

## Pediatric Inpatient Firearms Study

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### BACKGROUND

The United States (US) is the only developed country in which firearm violence is a major cause of death. Of all firearm deaths in high-income countries, 80% occur in the US.<sup>1</sup> Gun violence remains a top killer of young people in the U.S. In the year 2014, 2,549 young people (ages 0-19 years) were killed with a firearm in the US, most of whom were 15-19 years.<sup>2</sup> Firearm injuries and deaths can be categorized as homicides, suicides, unintentional shootings, legal intervention (police involvement), or undetermined. Unintentional shootings comprise 4% of all pediatric firearm deaths and often involve young children. Homicide and suicide, which comprise 94% of pediatric gun death, overwhelmingly affect teens.<sup>3</sup> Urban teen males suffer from high rates of gun homicide, while rural teen males die from gun suicide.<sup>4</sup>

In addition to the pediatric mortality associated with firearm violence, firearm injuries leading to hospitalization and other morbidities are a substantial public health issue that is less well-studied. In 2009, there were over 7300 hospitalizations of children and adolescents due to firearm injuries in the US, with nearly 3 children per day under the age of 15 being hospitalized for firearm related injuries.<sup>5</sup>

The American Academy of Pediatrics recommends a firearm-free household as the safest environment for children and teens. For families that own guns, safe storage with gun and ammunition kept locked in separate compartments protects young people from unintentional or intentional violence.<sup>3</sup> Studies of safe storage counseling have yielded mixed results. These interventions tend to focus on gun-owners, with counseling specifically on safe storage of firearms. There is a dearth of randomized-controlled trials on this subject.<sup>6</sup>

Everytown for Gun Safety is a group that was founded in the wake of the massacre at Sandy Hook Elementary School in order to work for safer gun laws and promote safe storage of firearms. They have created a non-political, non-legislative gun safety campaign called "Be SMART" to promote the principles of safe firearm practices in the home.<sup>7</sup> The campaign focuses on the responsibility of the adult to practice firearm safety, rather than asking children to behave responsibly around

firearms since this has been proven to be an ineffective strategy.<sup>8</sup> It also provides counseling for non-firearm-owning families, as it recommends asking about unsecured firearms prior to playdates. Thus, it can serve as a simple, universal counseling tool for parents who are gun-owning and non-gun-owning. It has not been formally evaluated as an educational tool.

Children's hospitals may be a good place to counsel on firearm safety. Large children's hospitals draw patients from surrounding areas that may include rural, suburban, and urban areas. A hospital-based intervention would allow outreach to children of all ages. The "free time" patients spend in the hospital, while either recovering or waiting for procedures or results, may make patients amenable to receiving such counseling. The inpatient setting has been successfully utilized to provide educational interventions to parents of hospitalized children on other topics, best studied in the area of smoking cessation.<sup>9-12</sup> Walley et al. utilized the "Smoking and Kids Don't Mix" video for parents/caregivers of hospitalized children, demonstrating successful reported behavior changes in parents/caregivers to reduce second- and third-hand smoke.<sup>12</sup> To our knowledge no other study has utilized the inpatient setting to address issues related to firearm safety counseling and education.

The primary aim of the study is to determine whether the Be SMART campaign delivered to parents in a hospital setting leads to an improvement in knowledge, attitudes, and practices about firearm safety. The secondary aim is to determine whether the intervention is more effective when delivered with physician face-to-face counseling in addition to with video and written materials, or with standardized video and written materials alone.

### **Study Aims:**

- 1) To measure whether parents' knowledge, attitudes, and practices change after a brief educational intervention on gun safety
- 2) To measure the knowledge, attitudes, and practices of parents in a tertiary care children's hospital regarding firearm safety practices
- 3) To compare the efficacy of two methods of delivery of counseling: a video alone versus a video plus a physician-delivered intervention
- 4) To measure whether these changes in practices are sustained one month after the intervention

## **METHODS**

*Study Design:* This is a randomized controlled 3-arm pre-/post-intervention study to investigate the effect of an educational intervention using a Be SMART video and written material on parental/legal guardian knowledge, attitudes and practices regarding firearm safety. An additional element of the study design includes a randomized controlled trial to investigate any additional effect of a pediatrician-delivered educational intervention on parental/legal guardian knowledge, attitudes

and practices regarding firearm safety. Given that tobacco smoke exposure interventions have been previously studied in hospitalized children, we will use a video and written materials on tobacco smoke exposure education as our control group.<sup>12</sup> We will use survey techniques to determine baseline and post-intervention knowledge, attitudes and practices regarding firearm safety in parents/legal guardians of hospitalized children <20 years old.

*Study population:* Parents/legal guardians of children <20 years old hospitalized at CHAM.

*Inclusion criteria:* All parents/legal guardians of children <20 years old hospitalized at CHAM who reside with the child.

*Exclusion criteria:* Previously enrolled in the study, parent/legal guardian preferred language other than English or Spanish, hospitalized in the Pediatric Intensive Care Unit/critically ill child, or parent/legal guardian acutely distressed.

*Study procedure:* Daily, residents on the primary medical team will ask the parents/legal guardians of new patients or parents/legal guardians not previously enrolled in the study if they would allow research personnel to speak with them about the study. If the parent/guardian allows, study personnel will then attempt to approach all parents/legal guardians of children <20 years old using the attached “Research Personnel Script” and the “Eligibility Form” to assess eligibility. If eligible for the study, the participant will then be approached for informed consent. If they consent, study personnel will conduct a standardized verbally-administered “Initial Parent/Guardian Survey”. Once the survey is complete, the participant will be randomized to one of 3 study groups: 1. Be SMART alone group: To view the Be SMART video and to receive Be SMART written material alone, 2. Be SMART + MD group: To view the Be SMART video and to receive Be SMART written material and subsequent standardized reinforcement/review with a pediatrician using the “MD Checklist for Intervention Review” or 3. Control Group: To view the “Kids and Smoke Don’t Mix”<sup>12</sup> and to receive written materials from the New York State Smokers Quitline. Study participants will be randomized in blocks of 15 by [www.randomization.com](http://www.randomization.com). For patients in the “Be SMART+MD” group, each physician will verbally review all 5 elements of Be SMART in person with the participants, as denoted in the attached checklist.

Following the intervention, study personnel will conduct a brief verbally administered “Post-intervention Parent/Guardian Survey”. One month later, study personnel will conduct the “One Month Follow-up Parent/Guardian Survey” verbally administered via telephone.

*Survey Instruments:* See attached surveys:

1. Inpatient Firearms Study—Eligibility Form
2. Inpatient Firearms Study—Initial Parent/Guardian Survey
3. Inpatient Firearms Study—Post-intervention Parent/Guardian Survey

4. Inpatient Firearms Study—One Month Follow-up Parent/Guardian Survey
5. Inpatient Firearms Study—Research Personnel Script

The questions in all of the Parent/Guardian surveys (Initial, Post-intervention and One Month Follow-up) were all adapted from prior published studies which used surveys addressing the topic of youth firearm exposure and safety,<sup>13-17</sup> and the control tobacco exposure questions adapted from other published studies on tobacco smoke exposure in children.<sup>12</sup>

*Intervention Checklist:* See attached—Inpatient Firearms Study—MD Checklist for Intervention Review.

*Outcomes:*

The primary outcome is the change in parent/legal guardian's behavior over the past 30 days with respect to how often they asked whether or not there are guns in the home when their child/children goes to play in another's person's home, as indicated by a Likert scale assignment of an ordinal value (1-5, 1= never, 2=rarely, 3=sometimes, 4=most of the time, 5=always).

Secondary outcomes will include:

- Change in the primary outcome (intention to ask noted above) between the intervention groups (Be SMARTalone vs. Be SMART + MD)
- Demographic factors associated with primary outcome
- Description of general knowledge on firearm safety of parents/legal guardians of patients in our community
- Description of attitudes about firearm safety of parents/legal guardians of patients in our community
- Description of general practices regarding firearm safety of parents/legal guardians of patients in our community
- Description of parents attitudes regarding physicians discussing firearm safety with them

*Data Analysis:*

The main objective of the data analysis is to assess within each intervention group whether the general parental practice of asking about firearms in the homes of others when their children go to play is increased after the intervention. A secondary objective is to perform a head-to-head comparison of the magnitude of the intervention effects between the groups. Our pilot data revealed the proportion of the population who either "always" or "most of the time" ask about firearms in the homes of others when their children went to play was 50%. With a sample size of 60 subjects in the Be SMART alone group, the study will have 80% power using the McNemar's test with a two-sided alpha=0.05 level to detect an absolute increase of 20% between the pre-intervention and post-intervention responses (i.e. raising the proportion of those who either "most of the time" or "always" ask about firearms in the homes of others when their children went to play from 50% to 70%). For the

Be SMART + MD group, we expect the pre- post intervention effect to be larger, i.e., increase from 50% before the intervention to 80% after the intervention in the proportion of the population who either “most of the time” or “always” asked about firearms. With a sample size of 60 subjects in the Be SMART + MD group, the study will have greater than 95% power to detect this difference using the McNemar’s test with a two-sided  $\alpha=0.05$  level. We expect minimal change in the pre- and post-survey responses in the control group. For the comparisons between treatment arms, we will focus on the subset of parents who initially responded that they were not likely to ask about firearms before the intervention (expected to be ~ 50% of parents) and assess whether the proportion who changed their response to “most of the time” or “always” after the intervention is greater in those who were in either of the Be SMART groups compared to the control group. With 60 subjects in each of the 3 study groups, the study will have 80% power to detect an increase in this proportion from 10% in the control group (which is a conservative assumption) to 40% in either the Be SMART alone or Be SMART + MD group using a two-sample test of proportions and a two-sided  $\alpha=0.05$  level.

We anticipate the majority of the subjects enrolled will complete the inpatient portion of the study, however, we estimate up to 20% will not be able to be reached by phone for the 30 day follow up call. Therefore given that our primary outcome is based on behavior assessed at the 30 day follow up phone call, we will add to each study group 15 patients to give each study group at total of 75 patients, and the overall study population will be 225 patients.

For within-group data analysis, we will use standard descriptive statistics to summarize the data and McNemar’s test or the paired T- test to assess the significance of pre-post intervention differences in binary and continuous outcomes, respectively. In secondary analysis, we will analyze the parents who responded before the intervention: “rarely”, “never”, or “sometimes” to ask about firearms in the homes of others when their children went to play groups and compare across interventions the proportion who changed their response to “most of the time” or “always” after the intervention using the chi-square or Fisher’s exact test. We will also use logistic regression models to analyze factors associated with the likelihood to ask about firearms in the homes of others when children go to play.

#### *Informed Consent:*

Parents of hospitalized children will be approached for written informed consent on the inpatient service by trained research personnel. Our form asks for consent to participate in the pre-intervention and post-intervention surveys, and to participate in the educational intervention, including randomization to one of the three study groups (Be SMART alone, Be SMART+ MD discussion, or the control group). Additionally the consent asks for permission to collect phone numbers in order to contact the parent/legal guardian one month later for a follow up survey. If consent is granted, a brief questionnaire will be administered followed by the intervention and very brief follow up survey.

#### *Risks:*

We do not anticipate any risks to the participants. Any information obtained that would permit identification of a participant, it will be held strictly confidential, will be used only for the purpose of this study, and will not be disclosed or released to others.

*Benefits:*

This study will examine knowledge, attitudes, and practices of parents/legal guardians regarding firearm safety and tobacco smoke exposure. While there may be no direct benefits to the participants themselves, through the educational intervention, they may increase their knowledge regarding gun safety and tobacco smoke exposure, particularly related to children, and may decide to change some of their own practices related to either or both firearm safety issues and tobacco smoke exposure and their children.

*Privacy:*

All parents/legal guardians will be assigned a study subject number. There will be no linkage of the study subject number to the hospitalized patient. A record will be kept with the study subject number to the parent/guardian name and phone number for the purpose of a follow up phone call, however, this information will be kept in a locked office in a locked cabinet accessible only to research staff. To maximize data integrity, privacy and confidentiality, all digital data related to this study will be kept secure on a password-protected computer, in a locked office. All hardcopies related to this protocol will also be kept in a locked office. All documents related to this study will be destroyed when the study is completed.

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