Protocol #: 17-2299
Project Title: Assisting in Informing Decisions in Emergency Departments (ED-AID) Study
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I. **Hypotheses and Specific Aims**: This pilot randomized controlled trial seeks to assess acceptability, feasibility and effects of a lethal means decision aid use among patients and providers, as well as feasibility of a subsequent trial. In three emergency departments, we will test (1) the lethal means decision aid (**LM-DA**; feasibility and acceptability); (2) preliminary effects on decision-making (knowledge, decision conflict, values concordance and behavior intent); (3) effect on home firearm storage (exploratory); (4) effect on suicide outcomes (exploratory); and (5) feasibility of conducting a subsequent, large-scale trial. We hypothesize that patients with higher quality decisions (defined as higher knowledge, lower decision conflict, and higher values concordance) after the LM-DA will be more likely to change their firearm storage to reduce access; should our pilot demonstrate feasibility, in a subsequent large Stage II/III trial we will test this hypothesis directly.

II. **Background and Significance**: Suicide is a leading–and growing–cause of death in the United States.[23] In 2014, it was in the top 4 leading causes of death for those aged 10 to 54 and was the 10th leading cause of death for all ages combined.[24] Between 1999 and 2014, the age-adjusted suicide rate grew by 24% at the same time that mortality for many other illnesses and other types of injuries was decreasing.[25]

Suicide prevention occurs across a spectrum. Effective suicide prevention requires a comprehensive approach encompassing multiple approaches in settings from the community to inpatient facilities.[26] Broad goals, as defined by the Suicide Prevention Resource Center,[27] include identifying and assisting those at risk (including increasing help-seeking behavior and reducing access to lethal means), enhancing life skills and connectedness, and responding to crises with effective treatment and care transitions. Reducing access to lethal means does not replace other key components of suicide prevention; rather it augments these approaches by reducing the likelihood of death among those who attempt suicide.

Reducing access to lethal means saves lives. “Lethal means safety” (or “lethal means restriction”) is a suicide prevention approach with a strong empirical foundation[6, 28, 29] and is based on the concept that reducing access to highly lethal means of suicide during a time of vulnerability can prevent suicide by reducing the lethality of attempts. It relies on the concepts that many suicides are impulsive[30-33] and that means substitution (choosing a different method if the first preferred method is unavailable), if it occurs, reduces the risk of a fatal outcome.[34] At the population level, reducing access to lethal means such as high bridges or toxic cooking gas dropped suicide rates by 30-50%.[6] Counseling by healthcare providers about reducing access to lethal means (i.e., lethal means counseling, **LMC**) is now recommended by multiple organizations and is a Goal in the National Strategy for Suicide Prevention.[3]

Firearms account for 50% of suicides in the U.S.[23] and are a key focus of LMC within the National Strategy for Suicide Prevention[3] and its Prioritized Research Agenda for Suicide Prevention.[35] Firearm availability at home increases the risk of firearm suicide (pooled odds ratio 3.24, 95%CI 2.41-4.40[29])[e.g.,36-39] because of firearms’ high lethality, the very short deliberation time preceding many suicide attempts (**SA**s; <10 minutes in nearly half),[33] and the way ease of access can influence choice of suicide method.[6] Reducing access to firearms among those with suicidal ideation (**SI**) or SA could lower short-term risk and prevent thousands of deaths each year.[35]

Modeling estimates suggest that, had household firearm access been reduced 25%, approximately 3,600-3,900 suicide deaths in 2010 could have been avoided.[35]

Emergency departments (**EDs**) are a key acute care setting for suicide prevention because they are typically the location where patients with SI/SA are referred for evaluation and possible psychiatric hospitalization. Nearly 650,000 ED visits annually relate directly to suicidal behavior,[40, 41] although this represents just the tip of a larger problem: 6-10% of all adult ED patients (8-13 million[42]), including those with a non-psychiatric reason for their visit, have current or recent SI.[43-45] In addition, multiple ED visits (for any reason) may be a marker of suicide risk.[46] For patients evaluated for SI/SA in EDs, many are discharged home; only about half of ED visits for SA result in hospitalization.[47] Thus robust safety planning (including LMC and connection with outpatient care) is particularly important for the many discharged home.[1, 48]

ED-based LMC could enhance home safety but is not routine. LMC is a key part of safety planning for patients with SI/SA[1] and an intervention that may improve home storage of lethal means.[13, 49] ED-based LMC is part of the National Strategy for Suicide Prevention[3] and is recommended by national organizations.[1] Provider training[50] adapted for EDs exists, but our prior work shows that EDs have not yet widely implemented LMC.[6, 7, 10, 51] In a recent multi-site study, only half of suicidal patients had medical record documentation that a provider had asked about lethal means access,[10] though many ED patients with suicide risk have firearms.[10, 52]

Patients and families may not know about the link between firearms and suicide risk. Surveys suggest both the general public and providers may be unaware of the role of firearms in suicide.[8] In a recent national survey, only 6% of firearm owners (and 15% of all adults) thought a firearm in the home increases suicide risk.[16] Yet firearm owners appear more open to provider counseling about firearm safety when they believe firearms increase suicide risk,[15] suggesting that improving awareness may facilitate LMC and, ultimately, reduced access for those at risk.

Addressable barriers to LMC include provider ignorance or discomfort discussing firearms,[8, 12, 14] as firearms are a sensitive topic and providers might fear alienating patients or potentially violating state laws.[14, 53] However, no current state or federal law prevents physician questioning about firearms in case of suicide risk.[54] Many patients appear open to respectful, nonjudgmental education from clinicians,[6, 12, 14, 54] including in the context of LMC.[12, 13] Yet distrust of physicians, especially those ignorant about firearms, is a barrier for patients.[18] System-level barriers such as time pressures and dynamic multi-disciplinary teams caring for multiple patients in a complex, busy environment might be overcome by thoughtfully designed and implemented interventions.[11]

This is the first study to develop a DA for LMC for suicidal individuals, although DAs have been developed for medication options for depression and safety planning in cases of intimate partner violence.[55] DAs facilitate complicated health-related decisions by identifying the decision to be made, describing risks and benefits of various options, assisting the patient in clarifying personal values, and activating the patient for decision-making.[20] In a large Cochrane systematic review, DAs were shown to increase patient knowledge and accurate risk perception, decrease decisional conflict, and positively affect patient-provider communication.[22] Many firearm owners have a strong belief in self-determination and individual liberty.[18] Especially in the context of this belief in autonomy, a DA could give the individual patient and his or her trusted family members and friends more opportunity to consider options on their own before discussing with clinicians. This has the potential to be more effective than a traditional approach of a clinician making general, prescriptive recommendations to remove firearms.

The complex ED environment represents both a barrier and an opportunity for LMC. ED “boarding” of patients awaiting psychiatric hospitalization remains unfortunately common; at the University of Colorado Hospital ED, the average length of stay for psychiatric patients is approximately 23 hours (similar to national estimates).[56-58] While patients wait with little to do, providers have little time to spare. A DA to engage patients in decision-making and augment counseling could enhance patient outcomes, provider satisfaction, and ease of implementation and dissemination.

A LM-DA built on language, messaging and support from the firearms community will be most acceptable and effective in encouraging at-risk patients to reduce firearm access. It may also be particularly helpful for providers who are themselves unfamiliar with firearms (and therefore perhaps less comfortable discussing them with patients). Firearm safety, including storage with restricted access, is a central tenet of responsible gun ownership,[59] but explicit messages from firearms organizations about lethal means safety for suicide prevention have appeared only recently.[60, 61] Building on the model of the New Hampshire "Gun Shop Project,"[62] we convened a suicide prevention group comprised of representatives from the firearms, medical, and public health communities. This "Colorado Firearm Safety Coalition" meets regularly to discuss suicide prevention interventions. Activities have included suicide awareness posters and brochures in gun shops, inclusion of suicide prevention information in firearm training courses, and other educational outreach to gun owners. These collaborations have facilitated exchange of ideas and recruitment of participants for qualitative interviews and surveys. Coalition members also work with various relevant state and national groups engaged in firearm suicide prevention (e.g., National Sports Shooting Foundation, American Foundation for Suicide Prevention).

A computerized LM-DA allows for branching logic and tailoring of information to the individual, and web-hosting allows for broad access. But we also plan to have a web-accessible, printable PDF version, as not all settings can provide patients with computer or tablet access. The web-based, computerized interface could also allow for dissemination to other states (with adjustment based on state laws regarding temporary transfer of firearms[63]) and other clinical settings (e.g., outpatient primary care or mental health), as well as adaptation for particular populations (e.g., veterans or adolescents).

III. **Preliminary Studies/Progress Report:**

ED-based interventions for suicide prevention: Dr. Betz is a practicing emergency physician and a nationally-recognized researcher and leader in ED-based care of suicidal patients.[45] As a site-PI for both Emergency Department Safety Assessment and Follow-up Evaluation studies (EDSAFE[46] and ED-SAFE-2; NIMH; PI: Boudreaux), she led analyses of the provider surveys.[33,44] These showed gaps not only in provider knowledge and confidence for suicide prevention but also general support for and overall feasibility of interventions. The analyses also identified addressable challenges to interventions, including concern about slowing down care in crowded clinical environments and low provider confidence in the ability to create personalized safety plans (which ideally include LMC).[33,44] Additional preliminary work includes surveys with ED administrators (NIMH; PI: C. Runyan) and qualitative interviews with providers (pilot data), all demonstrating support for ED-based LMC but concern over when and how to deliver it. As two ED providers (both firearm owners) said: "3 minutes is an enormous chunk of time in the emergency department" and "give [providers] something that's fast and practical…the lack of resources and long wait times are big barriers to people to feeling like they are getting good, compassionate timely care."

Lethal means safety: Using ED-SAFE data, our team found: (1) many ED providers do not routinely counsel suicidal patients about lethal means access;[37] (2) reported counseling increased after ED protocols for suicide risk assessment (even without specific training about LMC)[33]; and (3) only half of suicidal patients had medical documentation that someone asked about access to lethal means.[35] Additional work includes:

- Qualitative interviews with firearm owners (pilot work) exploring firearm storage and LMC messaging. One firearm owner said LMC is more likely to be effective "if it is more of a support type approach rather than an attacking approach."
- Surveys with firearm retailers and law enforcement agencies in 8 states about lethal means safety, including options for temporary out-of-home firearm storage;
- The "Means Matter" program (www.hsph.harvard.edu/means-matter);
- Qualitative analysis of public views about physician-patient firearm discussions[47] exploring firearm owner views on LMC and acceptable messages;

- Collaboration on a project examining laws affecting gun storage,[48] such as requirements for background checks for firearm storage that might impact a patient's decision about gun storage options;
- Convening of the "Colorado Firearm Safety Coalition" to encourage suicide prevention interventions for firearm owners through gun shops, gun shows, and other outlets. A firearm instructor in the Coalition said of the collaboration: "We actually have a chance here to listen and teach to each other."[49]

These prior experiences have led to numerous working relationships with stakeholders from firearm retailers and organizations.

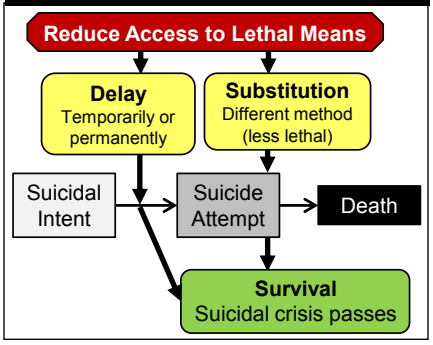
Additional related clinical research: Through the ED-SAFE studies, Dr. Betz has overseen enrollment of adults with active suicidal thoughts or behaviors (ED-SAFE; n=180). Study team members (Hindman, Runyan) worked on a pilot project to implement LMC at Children's Hospital Colorado, with online provider training and provision of storage lockboxes to 209 parents of adolescents with suicidal thoughts or behaviors.[31] At follow-up, among the 33% of gun-owning parents who had an unlocked gun at home on the day of the ED visit, none did on follow up. Dr. Betz is a Co-I on a new stepped wedge trial of LMC for adolescent patients in six Colorado EDs (American Foundation for Suicide Prevention). The study plans to enroll 1,350 parents of children (ages 10-17) to examine the effect of the LMC intervention (clinician training, written protocols, and patient handouts) on reported home storage of firearms and toxic medications.

DA development: Our preliminary studies, combined with other published work,[41,50] led to the conclusion that a firearm LM-DA could overcome some barriers to LMC, and we have partnered with a national expert in DA development (Matlock). Dr. Matlock, as Director of the Shared Decision Making Core at the Adult and Child Consortium for Outcomes Research and Delivery Science, has significant experience in the development, measurement, and implementation of patient DAs. This core is currently conducting the DECIDE-LVAD trial, a Patient-Centered Outcomes Research Institute (PCORI)-funded 3-year, type 2 effectiveness-implementation hybrid studying and implementing a DA for patients with advanced heart failure considering an LVAD (Left Ventricular Assist Device).[51,52] Halfway through, this trial is currently over-enrolling. Additionally Dr. Matlock has led previous PCORI-, NIH-, and foundation-funded work developing and testing decision aids for implantable defibrillators, colon cancer, and palliative care. He leads an innovative group using theories from cognitive psychology[53-55] and a user-centered design[56] to drive DA development. By combining theory with a user-centered approach, Dr. Matlock's group has a clear focus on designing tools suitable for implementation (a strength compared to other DA research).[57] Our current iterative development of the LM-DA (COMIRB Protocol #17-0670) draws on the knowledge and experiences of several stakeholder groups through qualitative interviews. Stakeholder groups include lived experience either as a patient or family member, firearm owners, ED providers, and suicide prevention experts.

IV. Research Methods

A. Outcome Measure(s): Key measures in this pilot trial (Table 1) are tied directly to our theoretical framework (Figure 1) and assess: (1) the intervention itself (feasibility and acceptability); (2) effect on decision-making (knowledge, decision conflict, values concordance, and behavior intent); (3) short-term effect on home firearm storage (exploratory); and (4) effect on suicide outcomes (exploratory). Additional domains of measures relate to the (5) feasibility of conducting a subsequent, large-scale trial. The baseline questionnaire will also

Figure 1. Conceptual Model of Lethal Means Safety [6]



address demographics, living situation, home firearms, and SI/SA measured by the baseline version of the Columbia-Suicide Severity Rating Scale (C-SSRS).[91]

(1) Intervention measures (LM-DA group only):

- Acceptability: The Ottawa Acceptability Scale (OAS) measures the comprehensibility of a DA, including: length; amount of information; balance in presentation of information about options; and overall suitability for decision making. The OAS is a 15-item scale (most with 4-point Likert scale response options)[84] We will use a target of 85% of patients and providers A rating the LM-DA as acceptable (global rating) as a criterion for progression to the next trial (Table 1).Provider domains will include knowledge, attitudes and self-reported practices concerning LMC, including questions from the ED-SAFE survey.[8]
- Feasibility of Use: Additional measures relate to the feasibility of LM-DA use in an ED setting. These will include duration of the LM-DA process (minutes taken by participants to work through the web-based LM-DA) as well as patient- and provider-identified barriers (surveys for feedback on the LM-DA, including how it could be better integrated into care and how it could be improved).

(2) Immediate Outcomes/Mechanistic Measures (LM-DA and Control groups): Knowledge, decision conflict/uncertainty, and value-choice concordance are key to decision quality, itself a fundamental element of the Ottawa Decision Support Framework[5] as a precursor to behavior change. We hypothesize that patients with higher quality decisions (defined as higher knowledge, lower decision conflict, and higher values concordance) after the LM-DA will be more likely to change their firearm storage to reduce access; should our pilot demonstrate feasibility, in a subsequent large Stage II/III trial we will test this hypothesis directly.

- Knowledge: Questions will assess knowledge of concepts presented in the LM-DA and control group pamphlet, such as the association between firearm access and elevated suicide risk.
- Decision Quality: The Decisional Conflict Scale (DCS) measures overall decision quality. It also

Table 1. Measures, Timing of Assessment, and Criteria for Progression to a Larger Trial
BL=baseline; family/friends also complete baseline assessment

Domain	Measure	Patients				Providers		Threshold for progression to larger trial
		Base-line	1 wk.	1 mo.	3 mo.	Sur-vey	Inter-views	
INTERVENTION								
Acceptability	Ottawa Acceptability Scale	X	X			X		85% rate LM-DA as acceptable
Feasibility of use	Time to complete; user feedback; web functionality	X				X	X	NA (informs next trial)
IMMEDIATE/MECHANISM								
Knowledge	Questions about suicide and LM	X	X					60% of patients identify firearm access as risk for suicide
Decision conflict	Decisional Conflict Scale (DCS)	X	X					Effect size 0.3-0.4 after intervention (target score <25)
Values concordance	DCS Values Clarity subscale	X						NA (informs next trial)
Behavior intent	Theory of Planned Behavior	X						NA (informs next trial)
SHORT-TERM								
Firearm access	Self-report	X	X					NA (informs next trial)
LONG-TERM								
Suicide attempts, deaths	Self-report C-SSRS (BL, 1 week); medical record review (BL, 1 & 3 months)	X	X	X	X			Able to review records for 85% of participating patients
TRIAL MEASURES								
Feasibility	Eligibility, participation	X						>50% participation
	Phone follow-up		X					>75% completion
	Suicide outcome ascertainment			X	X			Able to review records for 85% of participating patients
Provider training	Time to complete; user feedback						X	NA (informs next trial)
ADDITIONAL MEASURES								
Demographic and clinical characteristics	Questionnaire, C-SSRS; medical record review	X		X	X			NA (informs next trial)
Healthcare utilization review	Medical record review			X	X			Able to review records for 85% of participating patients

estimates decisional uncertainty through personal perceptions of issues such as uncertainty in choosing options, modifiable factors contributing to uncertainty, and effective decision making (e.g., expressing satisfaction with the choice). The DCS is a 16-item scale (with Likert scale response options) that has high reliability and test-retest correlation (Cronbach's alpha coefficients > 0.78).[92] In prior work, the DCS has been shown to discriminate between known groups who make or delay decisions (effect size 0.4-0.8).[92] Scores less than 25 (out of 100 total) are associated with implementing decisions;[92] we will use this threshold as one criterion for progression to the next trial (Table 1), as Dr. Matlock has done in other studies.

- Values Concordance: We will use the "Values Clarity"[92] subscale of the DCA to examine how much participants feel their decisions are in line with their values.
- Behavior Intent: We will measure self-reported intent to reduce access to firearms, including the chosen option(s) for storage, using a Theory of Planned Behavior questionnaire scale.[93]

(3) Short-Term Outcome: At phone follow-up, we will assess firearm storage (to identify changes from baseline). This will be a primary measure for the subsequent, larger trial.

(4) Long-Term Outcome: This pilot is not powered to detect change in suicide death rates (the outcome most likely affected by lethal means safety). We will assess suicidal behavior at phone follow-up (self-report of SI/SA) using the "since last visit" C-SSRS,[91] as well as via structured review of electronic medical records (ED visits for SI/SA) and vital statistics (deaths) at 1 and 3 months.

(5) Trial Feasibility Outcomes:

- Eligibility and participation rates: We will record demographic information (gender, age group, race/ethnicity) and reasons for non-eligibility or non-participation for patients not enrolled in this pilot trial to inform our planned trial. We will also record participant disposition (discharge home versus hospitalization) and how often participants have a family member or friend present in the ED (with willingness of companion to participate). We will analyze these data for each of the clinical sites.
- Follow-up rates: We will record rates for telephone follow-up at 1-week.
- Suicide composite measure: We will record the feasibility of accessing medical records and vital statistics.
- Provider training: Measures will include estimated training time required for competence (an important feasibility measure for future implementation) as well as user feedback about the training itself.

Analysis: We will describe the three sites in terms of demographics as well as the primary measure (DCS score <25) using appropriate statistical tests (e.g. anova, chi-square). If no differences are found between the three sites, we will ignore site and compare the proportion of the primary measure in the control and intervention groups as the primary analysis. If differences are found among sites and there are enough events, we will use a logistic regression model with a fixed effect for site and with a treatment indicator as the main predictor. Missing data for the primary measure should be minimal, given that this will be obtained before patients leave the ED. For secondary measures, we will use descriptive statistics including proportions with 95% confidence intervals for knowledge, acceptability and feasibility; whether the criteria in Table 1 have been met will be based on the confidence intervals of the proportions.

Table 5. Sample Size Estimates

% with DCS <25		Detectable	Total sample
Control	*LM-DA*	difference	size
0.6	0.9	0.3	64
0.5	0.8	0.3	78
	0.85	0.35	54
	0.9	0.4	40
0.3	0.6	0.3	84
	0.65	0.35	62
	0.7	0.4	48
0.2	0.5	0.3	78
	0.55	0.35	58
80% power, α=0.05			

Sample Size: Keeping in mind factors related to pilot trial feasibility, our target sample size (n=60; 30 LM-DA and 30 control) was chosen to allow detection of a 35% difference between the LM-DA and control arms for the primary measure (DCS score <25; Table 2). In a prior small study, 62% of parents of at-risk youth who received LMC reduced home

access to firearms, compared to 0% of those who did not receive LMC.[49] Estimates for the effect of LMC on behavior among adults with suicide risk do not exist, so our assumption of a 35% difference is conservative (prior work with other DAs has found an effect size of 40-80% on DCS between groups[92]). While this sample size will not allow for full power to analyze moderators by site (as related to either LM decision or trial feasibility measures), it should generate adequate pilot information concerning site selection for the subsequent trial.

B. Description of Population to be Enrolled: We will enroll three populations:

- **a.** 60 patients seen in the ED for SI/SA
- **b.** Up to 60 influential adult family members or friends (one per enrolled patient), either in person or by telephone (if not present in the ED; n=60 total). Enrollment of a family member or friend will not be required for a patient to participate.
- **c.** 100 emergency department providers for surveys and 20 for qualitative interviews (may participate in survey, interview or both)

Table 3. Inclusion/Exclusion Criteria

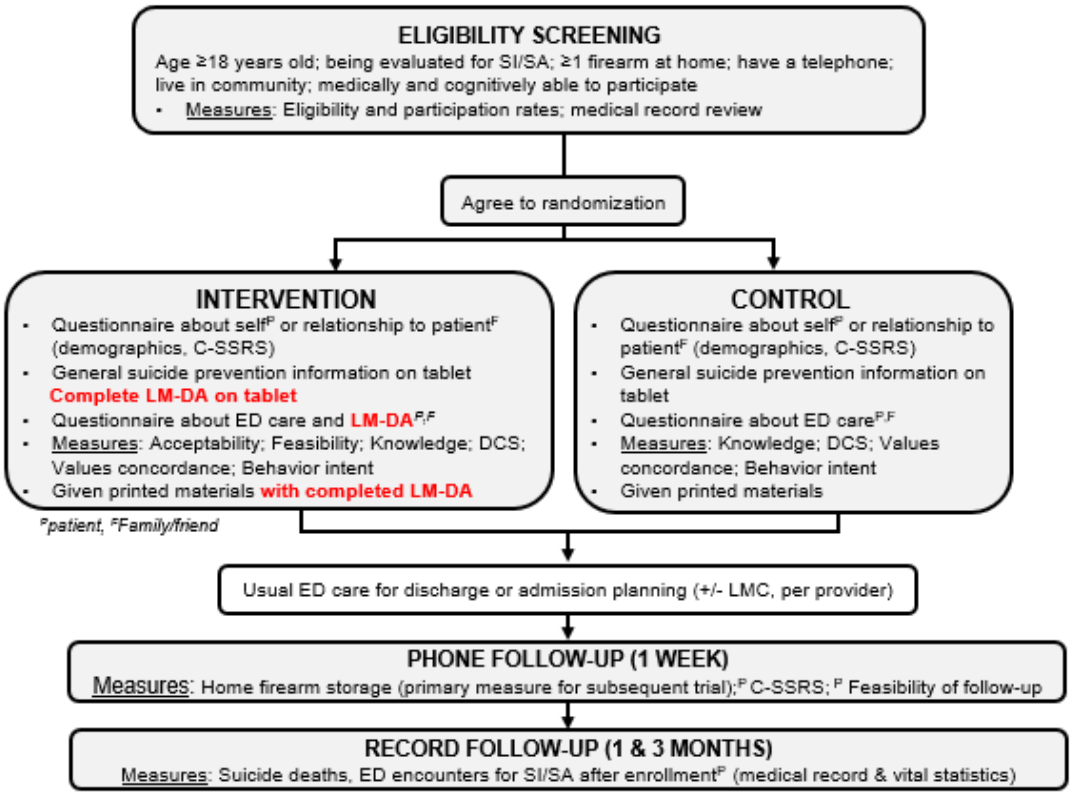
	Inclusion	Exclusion
Patients (n=60)	• Being evaluated in the emergency department for SI/SA. • Deemed medically stable by ED physician • Age ≥18 years • Able and willing to have telephone follow up at 1 week • Report ≥1 firearm at home	• Unable to participate medically or cognitively (e.g. sustained altered level of consciousness, hostility, psychosis, sexual assault victim, severe vomiting or pain) • Currently in legal custody • Live in group home or other supervised custody • Already enrolled
Family member or friend (n=60)	• Age ≥18 years	• Unable to participate cognitively • Already enrolled • Currently in legal custody
ED Providers (n=100)	• Physicians, physician extenders (i.e., physician assistants or nurse practitioners), nurses, and behavioral health evaluators (e.g., social workers, psychologists, advanced practice nurses) who work in the participating EDs • Cared for ≥1 participating patient • Completed current care of participating patient(s) prior to beginning the survey	• Current or former member of the study team (i.e. PI, CO-I, RA)

C. Study Design and Research Methods: In this pilot randomized controlled trial, we will test the LM-DA in a sample of 60 adult patients being evaluated for suicide risk at three large hospital EDs. Thirty nine patients will be randomized to the LM-DA group, while 21 will be randomized to the control group (13/7 at each site). Figure 2 displays the overall study flow. Analysis and reporting will follow CONSORT guidelines, and we will register the trial on clinicaltrials.gov. Family member or friends who are concurrently enrolled will also be enrolled in the ED, in the same randomization group as the patient. ED Providers will be surveyed separately.

Study Sites: To prepare for the subsequent multi-site trial, including by identification of moderators of LM-DA and study feasibility at different sites, the pilot will recruit patients, family members/friends, and providers from the EDs at three large, diverse Colorado Hospitals: (1) University of Colorado Hospital (tertiary care center without dedicated psychiatric ED; suburban Denver; part of UCHealth consortium); (2) Memorial Hospital

(hospital with dedicated psychiatric ED; draws from large catchment area in southern Colorado, including rural and urban populations; high firearm ownership rate; part of UCHealth consortium); and (3) Denver Health Medical Center.

Figure 2. General Study Flow



Enrollment:

- Patients: Research assistants (RAs) will identify potentially-eligible patients by monitoring the EDs' electronic tracking board and medical records in real-time for documentation about SI/SA. For patients who appear to meet initial eligibility criteria based on chart review, the RA will approach the ED physician caring for the patient to ask if the patient is medically stable and to ensure that study participation does not interfere with a behavioral plan or other aspect of clinical care. The RA will then ask for permission to speak with the patient and accompanying family or friends, with the goal of approaching all potentially-eligible patients to assess other eligibility criteria (Table 3). Given the potential sensitivity of discussing firearm access, the RA will explain the study is designed to enhance home safety and will assure patients that we will not record responses or report them to the police or any other authorities. For patients who are not interested in participating in the full study, RAs will record basic demographics and will ask permission to contact them at 1 week after their ED visit and to allow medical record review at 1 and 3 months. Screening, enrollment and consent will occur in the patient's current area of care in order to reduce disruption to concurrent clinical care. Additionally, moving a patient to a new setting within the hospital may remove

some of the precautions within hospital procedures for patients with suicide risk. These precautions often include the removal of items that could be used for self-harm or the addition of monitoring procedures for patients at elevated risk.

- Family member/friends: RAs will ask each enrolled patient to identify an influential adult family member or friend, preferably one with input into decisions about home firearm storage. The RA would then approach this person (if present in ED) or contact him/her by telephone. Family members or friends would have the similar eligibility criteria as patients (Table 3).
- ED Providers: Provider survey invitations will be emailed and will include a unique link to complete a REDCap online survey. To supplement these survey data, we will conduct qualitative interviews with 20 ED providers to further explore LM-DA acceptability, feasibility of real-world implementation, and training. All providers who are a part of a patient −subject's clinical team will be invited by email to participate in the initial survey. At the end of the survey, there will be an invitation to participate in a follow−up qualitative interview. Interested providers will be instructed to email or call the study team, as their name will not be on the survey. If more providers opt for qualitative surveys than anticipated, we will select a sample to optimize balance across provider groups and sites.
- All participants will receive a gift card as an incentive ($25 for patients; $10 for family or friends; $5 for providers who complete the online survey; $15 for providers who complete a qualitative interview for a total incentive of $20).

Randomization:

- Patients: At each ED, enrolled patients will be randomly assigned to the LM-DA or control arm (Figure 2). To reduce bias and achieve balance among arms, we will randomize patients in blocks.[90]
- Family members/friends: If a family member or friend is concurrently enrolled, they will be automatically randomized into the same arm as the patient, as they will potentially be reviewing the LM-DA with the patient and assisting with decision making.
- ED Providers: Providers will be asked to provide answers to a survey after the patient's visit. Thus, they are not randomized, nor can they feasibly be blinded given their ongoing care relationship with patients during the study.

Baseline Measurements & Intervention:

- Patients: The RA will give the patient a study tablet with an introductory short survey and basic information about suicide prevention. In the intervention arm only, patients will then complete the LM-DA on the tablet. All patients in both arms will answer questions about their ED care and their anticipated care plan (including knowledge about the rationale for reducing access to firearms as a safety measure, and their intent to decrease access to firearms at home). Study participation will not affect clinical care, including discharge or admission planning.
- Family member/friends: Enrolled family members or friends will complete a similar survey on a tablet; they will not complete the LM-DA themselves but could complete it with the patient, if the patient wishes, as might occur in real-world situations. All patients will receive print-outs of suicide prevention information and the results of their LM-DA (intervention arm only). Research staff will enter the LM-DA results (including identified plan for reducing access to firearms) into the patient's REDCap data file, along with data from the patient's electronic medical record from that ED visit.
- ED Providers: Providers will not receive the intervention, rather they will be asked to provide feedback on the use the LM-DA in the ED after a patient they cared for is part of the study.

Description, Risks and Justification of Procedures and Data Collection Tools:

This is a minimal risk study.

- Patients who enroll in the study will still receive standard clinical care in the ED but will gain the information provided to their respective randomized group, in either the control or LM-DA. Participants will receive a follow up call 1 week after their ED visit, an additional touch point above standard clinical practice, which fulfills a research purpose but also, for this vulnerable population, may provide some comfort and reduce isolation. The clear alternative to the participation is usual care.
- Family member/friends are not asked to provide any personal health information. The clear alternative to participation for family member or friends would be usual procedures and care provided to support in the ED.
- ED Providers will be providing feedback in an online survey.

Specific risks are outlined below.

Suicidal ideation or behavior:

- Patients: We do not anticipate that the LM-DA would trigger or worsen suicide risk, and the materials will specifically recommend that the participant ask a trusted individual to enact the firearm safety plan (so that the participant is not going home to handle the firearms him/herself). However, we will assess recent suicidal thoughts or behavior using versions of the Columbia-Suicide Severity Rating Scale (C-SSRS) ("baseline" at enrollment and "since last visit" at phone follow-up). This pilot trial is not powered to detect a change in suicide outcomes; however, should we notice any cases or issues suggesting safety concerns, we will pause enrollment while the DSMB reviews the concern (as described in the Data Safety Monitoring Plan). The DSMB is empowered to make recommendations about trial continuation, revisions or termination based on safety considerations. The DSMB Charter outlines the full role of the DSMB as well as plans for AE/SAEs. Research staff will complete basic QPR Gatekeeper Training (https://www.qprinstitute.com/) and have specific written guidelines for discussion with clinical staff (during baseline enrollment) or referral to a suicide crisis hotline, including 3-way connection during a telephone interview should a participant exhibit signs of significant distress.

  At baseline screening in the ED, an enrolled patient may communicate to research staff they will not participate in firearm storage planning. Given all enrolled participants will be under current evaluation for suicidal risk and have access to firearms, the patient's inability to create a storage plan of any kind would be reported to the patient's clinical care provider in the ED immediately to ensure proper treatment coordination and safety planning given that participant's response and risk levels. Similarly, if a patient reveals additional information to research staff that would be pertinent to their immediate safety, this would be reported to the clinical care provider. If a patient reports to research staff threats or thoughts to harm others, this will be reported to clinical ED staff in order to complete the protocol for duty to warn.

  At follow up, if a participant expresses suicidal ideation or appears at risk to themselves or others, the RA will connect the participant via 3-way call with Colorado Crisis Services (the free state hotline, staffed 24/7 with trained counselors). In the event the participant refuses to speak with the crisis line or the call is prematurely terminated, research staff will follow HIPAA clinical guidelines outlined for healthcare providers and the privacy rule in the event a person poses a serious or imminent threat to themselves or others. Under these circumstances, the Privacy Rule allows health care providers to disclose necessary information to law enforcement, family members of the patient, or other persons. If outside assistance is required due to imminent risk, the research staff may have to report the current risk level and location of the participant, though the nature of the study will be kept confidential.

  In this pilot, we will enroll patients regardless of admission or discharge status to examine

feasibility of a larger trial and real-world application. We will also enroll patients regardless of their patient status, i.e. placed on a Colorado M1 hold (more commonly referred to as a "mental health hold"). Per the State of Colorado, A M1 hold is indicated when a patient poses an imminent threat to themselves or others, or, is gravely disabled due to mental illness. As part of the M1 hold process, a patient has specific rights (covered in Colorado form M2). Voluntary participation in a research study does not contradict or violate these specific patient rights. A patient on a M1 hold may accept or decline participation in the research study. This will specifically be communicated as part of the consent process to reduce coercion.

Participating in this research study will not offer protection from future SI, future SA, future suicidal behaviors or future self-harm. As such, this will be communicated to both patient and family member/friend participants during consent.

Coercion (all participants): Because some study investigators are also affiliated with the clinical sites, there is the potential risk of coercion.

- Patients and Family Members/Friends: We will minimize this potential risk by being very clear that participation is completely voluntary, that withdrawal is always possible during the trial, and that usual clinical care will not be impacted by the decision to participate or not to participate in the clinical trial. Treating clinicians will not be involved in the consenting of patients and thus will not be in a position to coerce participants; recruitment will be performed by study staff. Additionally, study staff will encourage patients to have a family member or friend present for the consent procedure (especially as we will be recruiting one family member or friend per participant). There will be no exchange of payment for study participant referrals. The clear alternative to participation in the trial will be usual clinical care. Because research staff will be assessing patients current suicidality through the use of the C-SSRS, the potential for both patient participants as well as family/friend participants to be unclear on the roles of researchers versus their treating providers. Research staff will make clear their roles as researchers versus clinical staff during the consent process, specifically noting that decision to participate will not impact their clinical care.
- ED Providers: A study staff member without a clinical relationship to the ED or to the ED providers will be the only one aware of which providers have completed surveys ED.

Loss of confidentiality (all participants): Loss of confidentiality is a potential serious risk. We will be diligent in safeguarding protected health and other participant information in the collection, processing, and storage of information, and all the data generated by the study will be kept strictly confidential. No reports will be released containing protected health information or other identifiers that would allow a study participant to be identified. Individual participant contact information will be collected at the time of enrollment (prior to randomization) and this information will be kept in a secure, locked file cabinet in the Department of Emergency Medicine offices and in password protected, secure electronic files. Participants will not be identified by name or medical record number on any of the data forms or specimens except the initial enrollment and consent forms. Other paper and electronic data will be made anonymous using unique identification codes and participant initials. Electronic files will be stored on password protected computers, or REDCap, behind the University of Colorado Denver firewall.

Worry about firearm confiscation

- Patients and family members/friends: We recognize that participants may view this as a study risk, although it is not actually one. Specifically, some may fear that, if they reveal they have firearms at home, legal authorities will confiscate them. We will explain to every participant that study staff will not enter information about firearm access into the medical record, nor will they disclose access to any legal authorities. We will also not ask about how firearms were acquired (i.e., whether they were legally-purchased or transferred).

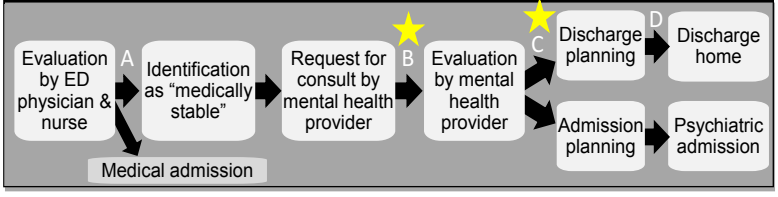
Should staff have concern about a participant's imminent safety, they would follow study protocols to notify clinical staff in the ED or connect the patient with a suicide hotline. While clinical staff may document firearm access, as they might during typical care, we will reassure participants that such information is not shared with legal authorities unless an individual is specifically threatening harm towards specific individuals (as per required reporting under the *Tarasoff* decision).

Language: As this is currently a small pilot trial, the LM-DA will not be translated into Spanish or other languages at this time. However, if analyses indicate a larger scale trial is indicated, the LM-DA would be translated into Spanish for larger scale testing.

E. Potential Scientific Problems: Identification of eligible patients and review of records could be difficult, given the high volume of patients seen in the complex EDs included in this study. However, all three sites use Epic for their electronic medical record system and have Epic-based ED tracking boards that research staff can monitor (as we have done previously in the ED-SAFE studies). Study staff have expertise with using Epic for enrollment and medical record review (at baseline and for later utilzation reviews). In addition, all three clinical sites (as well as a number of other Denver-area hospitals) are connected within Epic, such that subsequent visits to any of the linked EDs would be visible to staff. Staff also have experience accesing vital statistics records and we have a strong relationship with the Colorado Department of Public Health an Envirnoment. Another challenge is the sensitivity of disclosing firearm access, as some patients may be hesitant to reveal ownership or home access. During eligibility screening, study staff will first establish rapport, discuss the larger context for the study (improving home safety generally, without reference to firearms), and explain the basic outline of the study (participation requirements and incentive). They will also explain the confidentiality of the study (including that study staff will not record sensitive or identifiable details in the medical record or databases accessible by law enforcement or government agencies). Only then will study staff ask eligiblity questions, with the question related to firearms asked last in hopes of maximizing participant comfort and honesty in answering and in participating. Our enrollment estimates are intentionally conservative and take into account the issue of assessing firearm access. An additional challenge is timing of study procedures relative to ED care. Figure 3 displays the different stages of ED care, where broken arrows represent times ranging from minutes to hours. At point A, patients may be intoxicated or otherwise not medically or cognitively able to participate in the LMC or the study. Most suicidal patients speak with a mental health consultant, who is the person most likely to provide LMC. Assessment of lethal means access may occur during the mental health provider's evaluation (between points B and C), but actual LMC is likely to happen during the discharge process (point D). Thus, for this study, RAs will aim to approach patients during the periods represented by points B and C. In surveys and interviews with providers, we will assess how the LM-DA may have affected subsequent LMC or supported antecedent LMC, data which will inform future real-world implementation into clinical practice. The study staff will have work-spaces in or next to the EDs and the support of their site PIs, along with familiarity with ED patient flow. These factors should facilitate enrollment.

Another area of challenge is blinding to treatment arm. RAs will carry out all study procedures but cannot feasibly be blinded to study arm, as they will need to ensure the patient can access the LM-DA. To blind patients, we plan to use deception (with IRB approval) in the informed consent process such that patients know

Figure 3. Time Spent in ED by a Patient with SI/SA



the study is examining ways to enhance safety of suicidal patients but do not know that the LM-DA is the intervention of interest. ED providers will not be blinded to participant study group, as providers may review the LM-DA printed results with patients (as they would in real-world implementation). We will notify providers of the study at the start of enrollment and explain the purpose, with the request that providers continue to provide usual care (with or without LMC, as per their usual practice) for patients in the intervention and control groups. A third challenge is testing the role of family or friends. Not all suicidal patients have someone present with them in the ED, so there will be real-world variability in how family or friends are involved with DA completion. Ideally, the person with decision-making control over firearm storage would be involved, but may not be present with the patient. In the current proposal, we will record how often family or friends are present and are (or are not) the ones with control of firearm storage. We will also record how often they are willing to participate in the study – all of these findings will help lay the groundwork for future study. If we find any aspects of the LM-DA are unacceptable, we will revise those aspects and re-review with stakeholders prior to future implementation. Another limitation is finding differences across sites, but not enough events to adjust for site (with a fixed effect). In this case, given that this is a pilot study, we will use two strategies: (1) ignore site and summarize the overall results, and (2) analyze the results ignoring the site with few events. A future study will allow to account for differences across sites.

F. Data Analysis Plan: We will describe the three sites in terms of patient demographics as well as the primary measure (DCS score <25) using appropriate statistical tests (e.g. anova, chi-square). If no differences are found between the three sites, we will ignore site and compare the proportion of the primary measure in the control and intervention groups as the primary analysis. If differences are found among sites and there are enough events, we will use a logistic regression model with a fixed effect for site and with a treatment indicator as the main predictor. Missing data for the primary measure should be minimal, given that this will be obtained before patients leave the ED. For secondary measures, we will use descriptive statistics including proportions with 95% confidence intervals for knowledge, acceptability and feasibility; whether the criteria in Table 1 have been met will be based on the confidence intervals of the proportions**.** Keeping in mind factors related to pilot trial feasibility, our target sample size (n=60; 30 LM-DA and 30 control) was chosen to allow detection of a 30% difference between the LM-DA and control arms for the primary measure (DCS score <25; Table 2) While this sample size will not allow for full power to analyze moderators by site (as related to either LM decision or trial feasibility measures), it should generate adequate pilot information concerning site selection for the subsequent trial. Participants and RAs will enter survey data directly into REDCap. Participants completing REDCap surveys will be sent a unique link for participation. For follow-up calls, chart reviews and other documents, RAs will enter data into REDCap or store it on password-protected university servers. We will export data to SAS for analyses.

G. Summarize Knowledge to be Gained: The proposed research will provide the scientific foundation for improvement and examination of real-word implementation of an effective, patient-centered LM-DA in EDs and other settings. A web-based tool offers the potential to significantly enhance current care, decrease real-world access to lethal means of suicide, and thereby decrease short-term risk of suicide.

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