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Adapting the Evidence-Based Women's CoOp Intervention to Prevent Human Immunodeficiency Virus Infection in North Carolina and International Settings

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The intersection of substance abuse, poverty, low education level, unemployment, and homelessness contributes to health disparities and disease among minority women [1, 2]. In North Carolina, for example, African American women are disproportionately affected by human immunodeficiency virus (HIV) infection, compared with women of other races and ethnicities [3]. Building on a long history of research with out-of-treatment substance abusers at risk for HIV infection and the need for gender-focused research, the National Institute on Drug Abuse (NIDA) funded a project in 1998 that tested a woman-focused, culturally specific intervention for African American women who lived in the areas of Raleigh and Durham, North Carolina, and were using crack cocaine. The Centers for Disease Control and Prevention (CDC) evaluated this intervention, known as the Women's CoOp [4], and determined it to be a "best-evidence" HIV behavioral prevention intervention [5]. The Women's CoOp has been underway in North Carolina for more than 10 years, with follow-up of participants up to 7 years after enrollment [6].

The Women's CoOp is based on empowerment and feminist theory and encourages women to understand the risks of substance abuse and how abuse can affect personal power and leave women vulnerable to risky sexual behavior and victimization [7]. The framework of the Women's CoOp intervention includes facts about risks associated with substance abuse and the intersecting risky behaviors women face because they lack equality in most relationships. Core elements involve (1) role-play and rehearsal, to teach and practice condom use and how to negotiate condom use with sex partners, with the goal of reducing the frequency of risky sexual behavior; (2) active referrals to local service organizations, for women with needs that require extensive counseling and services; (3) a personalized riskreduction plan, to help set goals to reduce the frequency of substance abuse and risky sexual behavior, as well as other identified problems (eg, homelessness, unemployment, and victimization); (4) trained interventionists, who deliver the intervention via personalized, woman-focused cue cards that address women's risks in relation to substance abuse, sexual behavior, and violence; (5) access to HIV testing, via the program and/or referrals to local service agencies; (6) distribution of male and female condoms, lubricants, and other riskreduction materials; and (7) for international settings, translations in local languages, to reinforce intervention content. The skill-building exercises in the woman-focused

intervention help build participants' confidence in and mastery of risk-reduction strategies [8].

After the successful outcomes among Women's CoOp participants in North Carolina, the National Institutes of Health provided funding to determine the adaptability of this intervention to other North Carolina populations and in international settings. Subsequently, several domestic adaptations and a larger portfolio of international adaptations have been implemented to reach vulnerable women, such as sex workers, injecting-drug users, and female substance abusers who are at-risk for infection because of social status, race/ethnicity, and gender inequality in settings with a high prevalence of HIV infection.

The first adaptation in North Carolina, which was funded by NIDA in 2005, targeted pregnant African American women receiving substance abuse treatment. Responses from focus groups conducted during the formative research phase of this study indicated that pregnant women had risk factors for HIV infection, including continued substance abuse and unprotected sex, that were similar to those found in the other studies. However, women also reported that, during pregnancy, they experienced violence at a greater frequency than when they were not pregnant. Some of the women in the groups were living with HIV and had children who had different HIV birth outcomes. All of the women living with HIV shared the importance of their social networks, housing, and community support in their daily needs.

This adaptation used an important innovation that involved filming women while they talked about their risks and struggles during pregnancy, including substance abuse, violence, and the lack of accessible HIV-associated resources and substance abuse treatment. These powerful vignettes were inserted into the intervention for pregnant women to reinforce the information presented, making the vignettes a salient aspect of the adapted woman-focused intervention.

In 2007, the CDC supported a study to adapt the Women's CoOp for use in the Raleigh-Durham area, to help substance-using adolescent African American females who dropped out of school and were sexually active. This adaptation incorporated the advice of the Women's CoOp teen advisory board, the CoOp's long-standing community advisory board, and other experts by addressing more developmental issues, filming young women while they talked about their struggles, and using more-colorful visuals for a more upbeat presentation of the intervention material.

Adapting the Women's CoOp for Use in Diverse Cultural Settings

South Africa has become the focus of a growing HIV/AIDS epidemic and currently has the largest number of people in the world who are living with HIV [9]. Additionally, Black women are disproportionately infected with HIV, and the primary mode of transmission is heterosexual transmission [10].

The first of the Women's CoOp adaptations was implemented in South Africa in 2001, when attention focused on the high prevalence of HIV among pregnant women attending antenatal (ie, prenatal) clinics and on the estimated large number of babies that were acquiring HIV via mother-to-child transmission [11]. An overarching challenge was to appropriately adapt the Women's CoOp for a different population in a different cultural context.

One of the first steps for adapting the intervention involved fostering an open collaboration by generating participant and community involvement. These activities included in-depth interviews with substance-using women who were most likely sex workers, with local service providers, and with local researchers, as well as conducting focus groups involving

sex workers. In addition, a community advisory board comprising key stakeholders, such as service providers and South African researchers, was established to help ensure the project's success.

Furthermore, the study protocol was approved by relevant government agencies and institutional review boards in the United States and South Africa, which assured stakeholders that the study satisfied appropriate ethical criteria, including safety, and that the US research team had a long-term commitment to the well-being of the study participants. This element was an important part of the study because South Africans have, in the past, been exploited for data collection purposes, yet have not received adequate programs and resources to address the pressing public health problems identified during data collection. For example, although public health officials identified that HIV/AIDS was becoming epidemic among certain South African communities, the subsequent availability of antiretroviral treatment was, for a long period, very limited or nonexistent.

This initial project not only established important cross-cultural collaborations, it also represented the first risk-reduction intervention associated with HIV infection and substance abuse to simultaneously address the intersecting issues of substance abuse, risky sexual behavior, and gender victimization among vulnerable women. The success of the first South African adaptation of the Women's CoOp intervention and a small pilot randomized controlled trial [12, 13] subsequently led to a portfolio of larger studies. Table 1 presents the adaptations in South Africa, along with concurrent adaptations in North Carolina and Russia.

Research Strategies

The Women's CoOp adaptations use formative research methods to clarify how culture and gender affect the risky behavior of program participants. Topics, including substance abuse, risky sexual behavior, sexual partnerships, and gender-based violence, are addressed during in-depth interviews and by focus groups. Questions are also asked about the concerns and unmet needs of women. For example, in South Africa, high rates of untreated sexually transmitted infections (STIs) and HIV infection, high levels of unreported rape of women, and the lack of public health resources available to women were revealed. These findings informed the intervention and the need to develop linkages to nonstigmatizing services. In addition, the community advisory board became an asset in networking with professionals who provide services for women experiencing STIs, HIV infection, and sexual violence. Violence prevention sessions and instruments to measure outcomes were also developed. Of importance, the South African studies informed efforts in North Carolina, as violence and victimization were unaddressed issues in the original Women's CoOp study.

The Women's CoOp studies use a variety of strategies to keep women engaged and to maintain an acceptable follow-up rate. For example, staff offer needed transportation to the field site and, during the follow-up visit, share child care responsibilities. In addition, the program offers hot meals and baths, if needed, and provides donated clothes, toiletries, and food from food banks. During follow-up visits for data collection, grocery vouchers (which are approved for use by the institutional review boards) and bags of essential food items are offered as compensation for participants' time.

All of the pilot and larger studies used randomized designs in the community, with follow-up interviews conducted 3–12 months after enrollment. In each study, effect sizes for improvements in the main outcomes (ie, substance abuse, risky sexual behavior, and victimization) between baseline and follow-up in the woman-focused intervention ranged from small (ie, 0.2) to large (ie, \geq 0.8), using Cohen's classification of effect sizes [14].

Lessons Learned

One important aspect of these cross-cultural projects is that, as the projects progressed, the lessons learned from one project enhanced a subsequent project by improving the intervention. These improvements helped fashion interventions that have the potential to benefit communities and provide sustainable effects. For example, successful community-based research must reflect community norms and engage communities at large "where they are at" on multiple levels to effect change. This is similar to engaging with patients in a clinical setting, where practitioners must engage individuals "where they are at" and then help them change what might be considered risky behavior.

Another example is the evolution of our comparison conditions. The original Women's CoOp study used a 3-group design that included a delayed treatment control group and a relatively powerful comparison intervention (ie, the NIDA standard intervention). However, 3-group designs are prohibitively expensive, whereas delayed treatment control conditions do not provide equivalent contact time. Therefore, an attention-control intervention was developed for use in Russia, where a nutrition intervention based on the potato—a Russian food staple—was adapted. This intervention component subsequently informed the development of a community meal plan in South Africa that was based on healthy uses of the potato. Potatoes are a popular food (when fried as "chips") in South African township communities where the Women's CoOp operates. Consequently, as part of the intervention, there were demonstrations of ways in which a potato can be prepared with other fresh items from the corner vegetable stand to increase its nutritional value.

Moreover, there are few options for physical exercise in South African township communities. However, realistic options for women were explored, such as a women's netball team and walking clubs, and the most viable were included in the intervention to improve women's health and well-being. Also, when the Women's CoOp began its formative work with teens in the North Carolina study, the nutrition and wellness intervention was expanded to include issues associated with obesity and stress management. These refinements in the comparison condition have increased scientific rigor and provided substantial benefits (ie, improvements in general health) to women who are assigned to the comparison conditions.

Key Innovative Characteristics

Table 2 describes the key characteristics found across all the Women's CoOp studies. However, some important innovations to note include using computer-assisted self-interviewing and audio computer-assisted self-interviewing, inserting video vignettes of women telling their stories into the intervention, conducting the community interventions by using community peer leaders as the interventionists, conducting rapid biological testing (for pregnancy, substance use, and HIV), and assisting with immediate referrals to sites by using a comprehensive referral guide that is updated regularly (this activity is essential, irrespective of the setting).

Next Steps

Currently, the principal investigator of these studies is helping with the adaptation of the Women's CoOp intervention for use among college students at a historically Black university. We are also determining an appropriate adaptation for Latinas with service providers. The principal investigator is also testing a training package of the South African adaptation of this intervention, which has been included in the US Agency for International Development compendium of selected HIV programs in sub-Saharan Africa that integrate multiple gender strategies [15]. This package will expand implementation of the Women's

CoOp intervention to a variety of settings across South Africa and other sub-Saharan African nations.

Additionally, over the past few years, we have learned that to have a greater impact we also need to focus on men and issues of gender-based violence. Accordingly, our current work in Africa includes not only a women's intervention, but also an adapted intervention for men and couples, which addresses the interacting dynamic of couples, concurrent partnerships and risky sexual behavior, and how substance abuse affects risk and gender-based violence.

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Table 1

Adaptations of the Evidence-Based Women's CoOp Human Immunodeficiency Virus (HIV) Prevention Intervention

Adapted study	Location	Sample	Evidence source	Adaptation(s)	Lessons learned/outcomes
Sunnyside Pilot	Pretoria, South Africa	Black sex workers	In-depth interviews, focus groups, CAB, phase I RCT	Violent men, dry sex risks, rape issues, violence prevention	Various categories of other sex partners (ie, roll-ons/casual, clients, main partners) were associated with different levels of risk and violence. Decreased frequencies of unprotected sex and substance use were observed.
Pretoria Women's Health CoOp	Pretoria, South Africa	Black sex workers and women having unprotected sex	CAB, phase III RCT, indepth interviews	Translated all materials into Sotho and Zulu	Increased HIV knowledge, communication about condoms and condom use with main partners, and a decreased frequency of gender-based victimization were observed
Cape Town Women's Health CoOp	Cape Town, South Africa	Black and Coloured women	Focus groups, CAB, phase I RCT	Individual to group format	Use of alcohol and illicit drugs (confirmed by biological tests) and risky sexual behavior decreased in the group and among individuals 1 month after intervention implementation.
Pregnant Women's CoOp	North Carolina	African American pregnant women in substance abuse treatment	Focus groups, CAB, experts, phase I RCT	Prenatal issues and risk factors. ART, vignettes of recovery	Satisfaction with the adaptation and feasibility study, with reductions in homelessness, substance use, and violence, and an increase in HIV knowledge. Filmed vignettes of women's most memorable stories. The outcome was a reduction in the frequency of risky sexual behavior.
Russian Women's CoOp	St. Petersburg, Russia	Women injecting drugs who are in substance abuse treatment	In-depth interviews, phase I RCT	Alcohol and other drug risks in Russia, translations, nutrition intervention	Examination 90 d after detoxification revealed decreased frequencies of risky sexual behavior and injecting-drug use. High levels of HIV infection and injecting drugassociated risk factors remain. The study identified the need for gender-focused treatment and interventions to prevent HIV infection.
Westem Cape Women's Health CoOp	Cape Town, South Africa	Black and Coloured women aged 18–33 y	Expert panel, CAB, phase III RCT	New nutrition attention intervention, refinement of pilot women's intervention	The study is ongoing, although differences between the study communities are being found with regard to alcohol and other drug use. There are higher levels of HIV infection among Black women, and higher levels of methamphetamine use among Coloured women.
Young Women's CoOp Study	North Carolina	At-risk African American women aged 16–19 y	Expert panel, CAB and TAB, focus groups and in-depth interviews, pretesting and pilot testing, RCT	Developmental issues, teen pregnancy, problem solving, values, gang issues, dinner club, brighter colors, more visuals	The RCT phase was initiated in May 2010. Many barriers were found in recruiting these teens. The majority have had babies. Recruitment is ongoing.

Note. The term "Black" conveys meanings unique to South Africa. During Apartheid, the South African government defined the population in terms of 4 racial categories under the law: Black, White, Coloured, and Indian. Persons of mixed ancestry were considered to be Coloured, whereas those of Bantu ancestry were considered to be Black. ART, antiretroviral therapy; CAB, community advisory board; RCT, randomized controlled trial; TAB, teen advisory board.

Table 2
Key Characteristics Across All Women's CoOp Studies

Characteristic	Method(s) of operationalization
Education	Educate women about HIV/AIDS, STIs, substance abuse, and violence prevention within their cultural context (eg, by race/ethnicity and geography) to personalize risk
Formative assessment	Conduct formative assessment, using focus groups and/or interviews and meetings of the CAB and expert panel, to address specific issues of the target population
Focus on at-risk women	Focus on women who are at risk for HIV because of risky sexual behavior, substance abuse, and/or violent victimization
Community-based sites	Establish community-based sites that are easily accessible and comfortable for the target population
Interventionists	Hire and train women from target-population communities to deliver the intervention
Training	Conduct intensive training with hired staff, and supplement training with an intervention manual
Intervention sessions	Provide 2 or more brief individual and/or group intervention sessions
Community support	Establish community support for the intervention from established CAB members, community members, organizations, and service providers
Quality assurance	Implement and maintain quality assurance procedures

Note. AIDS, acquired immunodeficiency syndrome; CAB, community advisory board; HIV, human immunodeficiency virus; STI, sexually transmitted infection.