Randomized Trial to Improve Safe Firearm Storage

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Study Title: Firearm Access Reduction Through ER Intervention (FARTHER): Is Counseling Enough?

Descriptive Title on Grant Proposal: Efficacy of Gun Lock Distribution in Improving Firearm Storage Practices Over Counseling Alone in a Pediatric Emergency Department

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I. Abstract

Suicide has become the second leading cause of death in children and teens in the United States.[1] Since 2008, firearm suicide rates have increased by more than 89% making it the #2 cause of completed suicide in children.[1] During this period of time, the Emergency Department (ED) has been thrust into the forefront of suicide prevention; there has been a 329% increase among patients presenting to the pediatric emergency department (PED) for self-harm behavior since 2007.[2] Pediatric Emergency Medicine providers have a unique opportunity to intervene, counseling both caregivers and patients at risk for self-harm. Counseling in the medical setting is an effective means for creating behavior changes to improve patient safety, especially when families are given tangible resources/safety products.[3-6] Eighty percent of firearms used in childhood suicides are owned by family members.[7] Fortunately, safe storage of these firearms greatly decreases the likelihood of firearm-related death among children and adolescents.[8] The purpose of this study is to measure change of firearm storage practices in families after receiving either targeted ED-based safety counseling or counseling with a safe firearm storage product. Patients presenting to the PED with a chief complaint of "Psychiatric Evaluation", including those presenting for suicidal ideation, aggression, and depression, will be included. Patients who do not have access to a home firearm, or who don't present with a caregiver will be excluded. Patients will be randomized to one of two study arms (1) a control arm receiving targeted firearm safety counseling or (2) an intervention arm receiving targeted firearm safety counseling in addition to the provision of two firearm cable locks. Information obtained from families will include caregiver demographics, age and number of children in the home, and current storage practices of firearms and medication. Follow up phone surveys at 4 weeks post ED visit will describe self-reported storage practices, other subsequent ED visits, and satisfaction with the ED encounter for both groups.

II. Purpose of Study

The primary purpose of this study is to determine if distribution of informational resources (such as handouts) coupled with distribution of firearm safety locks, improves self-reported securement of all firearms with locking devices (ie. cable lock, lockbox, gun safe) over informational resources alone. Secondary objectives include: reporting how families view ED-based firearm safety counseling and describing relative improvement among other lethal means safety measures: (1) firearms stored unloaded (2) firearms acquired/removed from the home, (3) medications stored with locking device and (4) medications removed from the home. Our study will focus on families of children presenting for psychiatric evaluation in a pediatric emergency department. We hypothesize that families that receive informational resources and firearm locks will report all firearms stored with a locking device 25% more frequently than families who receive informational resources alone.

III. Background

Suicide is now the second leading cause of death in children and teens in the United States.[1] This is of particular importance to PED providers because there has been a 2.5 fold increase in the number of suicide-related visits among adolescents over the last several years.[2] In 2008 there were 529 firearm-related suicides in children compared to 1,003 in 2018.[1] Access to firearms has been shown to be a key risk factor for completed suicide.[8] Although a small minority of pediatric suicide attempts involve the use of a firearm, they are used in approximately 40% of all completed suicides, making firearms the second leading cause of completed suicide in children and adolescents.[1] This is due to the fact that suicide attempts with firearms results in much higher rates of mortality, with greater than 90% of attempts ending in death.[9] Among pediatric suicides in the US, over 80% of guns used in suicide attempts belong to a family member,[7] with the majority involving handguns.[10] Fortunately, this risk can be greatly mitigated with the safe storage of firearms, by as much as 78%.[8] The AAP defines safe storage as firearms kept locked, unloaded with ammunition secured and stored separately.[11] However, less than 40% of gun-owning families follow the AAP's safe storage guidelines leaving approximately 4.6 million American children living in households with at least one loaded, unlocked firearm.[12]

Several studies have demonstrated the ability of medical providers to positively impact behaviors affecting patient safety.[3,4,5,6] Pediatric Emergency Medicine providers have a unique opportunity to provide education to patients and families about firearm safety by providing targeted inventions during "teachable moments". One Pediatric ED in Colorado instituted a curriculum for counseling families of children with suicidal ideation which improved storage of medications and firearms after counseling received in an Emergency Department.[6] Not only did the majority of families hold favorable impressions of the counseling, but there was a 66% and 37% increase in safe storage of medication and firearms, respectively.[6] Furthermore studies have demonstrated that when families receive tangible resources, they are more apt to have the desired change in behavior.[4,6] There have, as yet, been no randomized controlled studies assessing the effectiveness of distribution of various resources on safe firearm storage in the PED setting.

IV. Study Design

This will be a prospective, non-blinded, randomized controlled study in a Pediatric Emergency Department to determine the effect of gun lock distribution with informational resources on firearm storage practices compared to informational resources alone. The study cohort includes parents or legal guardian(s) of patients presenting to the Cincinnati Children's Hospital Emergency Department for psychiatric evaluations who have any guns in their home. Parent or guardian of the patient must be present for enrollment. Informed consent will be obtained for those families agreeing to participate in the study. Parent/guardian will be asked if they are willing to complete a survey at time of encounter and again in 4 weeks from initial encounter. If they are unable to read, the survey will be read to them by the CRC. Families will be randomized, via block randomization, into one of two study arms: (1) a control arm receiving targeted firearm safety informational resources or (2) an intervention arm, receiving targeted firearm safety informational resources in addition to the provision of 2 cable-style firearm locks. Lethal means counseling (which includes discussion about locking hazardous items such as medications and firearms) is part of the standard safety planning that occurs when PIRC counsels families. All patients will still receive standard of care counseling by PIRC team members. The informational resources provided will include more specific information and advice related to firearm safety, discussing topics such as the four pillars of safe storage and the decreased risk of suicide when firearms are stored safely. Primary outcome is change in self-reported securement of **all** firearms with a locking device. Initial survey to be given before targeted information is provided. Follow up surveys at 4-6 weeks after the ED visit will determine self-reported storage practices of firearms and medications after receiving the intervention, and Likert-scale based satisfaction with pediatric ED encounter. Follow-up attempts will be attempted via text or phone. The surveys will be available in English only. The surveys will contain only the minimum PHI needed to allow for follow-up. Survey will be electronic with responses recorded via REDCap.

V. Duration

The study will take approximately 1.5 years. Approximately 3 months will be dedicated to development of survey and script for research coordinators. Three months will be allotted for obtaining lockboxes and firearm safety education for CRCs. Assuming a 65% acquiescence this should take approximately 8 months to achieve the desired sample size based on limitations of enrollment by CRCs and PI. Follow-up phone surveys to describe firearm storage will occur at approximately 4 weeks from encounter. Data analysis and manuscript preparation will take approximately 4 months to complete.

VI. Selection & Recruitment of Participants

The study participants include parents or legal guardian(s) of children who present to the Cincinnati Children's Base Campus Emergency Department ED for a Psychiatric Evaluation. Parents or legal guardian(s) of patients who meet the following eligibility criteria will be screened. A minimum amount of child's information (i.e. age, gender) will be used to determine eligibility of parents and this information will not be retained at CCHMC for the purpose of this research study.

Inclusion criteria include parent or legal guardians of patients for chief complaint of psychiatric evaluation (including other complaints such as "behavior problem", "aggression", etc) who are:

- English-speaking
- Screen positive for firearm possession (in at least one location the patient spends time)

Parent/legal guardian must be present for survey and distribution of firearm cable locking device(s). Disposition of patient (admit vs discharge) will not affect inclusion.

- Exclusion criteria include:
  - Guardian does not speak English
  - If patient behavior in the ED leads to an otherwise unsafe environment
  - Guardian not present for duration of encounter
  - Guardian unwilling/unable to answer follow-up questions

In order to provide follow-up phone calls/texts patient identification will need to be obtained. There are no other populations that will be subject to undue influence. Participants will be recruited and screened for eligibility to this study while in the Emergency Department. Participants will only be contacted via phone number provided.

VII. Process of Obtaining Consent

We will be seeking a waiver of documented consent for this study. Our study presents no more than minimal risk of harm or procedures that would normally require written consent. Our study is simply an expansion of the current standard of care counseling provided by PIRC, which written consent is not normally required for outside of the research context. The research staff will explain the study and present a study summary sheet to parent/caregiver (study participants). Participants will have the opportunity to ask questions prior to deciding whether to continue with enrollment or to decline. Assent will not be obtained because HIPAA identifiers from the child's medical record will not be used or retained at CCHMC.

Waiver of Consent and HIPAA Authorization for Screening Purposes

We are requesting a waiver of consent and HIPAA authorization to screen for patient eligibility using electronic medical records. Identifiable data about eligible and ineligible (i.e. missed eligible) patients such as MRN, encounter ID, date/time of visit, provider name, demographics, relevant clinical data, inclusion/exclusion criteria, etc. will be collected in a secure database hosted by CCHMC and used for assessing study operational needs. Access to the screening log is only available to Cincinnati Children's Emergency Department research staff. No research will be conducted from the data collected in the database; it is only used for research oversight. Consent would not be possible for patients because of the nature of presentation to the ED. It is possible that some patients will have arrived when no study staff is available. The rights and welfare of patients will not be affected by the data collection and they will still receive the same care regardless of study participation.

VIII. Study Procedures

1. Parents or legal guardian(s) of patients presenting for Psychiatric Evaluation will be identified by a member of the study team
2. Research team member will screen family for firearm ownership
3. Those parents or legal guardian(s) that screen positive for having a firearm will be screened for study eligibility.
4. For those deemed eligible and consent to participate, randomization into 1 of 2 arms will occur via block randomization
5. Participants will complete pre-intervention survey
6. All participants, regardless of randomization group will receive informational resources. Informational resources will be centered around the Ohio AAP "Store It Safe" program, which focuses on harm reduction through safe storage of firearms and ammunition. This information will be provided verbally by CRC or Bijan Ketabchi as well as in paper form.
7. Families will also receive gift card for agreeing to participate in study
8. Children/Patients may be present in the room during the gun safety intervention due to the nature of presentation to the ED. Parent/legal guardians are the primary intended audience of the intervention. Children are not a target of the intervention.
9. Patients and families randomized to receive firearm cable locks will obtain devices prior to leaving the ED
10. Follow-up surveys will be distributed via text, email or phone at approximately 4 weeks from encounter. Upon completion of the follow-up survey, a gift card will be sent via text or email provided. This information will be collected solely for the purpose of sending incentives and that information will not be used or retained in the research dataset.
11. Data collection will occur in REDCap

Studies Using Surveys or Questionnaires: This survey is modeled after a survey published in Pediatrics by Dr. David Grossman. After IRB approval, the survey will be piloted for readability and understanding among 5-10 families as well as PIRC social workers. This survey has not yet been validated. During the study CRC will be present during survey and available to read to guardian if guardian is unable to read themselves and to answer any questions the participants may have.

IX. Data Analysis/Methods

Data will be collected in REDCap and stored on a password protected computer available only to PI and co-investigators. Frequency of responses will be calculated at the completion of data collection. Analysis will be performed by the study team at CCHMC. Primary outcome is change in self-reported securement of **all** firearms with a locking device. This will be elucidated by comparing responses to the pre and post intervention surveys. Frequencies will be compared between the two study arms. For our secondary outcomes, questions regarding degree of satisfaction (which will be assessed via Likert scale), removal/acquisition of firearms, and (if applicable) use of provided gun locks. Based on prior studies that compared counseling to receipt of tangible resource[14], we can expect a 25% difference between

the groups. We will need 138 participants to detect a difference of this magnitude. Assuming a dropout rate of 30% a sample size of 200 will be necessary. The most recent CCHMC PIRC data show that 40-100 patient-families each month have reported gun ownership (This number is 100-150 pre-COVID). A Chi Squared test will be used to determine significance difference of proportions between the two groups. Limitations of our study include self-reporting of ownership and storage. This may be further limited as families who do not store weapon safely may be less likely to report ownership.

X. Facilities and Performance Sites

All initial surveys, handouts and gun locks will be distributed in CCHMC Burnet Emergency Department. Data collection and data analysis will also occur at CCHMC. As follow-up is by phone survey, there will be no specific facilities designated.

XI. Potential Benefits

Participants of intervention arm will receive 2 gun locks. Other potential benefits of the study include improving families' understanding of firearm safety and potentially improving safe storage of firearms. By increasing education and safe storage, patients and families will be at lower risk of injury due to firearms.

XII. Potential Risks, Discomforts, Inconveniences and Precautions

There are no significant risks to the study participants or their families. Discussion about firearms may make your teen more familiar with firearms in the home. However, the discussion had with the caregiver can happen without the teen present if you choose. As in every study, there is risk of loss of confidentiality, but we deem this risk to be minimal as our surveys will be kept anonymous and all other information will be kept on password protected computers in order to best protect participants.

XIII. Risk/Benefit Analysis

While there is some inherent risk in participating in any study, such as loss of confidentiality, the benefits of understanding current practices of firearm storage and the potential to improve patient safety far exceed this risk. Our study will help identify the need for further education and provision of firearm safety resources. This will ultimately allow physicians to give tangible resources to families of patients at high risk for harm from firearms.

XIV. Data Safety & Monitoring

DSMB is not necessary for this study as there is minimal risk to participants. Study data will be checked periodically throughout the study to ensure high quality data collection. Data will be stored on secure CCHMC network. All Adverse Events and Unanticipated Problems will be reported as per policy R-18.

XV. Privacy and Confidentiality

In order to respect the privacy of potential participants, subjects will only be contacted in the Emergency Department and via telephone number and/or email provided. Participation is completely voluntary, and participants may withdraw from the study at any time. After data analysis is complete, surveys will be de-identified.

The investigators at CCHMC will have access to the telephone numbers/emails provided by patients and their families, however researchers will not collect any other identifying information that can associate participants with their responses.

Future Use: Data collected in the study will no longer be used after the completion of our analysis.

XVI. Cost of Participation

There are no additional costs for participating in this study; however, standard text and data rates may apply per each subject's cell phone carrier.

XVII. Payment for Participation

Incentive for participation will be given during the Emergency Department encounter and upon conclusion of follow-up questions. A gift card of $10 value will be given to families who decide to participate and again at time of follow-up. Gift cards may be physical cards or electronic cards (as approved by CHMC accounting). In the event participant contact information is no longer valid, study staff will be unable to send the gift cards to the participant unless they contact the study with new contact information. If a participant declines payment, they may still participate.

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