Study Title: **Written safety planning vs the Safety Net app: A prospective randomized pilot trial**

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Background and Rationale

Scientific rationale: Suicide deaths are at an all-time high

Suicide is a leading – and growing – cause of death in the United States.[1] From 2008-2017, suicide was ranked the 10th leading cause of death for all ages combined, and from 1999-2017, the age-adjusted suicide rate rose by 33%.[2] Thus, suicide is a large problem nationwide.[3]

Safety planning is a brief, ED-feasible intervention which has been demonstrated to save lives,[4,5] and has been universally recommended by every recent expert consensus panel on suicide prevention strategies.[3,6-8] In one popular version of the safety plan developed by Stanley et al,[4] the patient is encouraged to write out the following items: identifying personal signs of a crisis; helpful internal coping strategies; social contacts or settings which may distract from a crisis; using family members or friends for help when in crisis; mental health professionals who can be contacted when in crisis; and restricting access to lethal means.[4] In most emergency departments, safety-planning is done by clinical personnel such as psychologists or social workers, but these providers are often too busy to perform safety-planning well or have multiple other patient care responsibilities.

This project aims to answer the following three research questions: (1) Will ED patients with suicidal ideation/attempt accept coaching on safety planning from non-clinical personnel; (2) Are these safety plans of high-enough quality for clinical personnel; and finally, (3) Will ED patients with suicidal ideation/attempt complete safety plans electronically?

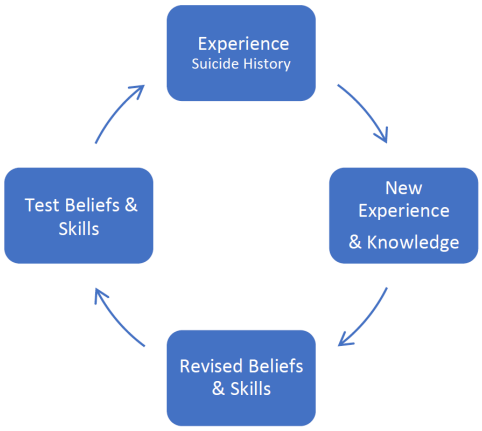
Please note that the study will not otherwise alter usual & customary care in the emergency department.

Concerns about peer vulnerability to relapse

Anecdotally, there have been concerns that peer-delivered interventions may not be effective in the ED, since peers may be vulnerable to relapse in the stress of the acute-care environment. As some authors have noted, working in acute care is stressful for many individuals, not just peers.[9] However, it is not true that peers are too “fragile” for a study of this type. Findings from peers in non-ED environments have generally indicated that peers receive positive benefit from the experience,[10] including increased confidence and self-esteem.[11] Nonetheless, peers will be given the opportunity to experience the ED environment before committing to this project (please see “Recruitment of peers for this project” and “Training of peers” below). In addition, peers will be closely monitored and debriefed by the sub-investigator of this project (Dr. Waliski), who is a licensed clinical counselor (please also see “Supervision and debriefing of peers” below). While

adverse events are not expected as a result of this intervention, the PI will carefully monitor for any such event and report any adverse event to the IRB. In addition, if a peer has a relapse or any psychiatric emergency during the course of the intervention, they may contact Dr. Waliski using the contact information provided during peer training. After this initial contact, Dr. Waliski will debrief the peer by meeting with them and further discussing the situation.

Figure 1: Suicide safety planning training cycle



Please note that although peers will receive mandatory confidentiality training required at the study institution, there is little concern that peers will "say the wrong thing" or break a patient's confidentiality. Given that these peers have personal experience of hospitalization, it is more likely that they will be willing to guard the patient's confidentiality and less likely than clinical staff to make insensitive remarks to a patient. However, all peers will be CITI-certified, with periodic reminders about patient confidentiality from the investigators.

Description of interventions

Written safety plan: Please see separate upload for the Stanley et al version of the safety plan. This safety plan contains 6 components, and is completed by the patient themselves. This intervention takes approximately 20-40 minutes to complete. As a former site for the ED-SAFE study,[12] the UAMS ED typically has patients complete safety plans if being discharged. This is typically done by the psychiatric nurse or social worker if they are available, and this individual then places a progress note in the electronic medical record (EMR). These clinical providers must approve all safety plans in this study as peer support specialists and other research staff do not have the ability to place notes in the EMR.

Stanley-Brown Safety Plan app (i.e., Safety Net app): The Safety Net app is an electronic version of a safety plan and it is available for download in Apple's App Store. A preview of this app is available at: https://apps.apple.com/us/app/stanley-brown-safety-plan/id695122998. This app is owned by Two Penguins Studios, LLC. It was developed in partnership with the New York State Office of Mental Health. Unlike the paper version, the Safety Net app allows participants to email a copy of their safety plan to whomever they wish. It also allows patients to dial 911 or the National Suicide Prevention Lifeline from the app.

Please see Figure 2 below for study flow. The app only stores deidentified data locally on UAMS secured tablets. Thus, the safety plan will have to be shown or emailed to clinical staff in order to be entered into the electronic medical record. Please note that peers and other research staff do not have the ability to place notes in the EMR.

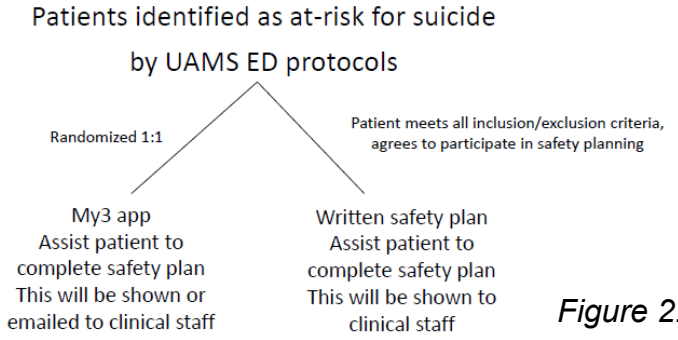


Figure 2. Study flow.

Study Design and Procedures

This is an effectiveness-implementations randomized controlled trial which will be conducted in the emergency department (ED) at the University of Arkansas for Medical Sciences (UAMS) in Little Rock, Arkansas. The UAMS ED is an urban emergency department which sees approximately 60,000 patients per year, including more than 1,200 suicidal patients.

This clinical trial will compare the intervention of ED patients completing an electronic safety plan with a peer or other research staff member to completing a traditional written safety plan with a peer or other research staff member. Patients triaged and flagged with the chief complaint of “SI”, “suicidal ideation”, “suicide attempt”, or “Psychiatric BEE” on the ED trackboard when a peer or other research staff member is available will be approached to participate. Patients will be approached after evaluation by an emergency physician.

Study flow: Utilizing trained nonclinical staff (i.e., peers or other research staff directed by the investigator team), staff will approach patients identified from the ED trackboard as being at risk for suicide until as many as 30 patients have been enrolled. Please see Figure 2 above for study flow. Patients are typically triaged by UAMS nursing staff as being “at-risk” after questions about self-harm. If so triaged, patients are then flagged with the chief complaint “SI”, “suicidal ideation”, “suicide attempt”, or “Psychiatric BEE” on the ED trackboard and placed in a special area of the ED for evaluation. A partial waiver of HIPAA for recruitment purposes is requested to allow peers and other research staff to visualize the ED trackboard, and is appropriate for the following reasons:

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on the fact that no PHI will be recorded, reused, or

disclosed to any other person or entity except as required by law or for authorized oversight of the research study.

- The research could not practicably be conducted without the requested waiver or alteration, as it would be difficult or impossible to identify ED patients at risk of self-harm in any other manner.
- The research could not practicably be conducted without access to and use of the PHI.

The trained peers and other research staff are UAMS nonclinical staff members who are participating in ED clinical research and who have received extensive training in safety planning (see below), data collection techniques, how to operate REDCap data collection software, and how to obtain informed consent. All are CITI certified and receive periodic reminders about confidentiality.

Upon approach by peers or other research staff, patients will be asked if they would like to participate in the study and if they would allow peers or other research staff to help them with safety planning. If the answer to both questions is yes, patients will be offered a brief screening procedure:

Inclusion criteria

- Presenting to the UAMS ED for suicidal ideation (SI) or after suicide attempt;
- Willingness to engage in safety planning with trained non-clinical staff;
- Have not already filled out a safety plan at the current visit

Exclusion criteria

- Prospective participants <18-years or >89-years of age;
- Presently incarcerated or in police custody;
- Non-English speaking;
- Critically-ill;
- Intoxicated with alcohol or other substances;
- ED staff objected against entering room;
- Unwilling or unable to complete the safety plan electronically;
- Unwilling or unable to use a tablet;
- Unwilling or unable to show/email this safety plan to clinical and research staff.

If participants indicate interest in the study and meet all inclusion/exclusion criteria, informed consent will be obtained using IRB-approved consent forms & processes. If they provide consent, participants (n=30) will be randomized in a 1:1 fashion to either the traditional written safety plan group, in which they will complete a written safety plan with a peer support specialist or other research staff member, or the electronic "Safety Net" safety plan group, in which they will complete an electronic safety plan with a peer support specialist or other research staff member (please see Figure 2 above). Participants will be randomized using the randomization function in REDCap. All participants will be allowed to complete the safety plan in the privacy of their ED treatment room. Please note that participants will be given a $25 gift card for participating regardless of which group they are randomized into for the study.

After completing the safety planning process, participants will then be asked to answer a short questionnaire concerning their demographics (e.g., age, biological sex), any history of previous suicidal ideation, suicide attempts, or related behaviors, and satisfaction with the safety planning process.

Regardless of whether the safety plan is completed in the traditional paper format or electronically, this will be shown to the UAMS ED psychiatric registered nurse or social worker for approval and entry into the EMR. Please note that the study will not otherwise modify care in the ED. It is possible, although not likely, that psychiatry consultants could choose to revise, edit, or otherwise start anew with safety planning for a particular patient. If so, the patient will be withdrawn from the study.

Other measures: All participants will complete a brief questionnaire regarding their demographics, history of suicidal behaviors, and satisfaction with the safety planning process. After the visit, the electronic medical record will be searched for the following data: date/time of ED triage and disposition; length of ED stay; ED chief complaint or reason for visit; patient disposition (observation/admission/discharge/transfer); psychiatric diagnoses; and frequency of ED visits 3 months before and after the intervention. Length of ED stay will be compared against two control groups (obtained using AR-CDR): a) length of stay of all ED patients during a similar time period; and b) length of stay of ED patients who presented for SI during a similar time period. No PHI will be recorded for either of these deidentified control groups. Peers and other research staff will also be asked to record the total amount of time that they spent performing the safety plan intervention.

Study retention: The study duration is limited to the ED visit (typically <6 hours for SI patients), with participation in the study limited to the interventions mentioned above. Consequently, no special measures designed to increase retention are planned.

Recruitment of peers for this project

Peers will be recruited through existing relationships with community suicide prevention organizations (i.e., Arkansas Foundation for Suicide Prevention, Arkansas Governor's Suicide Prevention Council, Veterans Service Organizations, etc.). Eligible recruits will complete an interview with Dr. Waliski where they will be informed about the responsibilities and expectations of working with this project. Training and supervision of peers and other research staff will be used to further monitor the appropriateness of the individual to assist patients in providing the intervention.

Training of peers and other nonclinical individuals

As this project utilizes peers that have lived through suicidal ideation or attempts and other nonclinical individuals, albeit ones with strong interest in suicide prevention, the training, debriefing, and supervision of research staff are paramount (please see "Supervision and debriefing of peers" below). Training will follow constructivism learning theory,[13] which posits that individuals learn best when they actively construct their own meaning of new information by relating it to their experiences, attitudes, and beliefs.[14,15] In this mode of instruction, instructors facilitate learning by asking guiding questions and providing individualized feedback, utilizing role play and role modeling, and providing a safe learning environment that promotes self-exploration and self-evaluation.[14-16]

As shown in the Suicide Safety Planning Training Cycle (please see figure 1), training conducted by sub-investigator Waliski, sub-investigator Thompson, and PI Wilson will extend over approximately 12 hours (please see "Training agenda" uploaded to the IRB as a separate document). Training will involve a four-step cycle that starts with exploring personal experiences about suicide and suicide prevention. Using videos, presentation slides, and active learning techniques, peers and other nonclinical individuals will be provided education about suicide and the safety planning intervention using training materials originally developed by Drs. Stanley and Brown.[17] The information presented to the peers or other nonclinical individuals may be new or previously known by them, but will be presented in a way that encourages deeper examination of the topic and how it relates to their experiences. The instructor will then facilitate the revision of beliefs and skills using guiding questions and individualized feedback based on comments from the peers and other nonclinical individuals. Examination and exploration will promote the revision of their knowledge and beliefs about suicide and the safety planning intervention. Finally, role modeling and role play will be used to allow the peers and other nonclinical individuals the opportunity to test their now-revised beliefs and skills related to suicide and safety planning intervention. This is an iterative process and will be performed as many times as needed for each member of the team.

Specific training will be conducted about how to conduct the safety plan intervention, using materials developed by Brown & Stanley. Five learning objectives will guide the development of the training structure (please see Table I below). The instructor (Drs. Thompson & Waliski) will present information using various didactic and technological methods, and will take place over approximately 12 hours. During initial topics, the focus will be on building a safe learning environment that utilizes the peers' and other nonclinical individuals' personal life experiences to understand empirical evidence of suicide and suicide prevention. Later topics will provide more specific training on the safety plan using materials from Brown and Stanley.[17] This portion of the training will also use videos, presentation slides, and role-playing. While lists of examples of warning signs, strategies for internal and external distractions, methods for restricting lethal means, and mental health treatment providers will be provided, peers and other nonclinical individual will be encouraged to provide input based on their own

Table I: Learning objectives in suicide safety planning training

Learning Objective	Learning Activities
1. Demonstrate active listening, genuineness, respect, and a desire to assist individuals at risk of suicide	• Videos and Powerpoints about suicide and suicide prevention • Role play with instructor and other students
2. Demonstrate ability to develop a safety plan	• Develop a personal suicide safety plan • Complete a safety plan using a written case study • Complete a safety plan as part of a role play activity • Verbalize plan to maintain appropriate self-care
3. Appropriately disclose personal experiences as a survivor suicidal ideations or attempts	• Discuss beliefs of suicide and suicide prevention • Instructor will role model appropriate reflections of personal suicide experience • Practice appropriate self-disclosure
4. Demonstrate the ability to problem solve, risk assess, make suggestions for multi-professional referrals to maintain and ensure patient safety	• Review referral and resource guide • Use case studies to practice how to appropriate refer for services and care
5. Demonstrate effective data collections and management	• Review policies and procedures for data collections and management • Use case studies to practice data collection and management

experiences. Finally, training will also involve a general orientation to the emergency department. This part of the orientation will be provided by Dr. Wilson, and will involve already- developed training materials for orienting new research staff to the UAMS ED. Follow-up trainings will be provided depending on identified need.

Special training about COVID-19: all patients presenting to the UAMS ED are universally screened for COVID-19 signs or symptoms (fever, cough, recent travel) and are placed into specially-marked isolation rooms. As part of training, research staff must demonstrate awareness of ED policies regarding the marking of these isolation rooms for suspected COVID-19 patients; must understand the importance of not entering these rooms; must understand and agree to use hand sanitizers when entering and leaving a patient's room ("foam in/foam out"); must demonstrate awareness of UAMS policies regarding screening of employees when they arrive for work; and must agree to stay home if they are feeling sick.

Please note that safety planning is a process that requires in-person interaction with participants due to the setting involved and confidentiality concerns. Having the special training detailed above in place reduces the health risk to potential participants and research staff. In addition to using the special training about COVID-19 detailed above, research staff will further minimize health risk by maintaining a safe social distance from participants during all study procedures and properly sanitizing all study equipment (pens, tablets, etc.) by using sanitizing wipes after use by each participant.

Supervision and debriefing of peers

Although anecdotally peers may be vulnerable to stress-induced relapse in the ED clinical environment, scant support for this idea is noted in the literature (please see above). Nonetheless, all peers will receive close supervision and debriefing during the study. Supervision will be provided using the discrimination model.[18]

As a licensed clinical counselor, Dr. Waliski will assess the provider's skill level and will become the role of a teacher, counselor, or consultant based on need. In other words, peers and mental health staffs will be provided with either instruction and direct feedback (i.e., the teacher role), support for reflection and processing of personal experiences (i.e., the counselor role), or encouraging confidence in required skills (i.e., the counselor role) depending on need.

In terms of direct supervision, Dr. Waliski will be on site during the first week of the intervention to observe performance and operation. She will ensure that the safety plan is being administered, documented, and managed appropriately by each provider (see also "Fidelity of the intervention" below). If deficits are identified, she will work with individuals to make needed improvements. During the first week of intervention implementation, Dr. Waliski will also conduct an individual face-to-face interview with each peer. Interview questions will be guided by the Consolidated Framework for Implementation Research (CFIR)[19] and focus on identifying and overcoming perceived barriers to implementation of the intervention.

Peers will also be provided with clear instructions on how to obtain help during any difficult or uncomfortable situations during the intervention. After the first week of the intervention, peers may inform ED clinical staff (social worker or psychiatric nurse) on site of such situations so that the staff may continue working on the safety plan with the participant. ED clinical staff are available 24/7 so peers would not have much trouble in finding and asking someone for help with a participant during these situations. Participants who do not complete the safety planning with a peer will be withdrawn from the study, but peers will be informed that their safety and well-being remains a priority when completing the intervention and so they should not hesitate to ask clinical staff for help. Peers may also contact Dr. Waliski using the contact information provided during

peer training in order to schedule an in-person meeting. Dr. Waliski will debrief the peer at these meetings by further discussing the difficult or uncomfortable situations.

Once the pilot project is underway, periodic debriefing of providers will be provided by Dr. Waliski. This debriefing will provide an opportunity to identify areas of needed improvement in the study protocol or in training (please also see “Fidelity of the intervention” below). Given this study utilizes individuals that have lived through serious suicide ideations and/or attempts, peers will likely have their own preconceived opinions about suicide and how to encourage survival. Debriefing will allow an opportunity to monitor how past experiences could be impacting the delivery of the intervention or how participating in the study could be impacting the provider. Dr. Waliski will also use this time to review personal safety plans and encourage providers to participate in appropriate self-care.

Please note that training on other aspects of the proposed research has been provided by Dr. Wilson. All research staff are trained on relevant IRB regulations & procedures, and required to be CITI-certified.

Measurement of safety plan quality: All safety plans will be evaluated by existing ED clinical staff for approval. If it needs to be modified, it will be documented that the research staff had to gather more information from the participant. Safety plans will also later be graded on a numerical rating scale (0-2 or 0-3, depending on grading component) by the investigators using materials developed by Gamarra et al for this purpose.[20] Using a “safety checklist,” responses for each of the 6 safety plan steps (with step 3 divided into two parts) and the “most important thing worth living for” section will be rated according to the personalization of the information in each section. In addition, each section will be independently rated for “completeness” (0=not complete, 1=partially complete, 2=complete) and “quality” (0=blank, 1=boilerplate, 2=some evidence of personalization, 3=highly personalized and specific). For instance, in the answer to the question “Warning signs (list 3 items),” patients may simply list “sad” which reflects a low-quality answer. Alternatively, the patient may answer “Feeling like I can’t stop crying or can’t stop being sad” which reflects a higher-quality more personalized answer. Each of the sections in a participant’s safety plan will be graded in this manner, with completeness having a maximum score of 16 and quality having a maximum score of 24. An overall score for the safety plan will be derived by adding the scores for all sections in a participant’s safety plan. Peers and other nonclinical individuals will be trained to coach participants towards higher-quality answers (please see above).

Monitoring: Adverse events or in case of psychiatric emergency

By definition, all patients have presented to the ED for an acute mental health crisis and will be under the care of trained ED physicians, trained ED nurses, trained

psychiatric ED nurses who typically complete the safety plan, and other psychiatric personnel as appropriate. In the unlikely event of psychiatric decompensation, peers will be instructed to stop the intervention and seek help from qualified personnel in the ED. The intervention will then not be continued.

Although adverse events (AEs) are not expected and are unlikely, the peers and mental health personnel who are responsible for approving the safety plan will nonetheless be instructed to communicate any and all AEs to the PI (Wilson). The PI will communicate any adverse events to the UAMS IRB, consistent with IRB policies & regulations.

Risks and Benefits

The main potential risk to study participants is loss of confidentiality. The researchers take confidentiality very seriously, and measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section below. Adverse events will be handled as above (please see “Monitoring: Adverse events or in case of psychiatric emergency” above).

Data Handling and Recordkeeping

The Principal Investigators will carefully monitor study procedures to protect the safety of research subjects, the quality of the data, and the integrity of the study. All study subject material will be assigned a unique identifying code or number in REDCap. Only Dr. Wilson, the study statistician, and select study staff will have access to the code and information that identifies the subject in this study. Safety plan material of patients will also be kept in a locked file in the office of the PI or co-investigator. Access will be strictly limited to study staff. Safety plans that are emailed contain no identifying information about the patient unless the patient has themselves listed this information. However, to guard against the very real possibility that these safety plans may allow identification of a particular patient despite having no identifying information, electronic safety plans will not take place on the patient’s cellphone. Instead, the patient will complete the safety plan on a UAMS research tablet and use this device to email the plan to clinical staff. This email will be sent directly from the “Safety Net” app, will utilize the secured UAMS wireless network, and this information will be erased before every patient. If patients would like a copy of their own safety plan, they may email it to themselves. If they are randomized to a written safety plan intervention, they will be given a copy of this document without their name.

Records will be maintained for 7 years per IRB requirements. At the discretion of the PI, records may be scanned and maintained in electronic format instead of paper format

once the study is complete. If so, electronic records will be audited to ensure high fidelity with the originals. These electronic copies will also be maintained on secure password-protected UAMS servers. When eventually destroyed, copies will be shredded per UAMS disposal guidelines.

Data collection will be performed through the Research Electronic Data Capture (REDCap) system on a secured UAMS wireless network, and it will be set up in cooperation with the UAMS Translational Research Institute (TRI) in order to assure 21 CFR Part 11 and HIPAA compliance.

Data Analysis

Outcome measures: Number of patients approached who agree to allow trained non-clinical staff to assist them with safety planning (if they do not agree, no other information about the patient will be recorded); the number of patients approached who meet all inclusion/exclusion criteria (if patients are not eligible for the study, no other information about the patient will be recorded); the number of participant safety plans which must be redone either by the peer support specialist, other nonclinical individuals, or clinical staff; the quality of completed safety plans; and patient satisfaction with each method.

Outcome 1: Evaluate the proportion of SI patients approached in the UAMS ED who agree to allow trained non-clinical staff to assist with safety planning. This number is currently unknown.

Outcome 2: Evaluate the proportion of patients approached who meet all inclusion/exclusion criteria. This number may be lower than the number of patients willing to participate in safety planning.

Outcome 3: Evaluate the quality of the completed safety plans. This will be done by retrospective review after the patient has left the ED. The number of safety plans that must be repeated or redone by clinical providers will also be tracked.

Outcome 4: Patient satisfaction with each method. This will be assessed by having the patient rate their experience with the safety planning process on a 7-point Likert scale (*strongly disagree; disagree; moderately disagree; neutral; moderately agree; agree; strongly agree*).

Power calculations and sample size: As this is a pilot study, no formal sample size calculation is planned. The investigators plan a priori to enroll 30 patients. The investigators therefore ask for permission to approach a maximum of 100 patients.

Initially, the randomization scheme will be validated by comparing the groups on key variables that could be associated with outcome (e.g., age, biological sex, prior suicide

attempts, prior completion of safety plan). Where we identify significant differences between groups, we will either adjust for these variables in analysis or conduct stratified analyses. Categorial variables will be analyzed with chi-square. Continuous variables will be analyzed by ANOVAs. Sub-analyses of potential prognosticators, including biological variables such as sex, will be descriptively presented, as the sample size will not likely permit sufficient testing of these variables.

Ethical Considerations

Written consent will be required for any study procedures. (please see “consent form.”). Please note that all study procedures will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

Potential participants will be identified from the ED track board and/or patient triage note. This requires a partial waiver of HIPAA for recruitment purposes only. No PHI will be recorded or disclosed without patient consent. Please see study flow above.

Peers or other research staff will approach the patient in an ED treatment room only if this can be done privately and safely (please see “Training of peers” above). The consent process will also be done privately in the same room. No patients will be approached in the waiting room or in a hall bed. The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study. The consent process will take place as described above, and subjects may take as much time as needed to make a decision about their participation.

Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process, including the fact that the PI will not be involved in the recruitment process if he is working in the ED at the time as an attending physician. This consent form must be signed by the subject and the individual obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in each subject’s research record.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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