Examples of Funded Grants in Implementation Science

Overview
The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let Implementation Science (IS) post excerpts of their dissemination and implementation (D&I) grant applications online.

About
We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. In addition, we only include a copy of SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches).

Copyright Information

Accessibility
Individuals using assistive technology (e.g., screen reader, Braille reader, etc.) who experience difficulty accessing any information should send an email to the Implementation Science Team (NCIdccpsISteam@mail.nih.gov).

424 R&R and PHS-398 Specific

Table Of Contents

SF 424 R&R Face Page

PI: Self-Brown, Shannon Renee

Grant Number: 1 R01 CA248551-01A1

Title: Establishing smoke-free homes with families involved in child protective services: An effectiveness-implementation trial of an integrated program

FOA: PAR18-559 Clinical Trial:Required

FOA Title: Cancer Prevention and Control Clinical Trials Grant Program (R01 Clinical Trial Required)

Organization: GEORGIA STATE UNIVERSITY

Department: Mark Chaffin Ctr Healthy Devel

Senior/Key Personnel: Shannon Self-Brown

Organization: Georgia State University Research Foundation, Inc.

Role Category: PD/PI

Project Abstract

Child exposure to secondhand smoke (SHS) is linked to multiple forms of cancer throughout the lifespan. Young children living in low-socioeconomic status households are at increased risk for SHS exposure. Families involved with the child protection system as the result of substantiated child maltreatment are an especially high-risk group for SHS, as these families are often living in poverty and report high daily smoking rates. Importantly, child maltreatment victimization also increases risk of cancer and premature death from cancer, independent of parent smoking behavior. Identifying ways to broadly disseminate effective SHS prevention programs to these high-risk families is an important strategy for reducing cancer disparities. We propose an effectiveness-implementation hybrid trial type 1 to examine the impact of integrating two evidence-based programs, Some Things are Better Outside (SHS prevention program) and SafeCare® (Child Maltreatment Prevention Program), on establishing a smoke-free home and on implementation process outcomes. Aim 1 focuses on the refinement of the standardized integration (systematic braiding) of the two programs into "Smoke-Free SafeCare (SFSC)." Aims 2 and 3 focus on the hybrid trial. Fifty certified SafeCare Providers will be recruited and randomly assigned to deliver either SFSC or Standard SafeCare. Providers will each serve ten research families (N = 500) who meet the inclusion criteria (Mother or another person residing in the home smokes at home). The primary outcome, smoke-free home status, will be measured via self-report at 4-timepoints (baseline, 8-weeks, 20-weeks, and 1-year), and validated via air nicotine monitor at 8 weeks and 1-year (Aim 2). Process measures will be collected to examine how the braided intervention impacts provider fidelity, delivery time and costs, and other process measures (Aim 3). If effective, SFSC can be efficiently disseminated for widespread adoption by the National SafeCare Training and Research Center to the over 100 accredited SafeCare agencies across the United States and worldwide that serve parents involved with child protection services, reducing cancer risk and disparities for a high-risk population.

Project Narrative

Evidence-based interventions to create smoke-free homes can reduce secondhand smoke (SHS) exposure among young children and thus decrease lifetime risk of cancer. The purpose of this project is to integrate two effective prevention programs, one focused on SHS and another focused on child maltreatment that is widely disseminated to families with young children involved with the child protection system (a high-risk group for SHS). A Hybrid Trial 1 of this integrated intervention, “Smoke-Free SafeCare,” will aid in identifying ways to disseminate effective SHS interventions to high-risk groups, an important strategy for targeting tobacco-related cancer disparities.

Specific Aims

Approximately 4 out of 10 children in the U.S. live in a home with at least one smoker, which significantly increases the likelihood of child exposure to secondhand smoke (SHS). SHS is linked to cancer, and is a major, yet preventable, threat to health throughout the lifespan. The home is the major source of SHS exposure for children. Although the percentage of homes with young children that are smoke-free has increased over the last decade, this trend has not generalized to low-socioeconomic status (SES) households. Evidence-based interventions to create smoke-free homes can reduce SHS exposure among children. In three randomized trials, our team documented the effectiveness of a brief intervention, *Some Things are Better Outside (STBO)*, for promoting smoke-free home rules in low-SES households. Identifying ways to disseminate STBO to low-SES households is an important strategy for targeting tobacco-related cancer disparities.

Low-SES is also a primary risk factor for substantiated child maltreatment, which can result in parental involvement with child protective services (CPS). Smoking is highly prevalent among CPS-involved parents; yet, limited research has examined how to best address the need for smoke-free homes with this population. There is a strong public health need to address SHS risk with these families. Children subjected to maltreatment are at increased risk for poor health outcomes (including cancer) because of their victimization experiences, and SHS can further exacerbate these negative health trajectories. CPS-involved parents typically receive a case plan to address immediate child safety needs, with limited attention to long-term child health. However, CPS systems have increasingly been implementing evidence-based programs that focus more comprehensively on child well-being. One such program is SafeCare®, a broadly implemented intervention that reduces parent-perpetrated maltreatment and improves child outcomes. Integrating effective SHS interventions with parenting programs already disseminated in CPS is a venue by which to increase the reach of these programs to low-SES households including children at high risk of SHS.

This proposal brings together a team of experts in SHS and child maltreatment research, the developers of STBO, and the purveyors of SafeCare, to test the integrated delivery of these interventions with CPS-involved families. The scientific premise of this proposal is that: 1) STBO is effective for reducing SHS in low-SES households; 2) SafeCare is effective in improving parent/child outcomes among CPS-involved, predominantly low-SES households; and 3) SafeCare is a mechanism to effectively increase the reach of STBO to reduce SHS exposure in at-risk families. In addition to testing the effects of the integrated program on smoke-free home rules, we will examine the impact of the braided approach on parenting outcomes and program costs.

We will utilize a Hybrid Trial 1 design to determine the effectiveness of the integrated intervention, Smoke-Free SafeCare (SFSC), and to study the process factors involved with implementation. Year 1 will focus on the refinement of the integration of the two curricula, and the recruitment of 50 SafeCare providers working at accredited SafeCare agencies for the hybrid trial. Providers who consent will be randomly assigned to: 1) SFSC or 2) standard SafeCare. Provider participants will recruit 10 mothers each (total N = 500) who either a) identify as a smoker who smokes in the home, or b) report living with a person who smokes in the home. Participating mothers will be assessed at four time points over the course of one year to examine intervention impact on smoke-free home status as the primary outcome.

Aim 1: Systematically braid the STBO and SafeCare curricula into an integrated "Smoke-Free SafeCare" intervention. *Systematic braiding is a validated method for integrating interventions such that fidelity to the curriculum and implementation practices for each intervention are maintained. SFSC will be piloted with 10 families and vetted with 10 SafeCare Providers to refine the curriculum for the Hybrid Trial 1.*

Aim 2: Evaluate the impact of SFSC on: a) establishment of a smoke-free home, b) maintenance and sustainability of a smoke-free home, and c) maternal parenting outcomes in CPS-involved households with a child under age six. *We hypothesize that SFSC mothers, compared to standard SafeCare mothers, will be significantly more likely to establish, maintain, and sustain a smoke-free home as measured via self-report (validated by air nicotine). We hypothesize that both groups will demonstrate positive parenting outcomes.* Mother smoking behaviors will be examined as exploratory outcomes.

Aim 3: Examine process outcomes for SFSC compared to standard SafeCare. *We hypothesize that SFSC providers will achieve equivalent fidelity ratings to standard SafeCare providers. It is anticipated that SFSC will have increased time/costs in delivery, but this will be offset by the reductions in SHS exposure.*

Study Impact. This study will be the first to document outcomes of a systematically braided intervention to address cumulative risk factors that impact cancer risk among children whose parents are involved with CPS. If effective, SFSC can be efficiently disseminated through the 100+ accredited SafeCare agencies serving high-risk families.

Research Strategy

A. Significance

A1. Public health impact of secondhand smoke on young children.

Exposure to secondhand tobacco smoke (SHS) is a major, yet preventable, threat to infant and child health. SHS exposure can cause sudden infant death syndrome, respiratory and middle ear infections, more frequent and severe asthma attacks, and impaired lung growth in infants and children.[1-4] Childhood SHS exposure has also been associated with higher risk for acute lymphoblastic leukemia and myeloid leukemia in childhood,[5,6] as well as head and neck cancer,[7] lung cancer,[8] pancreatic cancer[9,10] and mortality from chronic obstructive pulmonary disease[11] in adulthood. In addition to poor physical health outcomes, higher rates of behavioral problems and attention deficit hyperactivity disorder have been linked to SHS exposure in children.[12,13] SHS leads to increased health care utilization among young children, resulting in substantial economic costs.[14] Children are particularly vulnerable to the effects of SHS because of their early stages of physical and cognitive development and higher breathing rates.[3]

Whereas the prevalence of SHS exposure has declined among U.S. non-smokers overall, **SHS exposure remains disproportionately high among young children** (37.9% among children aged 3-11, compared to 22.0% among adults aged ≥20).[1] SHS exposure is estimated to cause approximately 42,000 deaths in the U.S. per year (including 900 infants) and $6.6 billion in lost productivity due to SHS-related diseases.[15] There is no safe level of SHS, and making children's environments completely smoke-free is the only way to protect children from SHS harms.[3]

The home environment is the principal source of SHS exposure for children, who spend relatively high amounts of time inside and have little control over tobacco use in their home.[3,16] Tobacco smoking in the home also results in thirdhand smoke (residual chemicals left in the air, dust, and on surfaces after tobacco has been smoked),[17] creating substantial risks for children who are often on surfaces that collect pollutants (e.g., carpet/floor) and insert non-food items into their mouths.[18] SHS exposure is significantly more common among people living with a smoker in the home.[1] While the prevalence of smoke-free home rules has increased in the U.S. overall,[16,19] the most recently available data suggest that only 61% of households with children and at least one adult smoker in the home had established smoke-free home rules.[16] Thus, 2 in 5 households with children and smokers in the home exposed children to the dangers of SHS.

SHS exposure is disproportionately high among children living in low-socioeconomic status (SES).[19-23] According to 2014 Census data, an estimated 21.1% of all US children under 18 years (15.5 million) lived in households designated as "poor." The inverse relationship between SES and SHS exposure is well documented.[19,24-27] Smoke-free homes reduce SHS exposure for both nonsmokers and children.[28-31] Programs targeting SHS prevention are of greatest need among families with specific risk factors, as smoking bans are least common among households with low-SES, one or two current smokers, parents with less than a college education, and single parents.[32] Given the 1) significant number of children living in low-SES conditions, 2) the higher rates of SHS exposure in these households, and 3) the negative health consequences of SHS exposure for children, **innovative strategies are needed to effectively disseminate evidence-based interventions focused on the creation of smoke-free homes for families at greatest risk.**[32]

A2. Cumulative risk for children living in low-SES households: SHS exposure and child maltreatment.

Young children living in low-SES households are disproportionately exposed to adverse childhood experiences that impact health.[33,34] **Child maltreatment is one of the most negatively impactful adverse experiences on young children's health, socioemotional development, and life course**. Brain imaging studies of the developing brain indicate that maltreatment early in life damages the brain's physical structure by impairing cell growth, interfering with the formation of health circuitry, and altering the neural structure and function of the brain itself.[35-37] Maltreated children have more mental health difficulties than non-maltreated children,[38-43] as well as long-term physical health problems.[44-50] Notably, findings from the Adverse Childhood Experiences study, a retrospective study of 17,000 people[33] with cumulative risk from childhood, suggest that **maltreatment increases risk for lung cancer and premature death from lung cancer.**[45]

In 2017, 674,000 children were substantiated as victims of child maltreatment resulting in child protective services (CPS) involvement.[51] This equates to a national rate of 9.1 victims per 1,000 children. Approximately 78% of the substantiated victims were 5 years of age or younger. Child neglect and physical abuse are the two most common forms of substantiated maltreatment. Low SES is one of the strongest and consistent predictors of child maltreatment.[52-54] **Children living in low-SES households are at 3 to 7 times greater risk for being victims of abuse and neglect compared to children in higher-SES households.**[53-63]

Many maltreatment reports are made because of imminent dangers in the home environment, which are the focus of intervention. However, there is an opportunity to address long-term dangers as well, such as SHS. Limited research has addressed the prevalence of smoking in the home among CPS-involved parents and/or SHS exposure among maltreated children. Research has documented associations between maternal smoking during pregnancy or a child's early years and subsequent child maltreatment.[64,65] **Recent preliminary work conducted by our research team indicates that 61% of CPS-involved parents report daily smoking** (*see section c2b*), in striking contrast to 13.7% smoking prevalence among U.S. adults.[66] Given substantial literature documenting associations among low-SES, family risk, adult smoking behavior, and child maltreatment risk, children whose parents are involved with CPS are very likely at increased risk for SHS exposure.

A3. Evidence-based intervention programming for child SHS exposure and maltreatment.

Longitudinal studies have found beneficial effects of prevention and intervention efforts for children exposed to poverty and other adverse experiences on long-term health and a range of social and psychological outcomes.[67–75] Evidence-based intervention programs exist for smoke-free homes and for child maltreatment risk. However, to our knowledge, no programs jointly target SHS exposure and maltreatment risk, despite the evidence that these risk factors often co-occur for children living in low-SES households.

Some Things are Better Outside (STBO) is a brief intervention, developed by Kegler (MPI), that is highly effective in promoting adoption of smoke-free home rules among low-SES households.[76-78] Three randomized controlled trials (RCTs) documented significant intervention effects, with 40.0 to 62.9% of clients reporting a smoke-free home when reached for follow-up at 6 months post-baseline.[76-78] Self-reported smoke-free homes were validated by air nicotine at 3-months post-baseline. STBO was also effective in a dissemination trial conducted with five 2-1-1 agencies across multiple states.[79] The **six-week** intervention was designed to be easy to deliver, consisting of three mailings of print materials and a 15-20 minute coaching call.

SafeCare is a brief parenting intervention that is highly effective in reducing child maltreatment perpetration and improving behavioral outcomes for CPS-involved parents of young children (0 to 5 years) as the result of child physical abuse or neglect (the two most common forms of substantiated maltreatment).[80-82] A cost benefit analysis conducted by the independent Washington State Institute on Public Policy concluded that SafeCare returns $21.60 in benefit for every dollar it costs to implement.[83] SafeCare is delivered in the home over 18-weeks, and the curriculum focuses on promotion of positive parenting skills, home safety, and child health. SafeCare is disseminated through the National SafeCare Training and Research Center (NSTRC) at Georgia State University (GSU), directed by Self-Brown (MPI) and Whitaker (Co-I).

In considering the best approaches for targeting SHS, it is imperative to consider how to integrate interventions with documented success for improving smoke-free rules and with high levels of parent engagement (which STBO has consistently demonstrated), into effective parenting intervention programs, such as SafeCare (which has also been demonstrated to be highly engaging).[84] Thoughtful integration would ensure the maintenance of active ingredients for both programs, and parent engagement.

A4. Increasing the reach of effective SHS interventions to low-SES households.

While the reach of STBO may increase with a recent posting of the intervention on NCI's Research Tested Interventions Program website, dissemination has been largely limited to a grants program through California's Tobacco Control Program and a few small research projects. The 2-1-1 agencies involved in testing the intervention and its dissemination potential were not able to sustain the intervention without additional funding. Thus, there remains a critical need for practical and efficient dissemination approaches to ensure widespread adoption. Given that SafeCare is already widely disseminated (25+ U.S. states, 100+ accredited sites), integrating STBO into SafeCare could **vastly expand the reach and resulting public health impact of this program for children at-risk for SHS**, with limited impact on program delivery costs and resources.

A5. Study Purpose and Scientific Premise

The scientific premise of this proposal is that: 1) STBO is effective in creating smoke-free homes and reducing SHS in low-SES households, 2) SafeCare is an effective parent training program that is broadly disseminated in CPS in the U.S., and 3) **SafeCare is a promising mechanism to effectively increase the reach of STBO to reduce SHS exposure in families with documented high rates of tobacco use and children with cumulative risk for negative health outcomes**.

We propose a Hybrid Trial 1 to determine the effectiveness of the integrated STBO and SafeCare intervention, or "**Smoke-Free SafeCare**," and to study the process factors involved with implementation of this program. In Year 1, we will finalize the systematic braiding and piloting of the two curricula with families, and

refine the Smoke Free SafeCare curriculum with SafeCare providers. Additionally, we will begin recruitment of the 50 certified SafeCare providers for the hybrid trial. Providers who consent to the study will be randomly assigned to: 1) Smoke Free SafeCare (SFSC) or 2) standard SafeCare. Provider participants will each be expected to recruit 10 mothers who either identify as a smoker who smokes in the home, OR report living in the home with a person who smokes in the home. Participating parents will be assessed at four time points over the course of one-year to examine intervention impact on smoke-free home status as the primary outcome**. Understanding whether there is additive benefit to the integration of these programs will inform policy about best practices for programs serving low-SES families, and will further establish a structured approach for systematically integrating evidence-based programs for populations who have cumulative risk.** We strive to document that a SHS intervention can be integrated into a parenting program for CPS-involved families without compromising the benefits of the parenting program.

B. Innovation.

1. **Delivery of STBO in an adapted format that could significantly enhance reach**. STBO was designed as a stand-alone program. However, the reach of this efficacious program is modest and could be expanded with successful integration into parenting interventions that are already broadly disseminated in child protection and prevention settings. SafeCare is just one of several broadly disseminated evidence-based parenting interventions in the U.S. Smoke-Free SafeCare could demonstrate that STBO can be seamlessly integrated with disseminated programs that serve families where SHS is highly prevalent.
2. **Smoke-free home intervention with a high-risk population**. To our knowledge, this will be the first study to promote smoke-free homes with CPS-involved families. Because these families tend to have low-SES and higher smoking rates, this is a critical target population for SHS prevention. This study includes a 12-month assessment timepoint to determine the sustainability of the primary outcome of smoke-free homes for caregivers who receive SFSC (STBO data has demonstrated 6-month sustainability).
3. **Use of systematic braiding as a structured approach to program integration.** Integration of evidence-based programming has been increasingly discussed in the scientific literature as a way to address co-occurring health issues.[97,98] Systematic braiding is a structured approach to program integration (rather than delivering them in parallel) that was developed and tested by the research team in the parent training field.[85-88] Applying this approach to STBO and SafeCare will offer further validation and explication for how to effectively integrate programs, while ensuring active ingredients and implementation practices are upheld. Results will be vital for informing future intervention integration efforts to address co-occurring risk in other domains relevant to cancer prevention.
4. **Advancing our understanding of how program integration impacts target outcomes and programmatic costs.** In addition to testing the effects of the integrated program on smoke-free home rules, we will examine the effects on parenting outcomes to determine whether the braided approach weakens this intervention effect. Moreover, the focus on time and delivery costs will determine whether the braiding of an effective program into a widely disseminated program can occur without a significant increase in overall program costs/resources.

C. Approach

C1. Research Team. Dr. Shannon Self-Brown [MPI; Professor, Georgia State University (GSU) School of Public Health (SPH)] has extensive expertise in child maltreatment prevention, behavioral parenting interventions, and implementation science. She is a clinical expert in SafeCare. Her research has been funded by several federal agencies (NIMH, NIMHD, NCTSN/SAMHSA, CDC, PCORI). Self-Brown has also held foundation funding, including serving as co-investigator of an Annie E Casey Foundation grant (PI Lutzker) through which systematic braiding, the intervention integration approach to be used in this study, was developed. **Dr. Michelle Kegler** (MPI, Professor, Emory University, Rollins School of Public Health) has expertise in tobacco control research focusing on developing, testing, and disseminating interventions. Kegler was the Principal Investigator for the NCI-funded, 5-year U01 project that created and tested SBTO in low-income households as described in preliminary studies. Kegler's cancer-related research has also been funded by CDC, ACS, Fogarty, and the Georgia Department of Health. **Dr. Regine Haardörfer** (Co-Investigator, Methodologist; Research Associate Professor, Emory University, Rollins School of Public Health) has extensive training and experience in the analysis of social science data to advance behavioral sciences in public health, especially for RCTs. She was part of the research team that (on an NCI-funded, 5-year U01

project) created the STBO intervention and guided all data analyses. **Dr. Daniel Whitaker** (Co-Investigator, Professor, GSU SPH) is an expert in child abuse prevention and implementation science, and has been funded as a Principal Investigator by CDC, ACF, AHRQ, and PCORI. Relevant to the proposed study, he is the Principal Investigator of an ACF grant focusing on the intersection of parenting, trauma, and substance abuse. **Dr. Claire Adams Spears** (Co-Investigator; Assistant Professor, GSU SPH) has expertise in interventions with a focus on low-SES and racial/ethnic minority smokers. Her K23 award developed and evaluated a smoking cessation intervention with low-income adults, and she was recently funded by NCI as the PI of an R01 to continue this research. Her research has also been funded by the Duncan Family Institute for Cancer Prevention and Risk Assessment, Cancer Research UK, and Fogarty International Center. **Dr. Jidong Huang** (Co-Investigator, Associate Professor, GSU SPH) has expertise in evaluating the economic and public health impact of tobacco-related policies and programs. He has a strong history of grant funding from NCI, and is currently the Principal Investigator of an R01 focused on the consequences of e-cigarette advertising. ***Consultant.*** **Dr. Kate Guastaferro's** (Consultant, Assistant Professor, Methodology Center, Penn State University) research focuses on advanced research methods to build effective, efficient, and scalable interventions for child maltreatment prevention. Guastaferro was the primary developer of the systematic braiding approach and she will offer consultation on the braiding approach for STBO and SafeCare.

C2. Preliminary Studies.

C2a. *Smoke Free Homes: Some Things are Better Outside (STBO).* Developed by Kegler and her team, this brief intervention promotes smoke-free homes in low-SES households.[76,89] The intervention, based on social cognitive theory and the transtheoretical model's stages of change, consists of three mailings of print materials and a coaching call delivered over 6 weeks at 2-week intervals. It encourages and supports change agents, either a smoker or a nonsmoker, through five steps to create a smoke-free home: decide you want a smoke-free home, talk to the people you live with about creating a smoke-free home rule, select a date for going smoke-free, implement your rule, and maintain your smoke-free home. STBO *efficacy* was tested in a RCT with 3- and 6-month follow-up.[76] The sample, recruited in partnership with 2-1-1 in Atlanta, was mostly female (82.7%), African American (83.3%), not working (76.5%), living with at least 1 child <18 (78.9%), and had household incomes of ≤$10,000 (55.6%). The majority of study participants smoked (79.7%). Significantly more intervention participants reported a full ban on home smoking than controls at both follow-ups (3-months: 30.4% v. 14.9%, $p = 0.0002$; 6-months: 40.0% v. 25.4%, $p = 0.002$). At 3-months, self-reported home smoking bans were validated by a passive air nicotine monitor. The process evaluation documented that the intervention worked well for both smokers and nonsmokers.[90] Next, an *effectiveness* trial was conducted in collaboration with 2-1-1 in North Carolina.[77] For this study, 2-1-1 line agents delivered the intervention. The study population was more diverse in terms of race/ethnicity, with 30.8% White, 61.4% African American, and 7.8% other. At six months, 43.2% of the intervention households were smoke-free and 33.2% of the control households were smoke-free. The third study in this series was a *generalizability* study in partnership with the 2-1-1 Texas/United Way Helpline in Houston.[78] Callers were even more diverse, with a larger Hispanic caller base. With 2-1-1 staff again delivering the intervention, 68% of the intervention group households created smoke-free homes in contrast to 38% of control households at six months. Intent to treat analyses were significant in all trials, as were sensitivity analyses in which those lost to follow-up were designated as failures and those with enforcement challenges were also treated as failures. A subsequent dissemination trial showed similar results with over 2,000 participants enrolled.[79]

To summarize, **three RCTs and a dissemination study documented success in creating smoke-free home rules**.[76-79] Moderator analyses drawing on pooled data from the trials showed no difference in intervention effectiveness by race/ethnicity, presence of children, or number of smokers in the home.[91]

C2b. *SafeCare and Smoking Risk among Enrolled Parents.* Self-Brown (MPI) and Whitaker (Co-I) are Co-Directors of the National SafeCare Training and Research Center (NSTRC) at GSU, the purveyor of the SafeCare model, and are clinical experts in SafeCare. NSTRC has SafeCare implementations in 25+ U.S. states, and as of 2020 there are 100+ accredited sites worldwide. Several RCTs have demonstrated the positive impact of SafeCare with high risk families, relative to case management services or to a no-treatment control, both in child welfare settings (after maltreatment has occurred) and in prevention settings (serving families at-risk for maltreatment).[80-82,92,93] In the largest published *effectiveness* study to date, a statewide comparative effectiveness trial of SafeCare in the Oklahoma child welfare system, SafeCare reduced child maltreatment recidivism by 26% (HR = .74) relative to usual care.[81] Self-Brown recently conducted secondary descriptive analyses of the baseline data from this study and found that *68% of parents (n=2150) reported*

using a tobacco product in the last year.

Whitaker and Self-Brown recently completed a PCORI-funded SafeCare effectiveness trial across five states (9 agencies). For this trial 237 service providers were recruited and randomized either to be trained to implement SafeCare or to continue with standard child welfare services. Parents were also enrolled in this study. Results indicated that SafeCare participation was associated with favorable effects on the primary outcomes of positive family functioning, positive child behaviors, and reductions in parenting stress.[94] Additionally, a recent examination of the baseline data from this study revealed that 71.5% of parents (n=203) reported tobacco use in the last year (prior to starting services), and that **an astonishing 61.3% (n=174) reported daily smoking**. Notably, **parents' daily or almost daily tobacco use was associated with** statistically significantly more child risk related to safety hazards in the home (β=0.36; 95% confidence interval: 0.08, 0.64; *p*=.01), as compared to parents who used tobacco less frequently.[95,96]

To summarize, SafeCare completers have significantly reduced risk for child physical abuse and neglect perpetration and improved parenting skills. Exploratory data from existing effectiveness trials indicate that smoking is alarmingly common for CPS-involved parents participating in SafeCare, and that parental smoking negatively impacts child safety in the home.

C2c. *Additional Preliminary Studies*. SafeCare Provider Survey. A survey was completed in August 2019 to examine SafeCare providers' opinions about incorporating smoke-free home materials into SafeCare. The survey was sent to the 621 active SafeCare providers in the U.S. Sixty-two providers completed the anonymous survey. Results indicated that 82% of providers routinely assess if caregivers use tobacco in the home, and 88% reported being comfortable counseling parents about the danger of exposing children to second hand smoke. Notably, 83% of providers indicated that they would be comfortable routinely discussing smoke-free home rules if provided with effective materials to do so with caregivers. Systematic Braiding. Self-Brown (MPI), Whitaker (Co-I), and Guastaferro (consultant) were Co-Investigators on an Annie E Casey grant (PI: Lutzker) that funded the development and testing of the systematic braiding approach with two evidence-based parenting programs. Systematic braiding is a methodological approach in which two models with complementary foci are combined while maintaining fidelity to program curriculum and implementation infrastructures.[85] The process achieves integration of content and implementation paradigms resulting in a streamlined implementation of the integrated curricula as opposed to augmenting one intervention onto another that could result in fidelity challenges and family burden. Steps for the Systematic Braiding include: (1) cross-training in both curricula to identify common content and pedagogical approaches; (2) development of the initial braided curriculum with input from experts; (3) piloting draft braided curriculum in an acceptability and feasibility pilot with end-users; (4) modifications and additional piloting as necessary; and (5) wide implementation of braided curriculum.

C3. Aim 1 Research Design and Methods: Systematic Braiding of Smoke-Free SafeCare (SFSC). There is an emerging literature[97,98] on best practices for integrating two (or more) evidence-based programs to effectively target multiple programmatic goals with populations experiencing cumulative risk. One approach is to implement the interventions in a *parallel* manner such that a client receives full doses of both programs with no adaptations. Limitations to this approach for clients may include greater time burden, as well as decreased engagement due to programmatic redundancies. An alternative approach is to systematically *integrate* the interventions by explicitly identifying the similarities and differences of the interventions' conceptual theory, active practices in program delivery, and implementation procedures.[97,98] Guastaferro, Whitaker, Self-Brown and colleagues[86] have recently standardized an integration method, **Systematic Braiding, which combines two (or more) models with complementary foci while maintaining fidelity to the curriculum for each model and the programs' implementation infrastructures.**

Systematic braiding will be used to integrate STBO and SafeCare. *Step 1*, to cross-train Kegler and Self- Brown in both curricula to identify common content/pedagogical approaches, has been completed. Table 1 below shows elements of the interventions and identifies shared and compatible elements. The programs share eligible participants, theoretical underpinnings, process assessments and fidelity monitoring. Social cognitive theory[99] is central to both interventions, with both addressing behavioral change by targeting: 1) behavioral capability (individual knowledge and skill change), 2) parental self-efficacy, 3) goal setting, and 4) environmental change.[100] STBO also incorporates the transtheoretical model (TTM)[100] by including motivational intervention components that are commensurate with the parent's readiness for change. Differences center on mode of delivery, dosage, and content, but STBO can be easily adapted.

Table 1 Step 1 Systematic Braiding of SafeCare and STBO

Elements	*SafeCare Elements*	*Shared Elements*	*STBO Elements*
Participants	Parents of young children involved with child welfare	Parents of children 0-5 years who are at increased risk for SHS exposure	Targets low-income households with at least one smoker and at least one nonsmoker
Focus	Parent skill-training for new parenting behaviors	Parent behavior change	Implement smoke-free home rules and change smoking behavior
Target for Session Delivery	Individual parent and child	Individual parent	Parent as household change agent
Mode of Delivery	In-person at home	In-home	Telephone and mail to homes
Dosage	Weekly for 18-20 weeks	Brief compared to field standards	Once every two weeks for 6 weeks
Length	18 Sessions	≥ 6 weeks	Four contacts in six weeks
Elements(cont.)	***SafeCare Elements***	***Shared Elements***	***STBO Elements***
Content	Explain, Practice, Model and Feedback approach to target behaviors for child safety and health, and parent-child interactions	Structured curricula with protocol guidance for intervention deliverers. Parent-friendly content to help generalize skill change.	"Five-Step Guide to a Smoke-Free Home" booklet, challenges and solutions booklet, stickers, signs pledges, newsletter, photonovella and coaching to set goals
Process Assessment	Observational and satisfaction measures	Program evaluation embedded in delivery	Relevance, usefulness, satisfaction
Theory	Social cognitive theory[99]	Social cognitive theory	Social cognitive theory, TTM[100]
Provider	Bachelor's degree or above	Bachelor's degree sufficient	None specified
Fidelity Monitoring	Score audio recorded sessions with fidelity checklist	Audio recordings of coaching	Documentation of mailing sent, audio recording of coaching calls and feedback

Step 2, which has also been completed, is development of the initial braided curriculum by experts in both interventions. The braided curriculum is entitled, "*Smoke-Free Home SafeCare (SFSC)*." SFSC includes the full SafeCare program,[101,102] a structured 18-session in-home behavioral parenting program that addresses the proximal risk behaviors for child neglect and physical abuse. Each session includes assessment, teaching, practice, and feedback for target skills. SafeCare contains three modules – health, safety, and parenting – that all families receive, and order of delivery is based on assessment identified needs. The *Child Health* module uses standardized, validated scenarios to teach parents skills to care for their children's health. Parents are taught to recognize symptoms of illness/injury and to use a structured health decision making approach. The *Home Safety* module aims to make homes safer for children while promoting parental supervision. Parents are taught about ten categories of home hazards, and how to eliminate or secure hazards. The *Parent-Child Interaction* module aims to increase positive parent interactions with the child in daily routines and play, and best practices in child behavioral management.

SFSC also includes the full program of STBO, but in a new delivery format. STBO originally consisted of three mailings and one coaching call.[89,103] To take full advantage of the home delivery mechanism of SafeCare, the content delivery has been adapted so that original mailings will be delivered in the SafeCare sessions as described below in Table 2. *STBO has been fully braided into the first 6 SafeCare sessions, regardless of the module (Health, Safety, Parenting) because providers start delivery with the module of greatest family need.*

Table 2 Step 2 Integrated Smoke-Free SafeCare Curriculum (*Sample Integration with Safety Module*)

Week	SafeCare Provider Content and Activities	STBO Provider Content and Materials
1	Conduct baseline assessments of three rooms to determine the number of hazards reachable and/or accessible to the child.	Hand deliver Kit to caretaker and provide a brief overview of materials following SafeCare assessment.
2	Using Safety Cards, teach parents to identify hazards, evaluate whether they are reachable/accessible, and reduce child hazard access. Work in one room, with the provider modeling and the parent practicing.	1) Inquire whether parent reviewed the materials. 2) Ask parent how important is it to create a smoke-free home? 3) Work with parent to generate list of reasons to create a smoke-free home.
3	Review explanation, risk, and child access to hazards. Select next room to begin removing hazards, with the provider modeling and the parent practicing.	Complete coaching protocol with goal-setting related to relevant step in the Five-Steps to a Smoke-free home process, including training mothers as a change agent.[104]
4	Review explanation, risk, and child access to hazards and how to remove or reduce hazards from Session 3 that remain. Select next room of focus, with the parent taking lead with provider coaching hazard removal.	1) Ask about progress toward achieving goal (e.g., family talk, setting a date). 2) Provide support for next step (e.g., practice family talk, remove ashtrays, post signs, help set up safe smoking space outside).
5	Using Safety Cards, address remaining hazards in rooms assessed and in additional rooms as requested by the parent. Discuss parental supervision and how supervision changes based on child development.	Hand deliver and provide overview of Challenges and Solutions booklet; a photo novella that role models a family establishing a smoke-free home, and e-cigarette insert that encourages inclusion of vaping in the rule.
6	Conduct post-module assessment and provide feedback on parent progress since baseline.	Hand deliver and provide a brief overview of newsletter, window cling, stickers, third hand smoke insert, etc.

Step 3 is to conduct an acceptability and feasibility pilot of the braided intervention with end-users (Aim 1). We will pilot SFSC and the proposed study assessments (*see Table 3*) for maternal participants with 10 high- risk families to refine intervention procedures and protocols to be implemented during the hybrid trial. SFSC will be delivered by two staff SafeCare experts at NSTRC, and families will be recruited from Hughes Spalding Children's Hospital (see letter of support). Inclusion criteria for mothers will be: 1) mother reports in-home smoking behavior by herself or another person residing in home (someone who lives in the home 3 or more nights a week); 2) mother reports at least two risk factors at initial screening that are commensurate with child maltreatment perpetration risk [low SES, low educational attainment, single mother status, young mother (less than age 21 at time of child's birth), 3 or more children under age 5, residing in a violent community], 3) Mother age 18 years or older, and 4) a child living in the home under age 6. Mothers will be compensated $50 for the pre-intervention assessment (REDCap measures), $10 per SafeCare session, and $60 for the post-assessment (REDCap measures, air nicotine measure, and a brief feedback interview).

Step 4 is to modify the intervention based upon results of Step 3. We will review the feedback collected in Step 3 with 10 certified SafeCare providers to refine, optimize, and finalize implementation and delivery protocols for SFSC to be used for the hybrid trial (Aim 2). The SafeCare providers will be asked to review the curriculum and engage in a semi-structured interview to offer feedback. Special attention will be paid to barriers that could impact STBO delivery. Recommendations for ensuring parental supervision and child safety within the context of SFSC will be solicited. SafeCare Providers will receive a total of $200 for their curriculum review (3 hours) and the follow-up interview (1 hour). Final edits will be integrated by Self-Brown, Kegler, and two NSTRC experts (who delivered SFSC to families in the pilot and will be the SFSC trainers for the trial). Training will then be conducted with the study providers in Oklahoma and Iowa who are randomized to SFSC.

Step 5 is wide implementation of braided curriculum. Process outcomes (Aim 3) will help inform the best approaches for implementation of SFSC (if supported by the randomized trial).

C4. Hybrid Trial Research Methods and Design (Aims 2 and 3). The proposed study is an effectiveness-implementation hybrid trial type 1 [16]. The sample will consist of 50 certified SafeCare providers who will be randomly assigned to either: 1) SFSC (N = 25) or 2) standard SafeCare (N = 25). SafeCare providers will provide process data while serving enrolled mother participants. A total sample of 500 CPS-involved mothers will be recruited in the states of Oklahoma and Iowa (250 for SFSC; 250 for standard SafeCare). These two states have large ongoing SafeCare implementations and documented high smoking rates (based on pilot research and CDC[105]). These states are located in the Midwest region, which has the highest cigarette smoking prevalence for adults amongst the U.S. regions.[106] Mothers will self-report smoke-free home status (primary outcome) at four timepoints [baseline, 8 weeks (post-STBO), 20 weeks (post-SafeCare), 1 year], which will be validated by air nicotine at the 8-week (post-STBO) and 1-year assessments.

C4a. *Hybrid Trial 1 Procedures*. The NSTRC at GSU is the purveyor of the SafeCare program, providing

standardized training and implementation support to agencies that adopt SafeCare. The rigorous training and implementation process, based on best practices from implementation science, supports SafeCare program fidelity in all accredited agencies. Agency accreditation occurs on an annual basis to ensure implementation standards and program fidelity are upheld. The research team will directly recruit SafeCare providers to participate in the study. The providers, in turn, will connect the research team to the referred mothers who agree to be contacted. We used this procedure successfully in our recently completed PCORI-funded trial.
SafeCare Providers. *Inclusion Criteria*: 1) Completed the SafeCare workshop and passed field Certification (9 sessions of SafeCare delivered with fidelity according to the SafeCare Fidelity Checklist); 2) Employed at an accredited SafeCare agency in a target state based on high adult smoking documented by CDC[102] or prior SafeCare research documenting high daily parent smoking rates. *Exclusion criteria*: 1) Plan for significant employment leave, resignation, or promotion during the study period.
Mother Participants. According to NSTRC accreditation data, approximately 92% of caretakers who participate in SafeCare are biological mothers, which will be our target population for the current study. *Inclusion Criteria*: 1) Referred to a SafeCare Provider study participant as the result of a child protection referral; 2) Reports in-home smoking behavior by herself or another person residing in the home (someone who lives in the home 3 or more nights a week); 3) Age 18 years or older. *Exclusion criteria*: 1) Reports that no one smokes in the home; 2) Demonstrates an inability to understand the consent form.
*Recruitment***.** We have a comprehensive recruitment strategy that has been successfully implemented by Self-Brown (MPI) and Whitaker (Co-I) to recruit SafeCare providers and CPS-involved mothers in previously funded trials (NIMH, PCORI). *SafeCare Providers*. Study recruitment will take place in partnership with accredited SafeCare agencies in Iowa and Oklahoma (see letters of support). Additionally, agencies trained in 2020 prior to receipt of grant funding that are located in states with high cigarette smoking rates according to CDC[102] (note: SafeCare training contracts are underway with South Carolina and Michigan) may be invited to participate, especially if recruitment challenges emerge. After attaining full Institutional Review Board approval, the GSU research team will work with identified state partners to develop and send recruitment emails to all SafeCare certified providers in that state. The email will advertise several webinars, conducted by one of the study investigators, that will describe study procedures, and the risk and benefits of participation. Providers can sign up and attend the webinars to determine whether they are interested in study participation. Immediately following the webinar, SafeCare providers will complete a two-question web-survey indicating their agency/team and their interest in participating in the research. For those who indicate interest, a follow-up call will be scheduled with a member of the research team, during which the consent process will be completed.
Mother Participants. Participating SafeCare providers will present a study recruitment flyer and verbal summary to mothers at the time of SafeCare referral. With permission, the provider will submit contact information to a GSU research team member. Next, a recruitment call will be made from the GSU team to the mother. The GSU team member will describe the study and screen for inclusion criteria. Mothers who meet inclusion criteria and note interest in study enrollment will complete the consent process (discussion of study risks, benefits, data protection, and voluntariness). An appointment with a local, trained assessor will be scheduled for the baseline assessment. The recruitment process will be carefully documented to assess reach and acceptability of addressing tobacco control within this setting (*see process measures c4g*).
Feasibility of proposed methods.
SafeCare Provider recruitment. Self-Brown (MPI) conducted an NIMH-funded exploratory implementation study to examine a technology-mediated approach to SafeCare delivery on implementation success.[107] The methodological approach used in that study supports feasibility for the proposed methods in the following ways: 1) SafeCare providers (*N* = 31) working across 17 agencies in eight states were recruited and retained for 6-months in a randomized trial, 2) SafeCare providers were randomized to two different delivery approaches in the context of an ongoing SafeCare implementation (current proposal will assign providers to two delivery approaches: SFSC or standard SafeCare), 3) SafeCare providers working in the same agency successfully implemented the two distinct intervention conditions without contamination, 4) Longitudinal implementation data for time outcomes (time diaries) were successfully collected. Importantly, recruitment and data collection were completed in a shorter time period than for the proposed trial (2 years versus 5 years).
Mother Recruitment. In the aforementioned PCORI study, more than 200 families were recruited across nine SafeCare sites in five states in a 1.5 year period (3-year grant). Local assessors were successfully hired and completed family assessments with procedures consistent with the current study.[108]

C4b. Randomization Procedures.

SafeCare Providers. Randomization will be stratified by state and will take place following completing the consent process. This will be completed by the project research coordinator based on a single sequence of computer-generated (using Microsoft Excel's rand function) random numbers.
Masking. Study personnel, including the PI and Co-Is (with the exception of Haardörfer) and assessment staff, will be masked to treatment condition until the database is locked. Limited staff will be unmasked to handle randomization codes, delivery support of interventions, and to complete reports.

C4c. Data Collection Procedures.

Data Collection for SafeCare Providers. Data collection from providers will begin once a mother they are serving becomes a participant in the research project. Data collection for providers will be via the NSTRC portal, a secure, web-based data collection system, used by all certified providers as part of standard SafeCare implementation, or Qualtrics, a research tool through Emory that allows for the creation and analysis of survey data. On a weekly basis, in follow-up to the completion of a SafeCare or SFSC session with a mother research participant, providers will complete and upload session audio recordings to the portal. Time diaries (see section C4g for description) and reports on parent engagement and service completion will be collected via Qualtrics. Data will be collected until the first module of SafeCare is completed (approximately 6 to 8 weeks) given this is the timeline for STBO delivery in the integrated SFSC. Once a SFSC provider has completed services with 10 study families, he/she will complete an exit interview providing feedback on the braided intervention. Providers will be compensated $10 each month they provide uploads (36 months on average, until they serve 10 study families), and $25 for the exit interview conducted in Y5Q1 (30 minutes).
Data Collection for Mothers. Mothers who consent to the study will participate in four assessments over the course of a 1-year period (baseline, 8-week (post STBO), 20-weeks [post SafeCare], and 1 year). Data collection for self-report items will be completed via REDCap, a tablet delivered online and secure data collection system. Questions will be presented one at a time and the respondent will reply using the touchscreen. There will be an option for the use of a text-to-speech engine, according to respondent preferences. In-home assessments will be conducted by trained research staff who will bring tablets to the assessment session. Study sites will be located across Oklahoma and Iowa; thus, local assessors will be hired and trained at each site and paid according to each assessment completed. At the 8-week and 1-year assessments, research staff will place an air nicotine monitor in the room where the family spends the most time and schedule pick-up. At the 8- and 20-week assessments, mothers will also complete intervention satisfaction measures. Mothers will be compensated $50 for their time for completing each assessment and for submitting the air nicotine monitor.
Study Retention. *SafeCare Providers*. We do not anticipate challenges retaining certified SafeCare Providers as study participants. NSTRC maintains close communication with implementing sites through the annual accreditation process and the NSTRC portal. The primary challenge to retention will be if the provider decides to change his/her job. An inclusion criterion for providers is planned job stability. If there is loss of providers due to job changes, we will work with our state partners to recruit newly certified SafeCare providers who are trained as a replacement. *Mother Participants*. Efforts to retain mothers will follow best practices for data collection among high-risk samples. With the participant's permission, we will (1) collect several types of contact information including phone, email, and address, (2) collect information on 3-5 contacts who may know of the participant's whereabouts, (3) obtain consent to update contact information from service provider records, (4) maintain contact in between assessment sessions with the family via email, text, or phone, by both the research team and SafeCare Provider, and (5) solicit from the client any other ways of keeping in touch with her/him. We will closely track retention rates and record reasons for study dropout, including loss to follow-up, active refusals, or dropout for other reasons.

C4d. *Study Interventions*.

Arm 1 will be the integrated program, **Smoke-Free SafeCare** described in detail in Section C3a. STBO will be integrated into the first module of SafeCare a provider delivers (Weeks 1 to 6). The SafeCare Provider will hand deliver STBO intervention materials and complete the coaching protocol in-person. As in the original intervention, intermediate behavioral targets include: making a list of reasons for a smoke-free home rule, having a family talk, signing and/or posting the pledge, posting smoke-free home signs, and calling the Quitline if interested in cessation. Once the mother completes the first integrated module of SafeCare, the other two standard SafeCare modules will be delivered in order of identified need.
Arm 2 participants will receive the usual **SafeCare** intervention without integration of STBO.

C4e. *Training of Smoke-Free SafeCare Providers*. Participating providers will already be certified in SafeCare, so no additional training for SafeCare is necessary. Providers assigned to the SFSC condition will

receive a 4-hour webinar workshop training. Post-workshop, trainees will participate in two practice sessions with the SFSC trainer via webinar, and will be rated for fidelity. Once a provider achieves fidelity on two sessions they will achieve SFSC certification. Continued monitoring will occur through the monthly coaching sessions that is a standard SafeCare implementation practice. The coaching session includes a submission of session audio recordings to NSTRC, fidelity scoring of the audio by SafeCare Trainers, and a consultation call during which the trainer discusses strengths, challenges, and future session plans with the provider.

C4f. *Measures for Aim 1 and 2.* See *Appendix A* for a copy of study measures.

Table 3 Study Outcomes for Mother Participants

	Primary Outcome: Smoke Free Home
Smoke-Free Home *(validated in prior STBO studies)*	Mothers will answer the following questions via REDCAP at every timepoint: "Which statement best describes the rules about smoking inside your home: a) smoking is not allowed anywhere inside your home; b) smoking is allowed in some places or at some times; c) smoking is allowed anywhere inside your home; or d) there are no rules about smoking inside your home." [109,110] "What smoking products are covered by the rules?" (response options include: smoke from cigarettes, cigars/cigarillos, marijuana, vapor/aerosol from Electronic Nicotine Delivery Systems (ENDs) "How often are your smoking rules broken by someone? (never, rarely, sometimes or very often)".
Validation of Smoke-Free Home Rules	At the 8-week and 1-year assessments, research staff will place an air nicotine monitor in one room in which the family spends the most time. The monitors, the size of a petri dish, will be labeled and left in place for 7 days. For quality assurance and control, one blank sample per 10 samples will be included, along with duplicate samples collected for 10% of the total sample. Research staff will return to the home after 7 days to collect the monitor. Monitors will be mailed in batches to the HERCULES Exposure Laboratory at the Emory Rollins School of Public Health. Time-weighted average airborne nicotine will be assayed. The amount of nicotine collected is determined in the laboratory using gas chromatographic analysis. The sensitivity of these devices is sufficient to quantify low levels of passive smoke exposures over a period of a few days.
	Secondary Outcomes, Exploratory Outcomes, and Covariates
Parenting Behavior	Parenting (Parenting Young Children Scale [PYCS]),[111] Parent-child relationship (Devereaux Early Child Assessment, [DECA]),[112] Parenting Stress *(*Parenting Stress Inventory [PSI]).[113]
Smoking Cessation	"Have you smoked a cigarette, even a puff, in the past 7 days?" How many cigarettes per day? "Did you use any counseling over the phone or in person to help you to quit /smoking?" "Have you used any nicotine products to help you to quit smoking, like the patch, gum, or inhaler?"
Demo-graphics	Parent and child age, sex, education, income, parent hourly wage marital status, family structure, number of children, living situation, relationship partners, and number of smokers in the home.

C4g. Measures Aim 3. See *Appendix A* for a copy of study measures.

Table 4 Process Measures to Assess Implementation, Cost and Potential Scalability

Time diaries	Study providers will complete one time diary per session (for sessions 1-6) for every participating parent. Information will include the specific amount of time in minutes spent on session-related activities prior to, during, ad following each session. The form was developed and validated in Self-Brown's NIMH R21[107]. These data will be used in the cost analyses described below.
Session Fidelity	SafeCare providers are required to audio record SafeCare sessions and to submit one audio session recording per month via the portal as an NSTRC implementation standard (Note: Family refusal of audio recording occurs in <10%). Audio recordings are rated on the *SafeCare Provider Fidelity Checklist*[102] by trained staff. Providers must achieve 85% fidelity to maintain SafeCare certification. In SFSC, the smoke-free home content will be delivered during the first module (first 6 sessions) of SafeCare delivery. Accordingly, participating study providers will be asked to submit the first 6 sessions of service for every research participant to the portal. SafeCare providers will be rated on items on the standard fidelity checklist. SFSC providers will be rated on this, as well as STBO fidelity items.
Parent Recruitment/ Engagement/ Completion	Providers will complete monthly Qualtrics surveys delivered via email. These surveys will ask providers: 1) the number of families with a smoker in the home who did NOT agree for their information to be shared with the research team, 2) questions related to parent session engagement for all project mothers they are currently serving. (validated in the PCORI project[108]), and 3) the number of SafeCare sessions completed for each project mother they are currently serving.
Parent satisfaction	Mothers will complete the *SafeCare Parent Satisfaction Measure*[102] via tablet at the 8-week and 20-week assessments. Mothers served by providers assigned to the SFSC group will complete a revised version of this measure that includes items related to STBO materials and satisfaction.[90]

C5. Analyses. We will conduct both intent-to-treat (ITT) and per protocol analyses. Frequency distributions will summarize categorical data, and measures of central tendency and dispersion will summarize continuous data. For the RCT, randomization will be assessed by comparing control and intervention participants on all relevant baseline criteria such as demographics and smoking behaviors using appropriate bivariate statistics. If there is significant imbalance due to randomization, relevant variables will be used as control variables in main RCT analyses. Similarly, missing data patterns will be investigated per data collection wave and across waves. Dependent on those findings, attrition weights might be calculated and used in all analyses. Analyses will control for demographics (age, race/ethnicity, education level, number of children). We will explore sex as a biological variable descriptively for provider participants; however, statistical analyses will not likely be viable given that most will likely be female. Sex as a biological variable will not be examined for caretakers, given study recruitment targets mothers exclusively. The overall study level of significance will be α=.05.

C5a. ***Aim 1.*** The 10 participants in Aim 1 will complete all measures described in ***section C4f*** prior to and upon completion of the first 6 sessions of SFSC. We will examine behavioral change from pre to post-intervention for smoke-free homes. We will gather qualitative feedback on overall satisfaction with the program and measures, what could be improved, and what challenges were experienced. Ten SafeCare Providers will also be selected to complete curriculum review feedback. Transcripts of the Mother and SafeCare Providers qualitative feedback from individual interviews will be reviewed by the research team and the SafeCare Training Specialists and incorporated into the final SFSC protocol to be used in the Hybrid Trial.

C5b. ***Aim 2.*** The main effect of the intervention will be assessed using self-report of the home smoking rule and air monitor data 8 weeks post-baseline. We will use complete case data and two-level logistic multilevel models accounting for nesting of participants in SafeCare providers with group assignment predicting a binary smoke-free home status (full ban/no full ban).The model equation will be $\eta_{ij} = \beta_{0j} + \beta_{1j}Group_{1ij} + u_{0j}$ where η_{ij} is the logit of the binary outcome, for person i who worked with provider j. With nicotine monitor data, we will use Receiver-operator curve (ROC)[114] analysis to determine the optimal thresholds for a smoke-free home as we have previously done.[76] All outcome models will use closest to ideal and farthest from random thresholds to test the sensitivity of the findings. The binary outcome data from the ROC analyses will be used as outcome data in a sensitivity analysis penalizing those who reported a smoke-free home but whose nicotine monitor recording rates above the ROC determined thresholds. Thus, the nicotine monitor data will be used to validate the self-report and be modeled as a second sensitivity analysis. We will also conduct a worst case scenario sensitivity analysis for the main outcome at each time point, conservatively assuming that all participants lost to the intervention would not have implemented a smoke-free home ban – if (as in previous trials) retention rates in the control group are not lower than in the intervention group.

We will assess maintenance of the intervention by replicating the above with self-report data 20-weeks post-baseline and sustainability by replicating the analysis with self-report data, validated by air monitor data, at 1-year post-baseline. Further, we will conduct two sensitivity analyses: one using the nicotine monitor data and one worst case scenario analysis parallel to the eight-week data analysis. Following analyses for individual follow-up time points, we will conduct growth curve analyses[115,116] with all available data, modeling data are missing at random. Initially, the shape of the change trajectory will be assessed through graphical analysis.[115] If this is the case again, a three-level binary logistic model (measurements nested in participant households, nested in SafeCare providers) with a linear change over time (if this is the case as in previous studies), group assignment, and an interaction effect between change over time and group assignment will assess if there is a significant intervention effect.

The impact on parenting outcomes is a test of non-inferiority.[117] We hypothesize that the braided intervention will be at least as effective as the SafeCare-only intervention on parenting. To test for non-inferiority, we must set a non-inferiority margin, i.e. the greatest lower margin at which we consider the SFSC non-inferior to SafeCare to ensure that the added aim to create a smoke-free home does not have negative unintended consequences on the impact of the SafeCare part of the intervention. To assess non-inferiority, we will conduct models parallel to the effectiveness and sustainability analyses, estimating standardized intervention effects for both groups for each of the child-parent relationship quality indicators for parent-child relations (measured by PYCS, DECA),[111,118] and parenting stress (measured by the PSI).[113] Non-inferiority is established if the upper bound of the 1-sided 90% CI is below the margin of equivalence, d = 0.30. If non-inferiority is established, we will assess superiority of SFSC over SafeCare using the 2-sided 95% CI.[119]

For secondary/exploratory outcomes intervention impact and sustainability will be assessed using the same modeling approaches among relevant sub-groups using appropriate link functions. Subsequently, we will

test for **moderators** of the intervention effect. We will assess interaction effects between group assignment and potential moderators to the multilevel models for each follow-up point. We will assess differences in intervention effect by sociodemographic characteristics and other variables of interest, such as number of smokers in the home. While power was determined for the main outcome analyses, given our conservative assumptions, we are likely to have power to detect medium size (Cohen's *d* = .5) moderator effects. The models will allow us to at least estimate moderator effect sizes which can inform future studies. Analyses will be conducted using SAS 9.4, Mplus 8.2, and HLM7.

C5c. *Aim 3*. Fidelity will be assessed through two-level random effects models where ratings are nested in providers and the key predictors is program. We will use the same non-inferiority approach as for Aim 2. The amount of time a provider spent on SafeCare or SFSC related activities will be compiled through the Time Diary, which includes the specific amount of time in minutes spent on activities prior to, during, and following each training session, as well as the additional time on webinars and fidelity monitoring for SFSC providers. For each provider, the amount of time will be aggregated by adding the time in minutes on each Time Diary collected from the same individual. Given the strong working relationship between the team and the SafeCare providers, we do not anticipate missing Time Diaries. However, if a provider has missing Time Diaries, we will replace missing values with the average time calculated from the rest of Time Diaries for the same individual. To examine the difference in time between SafeCare and SFSC providers, the following model will be analyzed: $Time_i = \beta_0 + \beta_1 SFSC_i + u$. Normality and heterogeneity of $Time_i$ will be inspected, and appropriate adjustments (e.g. log transformations for nonnormality and Huber-White standard errors for heterogeneity) will be used if needed. The estimated coefficient β_1 will reveal the average difference in time between SafeCare and SFSC providers. We expect β_1 to be positive and statistically significant.

The incremental costs per abstinent household associated with SFSC will be calculated using methods commensurate with existing cost-effectiveness smoking cessation studies.[120-123] Specifically, we will calculate the materials and opportunity costs for the additional time incurred for SFSC providers, which will be constructed by multiplying the average hourly rate across all SFSC providers by β_1.[124] The monetarized opportunity cost represents the added costs per provider associated with SFSC compared with SafeCare. The total added costs for SFSC will be calculated by multiplying per provider costs by 25. The added benefits of SFSC compared to SafeCare come from the reduction in healthcare costs due to the decrease in secondhand smoke exposure at home for SFSC children and non-smoking adults compared with those in SafeCare. The additional number of households that become smoke-free in SFSC compared with those in SafeCare will be obtained from the analysis in Aim 2. The incremental costs per abstinent household will be calculated by dividing the total added costs for SFSC by the additional number of households that become smoke-free under SFSC. The estimates of healthcare costs attributable to secondhand smoke exposure at home for each child and each adult will be based on existing studies[14,125,126] and inflation adjusted. The added benefits of SFSC will be constructed by multiplying the healthcare savings resulted from reduction in secondhand smoke exposure, measured in dollars per household, by the additional number of households that become smoke-free in SFSC. The added costs of SFSC will then be compared with its added benefits. We expect that the added costs will be smaller than the added benefits of SFSC. Previous studies have demonstrated that SafeCare is highly cost effective, and the benefits ($4,076 per participant) of SafeCare significantly outweigh its costs. We expect that SFSC will also be highly cost effective, with its benefits outweighing its costs.[84]

Additional process outcomes will be assessed descriptively (i.e. enrollment, satisfaction) and statistically (i.e. engagement and completion) using parallel methods to those used in Aim 2 and for fidelity. Data collected from SFSC providers during the exit interview will be audio-recorded, transcribed, and analyzed using the narrative analysis method.[127-129] As done in prior mixed methods projects led by Self-Brown, an open-coding process will be used to generate the themes.[130-133] To ensure interrater reliability, members of the research team will simultaneously examine and code the data. Coding differences will be discussed and rectified until an inter-coder agreement threshold of 80% is achieved.[134]

C6. Power Calculations. Our expected rate of smoke-free homes is derived from the original three RCTs[76-78] in which we observed average differences between intervention and control groups of 18.5% at 3 months and 16.4% at 6 months for smoke-free home rules. We used the more conservative 16.4% absolute difference in smoke-free homes between intervention and control households for the power calculations. PROC POWER in SAS 9.4 was used to determine raw sample sizes needed to detect an effect for a range of home rule changes for both intervention and control arm assuming 20% attrition. Subsequently, we adjusted sample sizes for

clustering using design effects (DEFFs) determined using formulas outlined by Moerbeek and Teerenstra.[135] **Table 5** → shows a range of sample sizes given the combinations of assumed characteristics of the samples tested with a typical DEFF of 1.1, based on ICC's we have observed in our past intervention studies, and a much more conservative DEFF of 1.5. The conservative sample size of 500 participants will allow us to detect a difference of 16.4% or larger even with a large design effect due to unmeasured factors affecting intervention impact at the clinic or even provider level. If the DEFF is at 1.1, we will be able to show a significant difference of just 12% or less depending on the control group percentage of smoke-free homes. For the non-inferiority analysis, we set the margin of equivalence at $d = 0.3$[119] to allow for a small to medium difference in effect. Power calculations indicate that our sample of 500 also allows us to demonstrate non-inferiority for an effect difference of $d = 0.301$.

Control SFH	Intervention SFH	Total N (DE = 1.1)	Total N (DE = 1.5)
10%	26%	227	310
20%	36%	309	421
30%	46%	362	493

C7. Timeline for Pilot and Hybrid 1 Trial

Table 6 Timeline

	Year 1				Year 2				Year 3				Year 4				Year 5			
TASK	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Planning/Hiring/IRB	√																			
Piloting SFSC		√	√																	
Finalize SFSC curriculum			√	√																
Enrollment of Providers			√	√	√															
SFSC Training				√	√															
Enrollment of Families for Randomized Trial				√	√	√	√	√	√	√	√	√	√	√	√					
Data Collection		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
Data Analyses			√	√					√	√	√	√	√	√	√	√	√	√	√	√
Dissemination of Findings				√						√	√	√	√	√	√	√	√	√	√	√

C8. **Impact.** The proposed research builds on existing data indicating extremely high smoking rates among parents involved with child protective services. Given the cumulative risk among youth who have been exposed to child maltreatment and SHS, disseminating effective programs to address these public health problems is imperative. STBO and SafeCare have strong empirical support as stand-alone programs. Systematically braiding these interventions (SFSC) to target a high-priority population is a promising solution. If effective, SFSC can be efficiently disseminated by NSTRC to the over 100 accredited SafeCare agencies that already serve parents involved with CPS. Effective dissemination will include augmenting SafeCare training to include: 1) an assessment of smoke-free home rules, 2) STBO curriculum review, and 3) training on how to effectively integrate the two programs in delivery to parents. Broader dissemination of STBO could expand the public health impact of this program for targeting cancer disparities among high-risk families.

References

1. Tsai J, Homa DM, Gentzke AS, et al. Exposure to secondhand smoke among nonsmokers - United States, 1988-2014. *MMWR Morb Mortal Wkly Rep*. 2018;67(48):1342-1346. doi:10.15585/mmwr.mm6748a3
2. USDHHS. The health consequences of smoking—50 years of progress: A report of the Surgeon General. *US Dep Heal Hum Serv Centers Dis Control Prev Natl Cent Chronic Dis Prev Heal Promot Off Smok Heal*. 2014. http://www.ncbi.nlm.nih.gov/pubmed/24455788. Accessed April 11, 2019.
3. USDHHS. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General, 6 Major Conclusions of the Surgeon General Report. *US Dep Heal Hum Serv Centers Dis Control Prev Natl Cent Chronic Dis Prev Heal Promot Off Smok Heal*. 2006. http://www.surgeongeneral.gov/library/secondhandsmoke/. Accessed April 11, 2019.
4. Anderson TM, Lavista Ferres JM, Ren SY, et al. Maternal smoking before and during pregnancy and the risk of sudden unexpected infant death. *Pediatrics*. 2019;143(4):e20183325. doi:10.1542/peds.2018-3325
5. Metayer C, Zhang L, Wiemels JL, et al. Tobacco smoke exposure and the risk of childhood acute lymphoblastic and myeloid leukemias by cytogenetic subtype. *Cancer Epidemiol Biomarkers Prev*. 2013;22(9):1600-1611. doi:10.1158/1055-9965.EPI-13-0350
6. Whitehead TP, Metayer C, Wiemels JL, Singer AW, Miller MD. Childhood leukemia and primary prevention. *Curr Probl Pediatr Adolesc Health Care*. 2016;46:317-352. doi:10.1016/j.cppeds.2016.08.004
7. Troy JD, Grandis JR, Youk AO, Diergaarde B, Romkes M, Weissfeld JL. Childhood passive smoke exposure is associated with adult head and neck cancer. *Cancer Epidemiol*. 2013;37(4):417-423. doi:10.1016/j.canep.2013.03.011
8. Vineis P, Airoldi L, Veglia F, et al. Environmental tobacco smoke and risk of respiratory cancer and chronic obstructive pulmonary disease in former smokers and never smokers in the EPIC prospective study. *BMJ*. 2005;330(7486):277. doi:10.1136/bmj.38327.648472.82
9. Chuang S-C, Gallo V, Michaud D, et al. Exposure to environmental tobacco smoke in childhood and incidence of cancer in adulthood in never smokers in the European prospective investigation into cancer and nutrition. *Cancer Causes Control*. 2011;22:487-494. doi:10.1007/s10552-010-9723-2
10. Vrieling A, Bas Bueno-De-Mesquita H, Boshuizen HC, et al. Cigarette smoking, environmental tobacco smoke exposure and pancreatic cancer risk in the European Prospective Investigation into Cancer and Nutrition. *Int J Cancer*. 2010;126:2394-2403. doi:10.1002/ijc.24907
11. Diver WR, Jacobs EJ, Gapstur SM. Secondhand smoke exposure in childhood and adulthood in relation to adult mortality among never smokers. *Am J Prev Med*. 2018;55(3):345-352. doi:10.1016/j.amepre.2018.05.005
12. Padrón A, Galán I, García-Esquinas E, et al. Exposure to second-hand smoke in the home and mental health in children: a population-based study. *Tob Control*. 2016;25(3):307-312.
13. Zhou S, Rosenthal DG, Sherman S, et al. Physical, Behavioral, and Cognitive Effects of Prenatal Tobacco and Postnatal Secondhand Smoke Exposure. *Curr Probl Pediatr Adolesc Health Care*. 2014;44(8):219-241. doi:10.1016/J.CPPEDS.2014.03.007
14. Yao T, Sung H-Y, Wang Y, Lightwood J, Max W. Healthcare costs of secondhand smoke exposure at home for U.S. children. *Am J Prev Med*. 2019;56(2):281-287. doi:10.1016/j.amepre.2018.08.013
15. Max W, Sung H-Y, Shi Y. Deaths from secondhand smoke exposure in the United States: Economic implications. *Am J Public Health*. 2012;102(11):2173-2180. doi:10.2105/AJPH.2012.300805
16. King BA, Patel R, Babb SD, Hartman AM, Freeman A. National and state prevalence of smoke-free rules in homes with and without children and smokers: Two decades of progress. *Prev Med*. 2016;82:51-58. doi:10.1016/j.ypmed.2015.11.010
17. Matt GE, Quintana PJE, Destaillats H, et al. Thirdhand tobacco smoke: Emerging evidence and arguments for a multidisciplinary research agenda. *Environ Health Perspect*. 2011;119(9):1218-1226. doi:10.1289/ehp.1103500
18. US EPA. *Child-Specific Exposure Factors Handbook (2008, Final Report)*. Washington, D.C.; 2008. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=199243. Accessed April 16, 2019.
19. Mills AL, White MM, Pierce JP, Messer K. Home smoking bans among U.S. households with children and smokers: Opportunities for intervention. *Am J Prev Med*. 2011;41(6):559-565.

doi:10.1016/J.AMEPRE.2011.08.016
20. Homa DM, Neff LJ, King BA, et al. Morbidity and Mortality Weekly Report Vital Signs: Disparities in Nonsmokers' Exposure to Secondhand Smoke-United States, 1999-2012. *Morb Mortal Wkly Rep*. 2015;64(4):103-108. http://www.cdc.gov/mmwr. Accessed April 16, 2019.
21. Gartner CE, Hall WD. Is the socioeconomic gap in childhood exposure to secondhand smoke widening or narrowing? *Tob Control*. 2013;22(5):344-348. doi:10.1136/tobaccocontrol-2011-050297
22. Holtby S, Zahnd E, Grant D, Park R. *Children's Exposure to Secondhand Smoke: Nearly One Million Affected in California*.; 2011. https://escholarship.org/uc/item/0vg2m7vg. Accessed April 16, 2019.
23. Orton S, Jones LL, Cooper S, Lewis S, Coleman T. Predictors of children's secondhand smoke exposure at home: A systematic review and narrative synthesis of the evidence. Lin ZC, ed. *PLoS One*. 2014;9(11):e112690. doi:10.1371/journal.pone.0112690
24. Kelly A, Denning-Kemp G, Geiringer K, et al. Exposure to harmful housing conditions is common in children admitted to Wellington Hospital. *N Z Med J*. 2013;126(1387):108-126.
25. Collaco JM, Aherrera AD, Ryan T, McGrath-Morrow SA. Secondhand smoke exposure in preterm infants with bronchopulmonary dysplasia. *Pediatr Pulmonol*. 2014;49:173-178. doi:10.1002/ppul.22819
26. Longman JM, Passey ME. Children, smoking households and exposure to second-hand smoke in the home in rural Australia: analysis of a national cross-sectional survey. *BMJ Open*. 2013;3:e003128. doi:10.1136/bmjopen-2013-003128
27. Merianos AL, Jandarov RA, Choi K, Melinda Mahabee-Gittens E. Tobacco smoke exposure disparities persist in U.S. children: NHANES 1999–2014. *Prev Med (Baltim)*. 2019;123:138-142. doi:10.1016/j.ypmed.2019.03.028
28. Gehrman C, Hovell M. Protecting children from environmental tobacco smoke (ETS) exposure: A critical review. *Nicotine Tob Res*. 2003;5(3):289-301. doi:10.1080/1462220031000094231
29. Biener L, Cullen D, Di ZX, Hammond SK. Household smoking restrictions and adolescents' exposure to environmental tobacco smoke. *Prev Med (Baltim)*. 1997;26:358-363. doi:10.1006/PMED.1997.0152
30. Wakefield MA, Chaloupka FJ, Kaufman NJ, Orleans CT, Barker DC, Ruel EE. Effect of restrictions on smoking at home, at school, and in public places on teenage smoking: Cross sectional study. *BMJ*. 2000;321:333-337. doi:10.1136/BMJ.321.7257.333
31. Pizacani BA, Martin DP, Stark MJ, Koepsell TD, Thompson B, Diehr P. Household smoking bans: Which households have them and do they work? *Prev Med (Baltim)*. 2003;36:99-107. doi:10.1006/PMED.2002.1123
32. Zhang X, Martinez-Donate AP, Kuo D, Jones NR, Palmersheim KA. Trends in home smoking bans in the U.S.A., 1995-2007: Prevalence, discrepancies and disparities. *Tob Control*. 2012;21:330-336. doi:10.1136/tc.2011.043802
33. Felitti VJ, Anda RF, Nordenberg D, et al. Relationship of childhood abuse and household dysfunction to many of the leading causes of death in adults: The Adverse Childhood Experiences (ACE) study. *Am J Prev Med*. 1998;14(4):245-258. doi:10.1016/S0749-3797(98)00017-8
34. Black MM, Walker SP, Fernald LCH, et al. Early childhood development coming of age: Science through the life course. *Lancet*. 2017;389:77-90. doi:10.1016/S0140-6736(16)31389-7
35. National Research Council and Institute of Medicine. *From Neurons to Neighborhoods: The Science of Early Childhood Development*. (Shonkoff JP, Phillips DA, eds.). Washington, D.C.: National Academies Press; 2000. http://www.nap.edu. Accessed April 16, 2019.
36. Shonkoff JP, Boyce WT, McEwen BS. Neuroscience, molecular biology, and the childhood roots of health disparities. *JAMA*. 2009;301(21):2252-2259. doi:10.1001/jama.2009.754
37. Bruce J, Gunnar MR, Pears KC, Fisher PA. Early adverse care, stress neurobiology, and prevention science: Lessons learned. *Prev Sci*. 2013;14:247-256. doi:10.1007/s11121-012-0354-6
38. Herrenkohl EC, Herrenkohl RC, Rupert LJ, Egolf BP, Lutz JG. Risk factors for behavioral dysfunction: The relative impact of maltreatment, SES, physical health problems, cognitive ability, and quality of parent-child interaction. *Child Abuse Negl*. 1995;19(2):191-203. doi:10.1016/0145-2134(94)00116-C
39. Gilbert R, Widom CS, Browne K, Fergusson D, Webb E, Janson S. Burden and consequences of child maltreatment in high-income countries. *Lancet*. 2009;373(9657):68-81. doi:10.1016/S0140-6736(08)61706-7
40. Fergusson DM, Boden JM, Horwood LJ. Exposure to childhood sexual and physical abuse and adjustment in early adulthood. *Child Abuse Negl*. 2008;32:607-619. doi:10.1016/J.CHIABU.2006.12.018

41. Thornberry TP, Ireland TO, Smith CA. The importance of timing: The varying impact of childhood and adolescent maltreatment on multiple problem outcomes. *Dev Psychopathol*. 2001;13:957-979.
42. Widom CS. Posttraumatic stress disorder in abused and neglected children grown up. *Am J Psychiatry*. 1999;156:1223-1229.
43. Horwitz A V, Widom CS, Mclaughlin J, Raskin H. The impact of childhood abuse and neglect on adult mental health: A prospective study. *J Health Soc Behav*. 2001;42(2):184-201.
44. Dube SR, Fairweather D, Pearson WS, Felitti VJ, Anda RF, Croft JB. Cumulative childhood stress and autoimmune diseases in adults. *Psychosom Med*. 2009;71(2):243-250. doi:10.1097/PSY.0b013e3181907888
45. Brown DW, Anda RF, Felitti VJ, et al. Adverse childhood experiences are associated with the risk of lung cancer: A prospective cohort study. *BMC Public Health*. 2010;10(20):1-12. doi:10.1186/1471-2458- 10-20
46. Dong M, Dube SR, Felitti VJ, Giles WH, Anda RF. Adverse childhood experiences and self-reported liver disease. *Arch Intern Med*. 2003;163(16):1949. doi:10.1001/archinte.163.16.1949
47. Dong M, Giles WH, Felitti VJ, et al. Insights into causal pathways for ischemic heart disease. *Circulation*. 2004;110:1761-1766. doi:10.1161/01.CIR.0000143074.54995.7F
48. Corso PS, Edwards VJ, Fang X, Mercy JA. Health-related quality of life among adults who experienced maltreatment during childhood. *Am J Public Health*. 2008;98(6):1094-1100. doi:10.2105/AJPH.2007.119826
49. Lanier P, Jonson-Reid M, Stahlschmidt MJ, Drake B, Constantino J. Child maltreatment and pediatric health outcomes: A longitudinal study of low-income children. *J Pediatr Psychol*. 2010;35(5):511-522. doi:10.1093/jpepsy/jsp086
50. Wegman HL, Stetler C. A meta-analytic review of the effects of childhood abuse on medical outcomes in adulthood. *Psychosom Med*. 2009;71(8):805-812. doi:10.1097/PSY.0b013e3181bb2b46
51. USDHHS, Administration for Children and Families, Administration on Children Youth and Families, Children's Bureau. Child Maltreatment 2017. 2019. https://www.acf.hhs.gov/cb/research-data-technology/statistics-research/child-maltreatment. Accessed April 22, 2019.
52. Morris MC, Marco M, Maguire-Jack K, et al. Connecting child maltreatment risk with crime and neighborhood disadvantage across time and place: a Bayesian spatiotemporal analysis. *Child Maltreat*. November 2018:107755951881436. doi:10.1177/1077559518814364
53. Slack KS, Holl JL, McDaniel M, Yoo J, Bolger K. Understanding the risks of child neglect: An exploration of poverty and parenting characteristics. *Child Maltreat*. 2004;9(4):395-408. doi:10.1177/1077559504269193
54. Lee BJ, Goerge RM. Poverty, early childbearing, and child maltreatment: A multinomial analysis. *Child Youth Serv Rev*. 1999;21(9/10):755-780. doi:10.1016/S0190-7409(99)00053-5
55. Barboza GE. The geography of child maltreatment: A spatiotemporal analysis using Bayesian Hierarchical Analysis with Integrated Nested Laplace Approximation. *J Interpers Violence*. 2019;34(1):50-80. doi:10.1177/0886260516639583
56. Coulton CJ, Crampton DS, Irwin M, Spilsbury JC, Korbin JE. How neighborhoods influence child maltreatment: A review of the literature and alternative pathways. *Child Abuse Negl*. 2007;31:1117- 1142. doi:10.1016/j.chiabu.2007.03.023
57. Drake B, Pandey S. *Understanding the Relationship between Neighborhood Poverty and Specific Types of Child Maltreatment*. Vol 20.; 1996. doi:10.1016/0145-2134(96)00091-9
58. Freisthler B, Merritt DH, LaScala EA. Understanding the ecology of child maltreatment: A review of the literature and directions for future research. *Child Maltreat*. 2006;11(3):263-280. doi:10.1177/1077559506289524
59. McLeigh JD, McDonell JR, Lavenda O. Neighborhood poverty and child abuse and neglect: The mediating role of social cohesion. *Child Youth Serv Rev*. 2018;93:154-160. doi:10.1016/j.childyouth.2018.07.018
60. Molnar BE, Goerge RM, Gilsanz P, et al. Neighborhood-level social processes and substantiated cases of child maltreatment. *Child Abuse Negl*. 2016;51:41-53. doi:10.1016/j.chiabu.2015.11.007
61. Zuravin SJ, Taylor R. The ecology of child maltreatment: Identifying and characterizing high-risk nieghborhoods. *Child Welfare*. 1987;66(6):497-506.
62. Liu Y, Merritt DH. Familial financial stress and child internalizing behaviors: The roles of caregivers' maltreating behaviors and social services. *Child Abuse Negl*. 2018;86:324-335.

doi:10.1016/j.chiabu.2018.09.002
63. Maguire-Jack K. Multilevel investigation into the community context of child maltreatment. *J Aggress Maltreat Trauma*. 2014;23(3):229-248. doi:10.1080/10926771.2014.881950
64. Tandon M, Grant JD, Madden PA, Bucholz KK, Heath AC. Smoking as an early risk factor for problematic parenting practices. *Scand J Child Adolesc Psychiatry Psychol*. 2017;5(2):52-54. doi:10.21307/sjcapp-2017-006
65. Wu SS, Ma C-X, Carter RL, et al. Risk factors for infant maltreatment: A population-based study. *Child Abuse Negl*. 2004;28:1253-1264. doi:10.1016/j.chiabu.2004.07.005
66. Creamer MLR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults - United States, 2018. *MMWR Morb Mortal Wkly Rep*. 2019;68(45):1013-1019. doi:10.15585/mmwr.mm6845a2
67. Gertler P, Heckman J, Pinto R, et al. Labor market returns to an early childhood stimulation intervention in Jamaica. *Science (80-)*. 2014;344(6187):998-1001. http://science.sciencemag.org/. Accessed April 16, 2019.
68. Hoddinott J, Maluccio JA, Behrman JR, Flores R, Martorell R. Effect of a nutrition intervention during early childhood on economic productivity in Guatemalan adults. *Lancet*. 2008;371:411-416. doi:10.1016/S0140-6736(08)60205-6
69. Maluccio JA, Hoddinott J, Behrman JR, Martorell R, Quisumbing AR, Stein AD. The impact of improving nutrition during early childhood on education among Guatemalan adults. *Econ J*. 2009;119:734-763. doi:10.1111/j.1468-0297.2009.02220.x
70. Walker SP, Chang SM, Vera-Hernández M, Grantham-Mcgregor S. Early childhood stimulation benefits adult competence and reduces violent behavior. *Pediatrics*. 2011;127(5):849-857. doi:10.1542/peds.2010-2231
71. Campbell F, Conti G, Heckman JJ, et al. Early childhood investments substantially boost adult health. *Science (80-)*. 2014;343(6178):1478-1485. doi:10.1126/science.1248429
72. Behrman JR, Calderon MC, Preston SH, Hoddinott J, Martorell R, Stein AD. Nutritional supplementation in girls influences the growth of their children: Prospective study in Guatemala. *Am J Clin Nutr*. 2009;90:1372-1379. doi:10.3945/ajcn.2009.27524
73. Walker SP, Chang SM, Wright A, Osmond C, Grantham-McGregor SM. Early childhood stunting is associated with lower developmental levels in the subsequent generation of children. *J Nutr*. 2015;145(4):823-828. doi:10.3945/jn.114.200261
74. Hoddinott J, Alderman H, Behrman JR, Haddad L, Horton S. The economic rationale for investing in stunting reduction. *Matern Child Nutr*. 2013;9(Suppl. 2):69-82. doi:10.1111/mcn.12080
75. Doyle O, Harmon CP, Heckman JJ, Tremblay RE. Investing in early human development: Timing and economic efficiency. *Econ Hum Biol*. 2009;7:1-6. doi:10.1016/J.EHB.2009.01.002
76. Kegler MC, Bundy L, Haardörfer R, et al. A minimal intervention to promote smoke-free homes among 2-1-1 callers: A randomized controlled trial. *Am J Public Health*. 2015;105(3):530-537. doi:10.2105/AJPH.2014.302260
77. Williams RS, Stollings JH, Bundy Ł, et al. A minimal intervention to promote smoke-free homes among 2-1-1 callers: North Carolina randomized effectiveness trial. *PLoS One*. 2016;11(11):1-15. doi:10.1371/journal.pone.0165086
78. Mullen PD, Savas LS, Bundy ŁT, et al. Minimal intervention delivered by 2-1-1 information and referral specialists promotes smoke-free homes among 2-1-1 callers: A Texas generalisation trial. *Tob Control*. 2016;25:i10–i18. doi:10.1136/tobaccocontrol-2016-053045
79. Bundy ŁT, Haardörfer R, Kegler MC, et al. Disseminating a smoke-free homes program to low socioeconomic status households in the United States through 2-1-1: Results of a national impact evaluation. *Nicotine Tob Res*. May 2018. doi:10.1093/ntr/nty256
80. Chaffin M, Bard D, Bigfoot DS, Maher EJ. Is a structured, manualized, evidence-based treatment protocol culturally competent and equivalently effective among American Indian parents in child welfare? *Child Maltreat*. 2012;17(3):242-252. doi:10.1177/1077559512457239
81. Chaffin M, Hecht D, Bard D, Silovsky JF, Beasley WH. A statewide trial of the SafeCare home-based services model with parents in Child Protective Services. *Pediatrics*. 2012;129(3):509-515. doi:10.1542/peds.2011-1840
82. Silovsky JF, Bard D, Chaffin M, et al. Prevention of child maltreatment in high-risk rural families: A

randomized clinical trial with child welfare outcomes. *Child Youth Serv Rev*. 2011;33:1435-1444. doi:10.1016/J.CHILDYOUTH.2011.04.023
83. Aos S, Lieb R, Mayfield J, Miller M, Pennucci A. *Benefits and Costs of Prevention and Early Intervention Programs for Youth*. Olympia, WA; 2004. http://www.wsipp.wa.gov. Accessed April 23, 2019.
84. Damashek A, Doughty D, Ware L, Silovsky J. Predictors of client engagement and attrition in home-based child maltreatment prevention services. *Child Maltreat*. 2011;16(1):9-20. doi:10.1177/1077559510388507
85. Guastaferro K, Miller K, Shanley Chatham JR, Whitaker DJ, McGilly K, Lutzker JR. Systematic braiding of two evidence-based parent training programs: Qualitative results from the pilot phase. *Fam Community Heal*. 2017;40(1):88-97. doi:10.1097/FCH.0000000000000129
86. Guastaferro K, Miller K, Lutzker JR, et al. Implementing a braided home-based parent-support curriculum: Lessons learned. *Psychosoc Interv*. 2017;26:181-187. doi:10.1016/J.PSI.2017.03.001
87. Guastaferro K, Lai BS, Miller K, et al. Braiding two evidence-based programs for families at-risk: Results of a cluster randomized trial. *J Child Fam Stud*. 2018;27:535-546. doi:10.1007/s10826-017-0886-2
88. Guastaferro K, Miller K, Lai BS, et al. Modification to a systematically braided Parent-support curriculum: Results from a feasibility pilot. *J Child Fam Stud*. March 2019:1-10. doi:10.1007/s10826-019-01369-w
89. Kegler MC, Escoffery C, Bundy L, et al. Pilot study results from a brief intervention to create smoke-free homes. *J Environ Public Health*. 2012;2012:1-9. doi:10.1155/2012/951426
90. Escoffery C, Bundy L, Haardoerfer R, et al. A process evaluation of an intervention to promote home smoking bans among low income households. *Eval Program Plann*. 2016;55:120-125. doi:10.1016/j.evalprogplan.2015.12.008
91. Kegler MC, Haardörfer R, Bundy LT, et al. Moderators of establishing a smoke-free home: pooled data from three randomized controlled trials of a brief intervention. *J Community Health*. 2019;44:121-126. doi:10.1007/s10900-018-0561-6
92. Carta JJ, Lefever JB, Bigelow K, Borkowski J, Warren SF. Randomized trial of a cellular phone-enhanced home visitation parenting intervention. *Pediatrics*. 2013;132(Suppl 2):S167-S173. doi:10.1542/PEDS.2013-1021Q
93. Lefever JEB, Bigelow KM, Carta JJ, et al. Long-term Impact of a cell phone–enhanced parenting intervention. *Child Maltreat*. 2017;22(4):305-314. doi:10.1177/1077559517723125
94. Whitaker D, Self-Brown S, Hayat M, et al. Effect of the SafeCare© model on parenting outcomes among parents in child welfare systems: A cluster randomized trial. *Under Rev*.
95. Osborne M, Self-Brown S. Tobacco Use and Home Safety Hazards in a Sample of Child Welfare-Involved Caregivers, monthly research seminar. In: *Georgia State University, School of Public Health Research Seminar*. Atlanta, Georgia; 2019.
96. Osborne MC, Weeks E, Whitaker D, Spears C, Kegler M, Self-Brown S. Tobacco use and home safety hazards in a sample of child welfare-involved caregivers. *Under Rev*.
97. Lecomte T, Corbière M, Simard S, et al. Merging evidence-based psychosocial interventions in schizophrenia. *Behav Sci (Basel)*. 2014;4:437-447. doi:10.3390/bs4040437
98. Cook CR, Frye M, Slemrod T, Lyon AR, Renshaw TL, Zhang Y. An integrated approach to universal prevention: Independent and combined effects of PBIS and SEL on youths' mental health. *Sch Psychol Q*. 2015;30(2):166-183. doi:10.1037/spq0000102
99. Bandura A. Human agency in social cognitive theory. *Am Psych*. 1989;44(9):1175-1184. http://www.stiftelsen-hvasser.no/documents/Bandura_Human_Agency_in_social_Cognitiv_theory.pdf. Accessed April 16, 2019.
100. Prochaska JO, Diclemente C. Transtheoretical therapy: Toward a more integrative model of change. *Psychother Theory, Res Pract*. 1982;19(3):276-288. doi:10.1037/h0088437
101. Self-Brown S, McFry E, Montesanti A, et al. *SafeCare: A Prevention and Intervention Program for Child Neglect and Physical Abuse*. 2nd Editio. (Reece RM, Hanson RF, Sargent J, eds.). Baltimore, MD: Johns Hopkins University Press; 2014.
102. Lutzker J, Bigelow K. *Reducing Child Maltreatment: A Guidebook for Parent Services*. New York, NY: Guliford Press; 2001.
103. Kim S, Wipfli H, Navas-Acien A, et al. Determinants of hair nicotine concentrations in nonsmoking women and children: A multicountry study of secondhand smoke exposure in homes on behalf of the FAMRI Homes Study Investigators. *Cancer Epidemiol Bio-markers Prev*. 2009;18(12):3407-3421.

doi:10.1158/1055-9965.EPI-09-0337
104. Escoffery C, Mullen P, Genkin B, et al. Coaching to create a smoke-free home in a brief secondhand smoke intervention. *Health Educ Res*. 2017;32(6):555-568. doi:10.1093/her/cyx072
105. Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion. Map of Cigarette Use Among Adults.
106. Center for Behavioral Health Statistics and Quality. *2016 National Survey on Drug Use and Health: Detailed Tables*. Rockville, MD; 2017.
107. Self-Brown SR, Osborne MC, Rostad W, Feil E. A technology-mediated approach to the implementation of an evidence-based child maltreatment prevention program. *Child Maltreat*. 2017;22(4):344-353. doi:10.1177/1077559516678482
108. Whitaker DJ, Hayat M, Weeks E, Zahidi R, Self-Brown SR, Willging C. *PCORI Final Research Report: Comparative Effectiveness Trial to Reduce Child Maltreatment, Improve Clinet Outcomes and Examine Client Burden & Disseminating SafeCare to Precent Child Maltreatment and Negative Health Outcomes*.; 2019.
109. King BA, Patel R, Babb SD, Hartman AM, Freeman A. National and state prevalence of smoke-free rules in homes with and without children and smokers: Two decades of progress. *Prev Med (Baltim)*. 2016;82:51-58. doi:10.1016/j.ypmed.2015.11.010
110. Kruger J, Jama A, Homa DM, Babb SD, King BA. Smoke-free home and vehicle rules by tobacco use status among US adults. *Prev Med (Baltim)*. 2015;78:9-13. doi:10.1016/j.ypmed.2015.06.004
111. McEachern AD, Dishion TJ, Weaver CM, Shaw DS, Wilson MN, Gardner F. Parenting Young Children (PARYC): Validation of a self-report parenting measure. *J Child Fam Stud*. 2012;21:498-511. doi:10.1007/s10826-011-9503-y
112. Powell G, Mackrain M, Lebuffe P. *Devereux Early Childhood Assessment for Infants and Toddlers Technical Manual*. Lewisville, NC: Kaplan Early Learning Corporation; 2007. www.devereuxearlychildhood.org. Accessed April 23, 2019.
113. Haskett ME, Ahern LS, Ward CS, Allaire JC. Factor structure and validity of the parenting stress index-short form. *J Clin Child Adolesc Psychol*. 2006;35(2):302-312. doi:10.1207/s15374424jccp3502_14
114. Gonen M. *Analyzing Receiver Operating Characteristic Curves with SAS®*. Cary, NC: SAS Institute Inc.; 2007.
115. Singer JD, Willett JB. *Applied Longitudinal Data Analysis: Modeling Change and Event Occurrence*. Oxford University Press; 2003.
116. Raudenbush SW, Bryk AS. *Hierarchical Linear Models: Applications and Data Analysis Methods*. Volume 1. Sage Publications; 2002. https://us.sagepub.com/en-us/nam/hierarchical-linear-models/book9230. Accessed April 22, 2019.
117. Hahn S. Understanding noninferiority trials. *Korean J Pediatr*. 2012;55(11):403-407. doi:10.3345/kjp.2012.55.11.403
118. Lebuffe PA, Kaplan JAN. *The Devereux Early Childhood Assessment*. Lewisville, NC: Kaplan Press Publishing; 1999. https://www.e-deca2.org/Content/DECARecordFormPreschoolEn.pdf. Accessed April 23, 2019.
119. Piaggio G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG, CONSORT Group for the. Reporting of noninferiority and equivalence randomized trials. *JAMA*. 2012;308(24):2594-2604. doi:10.1001/jama.2012.87802
120. Daly AT, Deshmukh AA, Vidrine DJ, et al. Cost-effectiveness analysis of smoking cessation interventions using cell phones in a low-income population. *Tob Control*. 2019;28(1):88-94. doi:10.1136/tobaccocontrol-2017-054229
121. van den Brand FA, Nagelhout GE, Winkens B, Chavannes NH, van Schayck OCP, Evers SMAA. Cost-effectiveness and cost–utility analysis of a work-place smoking cessation intervention with and without financial incentives. *Addiction*. 2019;115:534-545. doi:10.1111/add.14861
122. Feldman I, Helgason AR, Johansson P, Tegelberg Å, Nohlert E. Cost-effectiveness of a high-intensity versus a low-intensity smoking cessation intervention in a dental setting: Long-term follow-up. *BMJ Open*. 2019;9:1-8. doi:10.1136/bmjopen-2019-030934
123. Lee D, Lee YR, Oh IH. Cost-effectiveness of smoking cessation programs for hospitalized patients: A systematic review. *Eur J Heal Econ*. 2019;20(9):1409-1424. doi:10.1007/s10198-019-01105-7
124. Quah E, Mishan EJ, Quah E. *Cost-Benefit Analysis*. London: Routledge; 2007.

doi:10.4324/9780203695678
125. Yao T, Sung H-Y, Wang Y, Lightwood J, Max W. Healthcare costs attributable to secondhand smoke exposure at home for U.S. adults. *Prev Med (Baltim)*. 2018;108:41-46. doi:10.1016/j.ypmed.2017.12.028
126. Mason J, Wheeler W, Brown MJ. The economic burden of exposure to secondhand smoke for child and adult never smokers residing in U.S. public housing. *Public Heal Reports* . 2015;130(3):230-244. doi:10.1177/003335491513000310
127. Creswell JW, Poth CN. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*. 4th ed. Thousand Oaks, CA: SAGE Publications; 2007.
128. Holcomb, Pamela, Edin K, et al. *In Their Own Voices: The Hopes and Struggles of Responsible Fatherhood Program Participants in the Parents and Children Together Evaluation.* OPRE Report Number 2015-67. Washington D.C.; 2015.
129. Pate DJ. The color of debt: An Examination of social networks, sanctions, and child support enforcement policy. *Race Soc Probl*. 2016;8:116-135. doi:10.1007/s12552-016-9167-8
130. Self-Brown S, Osborne MC, Boyd C, et al. The impact of SafeCare® Dads to Kids program on father maltreatment risk and involvement: Outcomes and lessons learned from an efficacy trial. *Child Abuse Negl*. 2018;83:31-41. doi:10.1016/J.CHIABU.2018.06.014
131. Self-Brown S, Osborne MC, Lai BS, Brown NDV, Glasheen TL, Adams MC. Initial findings from a feasibility trial examining the SafeCare Dad to Kids Program with marginalized fathers. *J Fam Violence*. 2017;(Advanced online publication):1-16. doi:10.1007/s10896-017-9940-5
132. Rostad WL, Self-Brown S, Boyd C, Osborne M, Patterson A, Patterson A. Exploration of factors predictive of at-risk fathers' participation in a pilot study of an augmented evidence-based parent training program: A mixed methods approach. *Child Youth Serv Rev*. 2017;79:485-494. doi:10.1016/j.childyouth.2017.07.001
133. Self-Brown S, Cowart-Osborne M, Baker E, et al. Dad2K: An adaptation of SafeCare to enhance positive parenting skills with at-risk fathers. *Child Fam Behav Ther*. 2015;37(2):138-155. doi:10.1080/07317107.2015.1035992
134. Campbell JL, Quincy C, Osserman J, Pedersen OK. Coding in-depth semistructured interviews: Problems of unitization and intercoder reliability and agreement. *Sociol Methods Res*. 2013;42(3):294-320. doi:10.1177/0049124113500475
135. Moerbeek M, Teerenstra S. *Power Analysis of Trials with Multilevel Data*. Boca Raton, FL: CRC Press; 2015.