Planning for Real World Impact

Methods, models, & frameworks for planning pragmatic research.

August 11: 8am - 6pm MDT

August 12: 7:30am - 4:30pm MDT

Breakfast Session

Early Career Investigator Consultations

SPECIFIC AIMS

Substance use among pregnant women contributes to some of the most prevalent yet preventable public health issues in the U.S. Substance use during pregnancy increases risk for maternal and child health problems, such as experiencing major depressive episodes for mothers[11] and prematurity, malformations, and neonatal abstinence syndrome for children.[12] Pregnant women who misuse substances are a highly stigmatized population for lifelong substance use and related issues; thus, identifying and intervening with substance use among pregnant women is imperative.[11,13-16] Pregnancy is a window of opportunity for addressing substance use, as pregnant women are often motivated to take care of the health of their babies.[17-19] Under-detection of substance use (e.g., 9.9% self-reported tobacco use[20] vs. 18.9% laboratory evidence[21]) and subsequent under-utilization of treatment services among perinatal population, however, remain a challenge.[22-25] The proposed study seeks to systematically adapt and implement ***Screen, Brief Intervention, and Referral to Treatment*** **(SBIRT)**[26] and test its feasibility and acceptability to address substance use among pregnant women in **the Nurse Family Partnership (NFP)**, an evidence-based home visiting program for first-time, low-income mothers and their families.[27-35] NFP is implemented in at 260 sites across the country and has served over 317,000 low-income mothers and their families.[36] SBIRT[26] is a prominent screen-and-refer approach recommended by the American Congress of Obstetricians and Gynecologists (ACOG)[37] and the Substance Abuse and Mental Health Administration (SAMHSA)[38] as a part of prenatal care to increase service access and reduce substance use among pregnant women.[25] Although NFP has applied the SBIRT framework since its inception, there has been an increasing demand to improve the current practice to meet the needs of the population NFP serves. Systematic adaptation and implementation of SBIRT for delivery in the NFP has the potential to reach the significant proportion of low-income pregnant women who may not receive screening or referral for substance misuse in prenatal care. The project will rely on the Consolidated Framework for Implementation Research (CFIR)[39,40] as the overall guiding implementation science framework and the ADAPT-ITT[9,10] as the adaptation framework for systematic planning and evaluation of SBIRT adaptation.

Aim 1: Identify opportunities and challenges for engaging pregnant women with substance misuse. (*ADAPT-ITT*: *Assessment, Decision, Adaption*). We will conduct X in-depth interviews with key informants, including NFP clients with self-disclosed experiences of substance use (n=X), NFP nurse home visitors (NHV), and nurse supervisors (n=X) to inform SBIRT adaptation and implementation. We will identify facilitators/barriers of substance use disclosure and treatment access/utilization as well as stakeholder beliefs, attitudes, and preferences about SBIRT process and delivery methods. We will establish the Community Advisory Committee (CAC), consisting of NFP clients and key stakeholders who will provide feedback throughout the proposed study.

Aim 2: Adapt SBIRT to be implemented in the NFP setting (*ADAPT-ITT*: *Production, Topical Experts, Integration*). We will incorporate key informant preferences, the CAC's guidance, and feedback from topical experts into the adaptation of SBIRT for NFP. This process will produce a standardized training and delivery protocol for Nurse Home Visitors (NHVs), who will deliver the adapted SBIRT. We will refine NFP program materials and protocols based on the feedback we will gather.

Aim 3: Conduct a pilot test of the adapted SBIRT in two NFP sites in Colorado (n=X), using a mixed-methods approach (*ADAPT-ITT*: *Training, Testing*). NHV will deliver SBIRT to NFP clients. We will evaluate feasibility and acceptability of the SBIRT implementation and explore details of the protocols for a future R01 hybrid effectiveness-implementation trial. We will collect and analyze baseline and 6-month follow-up quantitative data using computerized surveys and qualitative data by conducting in-depth interviews with key informants (n=X), which will contribute to understanding results.

The proposed research builds on my background in mental health and substance use research and partners me with an exceptional mentoring team to advance my training. I will gain expertise in 1) perinatal substance use epidemiology, 2) dissemination & implementation science (D&I), and 3) mixed-methods research. Collectively, this project will facilitate my development as an independent investigator and pursuit of my long-term research goal, which is to improve mental health and well-being of pregnant and parenting young mothers by developing and implementing effective interventions. This K01 focuses on 1) substance use during pregnancy and 2) implementation science in effort to address "**real-world complexities**", which is one of the NIDA prioritized research goals. The study aims also are in line with and advance the NIDA Strategic Plan **Objective 2.3**: "Develop and test strategies for effectively and sustainably implementing evidence-based prevention interventions". The results of this K01 will provide preliminary data for an R01 proposal to NIDA to conduct a large-scale, hybrid effectiveness-implementation trial. This proposal and investment in my continued training have the potential to considerably improve delivery of substance use screening, detection of substance use, service uptake, and ultimately prevention or reduction of pregnant women's substance use.

1. Your name, credentials, current academic institution, and your role/title/academic rank at your institution, and your email address

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2. An overview of the health issue, the intervention(s) to be developed or tested, and the relevant context and types of stakeholders in which your study will be conducted

Women with intellectual and/or developmental disabilities (IDD) are less likely to receive cervical and breast cancer screenings as compared to women without disabilities. Previous research identified that only 55% of women with IDD receive Pap tests, compared to 85% of women without IDD. Additionally, American Indian (AI) women may not receive recommended cancer screenings as often as other minority groups and Whites. Our long-term goal is to decrease breast and cervical cancer disparities among AI women with IDD through culturally appropriate education. We are culturally adapting an evidence based breast and cervical cancer screening education program for women with IDD titled, *Women Be Healthy2* (*WBH2)*, in partnership with Hopi Cancer Support Services, a tribally run breast and cervical screening program, and Tucson Indian Center, an urban Indian center. The new curriculum titled, *My Health, My Choice,* will undergo feasibility testing in 2021 with 15 dyads (AI women with IDD and their caregiver) at each site for knowledge and self-efficacy outcomes.

3. Draft aims and hypotheses

Aim 1: Conduct an exploratory trial of My Health, My Choice (MHMC) curriculum with AI women with IDD and their caregivers in preparation for a future randomized controlled trial (RCT) to examine changes in: breast and cervical cancer screening knowledge and self-efficacy among AI women with IDD and their caregivers, and cancer screening service usage by AI women with IDD.

Hypothesis 1.1: Receiving the *MHMC* curriculum will increase cancer screening knowledge, self-efficacy, and receipt of cancer screening among AI women with IDD and their caregivers. The program will consist of six sessions provided one time a week. AI women with IDD (n=50) and their caregivers (n=50) will complete pre and post *MHMC* surveys assessing knowledge and self-efficacy changes. In accordance with evaluations of complex interventions, this exploratory trial will test components of the program. Three months post *MHMC* workshop completion, AI and IDD serving partners will conduct a records review to identify health services outcomes, such as evidence of cancer screenings for women who were part of the program.

Hypothesis 1.2: In-person delivery and telehealth will result in similar increases in knowledge and self-efficacy and adherence to recommended screenings. The culturally adapted *MHMC* program will be implemented in a hybrid approach to meet participant needs. The options for delivery will be in-person with a community health educator from the program site (n=25) or via a home-based tool kit with telehealth sessions with the community health educator (n=25). Results of the pre and post *MHMC* surveys will be compared between those who attended in-person and those who received telehealth for changes in knowledge and self-efficacy. The records review for receiving a cancer screening will also be compared between the two groups.

Aim 2: Assess the feasibility and acceptability of the culturally adapted and hybrid provided approaches to the MHMC program among program participants and AI-serving health providers.

Hypothesis 2: *MHMC* will demonstrate feasibility through the following benchmarks: 70% study retention rate, 90% fidelity, 50% of participants complete all six sessions. *MHMC* will demonstrate acceptability through the following: 75% of participants' reporting satisfaction with the program. The team will collect structured and semi-structured input from AI women with IDD in the in-person delivery (n=6), AI women with IDD in the telehealth delivery (n=6), caregivers in the in-person delivery (n=6), caregivers in the telehealth

delivery (n=6), providers of the curriculum (n=6) and community partner site staff (n=6) regarding the satisfaction with and feasibility of implementing the hybrid *MHMC* program. For all six sessions of the program, there will be a random selection of participants from the in-person and telehealth delivery *MHMC* programs. A member of the research team (i.e. student, PI) will complete a fidelity check of the randomly selected sessions. The fidelity check will involve reviewing a fidelity checklist guide for the session and the appropriate hybrid approach. These feasibility checks will help inform issues experienced when adopting the program to fit current activities. These checks will also allow for exploration of any further adaptation completed by trainers to best meet the needs of participants.

4. Any pragmatic study designs or frameworks you are considering for your project

RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) is being considered.

5. Any target funding agencies you are considering (e.g., NIH, AHRQ, PCORI) or grant mechanisms (e.g., K23, R01, other) and any important context we should know about any request for proposals to which you are applying

We are applying for the National Institute of Health/National Cancer Institute, Notice of Special Interest: Dissemination and Implementation Science for Cancer Prevention and Control Low Resource Environments, NOT-CA-20-025 grant opportunity.

https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-025.html#:~:text=NOT%2DCA%2D20%2D025,Control%20in%20Low%20Resource%20Environments

6. Challenges and Key Questions you would like to discuss with Group and Pragmatic Research Faculty Experts (pick **1 key** issue below that you want to discuss in this consult, and/or write-in no more than 3 different key challenges/questions):

What types of pragmatic study designs, methods, or measures would be best for testing my hypotheses?