hospitals, ranging from small community hospitals to large academic medical centers (see Table One). In order to make the results generalizable to the field at large, no site has a stand-alone psychiatric ED. In each phase, sites will staff the ED with research assistants (RAs) who will prospectively review medical charts in "real time." Any adult patient whom any level of self harm ideation or behavior documented on his or her ED medical chat will be considered eligible for approach. The threshold for initial approach will be kept low by approaching patients with any self-harm, not just suicidal self-harm per se, to avoid missing potential participants. The RAs will approach these individuals after they have been medically stabilized and sanctioned for approach by their treating clinicians, conduct an eligibility interview (see Table Two), and enroll a sample of 60 participants per site for each phase (480/phase), for a total of 1,440 prospective participants across the study.

All RAs will be trained centrally on the data collection procedures through multi-media teleconferences and supervised locally by an experienced emergency medicine investigator. The site will be given a detailed manual of procedures, and the site personnel will meet with ED-SAFE study leadership for monthly teleconference call to review progress, receive training updates, and problem solve.

[i]Several aspects of the study, including the adverse event monitoring system, a provider knowledge and attitudes survey, and an economic analysis are considered beyond the scope of the current discussion. All of these sub-studies will be addressed in forthcoming manuscripts.

2.2. Study oversite

A Steering Committee will direct and oversee the operations of the study. Study materials will be generated centrally at the coordinating center at Massachusetts General Hospital and distributed to the sites for submission to their respective Institutional Review Boards. NIMH will appoint an independent Data Safety and Monitoring Board (DSMB) with authority to shut down the study.

2.3 Outcome assessments

Across all three phases, outcome data collection will be performed in the same way. During each RA shift, all patients who enter the ED will be documented on a *screening log*, which will be used as the primary data for the Screening Outcome Evaluation to determine if screening and detection of suicidal ideation or behavior is impacted by the implementation of universal screening protocols. The log will contain basic demographic information and will indicate if the individual's chart documented any screening for self harm ideation or behavior. If such screening is documented on the chart, the RA will note whether the screen is negative (i.e., self harm ideation or behavior is documented as not present) or positive (i.e., self harm ideation or behavior is documented as present), and will be further classified by the RA as current (i.e., occurring during or immediately preceding the current ED visit); past (i.e., noted in the past but not currently); or unknown time (documented but without any clear time reference). All individuals with self harm will be approached by the RA and further evaluated specifically for suicidal ideation and behavior within the past week.

The participants who are enrolled into the prospective portion of the study will be followed post-discharge (from ED or inpatient, if admitted) using a *multi-method approach*. Follow-up assessments will occur 6, 12, 24, 36, and 52 weeks after discharge. Patient reported outcome assessments will be done through a centralized call center staffed by trained technicians blinded to baseline data. The study team chose the Columbia Suicide Severity Rating Scale (CSSRS)[11] as the primary instrument for assessing suicidal ideation and behavior based on the need to assess both suicidal ideation *and* behavior, its ease of the training, and its widespread use in clinical trials.

Table Three outlines the additional domains assessed and the schedule of assessments. In addition to the data gathered through the assessment calls, state and national vital statistics registries will be used to track participant outcomes for 12 months. Due to the variation in access to vital statistics registries between states, each site will develop its own protocol on how to access the registries, with guidance from study investigators. A uniform abstraction tool will be used to ensure similar data collection approaches across sites. A final review of the National Death Index will occur 24 months after the final participant is enrolled to validate the site level reviews. Finally, administrative databases associated with the site's healthcare system will be reviewed to monitor healthcare utilization, including ED visits and hospitalizations, both related and unrelated to self harm.

2.4 Study phases

The three sequential study phases (conditions) are summarized below.

Phase 1: Treatment as usual—The primary goal of Phase 1 (Treatment as Usual) is to provide baseline detection data that will serve as the control for the Universal Screening phase. Over the course of first ten months of the study, RAs at each of the eight sites will prospectively screen charts for documentation of intentional self harm. Patients will be treated according to the usual and customary care at the specific site, enabling a determination of the site's natural rate of screening and detection of self harm ideation and behavior.

Phase 2: Universal screening—As there are no validated primary suicide screening instruments that have been used for universal screening purposes in ED settings, one was created for this study. The three-item Patient Safety Screener (PSS) (see Figure Two) begins with the depressed mood item from the Patient Health Questionnaire (PHQ).[12] While not strongly predictive of suicide in and of itself, we believe it will be more clinically acceptable to patients to include the PHQ depression item as a "lead in" to the suicide questions; an assessment of mood will allow for an easier transition to an assessment of suicidal thoughts/behavior. The other two items assess active ideation (thoughts of killing oneself) and lifetime suicide attempt, with a follow-up question assessing the timing of the most recent attempt for those with a history of attempt. A "positive screen" will be individuals who either endorse active ideation or report a suicide attempt within the past 6 months.

During the Universal Screening phase, sites will incorporate the PSS into their standard clinical protocols. To guide the transition from Treatment as Usual (Phase 1) to Universal Screening (Phase 2), each site will create a performance improvement team to modify the site's policies and procedures and oversee the implementation of the PSS. Sites will use the Plan-Do-Check-Act cycle methodology, a performance improvement technique commonly applied in healthcare settings.[13] Online webinars will be used to provide standardized training to all sites in performance improvement methods and the creation of clinical guidelines. Conference calls between the site investigators, RAs, and the study's principal investigators will occur on a regular basis to discuss progress, challenges, and solutions to implementing screening.

While there may some natural variation in screening procedures across sites, key aspects of the screening process will be standardized. At all sites, the primary treating nurse, rather than the triage nurse, will conduct the screening; screening during triage will only occur for those cases presenting with a primary psychiatric complaint. The triage nurse often has limited time available and the conditions of triage are typically not ideal for asking highly sensitive questions. The primary nurse, however, has more time with the patient, is usually in a secluded treatment area, and has the opportunity to build rapport prior to asking more sensitive questions. These conditions are more likely to result in the administration of the screening questions and to yield honest patient responses. The screener will be embedded in the standardized chart templates or electronic health records at each site to promote and support its use.

During the Universal Screening Phase sites will be encouraged to further evaluate and treat individuals who screen positive, but the study will not be providing standardized treatment protocols. This study phase will examine screening in the absence of a standardized intervention so that we may obtain a clearer understanding of outcomes following mandated screening (see Section 2.5 for elaboration on how this will be done).

Phase 3: Intervention—During the Intervention Phase, sites will continue to administer the PSS as they did during the Universal Screening Phase. Patients who screen positive will be further evaluated by their treating physician, as is typically done. However, added in Phase Three, we will recommend the treating physician use a secondary screener consisting of a brief review of risk factors commonly associated with suicide (Figure Two) to aid in the decision to consult a mental health specialist. Like the primary screener, the secondary screener was created for the study, and it consisted of well-known risk factors, including the presence of suicidal intent or plan, previous psychiatric hospitalization, excessive substance use, and irritability, agitation, or aggression. The risk factors were chosen based on a review of the literature to identify the strongest and most consistent predictors among ED patients and the clinical experience of the Steering Committee. The list was reviewed by external experts unaffiliated with the study.

In addition, as part of this phase, all individuals who screen positive on the PSS, regardless of whether or not they receive a mental health consultation, will receive a printed safety plan that will include community resources and hotline numbers (see Figure Three). A safety plan is a structured tool that helps individuals identify early warning signs for suicidal behavior, internal and external coping resources, and plans for accessing social support and professional help if their first-line coping strategies do not work to reduce their suicidal thoughts. The safety plan was modeled after work by Stanley and Brown[14], but it is designed to be self-administered by the individual rather than therapist guided. The patient's primary nurse will be responsible for reviewing the safety plan's purpose and instructions for completing it with the patient upon discharge. We considered having the nurse complete the safety plan with the patient but the logistical demands associated with providing care in the ED do not support such a time-intensive, interactive strategy. Besides standardizing the primary screening, recommending the secondary screener be used to help decide whether psychiatry needs to be consulted, and requiring all individuals who screen positive on the primary screener receive outpatient suicide prevention resources, we did not standardize decision making or require any additional intervention components during the ED visit.

Following the ED visit, all eligible and consenting participants in this phase (n=60/site) will participate in a telephone-based intervention designed to reduce subsequent suicidal behavior and help promote outpatient treatment engagement. This intervention is a modification of the Coping Long-term with Active Suicide Program (CLASP) [Miller, R34MH073625, R01AA015950]. The CLASP-ED intervention is an adjunctive intervention that combines principles of case management, individual counseling, and family/significant other mobilization. Patients will receive up to seven telephone calls from a trained "advisor," while their significant other will receive up to four calls (with permission from participants). The schedule and content of the calls are summarized in Table Four. The CLASP-ED intervention will be centrally delivered by trained staff from Butler Hospital in Providence, Rhode Island.

2.5 Analysis Plan.[ii]

The *Screening Outcome Evaluation* examines the first step for prevention – detection of risk -- by comparing suicide screening and detection before and after universal screening is implemented. We hypothesize that implementing universal screening will increase detection of suicidal ideation and behavior when compared to Treatment as Usual. Data from the screening logs maintained during Phases 1 (Treatment as Usual) and 2 (Universal Screening) will be analyzed to determine if screening increased detection of suicidal ideation or behavior. First, we will determine if the screening rate actually increases after we implement the clinical protocol (i.e., do nurses actually carry out the protocol?). This will be determined by examining proportion of patients in the Screening Log who have any self-harm screening documented. If universal screening is implemented with fidelity, the proportion of patients who have any screening documented should increase between Phase 1 and Phase 2. Moreover, we will set as our target goal for Phase 2 that 75% of patients should have a documented screening; we did not set it to 100% because there are legitimate reasons why ED patients might not be screened, including altered mental status and emergency medical conditions.

Because the Screening Log will not only document whether a screening for self-harm risk was performed but also the outcome (i.e., whether there was self-harm ideation or behavior present or absent), we shall be able to determine whether detection of self-harm risk

[ii]For practical reasons, we do not discuss our planned statistical analyses here but, rather, simply outline the major comparisons that will be made. The specific analyses will be detailed in the primary manuscripts.

increases after universal screening by calculating the proportion of total patients in Phase 1 and Phase 2 who are positive for self-harm ideation or behavior.

The *Intervention Evaluation* will rely on data collected during Phases 2 (Universal Screening) and 3 (Intervention). We hypothesize that fewer participants enrolled during the Intervention phase will exhibit suicidal behaviors in the 12 months following the ED visit when compared to participants enrolled during the Universal Screening phase. This will be the suicide outcome data for the participants enrolled into the longitudinal portion of the study.

3. Methodological Considerations

In planning the study, there were several key considerations focused on the design itself, strategies for case identification, approaches to outcome assessments, and blinding.

3.1 Study design

We chose an interrupted time series design, rather than a randomized design, because we wanted to assess the impact of implementing systems-based changes, and designs involving site or individual level randomization did not seem appropriate given our study aims and certain constraints (e.g., budget, setting, etc). A cluster randomized trial was judged to be prohibitively expensive due to the required number of sites, which was estimated to be greater than 40. Designs requiring individual level randomization are a poor fit for screening studies, because randomly assigning patients to be screened or not by the treating nurse is logistically impossible.

Several methodological controls will be incorporated to help reduce artifact and bias. First, larger census sites might have greater access to mental health resources, are more likely to be affiliated with an academic teaching hospital, and may have other characteristics that could be independently related the outcomes. Consequently, the eight sites will be characterized based on whether they have higher or lower than the median census, randomly assigned to one of four cohorts, and randomly assign to a start date, with the start dates spaced approximately two months apart. This approach should help control for confounding site differences that may be introduced by the size of the hospital by ensuring that similar census sites do not all start at the same time. Moreover, the staggered start times for each cohort will help to control for historical effects, such as naturally rising screening rates, by allowing comparisons within similar time periods across sites in different stages. For example, while the last cohort to start, cohort four, is finishing the Treatment as Usual phase, the first cohort to start, cohort one, will be implementing Universal Screening. By comparing the changes in screening rates for this overlapping time period across cohorts in different phases of the study, we can deduce whether increases in screening rates were truly due to the implementation of the intervention, per se, or were simply naturally rising because of historical or secular trends. .

3.2 Case identification

To help avoid selection bias and maintain standardization across all sites and RAs, several procedures will address case identification and selecting individuals for study participation. First, training on all research protocols will be centralized and all sites will use a standardized manual of procedures. Second, in deciding whether to approach an individual for eligibility screening, RAs will use the threshold of *any* self harm, based on chart review, not just suicidal self harm. Second, all RAs will use a set of standard questions in a computer guided interview to limit subjectivity and exclude ambivalent cases (e.g. patients with an ambiguous overdose of recreational drug use who are not trying to kill themselves).

If the individual denies any intent to die, he or she will be considered ineligible. This two stage process of low threshold chart review and standardized eligibility screening helps to assure that we do not miss anyone who is potentially suicidal while only enrolling into the trial patients who are clearly suicidal, and centralizes (or standardizes) the eligibility determination, limiting site/RA level variability with respect to case identification.

Despite these controls, the samples collected across each of the three phases may still comprise different kinds of participants, and these differences may be related to the outcomes of interest. For example, patients who are enrolled in the treatment as usual phase may be more severely suicidal than those in the later phases, which could artificially inflate the intervention effect because the less severe patients enrolled during the later phases may have a lower likelihood of attempting suicide. In order to limit this potential bias, we will aim to enroll approximately half of each phase with participants who have actually attempted suicide within the past week (including the current ED visit) and half who have active suicidal ideation but no attempt within the past week. This equal representation of attempters and ideators will help to balance the sample composition for suicide risk severity across phases to help counteract selection bias. Finally, data analyses will be conducted to confirm that the composition of each group is equivalent and variances will be adjusted statistically. While there are sophisticated stratified sampling methods to help account for this kind of selection bias, they were judged to be infeasible for practical reasons (e.g., the time to enroll a sufficient sample would exceed the four year study period).

3.3 Outcomes and Power Calculations

The outcomes of interest reflect both systems-level data (screening and detection outcomes) and individual-level data (suicide behavior outcomes). It is unusual to have a study in which the primary outcomes, and therefore the unit of analysis, will occur at two levels. This has a practical effect on data collection methods. Specifically, it required data to be collected to identify if the system changed, such as through RA collection of screening log data, in addition to data reflecting individual impact, such as telephone follow-up after the ED visit. It also impacted analytic strategies, which required two separate data analytic plans to address the Screening Outcome Evaluation and the Intervention Evaluation separately (Figure 1). The multiple study outcomes made the power analysis difficult.

Briefly, we decided to power the trial based on the individual level outcome of suicide behavior, then examined how this would influence the power for the systems-level outcomes (i.e., screening and detection). Moreover, we determined the target sample of suicidal patients per phase by the needs of the Intervention Evaluation because the Screening Outcome Evaluation (phase 2 vs phase 1) and the Intervention Evaluation (phase 3 vs phase 2) would share data collected during the Universal Screening phase and we also wanted to power the study to allow a conditional post-hoc test using the Treatment as Usual phase (i.e., a comparison of phase 3 vs phase 1). The latter comparison would allow us to assess whether the Intervention led to better suicide outcomes than usual care. We recognized that the possibility that Universal Screening might be sufficient to improve suicide outcomes. If true, this would attenuate the difference between the Universal Screening and Intervention phases; the improvement from the intervention might not be statistically different from Universal Screening but, nevertheless, would represent a significant enhancement over Treatment as Usual.

Given the dearth of published data from which to derive base rate and effect size estimates, we made conservative assumptions to protect against under-powering. We set our anticipated proportion of the suicide composite in the Universal Screening phase at 20% over the 12 months post-visit versus 13% in the Intervention group. Under these assumptions, with an alpha <0.05 and beta 20%, and assuming a compound symmetry

covariance structure and within-person correlation of 0.7, the study would need to have 328 participants enrolled during each of the two phases. This would give us 80% power to detect a relative risk of 0.65. Because we anticipate an attrition rate of approximately 30% for telephone follow-up over 12 months in this patient population, we decided to oversample to 472 participants per phase. Finally, because we wanted to power the study to allow for the conditional post-hoc test, we also sought to recruit 472 participants in the Treatment as Usual phase.

Returning to the comparisons at a systems-level, our estimates of the number of patients who would have to be seen in the ED during RA shifts, and therefore logged into the screening log for the Screening Outcome Evaluation, in order to enroll the targeted number of participants for the prospective part of the study (n=60/site/phase) suggested there would be ample data recorded on the screening log to detect even small to modest improvements in suicide risk detection, such as an absolute improvement from 3 to 5% positive detection. This was important because even small differences in an outcome as important as suicide behavior, when applied to large populations, can translate into enormous public health impact.

Because of the unique requirements of researchers to act on suicide risk when assessed, the frequency and timing of the follow-up telephone assessments was very important. Assessments will occur 6, 12, 24, 36, and 52 weeks after discharge (see Table Three). In order to improve the validity of the assessments, participants must be interviewed frequently enough so that memory bias or forgetting will not be a major factor. However, because the responsibilities inherent in monitoring suicidal patients require the researcher to act if an individual is above a risk threshold, the number of assessments should be minimized to avoid introducing a contaminating effect.[15,16,17] As clearly outlined by Oquendo et al.[17], if the suicide monitoring and human participants protection procedures are “too good, the outcome measure rate may decrease in a way that is inconsistent with “real world” conditions, which at a minimum diminishes the study’s ecological validity and at worst makes the study impossible to conduct.” (p. 1559). The assessment schedule was judged to be a reasonable balance between the goals of maintaining the scientific integrity of the study with the need for strong human participants’ protections.

3.4 Blinding

In a study such as this, it is impossible to fully blind participants to their condition. They must provide informed consent and thereby are given knowledge about the condition to which they are consenting. However, as will be described in a later section, by using serial consent forms specific to each phase, each participant will only knows about the condition to which he or she is consenting. Individual participants will not know that there are other conditions, since these other conditions will not happen contemporaneously and it will never be an option for the individual to potentially be assigned to the other conditions. As a result, the participant will be partially blinded in that he or she will not have knowledge of the contrast between the condition in which he or she is enrolled and comparison conditions. To help reduce selection bias, the consent process will be kept as similar as possible for each of the three phases.

It is also impossible to blind the clinical staff – they are trained to perform the screening and interventions, so they have full awareness of the phases of the study. The outcome assessors will be blinded to baseline data, including the participant’s phase of enrollment, but they will know about the different phases of the study and are likely to be able to determine which participants are enrolled in which phase. This is unavoidable and will be partially mitigated by using a standardized, computer assisted telephone interview to help reduce the

influence of interviewer bias and the collection of objective data from vital statistics registries and healthcare administrative databases.

4. Human Participants Considerations

The potential ethical/human participant issues involved when studying patients with high suicide risk has resulted in decreased research efforts involving this population. Recognition that these potential ethical issues have severely hampered research and, in turn, limited progress in our knowledge of how to best treat suicidal patients has led to the publication of several papers providing guidelines for addressing these human participants issues so that the research can occur.[15–17] These guidelines informed our decision making with respect to human participants considerations when designing the trial.

4.1 Informed consent

Because screening is being implemented system wide during routine clinical care, patients will not consent to the screening. However, across all three phases, RAs at each site will obtain written informed consent for study participants who are enrolled into the prospective clinical trial portion of the study. Because ED-SAFE is not a randomized trial, and individuals are enrolled at the time of their ED visit, a potential participant will be eligible for only one condition (an individual who enrolled in one phase is ineligible for subsequent phases). All consent forms will describe the expectations associated with participation, including the telephone follow-up assessments, risks/benefits, the limits to confidentiality, and the Certificate of Confidentiality obtained, but will not discuss alternative conditions.

In Phase 3 (Intervention), identification of a significant other that can be included in the intervention will be encouraged, though not required. The significant other can be anyone whom the participant identifies, including a spouse, romantic partner, family member, or friend. If the study participant agrees, the designated significant other will be contacted via telephone. During the first call to a significant other, the patient advisors (interventionists) will fully explain the study procedures, risks, benefits, and alternatives and obtain audio-recorded, verbal informed consent. Although written informed consent is preferable to verbal consent, obtaining written consent will not be feasible because of the clinical need for timely initiation of contact with the significant other, difficulties physically locating significant others, and the burden on significant others if required to have face-to-face contact with research personnel. We will, however, send a copy of a written informed consent form to the significant other, and will request, but not require, that it be signed and returned to research staff.

4.2. Clinical back-up for assessments

While the individuals making the outcome assessment calls will be trained to conduct the outcome assessment protocol, they will not be mental health professionals. Given the high risk nature of the study population, we felt it prudent to have clinical back-up available in the event that imminent risk for suicidality was identified during an assessment call. The decision was made to use the resources available for telephone counseling through Boys Town National Hotline, which is part of the national network of crisis centers forming the National Suicide Prevention Lifeline (1-800-273-8355; www.suicidepreventionlifeline.org) and provides crisis intervention services to both adults and children. As part of their training in ED-SAFE study protocols, call center staff conducting the outcome assessments will be trained on when and how to connect study participants with a Boys Town crisis counselor. A study participant will be referred to Boys Town if they report: 1) active suicidal ideation at the time of an assessment call, or 2) a suicide attempt since the last call that was not treated by a health care professional. Prompts will be built into the computer assisted telephone

interview to alert the call technician when either of these conditions is present. Other situations which may lead to the interviewer connecting the study participant with the Boys Town National Hotline would be if the study participant is extremely distressed during the interview, makes ambiguous or evasive innuendos suggestive of imminent suicidal ideation or intent, or there is an imminent risk of harm to others.

When connecting the study participant with the Boys Town National Hotline, the interviewer will inform the participant that s/he will be connected directly with a crisis counselor, and will be placed on hold briefly while the connection is made. The participant will be asked not to hang up during this time. The interviewer will convey pertinent information to the crisis counselor including the participant's contact information and the contact information for the participant's emergency contact. After this information has been given to the crisis counselor, the interviewer will connect the participant to the crisis counselor, leave the call, and follow up with an email of the information to Boys Town.

5. Intervention Fidelity

Fidelity to intervention protocols are a critical component for any research project, particularly when, as is the case with ED-SAFE, the protocol is being implemented in 'real world' settings. When assessing a health behavior treatment, three strategies have been targeted for improving and measuring treatment fidelity: using a treatment manual, developing strategies to train and maintain provider skills, and checking adherence to protocol.[18] Monitoring the implementation of the ED-SAFE intervention protocols will be addressed by multiple overlapping activities. First, we will provide each participating site with a manual of procedures containing step-by-step instructions for each phase of the study. Second, all clinical staff at each site will be trained by site-trainers who will be trained by the study principal investigator and the ED-SAFE training director via webinars and teleconferences. Third, we will integrate study interventions (e.g., the suicide screener) into the pre-existing local medical documentation templates or electronic health records. This will increase the likelihood that the screener is completed by being an integral part of the medical record rather than a separate form. It will also create a more streamlined process for nursing staff to include the screener as part of their initial assessment.

We will measure protocol fidelity through chart reviews and patient interviews. The patient interviews will occur during the Universal Screening and Intervention phases. These interviews will be completed with a random subset of ED patients whose medical record indicates either an *absence* of suicidality (i.e., a "no" on the screening items) or has no screening documented. This interview will be completed by the research assistant and will ask the patient if he or she was asked the suicide screening questions by their nurse during the visit. These data will allow us to determine the proportion of patients with a negative screener or no documentation who were actually asked the suicide screening questions in the ED (versus simply documenting a negative screening but not actually asking the patient the question). The results of the chart reviews and patient interviews will be presented to the ED clinical staff on an ongoing basis; providers will be given graphs to track the progress of their performance (e.g., universal screening, documentation of secondary screening). In addition, during the Intervention phase, patients will be questioned by their CLASP-ED telephone advisor about several aspects of their ED care, including whether they were counseled, received a printed safety plan, and were given a referral list.

Conclusion

ED SAFE represents an example of an alternate approach to the randomized clinical trial when conducting suicide prevention research. The results of this study will help establish the

feasibility, effectiveness, and sustainability of a multi-component screening and intervention for suicide within general ED settings, will have significant practical implications for the prevention of suicide.

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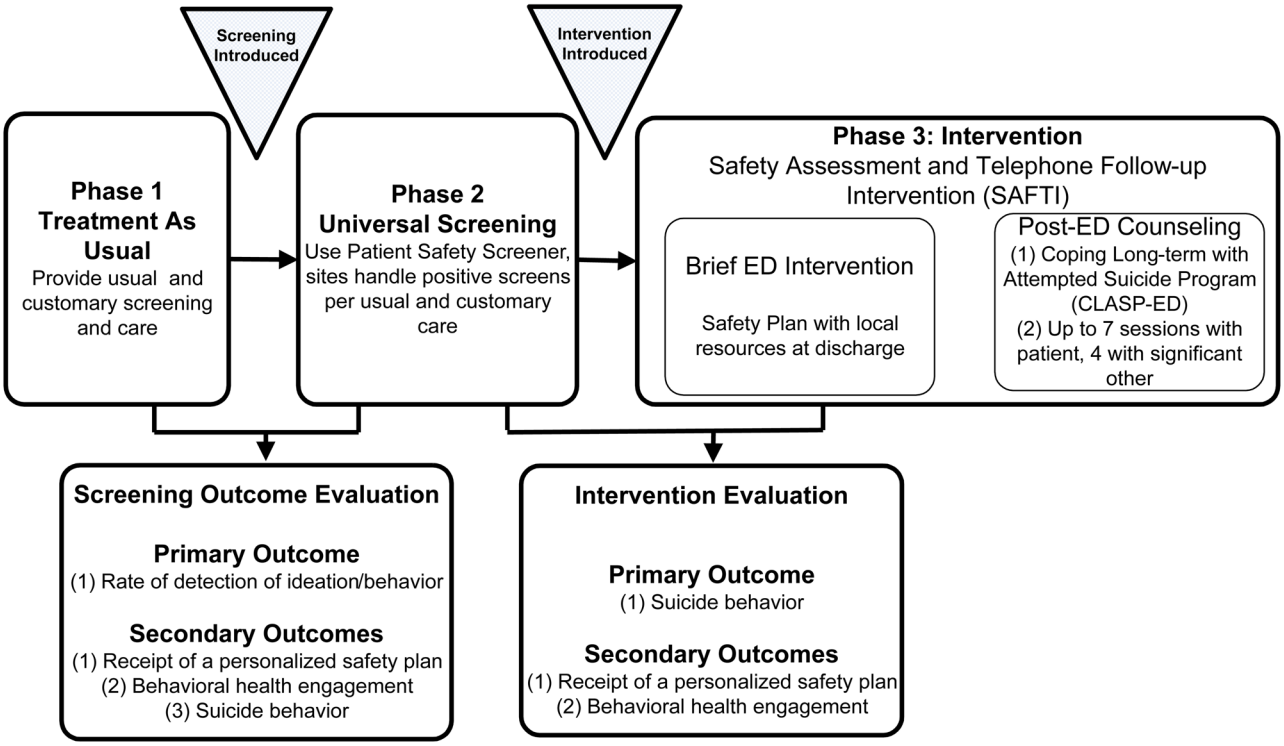

Fig 1.
Figure One: ED-SAFE Study Design

Patient Safety Screener (PSS)

To be administered by primary nurse during primary nursing assessment.

Introductory script: Because some topics are hard to bring up, we ask some questions of everyone.

Over the past 2 weeks,
1. . . . have you felt down, depressed, or hopeless? ☐ **Yes** ☐ **No** ☐ **Unable to complete**
2. . . . have you had thoughts of killing yourself? ☐ Yes ☐ No ☐ **Unable to complete**
3. Have you ever attempted to kill yourself? ☐ Yes ☐ No ☐ **Unable to complete**
4. . . . *If Yes to item 3, ask:* when did this last happen? ☐ Within the past 24 hours (including today) ☐ Within the last month (but not today) ☐ Between 1 and 6 months ago ☐ More than a six months ago

Secondary Screening
Done by Physician

A "Yes" on any of the items below means the treating physician should consider consulting a mental health professional for the patient.
1. Did the patient screen positive on <u>BOTH</u> PSS items – active ideation with a past attempt? ☐ Yes ☐ No ☐ Refused ☐ Patient unable to complete
2. Has the individual begun a suicide plan? ☐ Yes ☐ No ☐ Refused ☐ Patient unable to complete
3. Has the individual recently had intent to act on his/her ideation? ☐ Yes ☐ No ☐ Refused ☐ Patient unable to complete
4. Has the patient ever had a psychiatric hospitalization? ☐ Yes ☐ No ☐ Refused ☐ Patient unable to complete
5. Does the patient have a pattern of excessive substance use? ☐ Yes ☐ No ☐ Refused ☐ Patient unable to complete
6. Is the patient irritable, agitated, or aggressive? ☐ Yes ☐ No ☐ Refused ☐ Patient unable to complete

Fig 2.
Figure Two: Screeners

My Personal Safety Plan

Thoughts of suicide may come and go. Coming up with a safety plan can help you get through rough times. This safety plan can help you when you feel like you want to hurt yourself. Make this safety plan yours by reading it carefully and completing each step. Share it with your doctor or therapist. Make sure to keep it with you. **And remember, you are not alone!**

Step 1: Many people hurt themselves when they are upset or in a bad state of mind. Putting some distance between you and the things you can use to hurt yourself is important. It makes it less likely that you will act on your suicidal thoughts when they happen. It is best to remove things that you can use to hurt yourself as soon as you can. It will be harder to do so when you are under stress or having thoughts of killing yourself.

Ask yourself: ***How can I make my home safe, right now, before I am in crisis?***

- ☐ Get rid of pills I don't need; keep only quantities that are not dangerous. A doctor or pharmacist can advise you.
- ☐ Temporarily store all guns with a friend, relative, gun shop, or storage facility. Or ask someone to hold onto the keys to my gun locks/gun safe.

Others:

Step 2: For many, suicidal thoughts do not happen "out of the blue." There are usually signs or triggers. It will be easier to cope if you see your signs early and take action. Warning signs can be "internal" like sad mood or unhealthy thoughts. They can also be "external" like arguments or other stressful life events. These warning signs should let you know that you should follow your safety plan.

Ask yourself: ***What are my triggers or warning signs a crisis is developing?***

☐ Feeling down, sad	☐ Bad life events	☐ Feeling worthless, hopeless	☐ Being in pain
☐ Arguments, break-ups	☐ Drinking or using drugs	☐ Feeling trapped	☐ Feeling anxious, agitated
☐ Withdrawing, feeling isolated	☐ Feeling angry, wanting revenge	☐ Feeling stressed, overwhelmed	☐ Failing, doing poorly at something

Others:

Step 3: If you are feeling down or suicidal, taking your mind off of things can help. It is important to

find *healthy* ways to handle bad moods and bad times.

Ask yourself: *What healthy actions can I take to make myself feel better?*

☐ Remind myself: these thoughts are serious, but I can get through this.

☐ Talk to someone I trust	☐ Go for a walk, exercise	☐ Listen to music, watch a movie	☐ Take my medications as prescribed
☐ Go to a support group, meeting	☐ Do something nice for someone else	☐ Do a hobby, favorite activity	☐ Meditate, pray, go to your church or temple

Others:

Step 4: Sometimes it is important to remind ourselves what is important in our lives. Many people say that their family or friends are important. Others remind themselves that even when times are bad there can be value and growth.

Ask yourself: *What are the things that are most important to me?*

☐ My family and friends	☐ My religious beliefs	☐ My job	☐ My life's purpose
☐ My community	☐ My pet	☐ My hobbies	☐ My health

Others:

Step 5: Sometimes it is useful to talk with someone who you can trust or who can distract you if you have suicidal thoughts. If you don't have someone, sometimes there are support groups that can help. Try to pick people who are likely to be healthy for you.

Ask yourself: *Who can I talk to that makes me feel better?*

Name:	Phone:
Name:	Phone:

Step 6: There are people who can and want to help you! Even if you cannot reach your doctor, you can always call the Lifeline. The Lifeline has trained people who can help you through your crisis.

Ask yourself: *Where can I get help?*

My doctor:	Phone:
My counselor/therapist:	Phone:
The Lifeline (Free Crisis Hotline):	1-800-273-8255 (1-800-273-TALK)

Fig 3.
Figure Three: Personal Safety Plan Template

Table One

ED-SAFE Site Characteristics

Name	Location	Annual ED Visit Volume (2009)	Council of Teaching Hospitals (COTH)	Primary Emergency Medicine Residency Site
Beth Israel Deaconess Medical Center	Boston, MA	54,075	Yes	Yes
Maricopa Medical Center	Phoenix, AZ	50,000	Yes	Yes
Marlborough Hospital	Marlborough, MA	27,145	No	No
Memorial Hospital of Rhode Island	Pawtucket, RI	31,463	Yes	No
Ohio State University Medical Center	Columbus, OH	48,753	Yes	Yes
University of Arkansas Medical Center	Little Rock, AR	39,430	Yes	Yes
University of Colorado Hospital	Aurora, CO	43,903	Yes	No
University of Nebraska Medical Center	Omaha, NE	51,083	Yes	Yes

Table Two

Eligibility Criteria

Inclusion Criteria	Exclusion Criteria
• Age ≥ 18 years • Thoughts of killing oneself in the past week • An actual, aborted, or interrupted attempt to kill oneself in the past week, including current visit • Able to consent (alert, fully oriented, not intoxicated, able to paraphrase the study requirements) • Willing to complete telephone follow-up assessments at 6, 12, 24, 36, 52 weeks	• Otherwise medically or cognitively unable to participate in the assessment or counseling (e.g., sustained altered level of consciousness, psychosis, hostile behavior, victim of sexual assault, intubation, persistent vomiting, severe pain) • Currently dwelling in a non-community setting, including an acute psychiatric facility, physical rehabilitation, substance abuse treatment, or nursing home (except when otherwise deemed acceptable by the RA) • Currently in state custody • Pending legal action • Lack of permanent residence • Lack of reliable telephone service • Insurmountable language barrier • Enrolled in earlier study phase

Table Three

Schedule of Follow-up Assessments

Construct	Method	Instrument	Time (B=baseline; other times in weeks)					
			Outcome Calls					
			B	6	12	24	36	52
A. Demographics, contact information	INT		✓	✓	✓	✓	✓	✓
B. Suicidal ideation, lifetime, interval	INT	CSSRS[11]	✓	✓	✓	✓	✓	✓
C. Suicidal behavior, lifetime, interval	INT, DR, AD, CR	CSSRS[11]	✓	✓	✓	✓	✓	✓
D. Non-suicidal self- injury (NSSI)	INT	Modified Self-Injurious Thoughts and Behaviors Interview[19]	✓	✓	✓	✓	✓	✓
E. Healthcare utilization	INT, AD, CR		✓	✓	✓	✓	✓	✓
F. Lethal means restriction	INT	Various [20–22]	✓	✓				
G. Psyc. Distress	INT	Brief Symptom Checklist[23]	✓			✓		✓
H. Alcohol use	INT	AUDIT, short[24]	✓			✓		✓
I. Drug use	INT	Drug screener[25]	✓			✓		✓
J. Quality of life	INT	SF-6D[26]	✓			✓		✓

INT=Interview; DR=death registries; AD=Healthcare administrative database; CR=Chart review AUDIT = Alcohol Use Disorders Identification Test; SF-6D = Short Form Health Survey – 6D

Table Four

CLASP-ED Session Content Summary

Timing	Contact	Goals
Week 1 (ASAP after discharge from ED/ hospital)	Patient	• Establish rapport and explain program • Obtain history (psychiatric, suicide, thoughts/behavior) • Evaluate current status (suicide risk, psychiatric, treatment providers) • Develop/review safety/crisis plan if necessary • Introduce construct of values and living values based life
Week 2	Patient	• Evaluate current status (suicide risk, psych symptoms, treatment providers/adherence) • Review/evaluate safety/crisis plan if necessary • Continue values discussion • Develop “Life Plan” to monitor and mitigate identified potential risk factors • Obtain permission to contact significant other significant other • Discussion of importance of collaborative monitoring and problem solving with Significant Other
Week 3	Significant Other*	• Establish rapport and explain program • Review significant other concerns regarding patient • Brief psychoeducation regarding suicide + risk factors • Review Life/safety plan with significant other
Weeks 4, 10, 22, 34 and 48	Patient	• Evaluate current status (suicide risk, psychiatric symptoms) • Review/evaluate Life/safety plan and treatment adherence • Discussion/informal problem solving regarding identified issues/risk factors
Weeks 8, 20 and 32	Significant Other	• Review significant other concerns and perceptions of patient • Review of Life/safety plan and treatment adherence • Discussion/informal problem solving regarding identified issues/risk factors

* Significant others will be recruited to assist if there are emergencies