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Developing implementation strategies with stakeholders to promote firearm safety as a suicide prevention strategy in pediatric primary care: Project ASPIRE study protocol

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ABSTRACT

Introduction: The promotion of safe firearm practices, or firearms means restriction, is a promising but infrequently used suicide prevention strategy in the United States. *Safety Check* is an evidence-based practice for improving parental firearm safety behavior in pediatric primary care. However, providers rarely discuss firearm safety during visits, suggesting the need to better understand barriers and facilitators to promoting this approach. This study, Adolescent Suicide Prevention In Routine clinical Encounters (ASPIRE), aims to engender a better understanding of how to implement the three components of *Safety Check* as a suicide prevention strategy in pediatric primary care.

Methods and Analysis: The NIMH-funded Mental Health Research Network (MHRN), a consortium of 13 healthcare systems across the United States, affords a unique opportunity to better understand how to implement a firearm safety intervention in pediatric primary care from a system-level perspective. We will collaboratively develop implementation strategies in partnership with MHRN stakeholders. First, we will survey leadership of 96 primary care practices (i.e., practices serving children, adolescents, and young adults) within two MHRN systems to understand acceptability and use of the three components of *Safety Check* (i.e., screening, brief counseling around firearm safety, provision of firearm locks). Then, in collaboration with MHRN stakeholders, we will use intervention mapping and the Consolidated Framework for Implementation Research to systematically develop and evaluate a multi-level menu of implementation strategies for promoting firearm safety as a suicide prevention strategy in pediatric primary care.

Ethics and Dissemination: Study procedures have been approved by the University of Pennsylvania. Henry Ford Health System IRB has signed a reliance agreement with the

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 University of Pennsylvania IRB. Baylor Scott & White IRB has determined Aim 1 of the
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5 protocol qualified for exempt review and Aim 2 review is pending. Results will be submitted for
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7 publication in peer-reviewed journals.
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11 Keywords: *implementation, intervention mapping, means restriction, firearms, suicide,*
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13 *adolescent*
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For peer review only

STRENGTHS AND LIMITATIONS

Strengths

- The two participating health systems are diverse and located in two distinct geographical and cultural settings
- This study aims to engender a better understanding of how to implement the three components of a universal evidence-based firearm safety intervention (i.e., *Safety Check*) as a suicide prevention strategy in pediatric primary care. Previous studies have utilized targeted interventions focused on at-risk youth
- This study will advance the implementation science literature by using intervention mapping to systematically develop multi-level implementation strategies in partnership with stakeholders

Limitations

- The study will be conducted in two large health systems in the U.S., and the extent to which results will generalize to other health systems is unknown
- Both participating health systems are a part of the Mental Health Research Network (MHRN); health systems participating in the MHRN may have unique characteristics that may limit generalizability
- The effectiveness of *Safety Check* as a stand-alone firearm safety intervention specifically for suicide prevention in pediatric primary care is unknown

INTRODUCTION

The rate of youth suicide has increased steadily over the past 15 years.[1] The most recent statistics identify suicide as the second leading cause of death among adolescents in the United States (U.S.),[2] making this a critical age group to target for suicide prevention strategies. Firearms are the most common and most lethal method of suicide attempts in the U.S.; risk of suicide is two to five times greater in homes containing a firearm.[3] This is of great concern given that one in three American homes contain a firearm.[4] Thus, safe firearm practices in the home are of paramount importance in reducing death by suicide among youth.

Means restriction, or the promotion of safe firearm practices to make the environment safer, is a promising, although underutilized, suicide-prevention strategy. Several population-level natural experiments have supported the efficacy of means restrictions.[5] For example, in the 1960s, the United Kingdom substituted domestic gas with a non-toxic alternative, resulting in a 30% drop in the national suicide rate.[6-7] In the 1990s, the Sri Lankan government placed restrictions on the sale of toxic pesticides, the leading suicide method in the country at the time, and overall suicide rates dropped by 50%.[8] A 2006 Israeli policy designed to reduce soldier suicide required soldiers to leave their firearms on base during periods of leave, resulting in a 40% decrease in soldier suicides.[9] Estimates from case-control and simulation studies suggest that a firearm safety intervention implemented in the U.S. yielding even modest results (i.e., only ¼ of households restrict access to firearms) could lead to 3,600 to 3,900 adult lives saved annually.[5, 10] The risk of suicide for youth living in a home with firearms is at least as great as it is for adults, and implementation of a firearm safety intervention could prevent almost 500, or 11% of total youth suicide deaths by firearm each year.[11]

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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Although suicide prevention strategies for youth have traditionally been implemented in behavioral health settings,[12] only one-third of youth receive mental health treatment in the 12 months preceding a suicide attempt.[13-15] Yet four out of five youth who die by suicide will have visited primary care in the year prior to their death,[14] and 90% of youth visit primary care annually,[16] highlighting the advantages of implementing a universal prevention approach in primary care for firearm safety interventions. One intervention, *Safety Check*, a tri-pronged approach to firearm safety counseling, resulted in safer firearm storage practices in homes with children ages 2-11 years.[17] *Safety Check* includes screening about access to firearms, brief motivational interviewing informed counseling regarding firearm safety, and provision of free firearm locks.[17] In a large cluster-randomized trial of 137 pediatric primary care practices, families who received the *Safety Check* intervention were 21.4% more likely to engage in safe firearm storage practices compared to families in the control condition at six-month follow-up. Despite the substantial evidence base, as well as recommendations from the American Academy of Pediatrics[18] and Institute of Medicine,[19] the three components of *Safety Check* continue to be underutilized in U.S. pediatric primary care clinics.[10, 13]

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To maximize the likelihood that this promising intervention is translated into practice, it is essential to gain a more nuanced understanding of the implementation context from multiple levels. Importantly, it is necessary to understand barriers and facilitators to implementation that relate to characteristics of providers, organizations, and the health systems, as well as the states in which they work. Given the politically polarizing issue of gun control in America, firearm safety interventions may involve unique barriers that do not apply in implementing other safety interventions, such as seatbelts. Therefore this formative work is critical to the successful, large scale implementation of *Safety Check*.

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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The Consolidated Framework for Implementation Research (CFIR) provides a context to guide the project.[20] The CFIR[20] is an effort to synthesize the many conceptual frameworks in implementation science.[21] The five major domains that comprise the CFIR[20] include: (1) intervention characteristics (i.e., the features of an intervention); (2) outer setting (i.e., the economic, political, and social context within which an organization exists); (3) inner setting (i.e., the organizational setting); (4) characteristics of individuals involved in implementation; and (5) the implementation process (see Figure 1). In the case of *Safety Check* implementation, intervention characteristics such as terminology (e.g., means restriction versus firearm safety) may be important. At the provider level, low self-efficacy or lack of knowledge about best practices for firearm safety promotion and/or suicide prevention may contribute to provider reluctance to engage in discussions with patients about firearms.[22-25] At the inner setting, barriers and facilitators regarding availability of resources (e.g., firearm locks, educational pamphlets focused on safe storage of firearms) and organizational support (e.g., buy-in from front-desk staff and management) may be present. Outer setting barriers may include lack of policies to support implementation (e.g., absence of guidelines about firearm counseling and associated documentation in the electronic health records) and state legislation. For example, in 2011, the Florida Privacy of Firearm Owners Act was passed, which stipulates that providers must refrain from inquiring about firearm ownership and documenting firearm-related information in patients' medical record except under specific circumstances, such as when the healthcare practitioner determines that this information is relevant to the patient's safety or the safety of others. Of note, despite the stipulation permitting providers to inquire about and/or document firearms-related information when relevant to matters of safety, many providers mistakenly believe that it is illegal to discuss firearms during healthcare visits under any

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circumstances,[26] and thus, refrain from doing so. Similar legislation has passed in other states (e.g., Montana, Missouri, and Minnesota) and more restrictive legislation has been proposed elsewhere (e.g., a pending proposal in Ohio prohibits *any* inquiries related to firearm ownership or possession without exception).[26]

Intervention mapping has been used to develop a number of effective health-related programs, including those addressing sex education,[27] obesity,[28] cancer prevention,[29] osteoarthritis and low back pain.[30] Intervention mapping, used in concert with the CFIR,[20] can be applied to develop a menu of implementation strategies in a systematic and rigorous way.[31] To date, implementation strategies have not been developed methodically and have lacked rigor in their application.[32]

Objectives and Aims

Our goal in this study (Adolescent Suicide Prevention In Routine clinical Encounters; ASPIRE) is to collaboratively develop implementation strategies in partnership with stakeholders to understand how to most effectively implement a firearm safety intervention in U.S. pediatric primary care (operationally defined as including pediatrics, internal medicine, family medicine, and/or adolescent medicine). To date, there has not been a study to systematically examine factors that may impede or facilitate implementation of a firearm safety intervention as a suicide prevention strategy at the provider, organization, and system levels. This formative work is necessary to inform the development of multi-level implementation strategies to reduce death by suicide in youth. The NIMH-funded Mental Health Research Network (MHRN; www.mhresearchnetwork.org), a consortium of 13 healthcare systems across the United States, is an exceptional laboratory with established research infrastructure in which to better understand how to implement a firearm safety intervention in primary care from a system-level perspective.

Aim 1

We will survey the clinical leadership and providers of 96 primary care practices within two MHRN systems to understand (a) beliefs about the acceptability of screening, brief counseling around firearm safety, and provision of firearm locks within pediatric primary care and (b) use of these practices. Additionally, we will investigate if patient, provider, and system level characteristics predict acceptability and use of these practices.

Aim 2

In collaboration with MHRN stakeholders in these two systems, we will use intervention mapping and the CFIR[20] to systematically develop and evaluate a multi-level menu of implementation strategies for youth firearm safety as a suicide prevention strategy in pediatric primary care.

METHODS AND ANALYSIS

Setting

The MHRN is a consortium of 13 public-domain research centers based in large not-for-profit health care systems covering approximately 13 million lives in 15 U.S. states. The mission of the MHRN is to improve the management of mental health conditions by connecting research, practice and policy. We have recruited two MHRN health systems to participate in project ASPIRE. *Henry Ford Health System (HFHS)* has 36 primary care practices and serves 1 million lives annually; 12% percent of those individuals are under the age of 18. Thirty-eight percent are ethnic minorities, which is important, given evidence that there are widening disparities in African American youth and suicide.[33] *Baylor Scott & White (BSW)* has 60 primary care practices and serves 630,000 lives annually; nearly 20% of those individuals are under the age of 18. This system is located in Texas where proposed legislation prohibiting physicians from

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 asking about firearm ownership is currently under review,[34] and includes a number of rural
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5 practices which is important given disparities in rural and urban suicide.[31]
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Aim 1

Rationale

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10 We will survey clinical leadership and providers of pediatric primary care practices
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12 within the two systems of interest to understand variation in acceptability and use of the three
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14 components that comprise the *Safety Check* intervention.
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Firearm Safety Intervention

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22 The *Safety Check* intervention is an evidence-based firearm safety intervention targeted
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24 to parents of children aged 2-11.[17] It includes three components: screening, brief counseling,
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26 and provision of firearm locks. Given evidence that providers perceive components of evidence-
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28 based practices (EBP) differently,[35] we have elected to examine the acceptability and use of
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30 each of the three individual components separately rather than ask questions about the
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32 intervention as a whole. Additionally, in Aim 1, we are hoping to extend research on *Safety*
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34 *Check* by understanding acceptability and use in youth for suicide prevention. In the original
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36 study, the intervention was conducted on a different age group, with a focus on safe firearm
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38 storage for injury prevention; the firearm intervention was bundled with other injury prevention
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40 strategies (e.g., use of timeout). This will allow us to understand to what extent *Safety Check*
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42 adaptations are needed to maximize the success of broad health systems implementation efforts.
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Sample

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50 The target population for this survey will be clinical leadership and providers at all
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52 pediatric primary care practices within the participating MHRN sites. Current estimates suggest
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54 that the number of practices across both systems is 96. We will recruit two individuals (one
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3 physician manager and one other physician provider) at each of the 96 practices in the two health
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5 systems ($N = 192$; we anticipate 80% recruitment rate for a total n of 154).[36] A brief electronic
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7 survey will be sent to these clinical leaders and providers to determine acceptability and use of
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9 the three components of the Safety Check intervention at that site. The required elements of
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11 informed consent will be described on the first page of the electronic survey and, if they agree to
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13 participate, clinical leadership and providers will consent by proceeding to the second page of
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15 the electronic survey. We have obtained a waiver of written documentation of consent from the
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17 University of Pennsylvania Institutional Review Board (IRB). To ascertain our sample,
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19 investigators at each site will identify the physician managers of pediatric practices within their
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21 system and will use electronic health records to identify primary care providers who treat youth
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23 in those practices. To enhance participation, and based upon previous work suggesting that
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25 participation is very high if the request comes from a contact within the system, investigators at
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27 each site will initiate contact with potential participants at their site and send the web-based
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29 survey. Each participant who completes the survey will receive a \$10 gift card.
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36 Data Sources

37 38 *Primary data*

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41 The survey will query about acceptability and use of the three components of *Safety*
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43 *Check*. All of the items in the survey have undergone cognitive response testing with physician
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45 managers and physician providers in pediatric primary care to identify ambiguous wording,
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47 awkward instructional sets, and portions that may have been difficult to complete.[36]
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49 Respondents have also evaluated the face validity of the survey during this process. In addition,
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51 before and after piloting, content validity was evaluated by experts in suicide research and
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53 primary care.
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Secondary data

We will use publicly available data sources including data from the MHRN data warehouse, which includes a combination of electronic health records, insurance claims data, and the National Center for Health Statistics National Vital Statistics System.[36] A programmer from each MHRN system will extract information from the data warehouse for participating providers: patient demographics (age, gender, race and ethnicity and patient language); encounters (number of encounters; type of provider seen; e-codes related to suicide and self-inflicted injury);[36] provider demographics (specialty, age, gender, race, and year graduated); census (socioeconomic indicators for patients based on geocoded patient addresses); public census data (education, income and poverty); and mortality (patient death by suicide; this is only currently available in HFHS). Additionally, we will extract youth (aged 12-24) suicide deaths over the past five years by firearm at the county-level for each primary care practice location from the National Vital Statistics System.[36]

Analyses

Our quantitative analyses will identify the patient, provider, and site characteristics associated with acceptability and use of the three components. To examine the effect of patient, provider, and site factors on acceptability, we will use three separate ordinary least squares regression models. For each model, the dependent variable will be the mean of the acceptability items on the survey, measured on a 6-point scale. The independent variables will include measures of patient demographics (e.g., ethnicity/race), enrollment, provider demographics (e.g., age), and geographically derived socioeconomic and mortality indicators. Analyses will be conducted separately for the physician manager and physician provider samples. In the leadership group, respondents will report the percent of providers in the practice who make use

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3 of each component. We will use linear regression models to examine the extent to which the
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5 independent variables predict use of the three components in pediatric practices. With 77 survey
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7 responses in each group, our models will have 80% power to detect a moderate effect ($r^2=.09$) of
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9 the independent variable while controlling for 7 covariates. In the provider sample we will use
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11 logistic regression to predict any use (versus no use) of the three practices. Assuming 77 survey
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13 responses and that 24% of providers endorse use of each *Safety Check* component, we will be
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15 fully powered to detect between group differences of 11% versus 36% in use of any of the three
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17 components of *Safety Check*. For both samples, we will use multinomial logistic regression to
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19 model, among responders who report any use of each component at their site, the frequency with
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21 which they are used (rarely, sometimes, always). All models will control for health system.
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26 27 Outcome

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29 Based on the results generated from our survey, we will create a summary of
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31 acceptability and use of the three components of *Safety Check* across each system to present as
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33 part of Aim 2 to stakeholders.
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36 37 Aim 2

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39 In collaboration with MHRN stakeholders in these two systems, we will use intervention
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41 mapping and the CFIR[20] to systematically develop and evaluate a multi-level menu of
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43 implementation strategies for a firearm safety intervention as a suicide prevention strategy in
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45 pediatric primary care.
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48 49 Rationale

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51 While intervention mapping has been proposed as a method for designing
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53 implementation strategies,[36] it has yet to be widely used in this way. In a recently published
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55 proof-of-concept study, intervention mapping was employed to develop a multi-level
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3 implementation strategy to increase physicians' adherence to guidelines for depression.[36]
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5 Compared to implementation as usual, the implementation strategy developed using intervention
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7 mapping was found to increase adherence to the guidelines.[36] In the proposed study, we are
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9 applying these tools to the development of multi-level implementation strategies to change
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11 provider, organization, and system behavior around firearm safety-promotion practices in
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13 pediatric primary care. The approach is consistent with the CFIR.[20] To accomplish this, we
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15 will focus on the fifth step of intervention mapping, which focuses on planning for adoption,
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17 implementation, and sustainment.[37]
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22 Procedure

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24 The target behavior is implementation of a firearm safety intervention in pediatric
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26 primary care intended to be a suicide prevention strategy. As in other studies, the final content to
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28 emerge from intervention mapping cannot yet be specified because it depends on information
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30 gleaned from the intervention mapping process.
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34 *Needs assessment*

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36 Using the CFIR to guide us, we will assess the needs of stakeholders who will be
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38 impacted by implementing a firearm safety intervention in pediatric primary care.[20] We will
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40 conduct semi-structured interviews with MHRN stakeholders from the following groups: (a)
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42 parental and youth dyads (ages 12-24), (b) physician providers, (c) non-physician providers
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44 (nurses, physician assistants, medical assistants), (d) leaders of primary care practices, (e) leaders
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46 of behavioral health, (f) leaders of quality improvement in each system, (g) system leaders (h)
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48 third-party payers, and (i) members of national credentialing bodies (e.g., American Academy of
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50 Pediatrics). We will use purposive sampling[38] to recruit approximately six individuals from
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52 each stakeholder group and sample across the two systems to ensure diversity in responses. We
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3 will also return to Aim 1 participants and invite their participation and ask them who else in their
4 system we should interview. We estimate we will conduct approximately 54 interviews; however
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6 this number will depend upon thematic saturation. In the case of providers and leaders of primary
7 care practices, we will use stratified sampling to ensure that we recruit participants endorsing use
8 of at least one of the *Safety Check* components as reported in Aim 1. In Part I of the interview,
9 we will present practice stakeholders with the aggregated data on their system collected in Aim 1
10 and use the qualitative interviews as an opportunity to understand this data in a more nuanced
11 fashion (quan→QUAL)[39] as consistent with previous studies.[40] In Part II of the interview,
12 we will use the CFIR[20] to query around barriers and facilitators at the intervention, provider,
13 inner, and outer setting level, and the support needed to be able to provide a firearm safety
14 intervention in daily practice. In part III of the interview, we will use intervention mapping to
15 guide questions that identify program adopters, implementers, and sustainers; as well as the
16 specific behaviors that each set of stakeholders need to engage in to adopt, implement, and
17 sustain the *Safety Check* intervention. Participants will be paid \$25 for participating in individual
18 interviews.
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38 We will recruit stakeholders using methods described in a similar MHRN study.[36] To
39 sample youth and young adult participants, investigators at each site will identify and recruit
40 random samples of 100 English-speaking youth and their parents or legal guardians aged 12-17
41 and young adults 18-24 who visited a primary pediatric care site within the previous three
42 months from the electronic health records. Youth participants and their guardians will be sent an
43 invitation letter with an opt-out card with postage. After 10 days, participants who have not
44 returned the opt-out card will be called by phone and invited to participate in our study. To
45 sample providers, clinical leadership in pediatric primary care and behavioral health, leaders of
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3 quality improvement, and system leaders, investigators at each site will identify the appropriate
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5 individuals to contact within their system, personally reach out to each of these individuals and
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7 invite them to participate via phone or email. We will work with clinical leadership in pediatric
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9 primary care to email invitations to providers inviting them to participate.
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13 Interviews will be digitally recorded with the participants' permission, professionally
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15 transcribed, and loaded into NVivo software for data management and analysis. Analysis will be
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17 guided by integrated theory, which incorporates inductive and deductive features.[41] This
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19 approach uses an inductive process of iterative coding to identify recurrent themes, categories,
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21 and relationships in qualitative data. A comprehensive coding scheme is then developed on the
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23 basis of this analysis and applied to the data in order to produce a fine-grained descriptive
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25 analysis. A priori codes informed by CFIR[20] will also be applied (i.e., deductive approach).
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27 The research team will separately code a sample of the transcripts and compare their application
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29 of the coding scheme to assess the reliability and robustness of the coding scheme. Any
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31 disagreements in coding will be resolved through team discussion.
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36 37 *Implementation strategies*

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39 We will delineate implementation strategies based on existing theory, the scientific
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41 literature, and the information gleaned from our stakeholder interviews. Consistent with the
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43 intervention mapping process, these implementation strategies will be translated into practical
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45 strategies using a theory-based causal model. We hypothesize that a model that accounts for
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47 individual behavior and the environment would be most salient here, such as the Theory of
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49 Planned Behavior or Social Cognitive Theory.[42-43] Using whatever theory(s) best fit the
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51 identified determinants for the intervention, individual, inner, and outer setting; we will then
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53 delineate practical strategies which will become the multi-level menu of implementation
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3 strategies. For example, if providers are unfamiliar with firearm safety counseling, training may
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5 be identified as a promising implementation strategy whereas if providers are uncomfortable
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7 with implementing firearm safety counseling (i.e., low self-efficacy), specific intervention to
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9 improve their self-efficacy is warranted.
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Evaluation of feasibility and acceptability

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13 We will evaluate the multi-level menu of implementation strategies by returning to the
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15 initial stakeholders who completed the needs assessment and asking them to complete a brief
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17 survey assessing feasibility and acceptability. These participants will be paid an additional \$25
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19 for completing this survey. We will also present our findings to leadership of each MHRN site
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21 and have them rate the feasibility and acceptability of the strategies. This will allow us to
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23 generate a list of the most feasible and acceptable implementation strategies within each level;
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25 which will then be tested in a larger effectiveness-implementation trial.[44]
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DISCUSSION

Innovation

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37 There are conceptual and methodological innovations in the proposed study, the former
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39 referring to the potential to directly impact youth with suicidal thoughts and behaviors.
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41 Specifically, this study seeks to understand how to implement a universal firearm safety
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43 intervention in primary care. Previous studies have utilized targeted intervention approaches.[45]
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45 However, youth experiencing suicidal thoughts and behaviors often do not access services during
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47 times of heightened risk,[46] suggesting a universal approach has the potential to reach more
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49 youth and, ultimately, reduce suicide deaths. Addressing a highly prevalent social burden and
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51 understanding how health systems and their patients perceive a minimally intrusive yet common
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53 sense approach to improving firearm safety has the potential to improve patient quality of life
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3 while better tailoring limited healthcare resources. Methodological innovation refers to the
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5 impact of the proposed work on systematic and rigorous methods to develop implementation
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7 strategies. To date, few studies have used intervention mapping to develop a multilevel menu of
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9 implementation strategies.[37, 47-48] Further, this study will use the CFIR[20] as part of this
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11 process to develop implementation strategies at the individual (e.g., providers), inner setting
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13 (e.g., pediatric practices), outer setting, and intervention characteristics levels. Evidence from the
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15 health services literature suggests that multi-level implementation strategies may be more
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17 effective than single-level implementation strategies.[49-51]
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22 **Limitations**

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24 Despite the strengths of the current study, several limitations should be noted. A primary
25
26 limitation is that the study will be conducted in two health systems in the U.S., and the extent to
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28 which results will generalize to other health systems is unknown. Moreover, both health systems
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30 are a part of the MHRN; health systems participating in the MHRN may have unique
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32 characteristics that may limit the generalizability of study findings to other healthcare systems
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34 (e.g., an existing infrastructure to support partnerships with external researchers). Nonetheless,
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36 the diversity of the two systems, which are located in two distinct geographical and cultural
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38 settings, may mitigate threats to external validity. In addition, the *Safety Check* intervention was
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40 initially developed and tested as a broader safety initiative for parents of young children in which
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42 firearm storage was one of several safety targets. As such, the effectiveness of Safety Check as a
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44 stand-alone firearm safety intervention specifically for suicide prevention in pediatric primary
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46 care remains unknown. Additionally, the effectiveness of the intervention has been established
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48 based on parental self-report. It is possible that some parents may not be forthcoming when
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50 discussing matters related to firearm storage practices. Similarly, it is possible that providers
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3 and/or practice leaders may be reluctant to disclose information related to firearm safety given
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5 the sensitive nature of the topic.
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8 **Impact**

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10 The work proposed has the potential to impact public health in two important ways. First,
11 it will be a critical step in the research agenda of reducing death by suicide in children and
12 adolescents by engendering a better understanding of how to implement an evidence-based
13 firearms safety intervention, specifically *Safety Check*, in pediatric primary care. Second, it will
14 advance the implementation science literature by providing a process, informed by the CFIR,[20]
15 for how to systematically develop implementation strategies in partnership with stakeholders
16 across multiple levels of implementation (i.e., providers, inner and outer contexts).
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27 **ETHICS AND DISSEMINATION**

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29 Study procedures have been approved by the University of Pennsylvania (Protocol
30 number 824449). Henry Ford Health System IRB has signed a reliance agreement with the
31 University of Pennsylvania IRB. Baylor Scott & White IRB has determined Aim 1 of the
32 protocol qualified for exempt review and Aim 2 review is pending. We began data collection for
33 this project in August, 2016. Results of Aims 1 and 2 will be submitted for publication in peer-
34 reviewed journals.
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43 **DISCLOSURES**

44 **Authors' Contributions**

45
46 RB is the principal investigator for the study protocol. RB generated the idea and designed the
47 study, and approved all changes. CBW was the primary writer of the manuscript and is the
48 project director for the study. CBW, SJH, SM, BA, JZ, JF, GB, AL, and RB all made substantial
49 contributions to study conception and design. All authors reviewed and provided feedback for
50 this manuscript. The final version of this manuscript was vetted and approved by all authors.
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Competing Interests

The authors declare that they have no competing interests.

Data Sharing Statement

The data from this project will be available on request via email.

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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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Figure 1. Study guiding framework

Figure Legend: Figure adapted from Damschroder [52].

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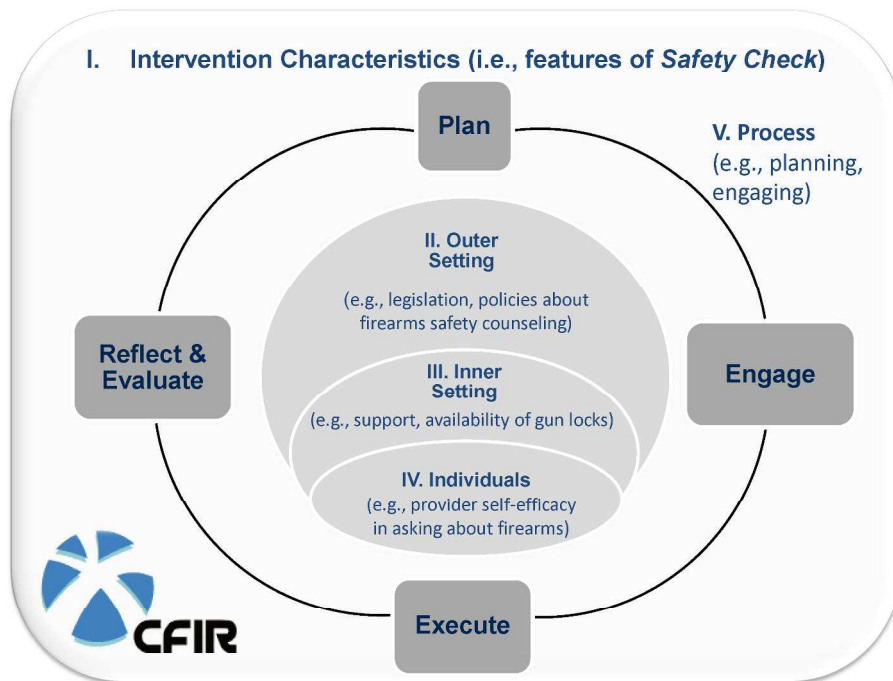


Figure 1. Study guiding framework
Figure Legend: Figure adapted from Damschroder [52].

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BMJ Open

Developing implementation strategies with stakeholders to promote firearm safety as a suicide prevention strategy in pediatric primary care: A study protocol

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Manuscripts

Developing implementation strategies with stakeholders to promote firearm safety as a suicide prevention strategy in pediatric primary care: A study protocol

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ABSTRACT

Introduction: The promotion of safe firearm practices, or firearms means restriction, is a promising but infrequently used suicide prevention strategy in the United States. *Safety Check* is an evidence-based practice for improving parental firearm safety behavior in pediatric primary care. However, providers rarely discuss firearm safety during visits, suggesting the need to better understand barriers and facilitators to promoting this approach. This study, Adolescent Suicide Prevention In Routine clinical Encounters (ASPIRE), aims to engender a better understanding of how to implement the three firearm components of *Safety Check* as a suicide prevention strategy in pediatric primary care.

Methods and Analysis: The NIMH-funded Mental Health Research Network (MHRN), a consortium of 13 healthcare systems across the United States, affords a unique opportunity to better understand how to implement a firearm safety intervention in pediatric primary care from a system-level perspective. We will collaboratively develop implementation strategies in partnership with MHRN stakeholders. First, we will survey leadership of 82 primary care practices (i.e., practices serving children, adolescents, and young adults) within two MHRN systems to understand acceptability and use of the three firearm components of *Safety Check* (i.e., screening, brief counseling around firearm safety, provision of firearm locks). Then, in collaboration with MHRN stakeholders, we will use intervention mapping and the Consolidated Framework for Implementation Research to systematically develop and evaluate a multi-level menu of implementation strategies for promoting firearm safety as a suicide prevention strategy in pediatric primary care.

Ethics and Dissemination: Study procedures have been approved by the University of Pennsylvania. Henry Ford Health System and Baylor Scott & White IRBs have ceded oversight

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 to the University of Pennsylvania IRB. Results will be submitted for publication in peer-
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5 reviewed journals.
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8 Keywords: *implementation, intervention mapping, means restriction, firearms, suicide,*
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STRENGTHS AND LIMITATIONS

Strengths

- The two participating health systems are diverse and located in two distinct geographical and cultural settings.
- This study aims to engender a better understanding of how to implement the three firearm components of a universal evidence-based safety intervention (i.e., *Safety Check*) as a suicide prevention strategy in pediatric primary care.
- This study will advance the implementation science literature by using intervention mapping to systematically develop multi-level implementation strategies in partnership with stakeholders.

Limitations

- The study will be conducted in two large health systems in the U.S., and the extent to which results will generalize to other health systems is unknown.
- Both participating health systems are a part of the Mental Health Research Network (MHRN); health systems participating in the MHRN may have unique characteristics that may limit generalizability.
- The firearm components of *Safety Check* have previously been bundled with other injury prevention strategies, thus the effectiveness of *Safety Check* as a stand-alone firearm safety intervention specifically for suicide prevention in pediatric primary care is unknown.

INTRODUCTION

The rate of youth suicide has increased steadily over the past 15 years.¹ The most recent statistics identify suicide as the second leading cause of death among adolescents in the United States (U.S.),² making this a critical age group to target for suicide prevention strategies.

Firearms are the most common and most lethal method of suicide deaths in the U.S.; risk of suicide is two to five times greater in homes containing a firearm.³ This is of great concern given that one in three U.S. homes contain a firearm.^{4,5} Thus, safe firearm practices in the home are of paramount importance in reducing death by suicide among youth.

Lethal means restriction refers to the promotion of practices to make the environment safer by reducing access to potentially lethal methods of suicide. Several population-level natural experiments have supported the efficacy of means restrictions.⁶ For example, in the 1960s, the United Kingdom substituted domestic gas with a non-toxic alternative, resulting in a 30% drop in the national suicide rate.^{7,8} In the 1990s, the Sri Lankan government placed restrictions on the sale of toxic pesticides, the leading suicide method in the country at the time, and overall suicide rates dropped by 50%.⁹ A 2006 Israeli policy designed to reduce soldier suicide required soldiers to leave their firearms on base during periods of leave, resulting in a 40% decrease in soldier suicides.¹⁰

Reducing access to firearms is one promising, although underutilized, suicide-prevention strategy. Firearm means restriction strategies include the promotion of safe firearm storage practices as well as gun control legislation to reduce availability to firearms generally, and to children in particular. In the U.S., broadly reducing access to firearms has been deemed infeasible.¹¹ Child access protection laws are associated with modest effects.¹² Estimates from case-control and simulation studies suggest that a firearm safety intervention implemented in the

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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U.S. yielding even modest results (i.e., only ¼ of households restrict access to firearms) could lead to 3,600 to 3,900 adult lives saved annually.^{6,13}

Although suicide prevention strategies for youth have traditionally been implemented in behavioral health settings,¹⁴ only one-third of youth receive mental health treatment in the 12 months preceding a suicide attempt.¹⁵⁻¹⁷ Yet four out of five youth who die by suicide will have visited primary care in the year prior to their death,¹⁶ and 90% of youth visit primary care annually,¹⁸ highlighting the advantages of implementing a universal prevention approach in primary care for firearm safety interventions. One intervention, *Safety Check*, includes a tri-pronged approach to firearm safety counseling and resulted in safer firearm storage practices in homes with children ages 2-11 years.¹⁹ *Safety Check* in its original form includes screening about access to firearms, brief motivational interviewing informed counseling regarding firearm safety, and provision of free firearm locks bundled with other injury prevention strategies (e.g., use of timeout).¹⁹ In a large cluster-randomized trial of 137 pediatric primary care practices, parents who received the *Safety Check* intervention reported they were 21.4% more likely to engage in safe firearm storage practices compared to parents in the control condition at six-month follow-up. Despite the substantial evidence base, as well as recommendations from the American Academy of Pediatrics²⁰ and Institute of Medicine,²¹ the three firearm components of *Safety Check* continue to be underutilized in U.S. pediatric primary care clinics.^{13,15,22}

To maximize the likelihood that this promising intervention is translated into practice, it is essential to gain a more nuanced understanding of the implementation context from multiple levels. Importantly, it is necessary to understand barriers and facilitators to implementation that relate to characteristics of providers, organizations, and the health systems, as well as the states in which they work. These perspectives have been understudied. In the case of firearms, it is also

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3 important to obtain the perspectives of both firearm-owning and non-owning stakeholders when
4 possible.²³ While information can be gleaned from efforts to implement other safety
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6 interventions, such as seatbelts, given that doctor-patient firearm conversations have been the
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8 topic of legislation in the U.S., firearm safety interventions may involve unique barriers.
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10 Therefore this formative work is critical to the successful, large scale implementation of *Safety*
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17 The Consolidated Framework for Implementation Research (CFIR) provides a context to
18 guide the project.²⁴ The CFIR²⁴ is an effort to synthesize the many conceptual frameworks in
19 implementation science.²⁵ The five major domains that comprise the CFIR²⁴ include: (1)
20 intervention characteristics (i.e., the features of an intervention); (2) outer setting (i.e., the
21 economic, political, and social context within which an organization exists); (3) inner setting
22 (i.e., the organizational setting); (4) characteristics of individuals involved in implementation
23 (e.g., providers); and (5) the implementation process (see Figure 1). In the case of *Safety Check*
24 implementation, intervention characteristics such as terminology (e.g., means restriction versus
25 firearm safety, endorsement of written materials by firearm organizations) may be important. At
26 the provider level, low self-efficacy or lack of knowledge about best practices for firearm safety
27 promotion and/or suicide prevention may contribute to provider reluctance to engage in
28 discussions with patients about firearms.²⁶⁻²⁹ At the inner setting, barriers and facilitators
29 regarding availability of resources (e.g., firearm locks, educational pamphlets focused on safe
30 storage of firearms) and organizational support (e.g., buy-in from front-desk staff and
31 management) may be present. Outer setting barriers may include lack of policies to support
32 implementation (e.g., absence of guidelines about firearm counseling and associated
33 documentation in the electronic health records) and state legislation. For example, the recently
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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 repealed Florida Privacy of Firearm Owners Act, passed in 2011, stipulated that providers must
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5 refrain from inquiring about firearm ownership and documenting firearm-related information in
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7 patients' medical record except under specific circumstances, such as when the healthcare
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9 practitioner determines that this information is relevant to the patient's safety or the safety of
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11 others. Of note, despite the stipulation permitting providers to inquire about and/or document
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13 firearms-related information when relevant to matters of safety, many providers mistakenly
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15 believed that it was illegal to discuss firearms during healthcare visits under any circumstances,³⁰
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17 and thus, refrained from doing so. Similar legislation has passed in other states (e.g., Montana,
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19 Missouri, and Minnesota) and more restrictive legislation has been proposed elsewhere (e.g., a
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21 pending proposal in Ohio prohibits *any* inquiries related to firearm ownership or possession
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23 without exception).³⁰
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29 Intervention mapping is a systematic approach to intervention development that has been
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31 used to develop a number of effective health-related programs, including those addressing sex
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33 education,³¹ obesity,³² cancer prevention,³³ osteoarthritis, and low back pain.³⁴ Intervention
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35 mapping, used in concert with the CFIR,²⁴ can be applied to develop a menu of implementation
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37 strategies in a systematic and rigorous way by helping identify who should be involved in
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39 adoption, implementation and maintenance of interventions; as well as what specific behaviors
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41 they need to engage in.³⁵ To date, implementation strategies have not been developed
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43 methodically and have lacked rigor in their application.³⁶
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Objectives and Aims

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49 Our goal in this study (Adolescent Suicide Prevention In Routine clinical Encounters;
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51 ASPIRE) is to collaboratively develop implementation strategies in partnership with stakeholders
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53 to understand how to most effectively implement a firearm safety intervention in U.S. pediatric
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primary care (operationally defined as including pediatrics, internal medicine, family medicine, and/or adolescent medicine). To date, there has not been a study to systematically examine factors that may impede or facilitate implementation of a firearm safety intervention as a suicide prevention strategy at the provider, organization, and system levels. This formative work is necessary to inform the development of multi-level implementation strategies to reduce death by suicide in youth. The NIMH-funded Mental Health Research Network (MHRN; www.mhresearchnetwork.org), a consortium of 13 healthcare systems across the United States, is an exceptional laboratory with established research infrastructure in which to better understand how to implement a firearm safety intervention in primary care from a system-level perspective.

Aim 1

We will survey the clinical leadership and providers of 82 primary care practices within two MHRN systems to understand (a) beliefs about the acceptability of screening, brief counseling around firearm safety, and provision of firearm locks within pediatric primary care and (b) use of these practices. Additionally, we will investigate if patient, provider, and system level characteristics predict acceptability and use of these practices.

Aim 2

In collaboration with MHRN stakeholders in these two systems, we will use intervention mapping and the CFIR²⁴ to systematically develop and evaluate a multi-level menu of implementation strategies for youth firearm safety as a suicide prevention strategy in pediatric primary care.

METHODS AND ANALYSIS

We began data collection for this project in August, 2016. The study is expected to conclude in April, 2018.

Setting

The MHRN is a consortium of 13 public-domain research centers based in large not-for-profit health care systems covering approximately 13 million lives in 15 U.S. states. The mission of the MHRN is to improve the management of mental health conditions by connecting research, practice and policy. We have recruited two MHRN health systems to participate in project ASPIRE. *Henry Ford Health System (HFHS)* has 37 primary care practices and serves 1 million lives annually; 12% percent of those individuals are under the age of 18. Thirty-eight percent are ethnic minorities, which is important, given evidence that there are widening racial disparities among youth in the U.S. such that suicide has increased among black children while decreasing among white children.³⁷ *Baylor Scott & White (BSW)* has 45 primary care practices and serves 630,000 lives annually; nearly 20% of those individuals are under the age of 18. This system is located in Texas where proposed legislation prohibiting physicians from asking about firearm ownership is currently under review,³⁸ and includes a number of rural practices which is important given evidence that suicide rates among adolescents and adults are higher in rural vs. urban communities and rural-urban disparities are increasing over time.^{35,39}

Aim 1

Rationale

We will survey clinical leadership and providers of pediatric primary care practices within the two systems of interest to understand variation in acceptability and use of the three firearm components that comprise the *Safety Check* intervention.

Firearm Safety Intervention

The *Safety Check* intervention is an evidence-based safety intervention targeted to parents of children aged 2-11.¹⁹ It includes three firearm components: screening, brief counseling, and

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3 provision of firearm locks. Given evidence that providers perceive components of evidence-
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5 based practices (EBP) differently,⁴⁰ we have elected to examine the acceptability and use of each
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7 of the three individual components separately rather than ask questions about the intervention as
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9 a whole. Additionally, in Aim 1, we are hoping to extend research on *Safety Check* by
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11 understanding acceptability and use in youth for suicide prevention. In the original study¹⁹
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13 examining the efficacy of *Safety Check* the intervention was conducted on a different age group,
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15 with a focus on safe firearm storage for injury prevention; the firearm intervention was bundled
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17 with other injury prevention strategies (e.g., use of timeout). This will allow us to understand to
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19 what extent *Safety Check* adaptations are needed to maximize the success of broad health
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21 systems implementation efforts.
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26 27 Sample

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29 The target population for this survey will be clinical leadership and providers at all
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31 pediatric primary care practices within the participating MHRN sites. Current estimates suggest
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33 that the number of practices across both systems is 82. We elected to recruit all leaders (i.e.,
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35 physician managers) of pediatric primary care practices and all physicians who had seen 100 or
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37 more youth patients within the preceding one year from each of the 82 practices in the two
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39 health systems ($N = 261$; we anticipate 80% recruitment rate for a total n of 209).⁴¹ A brief
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41 electronic survey will be sent to these clinical leaders and providers to determine acceptability
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43 and use of the three firearm components of the *Safety Check* intervention at that site. The
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45 required elements of informed consent will be described on the first page of the electronic survey
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47 and, if they agree to participate, clinical leadership and providers will consent by proceeding to
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49 the second page of the electronic survey. We have obtained a waiver of written documentation of
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51 consent from the University of Pennsylvania Institutional Review Board (IRB). To ascertain our
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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 sample, investigators at each site will identify the physician managers of pediatric practices
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5 within their system and will use electronic health records to identify primary care providers who
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7 treat youth in those practices. To enhance participation, and based upon previous work
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9 suggesting that participation is very high if the request comes from a contact within the system,
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11 investigators at each site will initiate contact with potential participants at their site and send the
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13 web-based survey. Each participant who completes the survey will receive a \$10 gift card.
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Data Sources

Primary data

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22 The survey will query about acceptability and use of the three firearm components of
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24 *Safety Check* as well as relevant demographic information (e.g., practice experience, firearm
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26 ownership). Sample questions include: “Asking all caregivers about the presence of firearms in
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28 the home would be an acceptable suicide prevention strategy in my practice” (rated from 1 =
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30 Strongly Disagree to 6 = Strongly Agree) and “How often do you screen caregivers of youth for
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32 the presence of a firearm in the home of youth” (rated from 0 = Never to 4 = Always). All of the
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34 items in the survey have undergone cognitive response testing with physician managers and
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36 physician providers in pediatric primary care to identify ambiguous wording, awkward
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38 instructional sets, and portions that may have been difficult to complete.⁴¹ Respondents have also
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40 evaluated the face validity of the survey during this process. In addition, before and after
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42 piloting, content validity was evaluated by experts in suicide research and primary care.
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Secondary data

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50 We will use publicly available data sources including data from the MHRN data
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52 warehouse, which includes a combination of electronic health records, insurance claims data, and
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54 the National Center for Health Statistics National Vital Statistics System.⁴¹ A programmer from
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each MHRN system will extract information from the data warehouse for participating providers: patient demographics (age, gender, race, ethnicity, patient language, Patient Health Questionnaire-9 [PHQ-9]⁴² score and diagnostic codes); encounters (e-codes related to suicide and self-inflicted injury);⁴¹ provider demographics (specialty, age, gender, race, ethnicity and year graduated); census (socioeconomic indicators for patients based on geocoded patient addresses); public census data (education, income and poverty); and mortality (patient death by suicide; this is only currently available in HFHS). Additionally, we will extract youth (aged 12-24) suicide deaths over the past five years at the county-level for each primary care practice location from the National Vital Statistics System.⁴¹ These data will be used as predictor variables in analyses examining characteristics associated with acceptability and use of firearm safety strategies.

Analyses

Our quantitative analyses will identify the patient, provider, and site characteristics associated with acceptability and use of the three components. To examine the effect of patient, provider, and site factors on acceptability, we will use three separate ordinary least squares regression models. For each model, the dependent variable will be the mean of the acceptability items on the survey, measured on a 6-point scale. The independent variables will include measures of patient demographics (e.g., ethnicity/race), enrollment, provider demographics (e.g., age), and geographically derived socioeconomic and mortality indicators. Analyses will be conducted separately for the physician manager and physician provider samples when questions were worded differently (e.g., “I would consider using this strategy in my practice” for physicians and “I would consider asking the providers in my practice to use this strategy” for managers). For questions that are worded identically (e.g., “Caregivers in my practice would

view this strategy as intrusive”) we will run a single model and include responder type as a covariate.

In the physician manager group, respondents will report the percent of providers in the practice who make use of each component. We will use linear regression models to examine the extent to which the independent variables predict use of the three components in pediatric practices. With 77 survey responses in each group, our models will have 80% power to detect a moderate effect ($r^2=.09$) of the independent variable while controlling for 7 covariates. In the provider sample we will use logistic regression to predict any use (versus no use) of the three practices. Assuming 77 survey responses and that 24% of providers endorse use of each *Safety Check* component, we will be fully powered to detect between group differences of 11% versus 36% in use of any of the three firearm components of *Safety Check*. For both samples, we will use multinomial logistic regression to model, among responders who report any use of each component at their site, the frequency with which they are used (rarely, sometimes, always). All models will control for health system.

Outcome

Based on the results generated from our survey, we will create a summary of acceptability and use of the three firearm components of *Safety Check* across each system to present as part of Aim 2 to stakeholders.

Aim 2

In collaboration with MHRN stakeholders in these two systems, we will use intervention mapping and the CFIR²⁴ to systematically develop and evaluate a multi-level menu of implementation strategies for a firearm safety intervention as a suicide prevention strategy in pediatric primary care.

Rationale

While intervention mapping has been proposed as a method for designing implementation strategies,⁴¹ it has yet to be widely used in this way. In a recently published proof-of-concept study, intervention mapping was employed to develop a multi-level implementation strategy to increase physicians' adherence to guidelines for depression.⁴¹ Compared to implementation as usual, the implementation strategy developed using intervention mapping was found to increase adherence to the guidelines.⁴¹ In the proposed study, we are applying these tools to the development of multi-level implementation strategies to change provider, organization, and system behavior around firearm safety-promotion practices in pediatric primary care. The approach is consistent with the CFIR.²⁴ To accomplish this, we will focus on the fifth step of intervention mapping, which focuses on planning for adoption, implementation, and sustainment.⁴³

Procedure

The target behavior is implementation of a firearm safety intervention in pediatric primary care intended to be a suicide prevention strategy. As in other studies, the final content to emerge from intervention mapping cannot yet be specified because it depends on information gleaned from the intervention mapping process.

Needs assessment

Using the CFIR to guide us, we will assess the needs of stakeholders who will be impacted by implementing a firearm safety intervention in pediatric primary care²⁴. We will conduct semi-structured interviews with MHRN stakeholders from the following groups: (a) parents of youth ages 12-24, (b) physician providers, (c) non-physician providers (nurses, physician assistants, medical assistants), (d) leaders of primary care practices, (e) leaders of

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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behavioral health, (f) leaders of quality improvement in each system, (g) system leaders (h) third-party payers, and (i) members of national credentialing bodies and professional organizations (e.g., American Academy of Pediatrics). We will use purposive sampling⁴⁴ to recruit approximately six individuals from each stakeholder group (three per health system) and sample across the two systems to ensure diversity in responses. We will also return to Aim 1 participants and invite their participation and ask them who else in their system we should interview. We estimate we will conduct approximately 54 interviews; however this number will depend upon thematic saturation (i.e., when no new ideas or themes are identified in subsequent interviews⁴⁵). We will use purposive sampling to recruit a sample of parents that includes at least 67% firearm owners. Fifty percent of those firearm-owning parents will also be parents of youth at high risk for suicide based on medical records (i.e., PHQ-9 scores). In the case of providers and leaders of primary care practices, we will use stratified sampling to ensure that we recruit participants endorsing use of at least one of the *Safety Check* firearm components as reported in Aim 1 and at least 50% firearm owners as reported in Aim 1. In Part I of the interview, we will present practice stakeholders with the aggregated data on their system collected in Aim 1 and use the qualitative interviews as an opportunity to understand this data in a more nuanced fashion (quan→QUAL)⁴⁶ as consistent with previous studies.⁴⁷ For example, “Your practice reported that about 50% of providers at your site screen for firearms in the home. Can you tell me more about how this is usually done?” In Part II of the interview, we will use the CFIR²⁴ to query around barriers and facilitators at the intervention, provider, inner, and outer setting level, and the support needed to be able to provide a firearm safety intervention in daily practice (e.g., “What kinds of changes or alterations to the intervention do you think would be needed for you to use it effectively?” and “What resources or support would be needed to effectively implement

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3 screening, counseling, and gun lock provision in your setting?”). In part III of the interview, we
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5 will use intervention mapping to guide questions that identify program adopters, implementers,
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7 and sustainers; as well as the specific behaviors that each set of stakeholders need to engage in to
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9 adopt, implement, and sustain the *Safety Check* components (e.g., “Who, specifically, in your
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11 health system would need to make the decision to implement this intervention with all guardians
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13 of adolescents presenting for well and/or sick visits at your site”). Participants will be paid \$25
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15 for participating in individual interviews.
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20 We will recruit stakeholders using methods described in a similar MHRN study.⁴¹ To
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22 sample parents of youth, investigators at each site will identify random samples of 100 English-
23
24 speaking parents or legal guardians of youth aged 12-24 who visited a primary pediatric care site
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26 within the previous three months from the electronic health records. Guardians will be sent an
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28 invitation letter with an opt-out card with postage. After 10 days, participants who have not
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30 returned the opt-out card will be called by phone, asked if they own a firearm (for sampling
31
32 purposes) and invited to participate in our study. To sample providers, clinical leadership in
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34 pediatric primary care and behavioral health, leaders of quality improvement, and system
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36 leaders, investigators at each site will identify the appropriate individuals to contact within their
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38 system, personally reach out to each of these individuals and invite them to participate via phone
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40 or email. We will work with clinical leadership in pediatric primary care to email invitations to
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42 providers inviting them to participate.
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48 Interviews will be conducted by phone, digitally recorded with the participants’
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50 permission, professionally transcribed, and loaded into NVivo software for data management and
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52 analysis. Interviewers include doctoral level researchers who have received extensive training
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54 and supervision in qualitative interviewing and bachelors and masters level research staff trained
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3 and closely supervised by the doctoral level members of the research team. Analysis will be
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5 guided by integrated theory, which incorporates inductive and deductive features.⁴⁸ This
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7 approach uses an inductive process of iterative coding to identify recurrent themes, categories,
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9 and relationships in qualitative data. A comprehensive coding scheme is then developed on the
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11 basis of this analysis and applied to the data in order to produce a fine-grained descriptive
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13 analysis. A priori codes informed by CFIR²⁴ will also be applied (i.e., deductive approach), such
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15 as coding for barriers and facilitators at the intervention, provider, and inner and outer setting
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17 levels. The research team will separately code a sample of the transcripts and compare their
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19 application of the coding scheme to assess the reliability and robustness of the coding scheme.
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21 Any disagreements in coding will be resolved through team discussion. We will also compute
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23 interrater agreement (i.e., kappa), which provides a complementary approach to determining
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25 agreement between raters.⁴⁵ We will ensure that reliability between raters is at least .80 or higher.
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32 *Implementation strategies*

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34 We will delineate implementation strategies based on existing theory, the scientific
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36 literature, and the information gleaned from our stakeholder interviews. Consistent with the
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38 intervention mapping process, these implementation strategies will be translated into practical
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40 strategies using a theory-based causal model. We hypothesize that a model that accounts for
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42 individual behavior and the environment would be most salient here, such as the Theory of
43
44 Planned Behavior or Social Cognitive Theory.^{49,50} Using whatever theory(s) best fit the
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46 identified determinants for the intervention, individual, inner, and outer setting; we will then
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48 delineate practical strategies which will become the multi-level menu of implementation
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50 strategies. For example, if providers are unfamiliar with firearm safety counseling, training may
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52 be identified as a promising implementation strategy whereas if providers are uncomfortable
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with implementing firearm safety counseling (i.e., low self-efficacy), specific intervention to improve their self-efficacy is warranted. If parents report that the intervention would seem off-putting if not done in the context of other safety conversations, an approach that bundles firearm safety conversations with promotion of other safe practices (e.g., use of bicycle helmets) may be appropriate.

Evaluation of feasibility and acceptability

We will evaluate the multi-level menu of implementation strategies by returning to the initial stakeholders who completed the needs assessment and asking them to complete a brief survey assessing feasibility and acceptability. These participants will be paid an additional \$25 for completing this survey. We will also present our findings to leadership of each MHRN site and have them rate the feasibility and acceptability of the strategies. This will allow us to generate a list of the most feasible and acceptable implementation strategies within each level; which will then be tested in a larger effectiveness-implementation trial.⁵¹

DISCUSSION

Innovation

There are conceptual and methodological innovations in the proposed study, the former referring to the potential to directly impact youth with suicidal thoughts and behaviors. Specifically, this study seeks to understand how to implement a universal firearm safety intervention in primary care. Previous studies have utilized targeted intervention approaches.⁵² However, youth experiencing suicidal thoughts and behaviors often do not access services during times of heightened risk,⁵³ suggesting a universal approach has the potential to reach more youth and, ultimately, reduce suicide deaths. Addressing a highly prevalent social burden and understanding how health systems and their patients perceive a minimally intrusive yet common

sense approach to improving firearm safety has the potential to improve patient quality of life while better tailoring limited healthcare resources. Methodological innovation refers to the impact of the proposed work on systematic and rigorous methods to develop implementation strategies. To date, few studies have used intervention mapping to develop a multilevel menu of implementation strategies.^{43,54,55} Further, this study will use the CFIR²⁴ as part of this process to develop implementation strategies at the individual (e.g., providers), inner setting (e.g., pediatric practices), outer setting, and intervention characteristics levels. Evidence from the health services literature suggests that multi-level implementation strategies may be more effective than single-level implementation strategies.⁵⁶⁻⁵⁸

Limitations

Despite the strengths of the current study, several limitations should be noted. A primary limitation is that the study will be conducted in two health systems in the U.S., and the extent to which results will generalize to other health systems is unknown. Moreover, both health systems are a part of the MHRN; health systems participating in the MHRN may have unique characteristics that may limit the generalizability of study findings to other healthcare systems (e.g., an existing infrastructure to support partnerships with external researchers). Nonetheless, the diversity of the two systems, which are located in two distinct geographical and cultural settings, may mitigate threats to external validity. In addition, the *Safety Check* intervention was initially developed and tested as a broader safety initiative for parents of young children in which firearm storage was one of several safety targets. As such, the effectiveness of *Safety Check* as a stand-alone firearm safety intervention specifically for suicide prevention in pediatric primary care remains unknown. Additionally, the effectiveness of the intervention has been established based on parental self-report. It is possible that some parents may not be forthcoming when

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2
3 discussing matters related to firearm storage practices. Similarly, it is possible that providers
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5 and/or practice leaders may be reluctant to disclose information related to firearm safety given
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7 the sensitive nature of the topic. In an effort to mitigate these potential concerns, we will speak to
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9 both firearm-owning and non-owning stakeholders when possible to obtain a range of
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11 perspectives. We will also seek to understand providers' concerns about parental reluctance to
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13 discuss firearm ownership and storage during qualitative interviews, as understanding these
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15 concerns will be important in the development of implementation strategies. However, this is not
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17 our primary focus; other ongoing work^{59,60} explores the perspectives of firearm owners in greater
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19 depth.
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24 Impact

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27 The work proposed has the potential to impact public health in two important ways. First,
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29 it will be a critical step in the research agenda of reducing death by suicide in children and
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31 adolescents by engendering a better understanding of how to implement an evidence-based
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33 firearms safety intervention, specifically components of *Safety Check*, in pediatric primary care.
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35 Second, it will advance the implementation science literature by providing a process, informed
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37 by the CFIR,²⁴ for how to systematically develop implementation strategies in partnership with
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39 stakeholders across multiple levels of implementation (i.e., providers, inner and outer contexts).
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43 ETHICS AND DISSEMINATION

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46 Study procedures have been approved by the University of Pennsylvania (Protocol
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48 number 824449). Henry Ford Health System and Baylor Scott & White IRBs have ceded
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50 oversight to the University of Pennsylvania IRB.. We began data collection for this project in
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52 August, 2016. Results of Aims 1 and 2 will be submitted for publication in peer-reviewed
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54 journals.
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DISCLOSURES

Authors' Contributions

RB is the principal investigator for the study protocol. RB generated the idea and designed the study, and approved all changes. CBW was the primary writer of the manuscript and is the project director for the study. CBW, SJH, SM, BA, JZ, JF, GB, AL, and RB all made substantial contributions to study conception and design. All authors reviewed and provided feedback for this manuscript. The final version of this manuscript was vetted and approved by all authors.

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Competing Interests

The authors declare that they have no competing interests.

Data Sharing Statement

The data from this project will be available on request via email.

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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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6 *Figure Legend:* Figure adapted from Damschroder⁶¹.
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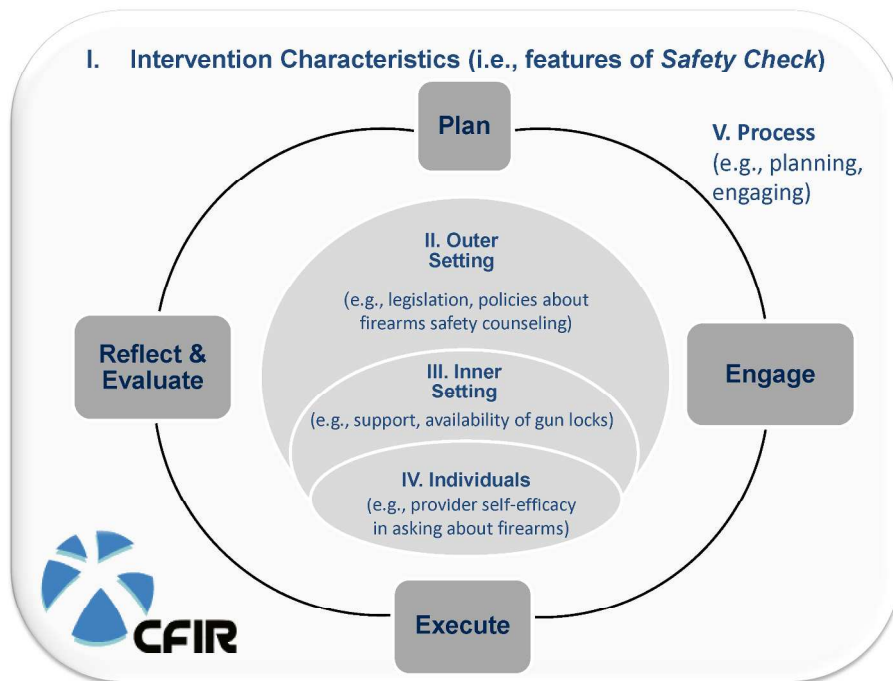


Figure 1. Study guiding framework
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BMJ Open

Developing implementation strategies for firearm safety promotion in pediatric primary care for suicide prevention in two large U.S. health systems: A study protocol for a mixed-methods implementation study

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Developing implementation strategies for firearm safety promotion in pediatric primary care for
suicide prevention in two large U.S. health systems: A study protocol for a mixed-methods
implementation study

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ABSTRACT

Introduction: The promotion of safe firearm practices, or firearms means restriction, is a promising but infrequently used suicide prevention strategy in the United States. *Safety Check* is an evidence-based practice for improving parental firearm safety behavior in pediatric primary care. However, providers rarely discuss firearm safety during visits, suggesting the need to better understand barriers and facilitators to promoting this approach. This study, Adolescent Suicide Prevention In Routine clinical Encounters (ASPIRE), aims to engender a better understanding of how to implement the three firearm components of *Safety Check* as a suicide prevention strategy in pediatric primary care.

Methods and Analysis: The NIMH-funded Mental Health Research Network (MHRN), a consortium of 13 healthcare systems across the United States, affords a unique opportunity to better understand how to implement a firearm safety intervention in pediatric primary care from a system-level perspective. We will collaboratively develop implementation strategies in partnership with MHRN stakeholders. First, we will survey leadership of 82 primary care practices (i.e., practices serving children, adolescents, and young adults) within two MHRN systems to understand acceptability and use of the three firearm components of *Safety Check* (i.e., screening, brief counseling around firearm safety, provision of firearm locks). Then, in collaboration with MHRN stakeholders, we will use intervention mapping and the Consolidated Framework for Implementation Research to systematically develop and evaluate a multi-level menu of implementation strategies for promoting firearm safety as a suicide prevention strategy in pediatric primary care.

Ethics and Dissemination: Study procedures have been approved by the University of Pennsylvania. Henry Ford Health System and Baylor Scott & White IRBs have ceded IRB

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 review to the University of Pennsylvania IRB. Results will be submitted for publication in peer-
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5 reviewed journals.
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8 Keywords: *implementation, intervention mapping, means restriction, firearms, suicide,*
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STRENGTHS AND LIMITATIONS

Strengths

- The two participating health systems are diverse and located in two distinct geographical and cultural settings.
- This study aims to engender a better understanding of how to implement the three firearm components of a universal evidence-based safety intervention (i.e., *Safety Check*) as a suicide prevention strategy in pediatric primary care.
- This study will advance the implementation science literature by using intervention mapping to systematically develop multi-level implementation strategies in partnership with stakeholders.

Limitations

- The study will be conducted in two large health systems in the U.S., and the extent to which results will generalize to other health systems is unknown.
- Both participating health systems are a part of the Mental Health Research Network (MHRN); health systems participating in the MHRN may have unique characteristics that may limit generalizability.
- The firearm components of *Safety Check* have previously been bundled with other injury prevention strategies, thus the effectiveness of *Safety Check* as a stand-alone firearm safety intervention specifically for suicide prevention in pediatric primary care is unknown.

INTRODUCTION

The rate of youth suicide has increased steadily over the past 15 years.¹ The most recent statistics identify suicide as the second leading cause of death among adolescents in the United States (U.S.),² making this a critical age group to target for suicide prevention strategies.

Firearms are the most common and most lethal method of suicide deaths in the U.S.; risk of suicide is two to five times greater in homes containing a firearm.³ This is of great concern given that one in three U.S. homes contain a firearm.^{4,5} Thus, safe firearm practices in the home are of paramount importance in reducing death by suicide among youth.

Lethal means restriction refers to the promotion of practices to make the environment safer by reducing access to potentially lethal methods of suicide. Several population-level natural experiments have supported the efficacy of means restrictions.⁶ For example, in the 1960s, the United Kingdom substituted domestic gas with a non-toxic alternative, resulting in a 30% drop in the national suicide rate.^{7,8} In the 1990s, the Sri Lankan government placed restrictions on the sale of toxic pesticides, the leading suicide method in the country at the time, and overall suicide rates dropped by 50%.⁹ A 2006 Israeli policy designed to reduce soldier suicide required soldiers to leave their firearms on base during periods of leave, resulting in a 40% decrease in soldier suicides.¹⁰

Reducing access to firearms is one promising, although underutilized, suicide-prevention strategy. Firearm means restriction strategies include the promotion of safe firearm storage practices as well as gun control legislation to reduce availability to firearms generally, and to children in particular. In the U.S., broadly reducing access to firearms has been deemed infeasible.¹¹ Child access protection laws are associated with modest effects.¹² Estimates from case-control and simulation studies suggest that a firearm safety intervention implemented in the

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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U.S. yielding even modest results (i.e., only ¼ of households restrict access to firearms) could lead to 3,600 to 3,900 adult lives saved annually.^{6,13}

Although suicide prevention strategies for youth have traditionally been implemented in behavioral health settings,¹⁴ only one-third of youth receive mental health treatment in the 12 months preceding a suicide attempt.¹⁵⁻¹⁷ Yet four out of five youth who die by suicide will have visited primary care in the year prior to their death,¹⁶ and 90% of youth visit primary care annually,¹⁸ highlighting the advantages of implementing a universal prevention approach in primary care for firearm safety interventions. One intervention, *Safety Check*, includes a tri-pronged approach to firearm safety counseling and resulted in safer firearm storage practices in homes with children ages 2-11 years.¹⁹ *Safety Check* in its original form includes screening about access to firearms, brief motivational interviewing informed counseling regarding firearm safety, and provision of free firearm locks bundled with other injury prevention strategies (e.g., use of timeout).¹⁹ In a large cluster-randomized trial of 137 pediatric primary care practices, parents who received the *Safety Check* intervention reported they were 21.4% more likely to engage in safe firearm storage practices compared to parents in the control condition at six-month follow-up. Despite the substantial evidence base, as well as recommendations from the American Academy of Pediatrics²⁰ and Institute of Medicine,²¹ the three firearm components of *Safety Check* continue to be underutilized in U.S. pediatric primary care clinics.^{13,15,22}

To maximize the likelihood that this promising intervention is translated into practice, it is essential to gain a more nuanced understanding of the implementation context from multiple levels. Importantly, it is necessary to understand barriers and facilitators to implementation that relate to characteristics of providers, organizations, and the health systems, as well as the states in which they work. These perspectives have been understudied. In the case of firearms, it is also

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3 important to obtain the perspectives of both firearm-owning and non-owning stakeholders when
4 possible.²³ While information can be gleaned from efforts to implement other safety
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6 interventions, such as seatbelts, given that doctor-patient firearm conversations have been the
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8 topic of legislation in the U.S., firearm safety interventions may involve unique barriers.
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10 Therefore this formative work is critical to the successful, large scale implementation of *Safety*
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12 *Check*.

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17 The Consolidated Framework for Implementation Research (CFIR) provides a context to
18 guide the project.²⁴ The CFIR²⁴ is an effort to synthesize the many conceptual frameworks in
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20 implementation science.²⁵ The five major domains that comprise the CFIR²⁴ include: (1)
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22 intervention characteristics (i.e., the features of an intervention); (2) outer setting (i.e., the
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24 economic, political, and social context within which an organization exists); (3) inner setting
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26 (i.e., the organizational setting); (4) characteristics of individuals involved in implementation
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28 (e.g., providers); and (5) the implementation process (see Figure 1). In the case of *Safety Check*
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30 implementation, intervention characteristics such as terminology (e.g., means restriction versus
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32 firearm safety, endorsement of written materials by firearm organizations) may be important. At
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34 the provider level, low self-efficacy or lack of knowledge about best practices for firearm safety
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36 promotion and/or suicide prevention may contribute to provider reluctance to engage in
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38 discussions with patients about firearms.²⁶⁻²⁹ At the inner setting, barriers and facilitators
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40 regarding availability of resources (e.g., firearm locks, educational pamphlets focused on safe
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42 storage of firearms) and organizational support (e.g., buy-in from front-desk staff and
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44 management) may be present. Outer setting barriers may include lack of policies to support
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46 implementation (e.g., absence of guidelines about firearm counseling and associated
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48 documentation in the electronic health records) and state legislation. For example, the Florida
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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 Privacy of Firearm Owners Act, passed in 2011, stipulated that providers must refrain from
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5 inquiring about firearm ownership and documenting firearm-related information in patients'
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7 medical record except under specific circumstances, such as when the healthcare practitioner
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9 determines that this information is relevant to the patient's safety or the safety of others. Of note,
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11 despite the stipulation permitting providers to inquire about and/or document firearms-related
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13 information when relevant to matters of safety, many providers mistakenly believed that it was
14
15 illegal to discuss firearms during healthcare visits under any circumstances,³⁰ and thus, refrained
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17 from doing so. Key provisions of this legislation were overturned in 2017;³¹ however similar
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19 legislation has passed in other states (e.g., Montana, Missouri, and Minnesota) and more
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21 restrictive legislation has been proposed elsewhere (e.g., a pending proposal in Ohio prohibits
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23 *any* inquiries related to firearm ownership or possession without exception).³⁰ Currently, there
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25 are no state or federal laws prohibiting provider questioning or counseling about firearms.
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32 Intervention mapping is a systematic approach to intervention development that has been
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34 used to develop a number of effective health-related programs, including those addressing sex
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36 education,³² obesity,³³ cancer prevention,³⁴ osteoarthritis, and low back pain.³⁵ Intervention
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38 mapping, used in concert with the CFIR,²⁴ can be applied to develop a menu of implementation
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40 strategies in a systematic and rigorous way by helping identify who should be involved in
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42 adoption, implementation and maintenance of interventions; as well as what specific behaviors
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44 they need to engage in.³⁶ To date, implementation strategies have not been developed
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46 methodically and have lacked rigor in their application.³⁷
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Objectives and Aims

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53 Our goal in this study (Adolescent Suicide Prevention In Routine clinical Encounters;
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55 ASPIRE) is to collaboratively develop implementation strategies in partnership with stakeholders
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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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3 to understand how to most effectively implement a firearm safety intervention in U.S. pediatric
4 primary care (operationally defined as including pediatrics, internal medicine, family medicine,
5 and/or adolescent medicine). To date, there has not been a study to systematically examine
6 factors that may impede or facilitate implementation of a firearm safety intervention as a suicide
7 prevention strategy at the provider, organization, and system levels. This formative work is
8 necessary to inform the development of multi-level implementation strategies to reduce death by
9 suicide in youth. The NIMH-funded Mental Health Research Network (MHRN;
10 www.mhresearchnetwork.org), a consortium of 13 healthcare systems across the United States,
11 is an exceptional laboratory with established research infrastructure in which to better understand
12 how to implement a firearm safety intervention in primary care from a system-level perspective.
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Aim 1

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29 We will survey the clinical leadership and providers of 82 primary care practices within
30 two MHRN systems to understand (a) beliefs about the acceptability of screening, brief
31 counseling around firearm safety, and provision of firearm locks within pediatric primary care
32 and (b) use of these practices. Additionally, we will investigate if patient, provider, and system
33 level characteristics predict acceptability and use of these practices.
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Aim 2

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43 In collaboration with MHRN stakeholders in these two systems, we will use intervention
44 mapping and the CFIR²⁴ to systematically develop and evaluate a multi-level menu of
45 implementation strategies for youth firearm safety as a suicide prevention strategy in pediatric
46 primary care.
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METHODS AND ANALYSIS

We began data collection for this project in August, 2016. The study is expected to conclude in April, 2018.

Setting

The MHRN is a consortium of 13 public-domain research centers based in large not-for-profit health care systems covering approximately 13 million lives in 15 U.S. states. The mission of the MHRN is to improve the management of mental health conditions by connecting research, practice and policy. We have recruited two MHRN health systems to participate in project ASPIRE. *Henry Ford Health System (HFHS)* has 37 primary care practices and serves 1 million lives annually; 12% percent of those individuals are under the age of 18. Thirty-eight percent are ethnic minorities, which is important, given evidence that there are widening racial disparities among youth in the U.S. such that suicide has increased among black children while decreasing among white children.³⁸ *Baylor Scott & White (BSW)* has 45 primary care practices and serves 630,000 lives annually; nearly 20% of those individuals are under the age of 18. This system is located in Texas where proposed legislation prohibiting physicians from asking about firearm ownership is currently under review,³⁹ and includes a number of rural practices which is important given evidence that suicide rates among adolescents and adults are higher in rural vs. urban communities and rural-urban disparities are increasing over time.^{36,40}

Aim 1

Rationale

We will survey clinical leadership and providers of pediatric primary care practices within the two systems of interest to understand variation in acceptability and use of the three firearm components that comprise the *Safety Check* intervention.

Firearm Safety Intervention

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The *Safety Check* intervention is an evidence-based safety intervention targeted to parents of children aged 2-11.¹⁹ It includes three firearm components: screening, brief counseling, and provision of firearm locks. Given evidence that providers perceive components of evidence-based practices (EBP) differently,⁴¹ we have elected to examine the acceptability and use of each of the three individual components separately rather than ask questions about the intervention as a whole. Additionally, in Aim 1, we are hoping to extend research on *Safety Check* by understanding acceptability and use in youth for suicide prevention. In the original study¹⁹ examining the efficacy of *Safety Check* the intervention was conducted on a different age group, with a focus on safe firearm storage for injury prevention; the firearm intervention was bundled with other injury prevention strategies (e.g., use of timeout). This will allow us to understand to what extent *Safety Check* adaptations are needed to maximize the success of broad health systems implementation efforts.

Sample

The target population for this survey will be clinical leadership and providers at all pediatric primary care practices within the participating MHRN sites. Current estimates suggest that the number of practices across both systems is 82. We elected to recruit all leaders (i.e., physician managers) of pediatric primary care practices and all physicians who had seen 100 or more youth patients within the preceding one year from each of the 82 practices in the two health systems ($N = 261$; we anticipate 80% recruitment rate for a total n of 209).⁴² A brief electronic survey will be sent to these clinical leaders and providers to determine acceptability and use of the three firearm components of the Safety Check intervention at that site. The required elements of informed consent will be described on the first page of the electronic survey and, if they agree to participate, clinical leadership and providers will consent by proceeding to

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3 the second page of the electronic survey. We have obtained a waiver of written documentation of
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5 consent from the University of Pennsylvania Institutional Review Board (IRB). To ascertain our
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7 sample, investigators at each site will identify the physician managers of pediatric practices
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9 within their system and will use electronic health records to identify primary care providers who
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11 treat youth in those practices. To enhance participation, and based upon previous work
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13 suggesting that participation is very high if the request comes from a contact within the system,
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15 investigators at each site will initiate contact with potential participants at their site and send the
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17 web-based survey. Each participant who completes the survey will receive a \$10 gift card.
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22 Data Sources

23 *Primary data*

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27 The survey will query about acceptability and use of the three firearm components of
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29 *Safety Check* as well as relevant demographic information (e.g., practice experience, firearm
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31 ownership). Sample questions include: “Asking all caregivers about the presence of firearms in
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33 the home would be an acceptable suicide prevention strategy in my practice” (rated from 1 =
34
35 Strongly Disagree to 6 = Strongly Agree) and “How often do you screen caregivers of youth for
36
37 the presence of a firearm in the home of youth” (rated from 0 = Never to 4 = Always). All of the
38
39 items in the survey have undergone cognitive response testing with physician managers and
40
41 physician providers in pediatric primary care to identify ambiguous wording, awkward
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43 instructional sets, and portions that may have been difficult to complete.⁴² Respondents have also
44
45 evaluated the face validity of the survey during this process. In addition, before and after
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47 piloting, content validity was evaluated by experts in suicide research and primary care.
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53 *Secondary data*

We will use publicly available data sources including data from the MHRN data warehouse, which includes a combination of electronic health records, insurance claims data, and the National Center for Health Statistics National Vital Statistics System.⁴² A programmer from each MHRN system will extract information from the data warehouse for participating providers: patient demographics (age, gender, race, ethnicity, patient language, Patient Health Questionnaire-9 [PHQ-9]⁴³ score and diagnostic codes); encounters (e-codes related to suicide and self-inflicted injury);⁴² provider demographics (specialty, age, gender, race, ethnicity and year graduated); census (socioeconomic indicators for patients based on geocoded patient addresses); public census data (education, income and poverty); and mortality (patient death by suicide; this is only currently available in HFHS). Additionally, we will extract youth (aged 12-24) suicide deaths over the past five years at the county-level for each primary care practice location from the National Vital Statistics System.⁴² These data will be used as predictor variables in analyses examining characteristics associated with acceptability and use of firearm safety strategies.

Analyses

Our quantitative analyses will identify the patient, provider, and site characteristics associated with acceptability and use of the three components. To examine the effect of patient, provider, and site factors on acceptability, we will use three separate ordinary least squares regression models. For each model, the dependent variable will be the mean of the acceptability items on the survey, measured on a 6-point scale. The independent variables will include measures of patient demographics (e.g., ethnicity/race), enrollment, provider demographics (e.g., age), and geographically derived socioeconomic and mortality indicators. Analyses will be conducted separately for the physician manager and physician provider samples when questions

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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2
3 were worded differently (e.g., “I would consider using this strategy in my practice” for
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5 physicians and “I would consider asking the providers in my practice to use this strategy” for
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7 managers). For questions that are worded identically (e.g., “Caregivers in my practice would
8
9 view this strategy as intrusive”) we will run a single model and include responder type as a
10
11 covariate.
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15 In the physician manager group, respondents will report the percent of providers in the
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17 practice who make use of each component. We will use linear regression models to examine the
18
19 extent to which the independent variables predict use of the three components in pediatric
20
21 practices. With 77 survey responses in each group, our models will have 80% power to detect a
22
23 moderate effect ($r^2=.09$) of the independent variable while controlling for 7 covariates. In the
24
25 provider sample we will use logistic regression to predict any use (versus no use) of the three
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27 practices. Assuming 77 survey responses and that 24% of providers endorse use of each *Safety*
28
29 *Check* component, we will be fully powered to detect between group differences of 11% versus
30
31 36% in use of any of the three firearm components of *Safety Check*. For both samples, we will
32
33 use multinomial logistic regression to model, among responders who report any use of each
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35 component at their site, the frequency with which they are used (rarely, sometimes, always). All
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37 models will control for health system.
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Outcome

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45 Based on the results generated from our survey, we will create a summary of
46
47 acceptability and use of the three firearm components of *Safety Check* across each system to
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49 present as part of Aim 2 to stakeholders.
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Aim 2

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3 In collaboration with MHRN stakeholders in these two systems, we will use intervention
4 mapping and the CFIR²⁴ to systematically develop and evaluate a multi-level menu of
5
6 implementation strategies for a firearm safety intervention as a suicide prevention strategy in
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8 pediatric primary care.
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11 Rationale

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13 While intervention mapping has been proposed as a method for designing
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15 implementation strategies,⁴² it has yet to be widely used in this way. In a recently published
16
17 proof-of-concept study, intervention mapping was employed to develop a multi-level
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19 implementation strategy to increase physicians' adherence to guidelines for depression.⁴²
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21 Compared to implementation as usual, the implementation strategy developed using intervention
22
23 mapping was found to increase adherence to the guidelines.⁴² In the proposed study, we are
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25 applying these tools to the development of multi-level implementation strategies to change
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27 provider, organization, and system behavior around firearm safety-promotion practices in
28
29 pediatric primary care. The approach is consistent with the CFIR.²⁴ To accomplish this, we will
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31 focus on the fifth step of intervention mapping, which focuses on planning for adoption,
32
33 implementation, and sustainment.⁴⁴
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41 Procedure

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43 The target behavior is implementation of a firearm safety intervention in pediatric
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45 primary care intended to be a suicide prevention strategy. As in other studies, the final content to
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47 emerge from intervention mapping cannot yet be specified because it depends on information
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49 gleaned from the intervention mapping process.
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52 *Needs assessment*

FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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Using the CFIR to guide us, we will assess the needs of stakeholders who will be impacted by implementing a firearm safety intervention in pediatric primary care²⁴. We will conduct semi-structured interviews with MHRN stakeholders from the following groups: (a) parents of youth ages 12-24, (b) physician providers, (c) non-physician providers (nurses, physician assistants, medical assistants), (d) leaders of primary care practices, (e) leaders of behavioral health, (f) leaders of quality improvement in each system, (g) system leaders (h) third-party payers, and (i) members of national credentialing bodies and professional organizations (e.g., American Academy of Pediatrics). We will use purposive sampling⁴⁵ to recruit approximately six individuals from each stakeholder group (three per health system) and sample across the two systems to ensure diversity in responses. We will also return to Aim 1 participants and invite their participation and ask them who else in their system we should interview. We estimate we will conduct approximately 54 interviews; however this number will depend upon thematic saturation (i.e., when no new ideas or themes are identified⁴⁶ in subsequent interviews). We will use purposive sampling to recruit a sample of parents that includes at least 67% firearm owners. Fifty percent of those firearm-owning parents will also be parents of youth at high risk for suicide based on medical records (i.e., PHQ-9 scores). In the case of providers and leaders of primary care practices, we will use stratified sampling to ensure that we recruit participants endorsing use of at least one of the *Safety Check* firearm components as reported in Aim 1 and at least 50% firearm owners as reported in Aim 1. In Part I of the interview, we will present practice stakeholders with the aggregated data on their system collected in Aim 1 and use the qualitative interviews as an opportunity to understand this data in a more nuanced fashion (quan→QUAL)⁴⁷ as consistent with previous studies.⁴⁸ For example, “Your practice reported that about 50% of providers at your site screen for firearms in the home. Can you tell me more

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3 about how this is usually done?” In Part II of the interview, we will use the CFIR²⁴ to query
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5 around barriers and facilitators at the intervention, provider, inner, and outer setting level, and
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7 the support needed to be able to provide a firearm safety intervention in daily practice (e.g.,
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9 “What kinds of changes or alterations to the intervention do you think would be needed for you
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11 to use it effectively?” and “What resources or support would be needed to effectively implement
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13 screening, counseling, and gun lock provision in your setting?”). In part III of the interview, we
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15 will use intervention mapping to guide questions that identify program adopters, implementers,
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17 and sustainers; as well as the specific behaviors that each set of stakeholders need to engage in to
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19 adopt, implement, and sustain the *Safety Check* components (e.g., “Who, specifically, in your
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21 health system would need to make the decision to implement this intervention with all guardians
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23 of adolescents presenting for well and/or sick visits at your site”). Participants will be paid \$25
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25 for participating in individual interviews.
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32 We will recruit stakeholders using methods described in a similar MHRN study.⁴² To
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34 sample parents of youth, investigators at each site will identify random samples of 100 English-
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36 speaking parents or legal guardians of youth aged 12-24 who visited a primary pediatric care site
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38 within the previous three months from the electronic health records. Guardians will be sent an
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40 invitation letter with an opt-out card with postage. After 10 days, participants who have not
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42 returned the opt-out card will be called by phone, asked if they own a firearm (for sampling
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44 purposes) and invited to participate in our study. To sample providers, clinical leadership in
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46 pediatric primary care and behavioral health, leaders of quality improvement, and system
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48 leaders, investigators at each site will identify the appropriate individuals to contact within their
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50 system, personally reach out to each of these individuals and invite them to participate via phone
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3 or email. We will work with clinical leadership in pediatric primary care to email invitations to
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6 providers inviting them to participate.
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8 Interviews will be conducted by phone, digitally recorded with the participants'
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10 permission, professionally transcribed, and loaded into NVivo software for data management and
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12 analysis. Interviewers include doctoral level researchers who have received extensive training
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14 and supervision in qualitative interviewing and bachelors and masters level research staff trained
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16 and closely supervised by the doctoral level members of the research team. Analysis will be
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18 guided by integrated theory, which incorporates inductive and deductive features.⁴⁹ This
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20 approach uses an inductive process of iterative coding to identify recurrent themes, categories,
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22 and relationships in qualitative data. A comprehensive coding scheme is then developed on the
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24 basis of this analysis and applied to the data in order to produce a fine-grained descriptive
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26 analysis. A priori codes informed by CFIR²⁴ will also be applied (i.e., deductive approach), such
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28 as coding for barriers and facilitators at the intervention, provider, and inner and outer setting
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30 levels. The research team will separately code a sample of the transcripts and compare their
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32 application of the coding scheme to assess the reliability and robustness of the coding scheme.
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34 Any disagreements in coding will be resolved through team discussion. We will also compute
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36 interrater agreement (i.e., kappa), which provides a complementary approach to determining
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38 agreement between raters.⁴⁶ We will ensure that reliability between raters is at least .80 or higher.
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46 *Implementation strategies*

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48 We will delineate implementation strategies based on existing theory, the scientific
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50 literature, and the information gleaned from our stakeholder interviews. Consistent with the
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52 intervention mapping process, these implementation strategies will be translated into practical
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54 strategies using a theory-based causal model. We hypothesize that a model that accounts for
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individual behavior and the environment would be most salient here, such as the Theory of Planned Behavior or Social Cognitive Theory.^{50,51} Using whatever theory(s) best fit the identified determinants for the intervention, individual, inner, and outer setting; we will then delineate practical strategies which will become the multi-level menu of implementation strategies. For example, if providers are unfamiliar with firearm safety counseling, training may be identified as a promising implementation strategy whereas if providers are uncomfortable with implementing firearm safety counseling (i.e., low self-efficacy), specific intervention to improve their self-efficacy is warranted. If parents report that the intervention would seem off-putting if not done in the context of other safety conversations, an approach that bundles firearm safety conversations with promotion of other safe practices (e.g., use of bicycle helmets) may be appropriate.

Evaluation of feasibility and acceptability

We will evaluate the multi-level menu of implementation strategies by returning to the initial stakeholders who completed the needs assessment and asking them to complete a brief survey assessing feasibility and acceptability. These participants will be paid an additional \$25 for completing this survey. We will also present our findings to leadership of each MHRN site and have them rate the feasibility and acceptability of the strategies. This will allow us to generate a list of the most feasible and acceptable implementation strategies within each level; which will then be tested in a larger effectiveness-implementation trial.⁵²

DISCUSSION

Innovation

There are conceptual and methodological innovations in the proposed study, the former referring to the potential to directly impact youth with suicidal thoughts and behaviors.

Specifically, this study seeks to understand how to implement a universal firearm safety intervention in primary care. Previous studies have utilized targeted intervention approaches.⁵³ However, youth experiencing suicidal thoughts and behaviors often do not access services during times of heightened risk,⁵⁴ suggesting a universal approach has the potential to reach more youth and, ultimately, reduce suicide deaths. Addressing a highly prevalent social burden and understanding how health systems and their patients perceive a minimally intrusive yet common sense approach to improving firearm safety has the potential to improve patient quality of life while better tailoring limited healthcare resources. Methodological innovation refers to the impact of the proposed work on systematic and rigorous methods to develop implementation strategies. To date, few studies have used intervention mapping to develop a multilevel menu of implementation strategies.^{44,55,56} Further, this study will use the CFIR²⁴ as part of this process to develop implementation strategies at the individual (e.g., providers), inner setting (e.g., pediatric practices), outer setting, and intervention characteristics levels. Evidence from the health services literature suggests that multi-level implementation strategies may be more effective than single-level implementation strategies.⁵⁷⁻⁵⁹

Limitations

Despite the strengths of the current study, several limitations should be noted. A primary limitation is that the study will be conducted in two health systems in the U.S., and the extent to which results will generalize to other health systems is unknown. Moreover, both health systems are a part of the MHRN; health systems participating in the MHRN may have unique characteristics that may limit the generalizability of study findings to other healthcare systems (e.g., an existing infrastructure to support partnerships with external researchers). Nonetheless, the diversity of the two systems, which are located in two distinct geographical and cultural

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3 settings, may mitigate threats to external validity. In addition, the *Safety Check* intervention was
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5 initially developed and tested as a broader safety initiative for parents of young children in which
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7 firearm storage was one of several safety targets. As such, the effectiveness of Safety Check as a
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9 stand-alone firearm safety intervention specifically for suicide prevention in pediatric primary
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11 care remains unknown. Additionally, the effectiveness of the intervention has been established
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13 based on parental self-report. It is possible that some parents may not be forthcoming when
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15 discussing matters related to firearm storage practices. Similarly, it is possible that providers
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17 and/or practice leaders may be reluctant to disclose information related to firearm safety given
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19 the sensitive nature of the topic. In an effort to mitigate these potential concerns, we will speak to
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21 both firearm-owning and non-owning stakeholders when possible to obtain a range of
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23 perspectives. We will also seek to understand providers' concerns about parental reluctance to
24
25 discuss firearm ownership and storage during qualitative interviews, as understanding these
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27 concerns will be important in the development of implementation strategies. However, this is not
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29 our primary focus; other ongoing work^{60,61} explores the perspectives of firearm owners in greater
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31 depth.
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Impact

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41 The work proposed has the potential to impact public health in two important ways. First,
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43 it will be a critical step in the research agenda of reducing death by suicide in children and
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45 adolescents by engendering a better understanding of how to implement an evidence-based
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47 firearms safety intervention, specifically components of *Safety Check*, in pediatric primary care.
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49 Second, it will advance the implementation science literature by providing a process, informed
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51 by the CFIR,²⁴ for how to systematically develop implementation strategies in partnership with
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53 stakeholders across multiple levels of implementation (i.e., providers, inner and outer contexts).
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ETHICS AND DISSEMINATION

Study procedures have been approved by the University of Pennsylvania (Protocol number 824449). Henry Ford Health System and Baylor Scott & White IRBs have ceded IRB review to the University of Pennsylvania IRB. We began data collection for this project in August, 2016. Results of Aims 1 and 2 will be submitted for publication in peer-reviewed journals.

DISCLOSURES

Authors' Contributions

RB is the principal investigator for the study protocol. RB generated the idea and designed the study, and approved all changes. CBW was the primary writer of the manuscript and is the project director for the study. CBW, SJH, SM, BA, JZ, JF, GB, AL, and RB all made substantial contributions to study conception and design. All authors reviewed and provided feedback for this manuscript. The final version of this manuscript was vetted and approved by all authors.

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Competing Interests

The authors declare that they have no competing interests.

Data Sharing Statement

The data from this project will be available on request via email.

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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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9 with this project.
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FIREARM SAFETY AND SUICIDE PREVENTION IN PRIMARY CARE

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Figure 1. Study guiding framework

Figure Legend: Figure adapted from Damschroder⁶².

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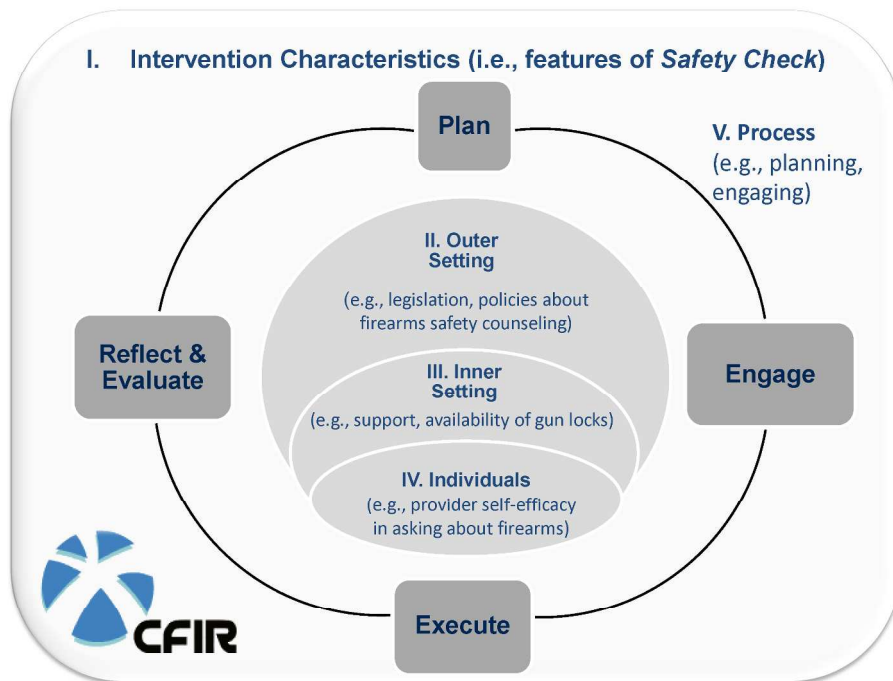


Figure 1. Study guiding framework
Figure Legend: Figure adapted from Damschroder [52].

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