Title Page

Title: Safety Education in the Emergency Department: A Pilot Study

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COMIRB Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD

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Project Title: Safety Education in the Emergency Department (SEED): A pilot study
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I. Hypothesis and specific aims

The goal of this proposal is to determine the feasibility and acceptability of using a video in the Emergency Department (ED) at the Children's Hospital Colorado (CHCO) to promote the safe storage of firearms, and safe firearm behaviors, in homes with children. We also intend to obtain pilot data to evaluate parental storage practices and knowledge surrounding temporary firearm transfer out of the home in times of crisis and determine whether these can be improved following a standardized ED intervention. Our overall hypothesis is that presenting a video during a child's ED stay will improve communication with the ED provider ultimately increasing safe firearm storage. In order to test this hypothesis, we are proposing a pilot study to test the feasibility,acceptability and effectiveness of a video intervention in the ED with the following aims:

Aim 1: Aim 1: Evaluate the effectiveness of safe firearm storage education for medical and surgical patients in the Children's Hospital Colorado (CHCO) ED by measuring change in self-reported safe storage at baseline and 3 months after a brief ED intervention.

Hypothesis: Safe storage counselling will improve safe storage practices by 15% over baseline rates, as measured by removing all guns from home or locking all guns and locking ammunition separately.

Aim 2: Evaluate the effectiveness of a brief ED intervention in improving parental knowledge surrounding temporary firearm transfer out of the home as a lethal means restriction strategy by measuring parental knowledge at baseline and 3 months after a brief ED intervention.

Hypothesis: Parents will not be aware of temporary firearm storage as a lethal means restriction strategy, and an ED intervention will be effective at improving this knowledge.

Aim 3: Compare the feasibility of having parents watch a short, 30-second, to a long, 3-minute, Be SMART firearm safety video in the CHCO ED.

Hypothesis: We believe that at least 10% more parents will complete watching the 30 second video compared with the 3-minute video as measured by data retrieved from the GetWell network.

Aim 4: Evaluate the acceptability of both videos to parents who view the video with a post-test survey administered in the ED using a survey modified from previous work done at our institution [1].

Hypothesis: We expect that the video will be acceptable to 75% of parents who view the video.

Aim 5: Assess the number of parents that participate in a follow up survey within 3 months after the ED visit.

Hypothesis: We hypothesize that 65% of parents will complete the entire follow-up survey.

This study is the first step in determining if offering a firearm safety video focused on safe storage in the ED is feasible and acceptable to our parents, and whether it is effective in a subset of families with older children known to have firearms in the home. The results generated from this study will lead to evaluating the effectiveness of the video at changing firearm storage and safety behaviors among a larger population of families. Given that we see 75,000 patients annually in our ED, we have the infrastructure in place to test this pilot study and future interventions. If effective, we also have the infrastructure to support broad implementation, including to our network sites, reaching a sizable and diverse population of Colorado families.

II. Background and significance

Firearm injuries, both intentional and unintentional, are a public health crisis in the United States. Among children and adolescents nationally, firearm related injuries are the second leading cause of death, accounting for more than 15% of all fatalities in individuals age 1-19 years old, and [2]. The intent of injury varies with age, with 26% of firearm deaths among children (1-9 years old) being unintentional [2]. In contrast, among adolescents (10-19 years old), nearly all deaths - 97% - were intentional with 39% due to suicide [2]. Suicide is of even greater concern in Colorado, which is the state with the 10th highest suicide rate in the country with a rate of 20 suicide deaths per 100,000 population, well above the national average of 14 per 100,000 [3].

The American Academy of Pediatrics (AAP) recommends storing firearms locked, unloaded, and separate from ammunition [4]. Each of these measures has proven protective against unintentional injuries and suicide by firearm in youth [5]. This effect on suicide *attempt* by firearm is critical as the use of lethal means plays a crucial role in whether an individual completes suicide [6]. Firearms are the most lethal means of suicide with a fatality rate of 90% [7], accounting for 54% of suicide deaths even though they were used in only 6% of attempts [8].

Firearms are *only safely stored in one third of homes with children* [9, 10]. This, despite most unintentional injuries being caused by a gun found in the home [11], and evidence that children cannot be "taught" firearm safety at a young age, playing with guns even when warned not to [12]. There is no improvement in storage practices in homes of children who are at higher risk for suicide [13]. Easy availability of firearms in the home correlates significantly with adolescent suicide rates, with 80% of youth suicides occurring in their home, most commonly with a parent's firearm [14]. In most of *these* cases, the firearms were not stored per recommended safe storage practices [5].

Improving rates of safe storage in homes with children and adolescents, thus decreasing access to firearms for this age group, is essential to decreasing firearm morbidity and mortality. The challenge lies in identifying the best mode and setting by which to communicate this to families. The ED is uniquely positioned to reach a broad population with an educational intervention. Pediatricians are excellent candidates to deliver this safety message as child health advocates, and do so effectively in the primary

care setting [15]. This message is also effective in the ED for patients who require evaluation for active suicidality. In this context, a five-minute intervention by a psychiatrist and provision of a lockbox proved effective at improving safe firearm storage and decreasing access to lethal means in patients at high-risk for suicide [1].

The aspect of the ED which makes it an excellent setting, in that patients are primed for safety education and providers are natural advocates, also presents challenges. Generally, providers spend less time with the patient and the physician-patient relationship is not as well developed as in primary care. In addition, ED resources are inadequate and providers too numerous to generalize in-person counselling.

Video-based patient education is effective in engaging and educating patients in other settings and topic areas [16], and is frequently used at CHCO to educate families about medical diagnoses or child safety. We expect an educational video to be an effective mechanism to provide firearm safety education in the ED as it is brief, reproducible, and obviates the need to train providers or utilize additional provider time.

The Be SMART campaign , developed by Everytown for Gun Safety, has developed firearm safety videos based on their messaging of "**S**ecure all guns in your home and vehicle, **M**odel responsible behavior, **A**sk about the presence of unsecured guns in other homes, **R**ecognize the role of guns in suicide, **T**ell your peers to be SMART" [17] – one 30-second video and a second 3-minute video. This framework is applicable to individuals regardless of firearm ownership. It is currently being studied as an educational model at a small number of pediatric inpatient units and primary care settings across the country. We do not know, however, if it is feasible to show these videos to parents of patients presenting to the ED, if the messaging will be acceptable in our population, or if they are an effective means of changing behavior.

We intend to address a portion of this knowledge gap with this pilot study to demonstrate the feasibility of 1) showing the video in the ED and 2) whether parents will participate in a 3-month up phone call to evaluate for improvement in safe firearm behaviors. We will evaluate the acceptability of the video using a modified version of a survey previously used at our institution [1]. In a subset of the population who are firearm owners, thus at higher risk, we will collect pilot data to understand whether this video, coupled with a handout, appears to be effective. If feasible and acceptable, we will seek to evaluate the effectiveness of the video, and compare the effectiveness of the two videos, via a randomized control trial.

III. Research Methods

A. Outcome Measure(s):

Specific aims 1 and 2:

Primary outcome measures:

1) Safe firearm storage will be measured by self- report based on the survey questions such as, "Are any of the guns in your home kept unlocked?", and "Are the bullets stored separately from the guns?".
2) Parental awareness of temporary firearm transfer will be measured by self-report based on questions such as, "Did you know that you can temporarily take your guns out of your home if you are concerned that someone in your house may hurt themselves or someone else?". Responses answers are yes or no.
3) Parental knowledge of temporary firearm storage options will be measured by the ability to name at least one location for temporary firearm storage OR describe the link for a map of storage locations.

Specific aims 1-5:

4) Feasibility of delivering the intervention in the Emergency Department (ED) measured by
    a. Proportion of caregivers approached who agree to participate in the study.
    b. Proportion of caregivers who complete the video in its entirety, based on data provided by the GetWell network who will be hosting the video content.
    c. Proportion of caregivers who complete the baseline survey, which will ask questions about general child safety behaviors, current firearm storage, acceptability of video content and acceptability of showing the video during the ED visit.
5) Acceptability of the educational videos as measured using a survey at baseline with primarily closed-ended questions such as "How useful was the information you received?" and "Was the information you received confusing?". There will also be an open-ended question to solicit additional feedback
6) Feasibility of completing a follow up survey with parents within 3 months after the intervention measured by the proportion of caregivers who complete the survey in its entirety either electronically or by phone.

B. Description of Population to be Enrolled:

Inclusion criteria**:**

1. Children > 30 days and < 18 years old presenting to the CHCO ED
2. Parent/guardian who is ≥ 18 and ≤ 85 years old
3. Specific aims 1 & 2 will include a subset of patients 10 years and < 18 years old with a firearm in the home.

Exclusion criteria:

1. Child is in an emergent/acute medical condition
2. Patient seen in our fast track area or other room without a television
3. Parent/guardian is non-English speaking.

For specific aims 1 and 2: Professional Research Assistants (PRAs) that staff the ED from 7am to midnight, 7 days per week will screen families, and approach any family with a child 10 years to < 18 years old to participate in a safety study. Caregivers who agree to participate will be asked to complete the first 10 questions of the baseline survey about child safety, including a question about firearm ownership and storage, on an iPad. Caregivers who answer the question "Are any of the guns in your home kept unlocked?" with "yes", "no", or "I don't know" will be included in the study. Those who answer "There are no guns in the home" will be excluded. Those included will complete the baseline survey.

For specific aims 3, 4 and 5: Professional Research Assistants (PRAs) that staff the ED from 7am to midnight, 7 days per week will screen families, and approach any family with a child 17 years or younger to watch a video about child safety. Caregivers who agree to participate will be asked to complete the first part of the baseline survey about child safety in general, including questions about firearm ownership and storage, on an iPad. Caregivers will then be randomized to watch either the 30-second or 3-minute Be SMART video. Following the video, caregivers will be asked to complete the second part of the baseline survey, also on an iPad, which will address acceptability of the video. In this part of the study, we will not restrict inclusion based on endorsed firearm ownership because it may be underreported, and we may miss messaging potential firearm owners. Additionally, the video includes

messaging about safe firearm behaviors that are more universally applicable, such as asking about firearms in other homes that children frequent.

C. Study Design and Research Methods

This will be an experimental pre-post pilot study performed in the ED at CHCO. Patients presenting to the ED with a non-emergent complaint will be screened by PRAs or the Principal Investigator and approached to participate after they are assigned an ED room and prior to leaving the room due to discharge, transfer or admission. Since this study is observational in nature, participation will not alter medical treatment or length of stay in the ED; therefore, after caregivers review a postcard consent about the study, they will be asked to answer a question in REDCap indicating if they agree to participate. If the child is of assenting age (7-17), we will have the child review a postcard assent about the study. They will then be asked to answer a question in REDCap indicating if they agree to participate. The postcard consent/assent will describe our goal as studying child safety in general and will not specifically refer to a firearm safety objective, in order to mitigate potential bias. We will debrief the caregiver about the minor deception after they complete the follow-up survey, as knowledge of study aims could bias answers to both the baseline and follow up survey.

Specific aims 1 and 2: To prevent potential contamination across providers in the ED, the intervention will only be given during one block of time. Families will be block randomized by date of presentation. In the first six months, or until we recruit the necessary number of participants, we will provide current standard of care with no new intervention – this will be group 1 (G1). In the following six months we will recruit into the intervention group – this will be group 2 (G2). In G1, parents will complete the baseline survey at time 0 (t0) and will complete the follow-up survey at 3 months (t3) via follow up phone call. In G2, parents will be asked to complete the baseline survey at t0 and will then be asked to watch the 3-minute Be SMART video. Parents in G2 will also complete the follow-up survey at t3 via follow up phone call.

Specific aims 3, 4 and 5: Those answer yes in REDCap indicating that they agree to participation will be randomized to watch either the 30-second or 3-minute Be SMART video. Each family enrolled will be asked to watch one of these two videos.

For all aims: The videos have been developed by "Be SMART" [17], an organization focused on responsible gun storage education and awareness. These videos describe safe firearm storage in the home, encourage parents to ask about firearm storage at homes their children frequent, and addresses removing firearms from the home if someone is having a mental health crisis. This messaging is applicable both to owners and non-owners of firearms. In addition, demographic information including subject's name, age, sex, parents' names, email addresses and telephone numbers will be collected. Clinical variables, such as presence or absence of mental health diagnoses, abuse, current presentation with mental health complaint, active suicidal or homicidal ideation and presentation with penetrating trauma, will also be collected from the electronic medical record (EMR) by the PI or other study investigators after the index visit.

Participants will be given a brief survey prior to the video to assess baseline storage habits along with other child safety behaviors.All families will also complete a survey immediately after the video to evaluate acceptability of the video. Participants will also receive a follow-up email or phone call to evaluate storage habits and firearm safety behaviors within 3 months after their visit. If we are unable to contact the family by email or phone, we will consider them a lost to follow-up (LTFU). For aims 1 and 2, we will give each family a $5.00 gift card for participation in the study at the initial visit. For aims 3, 4

and 5, we will give each family up to a $20 gift card for participation in the study - $10 after watching the video and completing both parts of the baseline survey, and $10 after completing the follow up survey.

Data from each subject will be entered into a REDCap database on a secure server. All identifiers will be removed from the data set after all participation is complete, including follow up, before data analysis. EMR review will occur after the index visit. Study investigators will manually review charts for descriptive and clinical characteristics. Each of these subjects' will already be registered in the secure REDCap database under a specific study number at the time of retrospective review and data will be entered here.

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

The study will consist of watching a brief video and responding to questions pertaining to pediatric safety. This intervention will not impact medical care or time spent in the ED in any way. Demographic characteristics to be recorded include age, sex, and race/ ethnicity of the child. Medical history and clinical variables will be collected such as presence or absence of mental health diagnoses, abuse, current presentation with mental health complaint, active suicidal or homicidal ideation and presentation with penetrating trauma.

The following measures will be taken in order to minimize the risk of breach of confidentiality that is always a concern with collection of protected health information (PHI). Each subject will be assigned a unique study number and all patient identifiers will be removed from the data set after participation is complete, including follow up, and before data analysis. All data including PHI will be stored in REDCap. (The UCD REDCap installation passed a rigorous 6-week security threat analysis performed by the UCD-Anschutz HIPAA Security Officer. All study data are stored on a secure database server which is separate from the web-facing server -- a best-practices for internet-based security. All user access requires user accounts and passwords. All user actions are recorded in a secure audit log. The database server is routinely backed-up. All security patches and application updates are applied immediately upon release by DISC.) Upon completion of the study, all patient identifiers in the data set will be removed.

F. Potential Scientific Problems:

The goal of this pilot study is to assess feasibility and acceptability of showing a firearm safety video in the ED, with the goal of a larger scale study to evaluate whether this video can improve storage practices and improve other firearm safety behaviors.

G. Data Analysis Plan:

We will collect demographic data from the patient's electronic medical record as well as survey results from the parent-completed survey.

Continuous variables will be described as means and standard deviations if normally distributed or median and interquartile range if non-normally distributed. Categorical variables will be described using counts and percentages. We will compare data between families who received the 30-second video and the 3-minute video using fisher exact tests, t-tests, or Wilcoxon rank sum tests as appropriate. All results will be presented in aggregate and performed in SAS (Cary, NC).

H. Summarize Knowledge to be Gained:

This study has the potential to utilize a novel approach to educating the public about safe firearm storage. If successful, it can improve rates of safe firearm storage where children and adolescents are living and increase safe firearm behaviors, thereby reducing morbidity and mortality caused by suicide, unintentional injuries, and assaults.

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