



Mapping Implementation Science with Expert Recommendations for Implementing Change (MIS-ERIC): Strategies to Improve PrEP Use among Black Cisgender Women Living in Mississippi

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Abstract

Background Blackwomen are disproportionately affected by the HIV epidemic. Strategies to increase Black women's use of pre-exposure prophylaxis (PrEP) are needed.

Methods Interviews were conducted in Mississippi (MS) with Black, cisgender women at risk for HIV, and community healthcare clinic (CHC) staff who work directly with this population. Reflexive thematic analysis was used to identify barriers and select appropriate implementation strategies to increase PrEP care.

Results Twenty Black women and twelve CHC staff were interviewed. PrEP use barriers resulted from low HIV risk awareness, lack of PrEP knowledge, and structural and stigma-related barriers. Methods for PrEP education and motivation included normalizing PrEP in public communications, providing education at places where women congregate, and tailoring PrEP content with Black women as educators. The Expert Recommendations for Implementing Change (ERIC) project provides a way for implementation scientists to select strategies that are consistent within research and practice across studies. Strategies from the ERIC project were selected to address implementation barriers.

Conclusions Tailoring PrEP implementation protocols to increase Black women's access, engagement, and adherence to PrEP is needed. This is one of the first implementation studies to incorporate these four implementation concepts into a single study: (1) implementation outcomes, (2) i-PARIHS, (3) ERIC's strategy list, and (4) operationalizing the strategies using the Proctor et al., guidelines. Results provide an in-depth comprehensive list of implementation strategies to increase PrEP uptake for Black women in MS.

Keywords HIV prevention · Implementation science · Pre-exposure prophylaxis (PrEP) · Black women in MS

Introduction

Black cisgender women continue to be disproportionately affected by the HIV epidemic [1], and women living in the South have even greater risk [2]. In Mississippi (MS), Black women are three times more likely to be diagnosed with HIV than White women [1]. There are several behavioral and sociodemographic factors that contribute to this vulnerability. Many Black women in MS live in communities with a high prevalence of undiagnosed or untreated HIV, placing them at heightened risk [3, 4]. Additionally, concomitant diagnosis of a sexually transmitted infection (STI), exchange of transactional sex, intravenous drug use (IDU), intimate partner violence (IPV), partners with unknown HIV status, and partners with a history of incarceration all influence risk

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[5–8]. Black cisgender women are often not fully aware of their risk while in relationships [9].

The Centers for Disease Control and Prevention (CDC) estimates that 400,000 Black women would benefit from pre-exposure prophylaxis (PrEP), but only 1% of those individuals obtain a prescription for it [10]. The ratio of new HIV diagnoses to active PrEP prescriptions is fourfold higher in women than men [11, 12]. In MS, approximately 721 individuals received PrEP in 2018; only 72 were women and 18 were Black women [13]. Difficulties with health literacy, perceived lack of HIV risk, shame and stigma related to sexual discussion, lack of awareness and access to PrEP, and insufficient PrEP knowledge among providers are some of the reported barriers to PrEP care [5, 14–20]. Less than 20% of Black women are aware of PrEP, but there are few programs to increase awareness [16, 21, 22]. Black women at high risk for HIV in the South who are knowledgeable about PrEP reported feeling motivated and empowered by their use of PrEP [23, 24]. Although information may improve willingness to use PrEP, many women still have concerns about the burden of a daily medication and the risk of angering their partners [24]. Black women are also concerned about PrEP-related stigma such as being labeled promiscuous, being presumed HIV positive, or receiving disapproval from social networks [15]. Finding ways to address these barriers to PrEP is necessary to end the HIV epidemic [25].

Implementation of a biomedical intervention, like PrEP, requires innovative strategies for increasing its uptake in various settings (e.g., community-based organizations (CBOs), pharmacies, and medical settings) and diverse methods for reaching those who need it (e.g., telemedicine, mHealth, counseling, and social networks) [26]. Although Black women are at risk for HIV, there are few interventions tailored to them. The CDC has suggested the following aims to better engage at-risk women in PrEP: (1) increase **HIV knowledge and PrEP awareness** among women and providers; (2) enhance **HIV risk communication**; and (3) **build** patient-provider relationships that facilitate shared decision making [14]. Although many methods have been tested to improve the uptake of PrEP in other key populations, few studies have focused on Black cisgender women [27]. Considerable efforts have been made to explore and understand the utilization of telemedicine, mHealth, social media, and counseling to increase PrEP use among sexual and gender minority populations [28–32].

To be effective, implementation strategies need to be carefully selected and tailored based on the needs, context, and attitudes of Black women living in MS and of the relevant healthcare organizations that provide or may potentially provide PrEP services [33]. Implementation science provides a framework and steps to accomplish this task [34]. The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) model was one of

the first implementation frameworks to facilitate evidence to support implementation strategies at the practice level and is widely used to help explain implementation success of evidence into practice [35]. Proctor and colleagues developed a taxonomy of implementation outcomes (i.e., acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability) to enhance efficiency and consistency in implementation research [36]. This study investigated facilitators and barriers to PrEP uptake among Black cisgender women at risk for HIV guided by components of the i-PARIHS model (innovation, recipient, context) [35] and Proctor's implementation outcomes of acceptability, feasibility, adoption, and fidelity that may inform PrEP use in this population. The Expert Recommendations for Implementing Change (ERIC) project provides a way for implementation scientists to select strategies that are consistent within research and practice across studies [37]. Strategies in this study were selected using the ERIC project and subsequently operationalized according to the Proctor et al., (2013) guidelines [33]. In this project, these methods are referred as Mapping Implementation Science with Expert Recommendations for Implementation Change (MIS-ERIC). These findings can inform tailored implementation protocols to increase Black women's access, engagement, and adherence to PrEP.

Methods

Sample

Interviews with Black women and community-based stakeholders (i.e., clinic staff and administrators) in MS HIV hot spots informed this study. Hot spots were defined as zip codes with census tracking between the 80th and 100th percentile for HIV burden (i.e., the highest HIV burden) [38]. The eligibility criteria for Black women were: (1) English-speaking, (2) age between 18 and 54 years old, (3) female sex assigned at birth, (4) identify as African American/Black, (5) reported, in the past year, of having sex with at least one man with unknown HIV status (or known to be HIV positive) or reported of testing positive for an STI (syphilis, gonorrhea, or chlamydia), and (6) reported of living or working in an HIV hot spot in or around Jackson. Given the differential impact of HIV on Black women of different ages, we recruited equal subsets of Black women who fell within the following age ranges: 18–34 years old and 35–54 years old. Stakeholders were recruited from clinics and CBOs who provide services to Black women who may be at risk for HIV. The eligibility criteria for clinical and non-clinical community-based staff were: (1) English speaking and (2) worked with Black women at a healthcare or community organization for at least 1 year.

Data Collection

Black women participants were approached at clinic visits in MS by research staff to inquire about interest in a study to discuss PrEP. If interested, participants were contacted by the study project director, screened for eligibility, and scheduled for an interview. Community-based stakeholders who met inclusion criteria were approached by project staff about interest in participating in a study to discuss PrEP implementation strategies for Black women. If interested and eligible, consent was obtained, and an individual interview was scheduled. Interviews occurred in-person, in a safe, convenient, private location or remotely via a video conferencing platform, Zoom. All interviews with Black women participants were completed by a Black female interviewer. Interview content was guided by the i-PARIHS framework and focused on the facilitators and barriers to PrEP within the framework's elements: (1) the innovation, (PrEP), such as its degree of fit with existing practices and values; (2) the recipients (Black women in MS), such as their motivation, goals, resources, support, and differences in age groups; and (3) the context of the setting (MS—urban, rural; agency—CBO, clinic) [35]. Additionally, interviews asked about the following existing methods of delivering PrEP for other populations: individual counseling [28, 29], couples-based counseling [30, 39, 40], campaigns [14, 41, 42], social platforms [43–45], telemedicine [31, 32], and mobile health/mHealth (text messaging, mobile phone, and computer-based interventions) [46–48]. Table 1 below outlines interview constructs and alignment with i-PARIHS and Proctor frameworks.

Data Analysis

All interviews were audio-recorded and transcribed by an outside, HIPAA-certified transcription company and reviewed for accuracy. Data were analyzed iteratively throughout data collection, and interview guides were adapted as needed. Interviews were completed until content saturation was met, and data were organized using NVivo software. Reflexive thematic analysis was used to deductively analyze the data [49]. Reflexive thematic analysis is a six-step process for analyzing and reporting qualitative data. The steps include familiarization with data, generating codes, constructing themes, and reviewing, defining, and naming themes. The i-PARIHS and Proctor frameworks and existing methods of delivering PrEP were used to create an a priori coding schedule to determine themes relevant to selecting appropriate implementation strategies to increase PrEP use among Black women in MS. The coding scheme covered: HIV risk awareness, stigma-related barriers, PrEP knowledge, structural barriers, PrEP public communications, PrEP education content, locations for providing PrEP education, who should provide PrEP information, location for PrEP prescriptions, relationship between patients and PrEP providers, and forms of PrEP [50]. Coders read the text line by line and identified if any of the codes from the a priori coding framework were potentially at play in each piece of text. Double or triple coding was allowed when relevant. When a piece of text from transcripts represented a new important idea that was not represented in the current list of a priori codes, coders created and defined a new code. Seven team members (TA, LW, KKG, AB, CSG,

Table 1 Qualitative interview guide content

| Proctor | i-PARIHS | Constructs | Thematic categories derived from interviews |
|-------------------------------------|------------|--|--|
| Acceptability | Recipients | HIV risk awareness | <i>PrEP use barriers</i> |
| Acceptability | Recipients | Stigma related barriers | |
| Adoption | Recipients | PrEP knowledge | <i>Methods for PrEP education and motivation</i> |
| Feasibility | Context | Structural barriers | |
| Acceptability | Innovation | PrEP public communications | |
| Acceptability | Innovation | PrEP education content | |
| Feasibility | Context | Locations for providing PrEP education | |
| Adoption | Context | Who should provide PrEP information | <i>Methods for delivering PrEP</i> |
| Feasibility | Innovation | Location for PrEP prescriptions | |
| Fidelity | Context | Relationship between patients and PrEP providers | |
| Acceptability | Innovation | Forms of PrEP | |
| Existing methods of delivering PrEP | | | |
| Individual counseling | | Couple's counseling | |
| Campaign events | | Utilizing social platforms | |
| Telemedicine | | Text messages | |

AL, LKB) completed the coding and participated in team meetings to discuss the coding process. Inter-coder reliability was assessed by having 50% of the interviews coded by two independent raters. Coding discrepancies were resolved, and all new codes were discussed at team meetings. Through discussion, the team arrived at a consensus as to what a piece of text signified in terms of coding and defined each new code in detail. Next, through a consensus and discussion method, codes were grouped according to alignment with i-PARIHS constructs and Proctor outcomes, and specific thematic categories were created to define these groupings (see Table 1). The resulting thematic categories derived from the interviews included (1) PrEP use barriers, (2) methods for PrEP education and motivation, and (3) methods for delivering PrEP. These themes informed facilitating PrEP using i-PARIHS components (innovation, recipients, and context), identifying relevant implementation outcomes (acceptability, feasibility, adoption, and fidelity) [36], and were used to select ERIC implementation strategies [37]. Data were mapped onto implementation constructs, and strategies from the (ERIC) project were selected [37] to address identified barriers to implementation. Strategies were then operationalized using the Proctor guidelines [33], and the mechanism of change for each strategy, factors that describe how an implementation strategy works, was identified [51, 52].

Compliance with Ethical Standards

The authors have no relevant financial or non-financial interests to disclose. Informed consent was obtained from all individual participants included in the study, which included consent to publish their data. All study procedures were in accordance with the ethical standards of the institutional and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Results

Sample

Thirty-two semi-structured interviews were completed between April and August of 2021. Of these interviews, 20 were with Black, cisgender, PrEP-eligible women, and 12 were with clinic and CBO staff who worked with Black women for at least 1 year. Each interview lasted approximately 45–60 min.

Tables 2 and 3 provide demographic characteristics for the Black women patients and community-based stakeholder participants, respectively. Among PrEP-eligible women, almost all had a high school diploma (90%) and some had

Table 2 Patient demographic variables (N=20)

| <i>Educational attainment</i> | <i>Percent of participants</i> |
|---|--------------------------------|
| Some high school | 10% (N=2) |
| High school graduate | 20% (N=4) |
| Some college but no degree | 35% (N=7) |
| Associate degree | 25% (N=5) |
| Bachelor's degree | 10% (N=2) |
| <i>Household income</i> | |
| Less than \$10,000 | 20% (N=4) |
| \$10,000 to \$29,999 | 35% (N=7) |
| \$30,000 to \$49,999 | 25% (N=5) |
| \$50,000 to \$69,999 | 10% (N=2) |
| \$70,000 to \$89,999 | 5% (N=1) |
| Not reported | 5% (N=1) |
| <i>Relationship status</i> | |
| Single, never married | 45% (N=9) |
| In a relationship, never married | 20% (N=4) |
| Married | 20% (N=4) |
| Separated | 15% (N=3) |
| <i>Living with a partner</i> | 25% (N=5) |
| <i>Been pregnant</i> | 70% (N=14) |
| <i>Has health insurance</i> | 85% (N=17) |
| <i>Affected by depression, low self-esteem, or anxiety in past year</i> | 30% (N=6) |
| <i>Condomless sex in the past year</i> | 85% (N=17) |
| <i>Sex while intoxicated in the past year</i> | 35% (N=7) |
| <i>Ever experienced sexual violence</i> | 25% (N=5) |
| <i>Assertive regarding condom use</i> | 85% (N=17) |

some college experience (35%). A little over half (55%) of the participants had an annual household income of \$29,999 a year or less. Forty percent of the women reported being in a relationship, and 25% reported living with their partner. The majority (85%) had health insurance. Most (85%) reported having sex without a condom in the past year (Table 2).

Table 3 provides demographic characteristics for the clinic and CBO staff participants. Clinic and CBO staff participants had an average of 4.6 years ($SD = 3.0$ years) of experience working with Black women in MS. All staff participants were female and had at least an Associate degree, and 33% had a doctoral or professional degree. Almost all (83%) spent at least 25% of their time at work providing care directly to Black women.

Table 4 provides responses to PrEP-related survey questions from Black women patients. Although few (15%) had previously taken PrEP, almost all (80%) had heard about it. Many of the women (70%) were concerned about PrEP side effects, and several (65%) were concerned about paying for PrEP. Most women (90%) were willing to take PrEP if they knew they were at risk for HIV.

Table 3 Clinic and CBO staff demographic variables (N=12)

| <i>Education attainment</i> | <i>Percent of participants</i> | |
|--|--------------------------------|-----------|
| | <i>Yes</i> | <i>No</i> |
| Associate degree | 25% (N=3) | |
| Bachelor's degree | 25% (N=3) | |
| Master's degree | 8% (N=1) | |
| Doctoral degree or professional degree | 33% (N=4) | |
| <i>Job title</i> | | |
| Nurse | 25% (N=3) | |
| Administrator | 25% (N=3) | |
| Research specialist | 17% (N=2) | |
| Pharmacist | 8% (N=1) | |
| Social worker | 8% (N=1) | |
| PrEP navigator | 8% (N=1) | |
| <i>Time spent providing direct care to Black women</i> | | |
| < 25% | 8% (N=1) | |
| 25–50% | 25% (N=3) | |
| 51–75% | 25% (N=3) | |
| 76–100% | 33% (N=4) | |

^a. Missing demographic data for one staff participant.

Table 4 Patient PrEP-related variables (N=20)

| <i>PrEP question</i> | <i>Percent of participants</i> | |
|---|--------------------------------|-----------|
| | <i>Yes</i> | <i>No</i> |
| Have you taken PrEP before? | 15% | 85% |
| Was today the first time you heard about PrEP? | 20% | 80% |
| Are you worried about PrEP side effects? | 70% | 30% |
| Are you worried about paying for PrEP? | 35% | 65% |
| Are you worried about taking a medication every day? | 30% | 70% |
| Are you worried about interactions with other drugs? | 40% | 60% |
| Are you worried about people thinking you are HIV positive? | 40% | 60% |
| Would you be more likely to take PrEP if you knew it could lower your chance for acquiring HIV? | 85% | 15% |
| Would you be more likely to take PrEP if you knew your partner was HIV positive? | 95% | 5% |
| Would you be more likely to take PrEP if you knew you were at high risk for HIV infection? | 90% | 10% |

Themes

Table 5 provides a detailed description of the identified themes. Themes are described in detail, with representative quotes, below. Implementation determinants are specific factors that influence implementation outcomes and can be barriers or facilitators. Table 5 also highlights which implementation determinants can increase (+) or decrease (–) the implementation of PrEP among Black women in MS. All determinants listed under PrEP use barriers are negative determinants. All determinants listed under methods of PrEP education and motivation are positive determinants, as well as those listed under methods/locations for delivering PrEP. Each determinant is discussed in more detail below.

PrEP Use Barriers

Participants reported several barriers to PrEP care including low HIV risk awareness, limited PrEP knowledge, stigma, and structural barriers.

Low HIV Risk Awareness (i-PARIHS: Recipients)

Many Black women were not aware of their HIV risk. Participants reported that women often feel like they are at low risk because they are married, in a perceived monogamous relationship, or that they have partners who report not having sex with men. However, participants acknowledged risk for HIV when in a sexual relationship. One participant reported finding out that her partner was also having sex with men:

Table 5 Description of qualitative interview results

| Theme | Implementation determinant (+/−) | Implementation determinant information | i-PARIHS |
|--|---|--|------------|
| <i>PrEP use barriers</i> | Low HIV risk awareness (−) | <ul style="list-style-type: none"> • Unaware of HIV risk • Fail to acknowledge HIV risk because they are married. • Uninformed whether partners are having sex with others | Recipients |
| | Limited PrEP knowledge (−) | <ul style="list-style-type: none"> • Lack of PrEP knowledge • Side effects <ul style="list-style-type: none"> - Interactions with other drugs - Weight changes - Mood changes - Impact on fertility and birth defects | Recipients |
| | Structural barriers (−) | <ul style="list-style-type: none"> • Lack of time for self-care • Paying for PrEP • Transportation | Context |
| | Stigma related barriers (−) | <ul style="list-style-type: none"> • Fear of judgment from partners, family, and friends <ul style="list-style-type: none"> - Assumption of having multiple partners - Family disapproval - Assumption they are living with HIV | Recipients |
| <i>Methods for PrEP education and motivation</i> | Normalize PrEP in public communications (+) | <ul style="list-style-type: none"> • Advertisements are tailored to MSM population; Black women assume PrEP is only for men • Include Black women in advertisements for PrEP • Advertisements should include a variety of ages, races, relationship types (married and unmarried individuals) and genders | Innovation |
| | Provide PrEP education at places where women publicly congregate (+) | <ul style="list-style-type: none"> • Gynecologist offices • College campuses • Health/medical fairs • Resource offices (food stamp office, the WIC office) • Community events • Gyms • Salons • Women focused seminars • Pharmacies • Churches | Context |
| | Utilize social media platforms and text message interventions to provide PrEP education (+) | <ul style="list-style-type: none"> • Social media platforms: Instagram, TikTok, Facebook, Twitter • TV commercials • Text message interventions | Context |
| | Tailor PrEP education content to Black women (+) | <ul style="list-style-type: none"> • How PrEP impacts women's health specifically (reproductive health, mood, weight) • PrEP is used to prevent HIV and can be useful to Black women | Innovation |
| | Use Black women as PrEP educators (+) | <ul style="list-style-type: none"> • Offer Black women peer-guided PrEP education • Provide PrEP testimonials from Black women | Context |
| | Offer PrEP at clinics women use (+) | <ul style="list-style-type: none"> • OBGYN offices • Primary care clinics • Family planning clinics • Pharmacies • College campuses • Health departments | Innovation |
| | Strengthen trust and communication between patients and PrEP providers (+) | <ul style="list-style-type: none"> • Confidentiality and privacy are important • Ensure providers are well informed about PrEP • Have providers fully explain the benefits and risks of PrEP use in a nonjudgmental way | Fidelity |
| Offer different forms of PrEP (+) | <ul style="list-style-type: none"> • No consensus regarding best form of PrEP (pill, injection, and implant) • Providing options for women would be optimal for best implementation | Innovation | |

“I was unprotected having sex with someone only to find out that they were having sex also with a man. He’s one of them—what you call them? Down-low brothers or something.” - Patient, age 50, not on PrEP

Another patient reported that many Black women are in denial or unaware about their partners actual behavior:

“We’re still in the southern areas, so a lot of women think you have to had been with someone who’s gay in order to contract this particular disease. They’re in denial about the people that they’re with, first of all, number one.” - Patient, age 43, not on PrEP

A clinic staff member agreed with this lack of risk awareness and said women are not being properly educated about HIV:

“Because I feel like a lotta guys are on the down-low, and most of the guys have multiple sex partners, and it’s like the females just think they’re the only ones ‘til they get a STD. Once you get a STD, she’s like, ‘You know, I thought it was just me and him and nobody else,’ so it’s kinda like a mind thing, like, for them listen to the male. So, I feel like if they was to just take it more seriously and realize that, ‘If I can get gonorrhea, chlamydia, syphilis, I can also get HIV,’ but I don’t think HIV is being explained to them in school.”
-Staff, Nurse

Limited PrEP Knowledge (i-PARIHS: Recipients)

Most participants reported that Black women are not PrEP-informed and that many women would be interested in taking PrEP if provided information and the resources to get it. This is exemplified by the following statement: *“I think a lot of it’s not that they don’t wanna take PrEP. They just never heard of it.”* - Staff, Nurse. Many participants reported not fully understanding the side effects of PrEP and were concerned with interactions with other drugs, and its impact on weight, mood, and fertility. Information regarding these unique side effect concerns for women should be included when providing education about PrEP to women. One woman reported that she would want to know how PrEP impacts weight and mood, saying, *“My only concern would be side effects as far as weight gain. Uh, mood effects. Things like that. But I wouldn’t expect that from a medicine like that also.”* - Patient, age 42, not on PrEP

Structural Barriers (i-PARIHS: Context)

Black women reported being interested in taking PrEP once provided education but noted that others may experience the following structural barriers: paying for PrEP, lack of time for self-care, and transportation to the clinic

and/or pharmacy. Several participants reported a concern with paying for PrEP and desired to know about available financial services. A patient reported that it is difficult for many Black women to pay for medication without health insurance,

“African American women have a lot of stereotypes on us, and we don’t get a lot of benefits—as then payin’ like health care benefits and paying for it. So it’s a defect, especially bein’ an African American woman. I know it’s sometimes hard for me to pay for my medicine, but thanks to health care, I can be able to afford it. But a lot of people do not have health care benefits. They could not afford this medication. A lot of people do not go to the health care clinic to get checked and see about these, um, opportunities to help that.”
- Patient, age 25, not on PrEP

One medical provider stated that the Black women she works with report having several obligations and not enough time to focus on their own health, or they deny the need for medical care. Specifically, she stated,

“Most Black women have this superhero syndrome. We think we the superhero. We gotta save everybody. We do everything. We put ourselves last in a lotta situations, so I think it’s ingrained culturally. When you grow up, you taught to take care of everybody a lotta times, and yourself is last. I can only speak for the African-American culture, but you grew up taught no matter what, you support your man. You know, you don’t leave if they cheat. You imagine everything is perfect. We don’t like to talk about difficult conversations—because that’s how we’re brought up. We the superhero, you know? We take care of everybody else.”
- Staff, Social Worker

Stigma (i-PARIHS: Recipients)

Participants reported concern about privacy and fears of judgment from partners, friends, and family if they found out they are taking PrEP. Many participants reported that others may assume they have multiple partners or are living with HIV. Some participants reported that other Black women would have difficulties taking PrEP because of the cultural views on medication in the Black community. One participant stated,

“I think that if African American women did take it, they would not tell people that they were taking it just because of the hush-hushness. I honestly think the Black community, even more so than the White community, it will be harder to get them to take things because the Black community, stuff like this is just so hush-hush. And then people, in the Black community,

it's hard to get people to take their medications any-way." - Patient, age 42, not on PrEP

Interestingly, one healthcare worker reported that a Black female patient was suspicious that her husband was unfaithful, but that the stigma related to HIV testing kept her from getting tested:

"She's thinkin' her husband has some infidelity episodes. And I have told her to go get tested, and her thing is, 'He wouldn't do nothin' like that. I'm fine,' but it's a stigma that if you marry, you can't go get tested. She said she tried to get tested in the past, and the doctor said, 'No. Because you're married, I'm not gonna test you.' So we overcomin' that, too."- Staff, Social Worker

Methods for PrEP Education and Motivation

Participants offered many strategies for improving PrEP education and motivation. Many women felt that PrEP advertisements were not tailored to Black women; thus, they felt like they would not benefit from PrEP. Participants suggested diversifying PrEP advertisements to include Black women, providing PrEP information online and where women publicly congregate, tailoring PrEP education content to women, and using Black women who have taken PrEP as educators.

Normalize PrEP in Public Communications (i-PARIHS: Innovation)

Participants reported that Black women should be included in PrEP advertisements. Most women reported never seeing women in advertisements for PrEP, and many assumed PrEP was only for men who have sex with men (MSM). One participant said commercials and campaigns should emphasize that anyone can be at risk for HIV, it is not just for certain groups like MSM,

"Yeah, but to kinda tailor at least some of their commercials or campaigns or whatever towards women. I will say, put it out there, and make it different than what it is with, you know, like I said, 'cause it looks like it's always catered to the gay men." - Patient, age 24, taking PrEP

Participants emphasized the importance of seeing Black women in PrEP advertisements to help reduce stigma. A participant said,

"Well, I think we need to do what we've done with every other group that we have targeted for PrEP. We need to normalize the conversation. We need to have people that look like us giving the message so that the stigma is not there and also tryin' to let people know

that the categories of people that they think should take PrEP are not necessarily just people that are involved in sex work or that kinda thing. So I think normalizin' that conversation, answerin' those questions for women and using some faith-based partnerships, too, because a lotta the stigma is related and rooted in religion. So normalizin' that conversation among faith-based community so that you can have people that actually put out information about prevention, about being healthy." - Staff, Non-Clinical

Provide PrEP Education at Places Where Women Publicly Congregate (i-PARIHS: Context)

Participants consistently reported that PrEP education should be provided via talks or flyers at places where women congregate. One participant reported that PrEP education should be provided in colleges:

"College is more diverse than high school and middle school and elementary. I feel like PrEP should be a course that is held in college as a freshman. That should be the first thing we learn about. We gonna need this information literally all our life, for the rest of our life. So, um, it would be nice to put into schools, colleges preferably." - Patient, age 19, not on PrEP

Another participant reported that PrEP education should be provided in community settings. She described:

"Well, it could be held in a community setting. It could be in beauty shops, barber shops. Those are other places where that kinda information could be given, too, because that's the other thing. We do a lot of our talkin' in the barber shop or in the beauty shop. So, um, recognizin' where people congregate and then tryin' to get the information out there so they'll see it." - Staff, Non-Clinical

Utilize Social Media Platforms and Text Message Interventions (i-PARIHS: Context)

In addition to providing PrEP education at places where women physically congregate, participants noted that social media and text message interventions should be utilized to enhance PrEP awareness among Black women in MS. One participant reported that PrEP education should be listed on not only medical facility websites, but also their social media platforms:

"Yes, along with your hospital website, you know, social media. You know how they're—you know how hospitals run their ads also on social media? You

know, maybe if they would see—you know, see <Hospital> or something like that advertisement, they may click that link to discover what's going on. It's—you got to grab the attention—something like—'cause everybody's phone scrolling so fast. I mean, if it's not eye appealing within the first five seconds, they scroll on past it.” - Patient, age 50, not on PrEP

Another participant reported that receiving information about PrEP via text message would be a convenient way to reach a lot of people. She stated:

“A lot of people keep their phones in their hands. And I constantly check my emails throughout the day. Um, people constantly textin' and stuff like that, so that would be a great way.” - Patient, age 37, not on PrEP

Tailor PrEP Education Content to Black Women (i-PARIHS: Innovation)

Participants reported that PrEP education should address the specific concerns of Black women. For example, information about how PrEP may impact fertility is important for women to know. One participant noted the importance of making PrEP education focused on reproductive health and not just HIV prevention, saying,

“I think this needs to become a conversation about reproductive health, not just about preventing HIV or STDs. I think it is, ultimately, about that, but I think that women need to also understand that havin' a healthy baby later in life means havin' a healthy body now.” - Staff, Non-Clinical

Another participant noted that PrEP content should include how PrEP can be useful for even married women and emphasized the importance of not making assumptions about patients. Specifically, she said,

“The woman was married, and she didn't need to get tested. And I'm like, “Yes, you do. That has nothin' to do with it. This is for you, not for him,” but she just don't wanna deal with it. So I think, you know, marital status has nothin' to do with it. I think that's a hurdle that we have a, you know—and you can't always assume that the male spouse is having extramarital affairs; it could be the female. We just have so many assumptions about people, and they miss out.” - Staff, Social Worker

Use Black Women as PrEP Educators (i-PARIHS: Context)

Participants expressed Black women would like to hear about PrEP from other Black women who are taking PrEP.

One participant described Black women are comfortable talking to peers who are similar to themselves, saying,

“People are comfortable with people who look and act and sound like them. So if it's a woman, a woman. If it's a African American woman, a African—you know, they tend to gravitate towards people that they're comfortable with.” - Staff, Nurse

Another participant explained how testimonials from Black women taking PrEP may be a helpful way to provide PrEP education. This participant stated:

“I feel like it should be a Black woman saying basically her experience, taking PrEP and explaining why she takes PrEP and why should other Black women take PrEP.” - Patient, age 29, not on PrEP

Further, participants reported that hearing about women taking PrEP may increase normalization of PrEP use, similar to birth control. One participant stated:

“Normalizing it. Put the word out there, do word of mouth. One person does it. They let their friends and stuff know. It would eventually become, like, a regular birth control. Like, it's not a bad thing. Birth control is normalized. Some people don't see anything wrong with it.” - Patient, age 23, not on PrEP

Methods/Locations for Delivering PrEP

Participants suggested offering PrEP at clinics used by women, strengthening trust and communication between patients and PrEP providers, and offering women different forms of PrEP (pill, injection, gel).

Offer PrEP at Clinics Women Use. (i-PARIHS: Innovation)

Participants reported that Black women would feel most comfortable obtaining PrEP from a provider with whom they have an established relationship. However, many women reported that their medical providers were not knowledgeable about PrEP. One participant noted that women would feel comfortable getting PrEP from their gynecologist stating, “Because I feel like some women will listen to their gynecologist more so than anybody else 'cause sometimes there's like a-a trust or a bond already built” - Patient, age 29, not on PrEP

Another participant explained how Black women may mistrust new providers compared to existing providers. This could be a barrier to receiving care at clinics solely designated to PrEP or STI related care.

“Because, too, one, you have to realize in that population of people, African American women, they don’t hardly trust medical providers as it is. So I have this random person wantin’ to give me information. I’m like, ‘No, thank you’ basically.” - Staff, Nurse

Strengthen Trust and Communication Between Patients & PrEP Providers (i-PARIHS: Context)

Participants mentioned trust as a barrier when discussing confidentiality of their health information. One participant described,

“Um, on that, I’m prayin’ it’s the case, but you know some people are very just, uh, deceiving, and they’ll try to slide somebody information that they see, um, in the doctor office. Everybody cannot be trustworthy, so I’m praying that whoever their health physician is, they can trust them in order to keep their information safe.” - Patient, age 25, not on PrEP

Some participants reported that their providers had never offered them PrEP. One individual said that providers should describe how PrEP could reduce the HIV epidemic in their community. She said,

“If the doctors were suggesting this and saying ‘Hey. This will be good to get down the AIDS population. Dah...dah’ Yeah, you’d probably be open to taking it if the doctor said, ‘Oh. It’s just this pill that’s doing this.’ You know? You may look at it a lot differently. But I’ve never told that; it has never been suggested to me ever.” - Patient, age 42, not on PrEP

Other patients reported a need for providers to receive additional PrEP training and enhanced provider-patient communication about PrEP. A participant even described being dissuaded from going on PrEP. She explained,

“And my OB, she was just like questioning me on why I should take PrEP, and she’s never heard of anybody with a fear of HIV that they wanna get on PrEP. She was just like, ‘I only have patients that have husbands or a significant other has HIV and are taking it,’ so that made me second guess that I need a prescription for it.” - Patient, age 24, taking PrEP

Offer Different Forms of PrEP (i-PARIHS: Innovation)

There was no consensus among participants regarding the best form of PrEP (pill, injection, gel, or implant). Some participants reported not being good at taking daily medications while others reported a fear of needles. An older participant reported,

“A lot of people are not good at even taking pills that they need. Like their blood pressure pills. A lot of people aren’t good with daily medications. For me, personally, I would rather take the shot and get it over with and be done with it instead of taking the pill. But again, a lot of people are just so scared of shots.” - Patient, age 42, not on PrEP

Participants emphasized the importance of offering women options for the form of PrEP that works best for them. One shared,

“Well, all women are a little different, so you might have a majority of ‘em that would do the pill, and maybe the shot, and then you would have some that would probably do that ring too.” - Patient, age 38, not on PrEP

Existing Methods of Delivering PrEP

Interviews inquired about several methods of delivering PrEP: individual counseling [28, 29], couple’s counseling [30], campaign events [16, 3], utilizing social platforms [42], telemedicine [31, 32], and the use of text messages [32–36]. Some methods were described as more feasible and acceptable for Black women, compared to other options.

Individual Counseling

Black women were optimistic about using individual counseling to promote PrEP, given it provides a private space and the opportunity for women to ask questions.

“Like being with someone one-on-one, it builds deeper connection. You get, like—you feel the emotions, like, from the two people in the room. So, of course, like, there’s no instructions. Um, and if you one-on-one, I would say you can get a little personal, add little personal things in there so they can, like, you know, feel you a little bit more understand you better.” - Patient, age 19, not on PrEP

Couples Counseling

Black women did not see couple’s counseling as a helpful option for most women, because it may indicate doubt regarding partner’s fidelity. Women felt this would be a good option for those who have partners supportive of PrEP.

“I think that would be extremely helpful if she can get the guy to come or the other person to come. I think that’d be extremely helpful. And, that way, all sides

are seen, and it's not accusatory, and—now, they can understand exactly what's happenin'." - Staff, Research Specialist

Some participants reported that couples counseling may be useful for women who have partners with an open mind. When asked if couples counseling would be beneficial for Black women one participant responded;

"Yes and no—because—yeah, I-I think it's very beneficial, but got the pros and cons to them that, well, why do we feel like we need to be doing this, I'm not doing anything. Can cause controversies. They have to be very open-minded about this." - Patient, age 50, not on PrEP

Campaign Events

Women suggested hosting events at churches or conferences to provide in-person PrEP education and empower women to take PrEP.

"You could do a women well outreach program. Churches. And more commercials, TV, radio. You might could even just present it doin' one of those walks, like a breast cancer walk. You could do a PrEP walk and just tellin' the public about it." - Patient, age 38, not on PrEP

Utilize Social Media

Women reported that more PrEP advertisements should be included on social media platforms.

"You can actually use social media 'cause, you know, everybody be relyin' on social media for intel and ideas and—you know? Social media really is the most powerful influence right now. So, yeah." - Patient, age 19, not on PrEP

Telemedicine/Home Testing

PrEP telemedicine enhances privacy and would help women who are less willing to come to a clinic for PrEP. Some women reported a preference to see their provider in person. Many women were hesitant about doing home STI testing and reported being less likely to trust their test results if completed at home.

"Um, for some women who may not have transportation needs, um, as well as some of them who may feel skeptical or, um, uncomfortable with going into a public setting. And then with the telemedicine, I feel like it's also like, as if you would go to a regular

clinic if you need anything asked or answered, you can just ask it to the person through the-the web-chat." - Patient, age 24, not on PrEP

"I rather just go to the office, let them do the testing, and then just let them write the 'scription for, like I said, for the year. I don't wanna do my own 'cause I don't know what I'm doin'." - Patient, age 55, not on PrEP

Use of Text Messages

Women reported the use of text messages would be convenient and helpful; however, a few women reported concerns about privacy and that they do not respond to messages from unknown numbers.

"Yes, 'cause, uh, about 95 percent of people have their phones in their hand, and so that's how we communicate nowadays. So I think it would be very, very beneficial for African American women." - Patient, age 25, not on PrEP

"Yes, ma'am, but at the same time, no, ma'am, I don't because people like me that get anonymous text-text messages or email and don't know where they're coming from." - Patient, age 50, not on PrEP

Implementation Strategies

Table 6 outlines the MIS-ERIC implementation strategies identified from data presented in the interviews. Below we recognize the facilitators and barriers to PrEP uptake for cisgender Black women in MS by implementation outcome (acceptability, adoption, feasibility, and fidelity) [36] and by each i-PARIHS model component (innovation, recipient, context) [35]. Based on the data, we selected strategies from the ERIC project [37], operationalized the strategies according to the Proctor guidelines [33], and identified the mechanism of change for each strategy.

Discussion

Despite the ongoing HIV disease burden among cisgender Black women, much of the HIV prevention efforts in the USA have focused on MSM and transgender women [53]. The CDC encourages the implementation of interventions that are evidence-based, scalable, cost-effective, and have a high likelihood of population-level impact, but, as of yet, there are no evidence-based interventions to increase the use of PrEP among Black women [54]. Our results, as shown in the MIS-ERIC table (Table 6), support and highlight

Table 6 MIS-ERIC PrEP implementation strategies for Black women in Mississippi (MS)

| Implementation outcome (Proctor) | | Implementation barrier/ determinant (+/-) | i-PARIHS component | Strategies | Mechanism of change |
|----------------------------------|---|--|--|---|---|
| Outcome | Definition from Proctor et al. | Definition from qualitative interviews | | ERIC strategies | |
| Acceptability | “Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.” | Black women’s perceptions of PrEP | <p>Recipients: Knowledge, education, motivations</p> <p>Recipients: Motivations and beliefs</p> <p>Innovation: Degree of novelty</p> <p>Recipients: Readiness for change, motivations, values, and beliefs</p> <p>Innovation: Degree of fit with existing practice and values</p> <p>Recipients: Knowledge, education, motivations, values, and beliefs</p> <p>Innovation: Degree of novelty</p> | <p>Conduct educational meetings</p> <p>Develop educational materials</p> <p>Involve patients/consumers and family members</p> | <p>Awareness building. Conduct educational meetings with Black women in MS to provide education about HIV risk and PrEP side effects to increase Black women’s awareness of HIV risk and need for PrEP.</p> <p>Knowledge acquisition. Develop and format HIV risk and PrEP education materials that include concerns specific to Black women to increase PrEP acceptance and uptake.</p> |
| Adoption | “Adoption is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice. Adoption also may be referred to as “uptake.” | Black women’s intention to take PrEP, or PrEP uptake | <p>Lack of PrEP education and are unaware PrEP is for women (-)</p> <p>Distribute PrEP educational materials in places where Black women congregate (+)</p> <p>Utilize social media platforms and text message interventions (+)</p> <p>Include Black women in advertisements for PrEP (+)</p> | <p>Distribute educational materials</p> <p>Involve patients/consumers and family members</p> | <p>Awareness building. Distribute PrEP educational materials in places where Black women congregate to enhance PrEP awareness among Black women living in MS.</p> <p>Awareness building. Utilize social media platforms and text message interventions to provide general PrEP information to Black women.</p> <p>Social norms. Recruit and train Black women who have taken PrEP to share their PrEP testimonials and PrEP education with other women to increase PrEP knowledge and acceptance in the community.</p> |

Table 6 (continued)

| Implementation outcome (Proctor) | | Implementation barrier/determinant (+/-) | | | Strategies | |
|----------------------------------|--|---|--|--|---|--|
| Outcome | Definition from Proctor et al. | Definition from qualitative interviews | i-PARIHS component | ERIC strategies | Mechanism of change | |
| Feasibility | “Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.” | Feasibility of PrEP delivery at clinics in MS | <p>Recipients: Time and resources Context: Policy drivers</p> <p>Recipients: Motivations, beliefs Context: Culture, inter-organizational relationships</p> <p>Recipients: Time and resources Context: Policy drivers, inter-organizational relationships</p> | <p>Make billing easier</p> <p>Change service sites</p> | <p>Real-time training and resource sharing. Provide information about PrEP payment assistance resources to clinics that provide care to Black women to increase provider and Black women’s awareness of the resources available to pay for PrEP and PrEP appointments. Leadership support. Diversify and increase the number of service sites and providers offering PrEP to help enhance Black women’s comfort in getting PrEP.</p> <p>Skill acquisition, refinement, mastery. Develop partnerships with clinics who see Black women patients to help provide PrEP education and resources to increase Black women’s access to PrEP care.</p> | |

Table 6 (continued)

| Implementation outcome (Proctor) | | Implementation barrier/ determinant (+/-) | i-PARIHS component | Strategies | Mechanism of change | |
|----------------------------------|--|--|--|---|---|--|
| Outcome | Definition from Proctor et al. | Definition from qualitative interviews | | ERIC strategies | | |
| Fidelity | “The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the developers.” | Clinic and provider’s knowledge of PrEP and confidence prescribing does not allow PrEP to be delivered as intended | Providers are not PrEP informed or do not offer PrEP and are not aware of patient’s HIV risk and do not realize when PrEP is appropriate (-) | Context: Structure, systems, and processes, organizational priorities Innovation: Clinical and patient experience, degree of fit with existing practices, trialability | Develop resource sharing agreements Use train-the-trainer strategies Conduct educational meetings | Real-time training and resource sharing. Train designated clinicians to help provide PrEP education to other medical providers to increase likelihood of providers offering PrEP to Black women. Skill acquisition, refinement, mastery. Conduct educational meetings with clinic staff and clinicians to increase providers’ knowledge and awareness of PrEP and increase fidelity to delivery of PrEP. Real-time training and resource sharing. Provide training to providers about the different forms of PrEP (pill, gel) and encourage providers to offer options to women. |
| | | | Context: Structure, systems, and processes, Innovation: Clinical experience, degree of fit with existing practices | | | |
| | | | Offer different forms of PrEP (+) | | | |

the importance of comprehensive, culturally tailored PrEP implementation strategies to address the complex determinants of HIV and STI risk among Black women. We selected several strategies from the ERIC project [37] and operationalized the strategies according to the Proctor guidelines [33] as described below.

Acceptability

For PrEP to be successfully implemented among this population, Black women must perceive PrEP to be a beneficial medication for themselves. Even though Black women in MS are at an increased risk of being diagnosed with HIV, they continue to be unaware or fail to acknowledge their risk for HIV [1]. Further, many Black women in MS are uninformed about PrEP. Not understanding the side effects of PrEP is a barrier to PrEP persistence among Black women living in MS with a history of taking PrEP [55]. To enhance awareness of HIV risk and acceptability of PrEP, it may be helpful to conduct educational meetings with Black women in MS to provide information about their HIV risk and common PrEP side effects. The provisioning of PrEP information may improve Black women's willingness to use PrEP; however, like other studies, concerns related to social stigma and fear of judgment from social networks pose an additional barrier [15, 24]. One strategy is to consult Black women when developing HIV risk and PrEP education materials to address their specific concerns. For example, a recent study found that Black women prefer positive PrEP messages presenting PrEP as a form of autonomy, self-care, and resilience [55].

Adoption

Intention to take PrEP and overall PrEP uptake has been insufficient among Black women living in MS. PrEP has been primarily advertised and promoted for MSM [56]. In addition to lack of PrEP education, our sample reported a belief that PrEP is needed only by MSM. However, once participants were provided education about PrEP and knowledge of how PrEP can be beneficial to women, our sample thought PrEP was an attractive option for HIV prevention, comparable to other studies with women [16]. One strategy suggested by the participants to increase PrEP awareness and uptake is to distribute PrEP educational materials in places where Black women already congregate (e.g., malls, salons, gyms, and grocery stores). One study found that Black women in the USA were comfortable with their hair stylists providing PrEP education. This may be a feasible, culturally appropriate way to reach social networks of Black women who may benefit from PrEP [57]. The use of racial and gender concordant individuals (i.e., Black women) to provide HIV education and/or deliver HIV-related interventions

has been an effective strategy used in HIV prevention for women studies to increase trust and encourage comradery [58, 59]. Encouragement from social networks and support from other cisgender women on PrEP can be a facilitator to PrEP use [60]. Similarly, Black women in our study stated that the person providing education about PrEP should be "relatable." Thus, Black women taking PrEP may be good PrEP educators. PrEP-experienced Black women could be recruited and trained to share their PrEP testimonials and education with other women to increase knowledge and acceptance in the community. Another suggested strategy to promote the adoption of PrEP among Black women is to utilize social media platforms and mHealth interventions (e.g., text messaging, mobile phone, and computer-based interventions). Social media and mHealth interventions have proven beneficial for other populations [43–48] and may serve as a way to reach a number of Black women in MS.

Feasibility

The delivery of PrEP in diverse healthcare settings (i.e., primary care offices, OG/GYN clinics, etc.) in MS is limited. Barriers to PrEP use include the limited availability of healthcare settings that provide PrEP, and concerns about payment [61, 62]. Many Black cisgender women do not seek healthcare in settings focused on sexual health and prefer discussing sexual health with their primary care doctor or OB/GYN, rather than with an infectious disease specialist [63]. Black women in our study reported wanting to be able to receive PrEP at the clinics that they already attend. To enhance feasibility of PrEP, we suggest increasing the overall number of service sites offering PrEP to provide additional options for women thus, help enhancing Black women's comfort and availability to get PrEP. An option to increase sites for access to PrEP is the use of telemedicine, especially in remote settings where resources are lacking [31]. The use of PrEP telehealth has been successful in enhancing implementation among MSM [31, 32] and racially diverse populations [64]. Participants in this study reported that telehealth may be a feasible option for Black women who are concerned about privacy during a PrEP appointment. In addition to increasing the number of service sites, another way to enhance feasibility is to provide information about PrEP payment assistance resources to clinics that provide care to Black women. Programs to eliminate or reduce the financial burden of PrEP and to increase access to skilled providers have proved helpful [65–67].

Fidelity

Our study found that the use of PrEP may be improved by offering PrEP training to clinicians and increasing PrEP modality options (e.g., pills, injections, and implants).

Healthcare providers are not always PrEP-informed or comfortable prescribing PrEP. A recent study found that healthcare providers have some hesitancy about discussing PrEP with women, fearing they will insult the patient [68]. However, Black women want to be educated about PrEP and other protective measures. Further, research suggests providers with an existing trusting relationship may be the best sources to offer information about PrEP to Black women [16] and may positively influence PrEP adherence [69]. Given that Black cisgender women do not often seek healthcare in settings focused on sexual health [63], it is imperative that clinicians in a variety of specialties are properly trained to discuss and offer PrEP to women. To enhance fidelity of delivering PrEP, we suggest training designated clinicians to help provide PrEP education to other medical providers and conduct educational meetings with clinic staff and clinicians to increase providers' knowledge and awareness of PrEP and increase fidelity to delivery of PrEP to Black women. This includes training providers on how to identify PrEP-eligible candidates. Additionally, it may be beneficial to offer different forms of PrEP. There was no consistency regarding preferred form of PrEP among participants. Black women may be more likely to take PrEP if provided education about and offered diverse forms of PrEP, which is consistent with existing literature. For example, one study found that women selected a form of PrEP based on ease of use and comfort [70]. Diversification of PrEP modalities and prioritization of those coinciding with popular contraception practices (e.g., pills, injections, and implants) may help to optimize PrEP acceptability and increase overall PrEP use among women.

Limitations

Our results are limited to Black women and stakeholders who were willing to engage in a research interview to discuss PrEP. In addition, our sample was limited to Black women and stakeholders living in MS, with only a small number of women having taken PrEP previously, limiting the generalizability of the results. Due to COVID-19 restrictions, some interviews were conducted via Zoom, which may be a strength and a weakness of the study. Some participants may have been more comfortable meeting via Zoom and more open with their responses, while others may have been less comfortable. Lastly, many of our data coders were not Black women, which may have caused some bias in the analyses.

Conclusions

Black women's HIV prevention needs can be prioritized through the development of culturally competent, feasible, and cost-effective techniques for the provision of PrEP. To

our knowledge, this is the first implementation study to incorporate these four implementation concepts into a single study: (1) implementation outcomes [36], (2) i-PARIHS [35], (3) ERIC's strategy list [37], and (4) operationalizing the strategies using the Proctor et al., guidelines [33]. Utilizing these models and MIS-ERIC helped provide an in-depth comprehensive list of implementation strategies to increase PrEP uptake for cisgender Black women in MS. Future research should further refine and assess the feasibility and acceptability of selected implementation strategies and adapted methods and develop tailored implementation protocols.

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Declarations

Ethics Approval All study procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by both the Rhode Island Hospital and University of Mississippi Medical Center Institutional Review Boards.

Consent to Participate Informed consent was obtained from all individual participants included in the study, which included consent to publish their data.

Conflict of Interest The authors declare no competing interests.

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