

## **Cognitive-Behavioral Stress Management Interventions for Ethnic-Minority HIV-Positive Alcohol/Drug Abusers in Resource Limited and Culturally Diverse Communities**

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**Abstract:** The article reports our intervention work with Alcohol and Other Drug Abusing (AOD) People Living With HIV (PLWH). Present research has involved adapting Cognitive Behavioral Stress Management (CBSM) and other strategies to improve quality of life and health outcomes for PLWH. Historically, CBSM has used relaxation and coping skills training to reduce negative mood and improve coping behaviors. The efficacy of CBSM interventions to improve functioning has been demonstrated in many disease groups and, more recently, in ethnic-minority HIV+ samples in the US CBSM HIV risk reduction interventions are similar to other cognitive-behavioral therapies in emphasizing skills training and stress reduction. Among the most precarious and challenging clinical populations are HIV infected individuals with a history of alcohol and/or drug abuse. Compared to their counterparts with no history of alcohol or drug abuse, not only are they more likely to transmit the virus to others, but they are also at risk for problems in adhering to antiretroviral regimens. A main focus of this article is to report on our intervention work with very resource-limited, ethnic-minority PLWH with substance abuse problems, particularly our NIH funded projects in Miami and Haiti and the opportunities presented by the emerging science of biological vulnerability and genomic factors.

**Key words:** HIV, substance abuse, HIV infection, minorities

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### **INTRODUCTION**

The epidemiological evidence of an HIV/AIDS crisis among ethnic minorities in the US is now commonplace but evidence of what to do in response is just beginning to be developed. The cognitive-behavioral model is one approach to interrupting the pathways of risk by introducing psychosocial supports that cohere with the life experience and sexual decision-making realities of the most vulnerable populations.

Among the most precarious and challenging clinical populations are HIV infected individuals with a history of alcohol and/or drug abuse. Compared to their counterparts with no history of alcohol or drug abuse, not only are they more likely to transmit the virus to others, but they are also at risk for failure in adhering to antiretroviral (ARV) regimens. Thus, they are likely to remain marginal to innovations, particularly when their share of the potential public health burden looms large as policymakers count the costs of resistant HIV strains due to adherence failure and treatment losses because of relapse. The consequent risk of earlier morbidity and mortality is compounded if such individuals are of an ethnic/racial minority, such as in the case of African

Americans, who are less likely to receive antiretroviral therapy, regardless of income, education, insured status, or other socioeconomic and demographic factors<sup>[1]</sup>.

A main focus of this article is to report on our intervention work with very resource-limited, ethnic-minority People Living With HIV (PLWH), with Alcohol and Other Drug (AOD) abuse problems, particularly our NIH funded projects in Miami and Haiti and the opportunities presented by the emerging science of biological vulnerability and genomic factors. One of our primary approaches to improving quality of life and health outcomes for these individuals has been the adaptation of Cognitive Behavioral Stress Management (CBSM) and related strategies that can address their long-term project of managing HIV sexual transmission risk, their ARV regimens, health services and psychosocial health.

**Evolution of our experience with Cognitive-Behavioral Stress Management (CBSM): From secondary prevention to transmission risk reduction:** The rationale for the CBSM approach to HIV+ AOD users has been the observation that stressful life events and social stigmas are frequently

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experienced in addition to the direct burdens of addiction and HIV infection. Not only are many of these individuals socially isolated, but they often lack skills and resources necessary to cope with the biopsychosocial concomitants of addiction and HIV infection. During potentially stressful periods, these individuals may be highly aroused, overwhelmed and employ maladaptive coping strategies. Combined with social isolation, there is an increased likelihood of distress, poor quality of life, risky sex and substance use and inconsistent adherence to medical regimens with the concomitant compromises in health.

Such difficulties have grave implications for personal health and also public health and have led federal agencies (e.g., CDC/NIH/HRSA)<sup>[2]</sup> to prioritize prevention for positives (defined as reducing HIV transmission risk among PLWH) because of several reasons: PLWH (1) Are an obvious source of HIV transmission to uninfected sexual and needle-sharing partners; (2) May transmit treatment resistant HIV strains and other pathogens to both HIV+ and HIV-partners; (3) May have a much greater possibility of transmitting HIV, including resistant strains, given that ARV medications are increasingly being improved, leading to enhanced longevity, health and sexual desire; (4) Are themselves at greater vulnerability to co-infection with other pathogens (e.g., sexually transmitted infections or STIs), since such behavior increases the likelihood of contracting a more virulent HIV strain and other STIs<sup>[3]</sup>. Other STIs are likely to further accelerate HIV disease progression in HIV+ AOD users, who are especially susceptible to reinfection because of their immune-compromised status from AOD use and their numerous health problems<sup>[4]</sup>.

CBSM is unique in being developed as a secondary prevention strategy to reduce morbidity and address the distinctive daily living challenges associated with HIV infection and treatment, such as the need to sustain rigorous, long-term ARV adherence<sup>[5-8]</sup>. In the beginning, CBSM was tested as an intervention to improve quality of life and health outcomes for HIV infected individuals by using relaxation and coping skills training to reduce negative mood and slow disease progression<sup>[7,8]</sup>. As ARV regimens were introduced, CBSM was refined to also enhance adherence to prescribed regimens. Malow and Dévieux were extensively involved in this study<sup>[5,6,9,10]</sup> and in applying CBSM to drug abusers. CBSM has been shown effective in improving adherence and quality of life and coping with stress. As the ARV regimes improved to the point of making HIV a chronic disease, CBSM methods were further adapted to focus on

reducing HIV transmission risk, specifically sexual risk reduction, which has been increasingly emphasized as more HIV-positive individuals are living healthier lives with increasing advances in ARV medication regimens.

CBSM is based on cognitive social learning<sup>[11]</sup> relapse prevention theory<sup>[12]</sup> and stress and coping theory<sup>[13]</sup> with other antecedents found in social support<sup>[14]</sup> and skills training<sup>[15,16]</sup> approaches to primary and secondary HIV prevention. A challenging test of the CBSM intervention approach has been in the area of breast cancer research. While studies had demonstrated improvements in psychological outcomes in coping with breast cancer, it remained unclear whether a CBSM approach could influence biological outcomes<sup>[17]</sup>. However, in a recent study of a CBSM intervention with women in treatment for non-metastatic breast cancer<sup>[18]</sup>, found actual and sustained reductions in serum cortisol compared to the control group, over a 12 month period. Before this, evidence of influence on biological outcomes had been inconsistent, mostly pointing to indirect pathways, in which positive changes in disease status, immunity and health were attributed to positive behavioral changes<sup>[19]</sup>.

A similar pattern has been found in intervention research with HIV-positive patients. As noted in a meta-analytic review<sup>[20]</sup>, CBSM-type approaches have demonstrated positive psychosocial outcomes, but the data have been inconsistent for biological indicators like immune and hormonal function. A similar conclusion was reached in the review by Brown and Vanable<sup>[21]</sup>. Both reviews concurred, however, that longer assessment periods may be needed to detect positive changes in biological outcomes. In addition, both have called for studies with more diverse HIV infected samples, particularly with ethnic minorities and subgroups such as AOD abusers. Brown and Vanable<sup>[21]</sup> have noted the importance of including comparison groups of equivalent intensity and length and measures of clinical significance as well as statistical significance. Scott-Sheldon *et al.*<sup>[20]</sup> have additionally emphasized the need of including moderator and mediator analyses in order to understand what dampens or facilitates intervention efficacy.

Our CBSM intervention work with HIV infected individuals has endeavored to include these elements: understudied populations with both ethnic-minority and AOD samples, comparison groups equivalent in intensity and length, longer assessment periods and a focus on mediators and moderators of intervention effects. We have been motivated to pursue this line of research because of the existing evidence that CBSM may promote clinical improvement in affective distress and positive changes in relevant behavioral and coping

skills, social support and stress levels, which may be particularly problematic in HIV-positive subgroups with multiple problems. Such psychosocial outcomes are important because these in turn are posited to translate into enhanced medical adherence and safe sex, since these behavioral changes are unlikely to occur if individuals are severely stressed, socially isolated, lacking in coping skills and/or abusing alcohol or drugs<sup>[5,6,22]</sup>. According to Moos<sup>[23]</sup>, Cognitive-Behavioral (CB) interventions may be useful because they mirror protective social processes in the life contexts of participants' lives: "These processes involve bonding, goal direction and monitoring from family, friends, religion and other aspects of traditional society; participating in rewarding activities that preclude or reduce the likelihood of substance use; selecting and emulating individuals who model conventional behavior and shun substance use and building self-confidence and effective coping skills" (p. 14). Interventions like CBSM mirror these by increasing self-efficacy in resisting risk and improving skills in coping with high risk situations.

Throughout its development, the core design of CBSM has focused on delivering: (a) Coherent information about HIV transmission and treatment and the intersecting nature of risk behaviors related to serostatus, morbidity and mortality for self and others, (b) Skills training to build coping capacities for both intra- and interpersonal stressors, (c) Techniques and support for appraising risk, (d) Conflict resolution skills such as anger management and assertiveness training and (e) The provision of group support and social network awareness.

**CBSM-A intervention developed/manualized for AOD users in Miami:** To address this very significant high-risk group of HIV-positive drug abusers, NIDA funded five projects in response to the RFA entitled "HIV Therapy for Drug Users: Access, Adherence, Effectiveness." One of the projects funded was awarded to our research group (R01DA013802, Malow/Devieux PI/Co-PI), which we conducted in Miami at Florida International University. Miami-Dade has the second highest AIDS rate among U.S. counties, with the majority being Black or Hispanic<sup>[24]</sup>. Late entry into HIV care is high among Blacks and Hispanics in the county. In 2004, 66% of HIV/AIDS related deaths in Miami-Dade occurred among Blacks. Moreover, over half of PLWH in the county have a substance abuse problem and the county has among the highest rates of unmet need for treatment services. In addition, high incidence rates of secondary syphilis, hepatitis B, chlamydia and gonorrhea have also been reported.

Recruitment Sites for our CBSM-AOD project were primarily located in densely populated, multicultural, low income, urban areas of Miami with high rates of non-injection substance abuse, HIV, violence and poverty, with the vast majority of the population being uninsured and suffering from multiple health disparities. Approximately 85-95% of the clients served by these agencies are African American, Caribbean Islander and Hispanic. The vast majority of eligible participants is in the lowest SES and receives Medicaid, with the exception of those who are ineligible due to immigration status. Of the total number of women served by the recruitment sites, approximately 85% have a history of alcohol and drug abuse and 80% of these have had an episode of unprotected vaginal or anal intercourse within the past year.

The CBSM-A intervention that we developed and manualized for AOD users derives from our transmission-focused CBSM work, yet shares the same focal points and areas of effectiveness as the secondary prevention-focused CBSM but with the added advantage of having targeted and demonstrated effectiveness in reducing HIV transmission risk.

**Aims and target population:** Our recently completed 5 year funded study (2000-2006) was a randomized experiment comparing the effects of the CBSM-AOD with a standard of care comparison group, matched for time and attention. Our aim was not only to evaluate effectiveness but also to differentiate the context of risk for seropositive inner-city minorities with a history of substance abuse, who are often taken as a uniform high-risk group. Fundamental to the effort was the identification of mediators and moderators of outcomes, such as psychopathology, gender, ethnicity and dyadic relational factors, utilizing hierarchical linear and structural equations modeling to explore how study variables interrelate to predict outcome.

Although the randomized research framework and manualized content and procedures necessitate standardization interventions, group process was at the core of the CBSM-AOD design. Experiential learning and feedback were integral, thus allowing the heterogeneity of our Miami study population to add further definition to the process and content and ultimately the research knowledge to be gained. It also imposed a discipline on interventionists to not merely deliver risk reduction skills and constructive social networks, but more fundamentally to build upon the contextual realities and incipient structures that individuals bring to the process. The CBSM-AOD has developed into an approach that distinctively focuses on

contextual-community factors, with strategies that draw upon the target population's oral and visual traditions, linguistic culture, dominant participatory learning style and the collective consciousness of their ethnic/racial and socioeconomic communities. Moreover, it integrates participants' own experiences with HIV, drug abuse and recovery and the problems in negotiating safe sexual activity.

The low-income, inner-city minority HIV-positive recovering drug abusers in our CBSM-AOD study were actually quite heterogeneous, representing multiple subcultural and racial/ethnic groups. The target population was predominantly Hispanic (40%) and Black Non-Hispanic (40%), reflecting the current ethnic/racial composition of HIV+ AOD abusers in the Miami-Dade County area. Within the Hispanic grouping the dominant ethnic group were Cuban, while the dominant group within the Black Non-Hispanic category were African American followed by Caribbean Blacks, primarily Jamaican.

The great majority were recovering from smoking/freebase use of crack cocaine, which has been the drug of choice in South Florida. This shift in the comorbidity of HIV risk, from injection drug abuse to smoking or free-base use of crack cocaine, has reinforced our attention on the psychosocial, intimate interplay of sex, addiction and micro-macro determinants. We found that the problems related to poverty (e.g., housing, child care, transportation, employment, medical care, violence) and the drug lifestyle often take precedence over efforts to medically manage HIV infection. Additionally, crack cocaine abusers present a number of other shifts in context<sup>[25,26]</sup>. First, crack abusers engage in higher levels of unsafe sexual behavior and present distinctive treatment needs and patterns of psychopathology. Second, the use of stimulants like crack has been associated with increases in sexual behaviors (e.g., sexual arousal, disinhibition and multiple contacts) that are related to an enhanced risk of transmitting HIV/STD<sup>[27]</sup>. Third, crack use may reduce immune functioning directly and indirectly through circumstances associated with the crack using lifestyle (e.g., inadequate medical care, poor nutrition and increased frequency of STDs). Fourth, smoking crack often results in lesions to the lips, tongue and esophagus, which may enhance the likelihood of acquisition or transmission of STD/HIV during oral sex. Fifth, stimulant use itself has most recently been shown to increase the infectivity of HIV<sup>[28]</sup>. Finally, with habitual crack use, it often becomes increasingly difficult for men to ejaculate. The extended and rough oral, anal, or vaginal sex necessary for the male crack-using partner to ejaculate produces an increased

likelihood of developing mucosal lesions and transmitting or acquiring STDs. Given these differences, HIV+ crack abusers require additional tailoring of interventions than for intravenous drug users.

Consistent with the public health model of intervention highly prioritized by NIH<sup>[29]</sup>, exclusion criteria in our CBSM-AOD study were minimized and a wide diversity of recruitment sites were incorporated into the protocol, such as drug abuse programs, STD and other health clinics, HIV testing sites, ministries and churches. The rationale was to let safety concerns govern the choice of exclusion criteria, rather than the traditional dictates of selecting a homogeneous sample to maximize control over extraneous sources of variation. Again, it can be observed how the priorities of ecological validity and applicability to clients of "real world" clinical settings must necessarily affect the interventionist's choices along the entire spectrum of research and intervention design—from the selection of a sample to the very process of the intervention itself.

Eligibility criteria included: (a) >18, but <60 years of age; (b) Fluency in spoken English (as opposed to written proficiency), which is required to complete assessments and to participate in the intervention groups; (c) Acknowledgement of HIV+ status and willingness to be tested to confirm this serostatus; (d) a recent history of AOD abuse; (e) currently not cognitively impaired, as determined by the HIV dementia scale, or psychotic or suicidal, since these conditions might compromise the ability to comprehend and participate in the assessment and intervention.

The CBSM-AOD was comprised of 10 sessions administered over a 10-week period in groups of 8. Pilot research has shown that this group size promotes interpersonal interactions and disclosures and affords the opportunity for cognitive rehearsal and role playing of risk reduction skills. Embedded in the group sessions are procedures to help comprehension and retention of presented material, since many pilot study participants encountered difficulties in this area.

Participants were separated into male and female groupings. Previous studies, pilot data, literature and the ethnic/racial composition of the participants all indicate that same-sex formats provide greater comfort in discussing sensitive and private issues, such as sexual practices and drug abuse. Other studies reveal that the HIV/AIDS illness experience for women and men encompass different concerns that can potentially affect safe sex practices with partners, medication adherence, continued abstinence from drugs and development of self-efficacy<sup>[30-33]</sup>. For example, women often demonstrate concern for family matters,

especially their children's future welfare, effects of antiretroviral therapy on pregnancy, avoiding physical abuse and gender-based problems in communicating with health care providers, partners, family and friends.

Fidelity to the study protocol was ensured in our CBSM-AOD study by several mechanisms. A detailed manual was developed for both intervention and control conditions, with specific instructions for tailoring the condition to differences in gender, literacy and ethnic/cultural background. In addition, both facilitators and participants completed an integrity rating scale to assess the degree to which important aspects of the protocol have been administered. In addition, group sessions are audiotaped and then randomly rated for treatment integrity.

The CBSM-AOD protocol comprised two broad domains: risk reduction/health maintenance strategies and stress management techniques. It specifically targets activities to the interrelationships between HAART adherence, sexual risk behavior and substance abuse. Thus, activities focus on: (a) Awareness of prescription guidelines and the health consequences of continued drug abuse, high-risk sex and inconsistent adherence; (b) Self-efficacy in adopting health-promoting behaviors and self-awareness of vulnerability; (c) Adaptive coping strategies (e.g., planning and scheduling medication and food intake within daily routines); (d) Recognition of triggers for substance use, unsafe sex and poor adherence; (e) Harm reduction and risk appraisal cognitions; (f) Skills for interacting within health care, family and peer networks.

The design of cultural and contextual congruence in the adaptation of the CBSM has proceeded according to the recommendations of Kalichman (1998), who calls upon the interventionist to formally provide for input from the following: (a) Focus groups that are demographically and culturally representative of the target population, (b) In-depth interviews of men and women with a recent history of drug dependency, (c) Practitioners from local community-based organizations serving the target group, (d) Social context analysis by a medical anthropologist, who is part of the research team and local experts accustomed to delivering interventions to culturally diverse groups and (e) The empirical literature.

Complementing these features is selection of the facilitator teams that conducted the intervention. The CBSM-AOD is designed for two-member facilitator teams, consisting of a professionally trained therapist (defined as having at least a masters degree in psychology, counseling, social work or the equivalent with at least three years of experience conducting group

psychotherapy with the target population) and a recovering addict paraprofessional with a well-established record of uninterrupted abstinence. In pilot research, paraprofessionals emerged as excellent role models, lending credibility to the study and demonstrating greater sensitivity to the nuances of addictive behavior than other types of staff. They also fostered greater trust and rapport with participants who have often experienced multiple instances of social deprivation, devaluation and stigma by virtue of their various illness conditions. Because the gender and ethnic/racial background of group facilitators may be salient to the predominately Hispanic and Black, Non-Hispanic participants, each facilitator team included a Hispanic and a Black, Non-Hispanic individual. Likewise, each team had a male and female cofacilitator. Previous pilot experience with mixed gender facilitator teams shows that this composition enhances the effects of modeling, role playing and safer sex messages. Moreover, it contributes to greater face validity since mixed gender teams more closely simulate the "real world" experience of participants, who are most often heterosexual in this target population.

The key organizing framework is cultural relevance and integration with the life experience of the participants, structured by meaningful examples and cognitive rehearsals or role-playing exercises, group discussion and interaction and information, each directed at the critical issues of negotiating the demands posed by intimacy and culture, participant's life realities, risk behavior reduction and HAART adherence. Consequently, examples and group exercises incorporated terminology and expressions familiar to local African American and Hispanic communities and build upon concepts specific to spiritual and religious traditions, family and group relationships and the oral tradition. The use of oral and group-centered strategies are designed to be more reflective of the learning styles, collective orientations, values and educational levels of participants and to utilize the possibilities of a feed-back loop to incorporate their "real life" examples and concerns. Further, the adaptation incorporates terminology and expressions meaningful to HIV+ drug abusers and formats relevant to participants, such as "The Serenity Prayer," with a focus on relapse prevention and long-term maintenance.

**CBSM-A intervention developed and manualized for PLHW in Haiti:** Although our prior work and that of others with CBSM type interventions have been promising, key issues remain concerning the

transportability of these findings, namely, (1) Whether the CBSM can be effectively “translated” or adapted for HIV+ individuals in resource-poor countries; (2) what are the conditions of effectiveness in the delivery of the CBSM-A by staff in this different setting.

To address these issues, we conducted a randomized pilot study of CBSM-A in Haiti’s GHESKIO clinics (the Haitian Study Group on Kaposi’s Sarcoma and Opportunistic Infections Center) and documented the efficacy of the CBSM-A approach for reducing sex risk behavior in HIV+ AOD abusing adults. Our research team was awarded a NIDA supplement to a funded project (R01 DA 0952, PI-Malow; Co-PI Dévieux) to adapt CBSM for HIV-positive men and women receiving ARV treatment at GHESKIO, urban Haiti’s foremost HIV/AIDS research/treatment center. Devieux first worked with our GHESKIO collaborators in 1989 to develop a workplace HIV prevention intervention program designed for factory workers and our research team has collaborated with GHESKIO for over a decade, principally on this project, access barriers<sup>[34]</sup> and mother-to-infant transmission and infant feeding studies<sup>[35,36]</sup>.

After the US CDC, GHESKIO is the next oldest institution with a program dedicated to HIV/AIDS control and prevention and is comprised of clinical services, research and training programs, including HIV testing and counseling, AIDS care, prenatal care and management of tuberculosis and sexually transmitted infections. GHESKIO’s inception in Haiti parallels that of institutions in the US devoted to HIV primary care and research, having been founded upon the detection of Kaposi’s sarcoma and unusual opportunistic diseases that first signaled evidence of the epidemic. In 1983, its Director, Dr. Jean Pape, published a seminal report in *The New England Journal of Medicine*, documenting the first AIDS cases in a developing country (Haiti) and observing the same risk factors that had been identified in the US. Dr. Pape, a Cornell-trained internationally recognized infectious disease expert, founded GHESKIO in 1982 and continues today as its director, with his contribution recently acknowledged with the French Legion d’honneur.

AOD use, especially involving risky sex, is much understudied in Haiti compared to research on this issue in other resource-poor countries hard hit by HIV. Weiser *et al.*<sup>[37]</sup> have reviewed the issue of alcohol use and high risk sexual behavior in sub-Saharan Africa and have conducted a population-based study focused on Botswana, finding that alcohol use proximate to sex was highly associated with higher HIV prevalence, alarmingly higher rates of multiple sex partners and

unprotected sex, a higher probability of selling sex and intergenerational sex relations. They conclude that the lack of attention to alcohol use in high seroprevalence, resource-poor countries is of grave concern since it may be a significantly modifiable HIV risk factor. In Haiti, Gage and Suzuki<sup>[38]</sup> have reported evidence that cumulative stressors contribute significantly to alcohol use. Intimate partner violence is high in Haiti (approx. 27% of ever-married women) and Gage and Hutchinson<sup>[39]</sup> have identified alcohol abuse by the cohabiting partner as a risk factor for partner sexual violence. Living in a household with adult problem drinking increased the likelihood of being a regular user of alcohol rather than an abstainer by 3.9 times in Haitian men<sup>[38]</sup>. Also, alcohol users were more likely to have witnessed parental violence, to live in neighborhoods with high levels of youth lifetime drinking and to report more than one sex partner. As we report from our pilot work in Haiti (C.6), problem drinking appears to be a neglected risk factor among our target population, with most participants reporting problems with drinking.

Our NIDA funded pilot study (R01AA017405-02S1, Malow/Devieux PI/CoPI) consisted of three phases: (1) Linguistic Translation of Assessment Instruments, (2) Cultural Translation, involving focus groups with PLWH and service providers from GHESKIO clinics, resulting in the length of the intervention being reduced from 10 to 8 sessions and the addition of three new instruments to assess HIV status disclosure and stigma, which were identified as significant in the target population and (3) The randomized trial and evaluation. Sessions were conducted in a small-group format, twice a week in 2 h sessions. Fifty-six subjects were enrolled in the study with mean age of 38.57 (SD = 6.24). Fifty percent of subjects were male and all subjects identified themselves as heterosexuals. Only 19.6% of subjects were married. Seventy-three percent of subjects had children and 5.4% of subjects had at least one child with HIV. Thirty-five percent had an education level of eighth grade or less, 43% reported attending high school and 22% reported having graduated from high school or attended some college. Thirty-four percent had an income level of less than five thousand dollars, 34% reported an income level of between five and ten thousand dollars and 32% reported an income of over ten thousand dollars. Only 9% reported that they were employed at the time of data collection and 12% reported that they were homeless. Only one subject reported that they have health insurance through an employer. All, but one of the subjects reported being on ARV medications. At baseline, approximately 70%

reported drinking problems (e.g., felt they should cut down, people in their life annoyed them by criticizing their drinking). At 3-month follow-up, there was evidence of reduced problem-drinking in the experimental group with only 16.1% reporting problems. Similarly at baseline, approximately 40% reported unsafe sex within the past 90 days and at 3 month follow-up only 12% reported unsafe sex in the past 90 days.

**NIAAA Clinical Venue Trial of CBSM-A with HIV+ Alcohol Abusers in Haiti:** Because alcohol use is more of a problem in Haiti than illicit drug use, we subsequently focused on adapting our CBSM-A protocol to alcohol abusers. In 2008, we were awarded one of four R01 grants from the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) RFA-AA-08-011 entitled, International Research on Venue-Based Interventions for HIV/AIDS and Alcohol Use. The intervention site of the 5-year HIV/AIDS prevention grant is Port-au-Prince, Haiti in collaboration with GHESKIO and is titled "Intervening with Haitian HIV+ Alcohol Abusers: An Environmental Psychosocial Framework" (1R01AA018084-01, Malow-PI).

The purpose of the RFA competition was to fund collaborative international research on HIV/AIDS venue-based interventions that are social ecologically sound and that advance the investigation of alcohol use within environmental and contextual facilitators of risk. It has become a high priority with the National Institutes of Health to (1) Foster international research collaboration between US researchers and particularly researchers from resource-poor countries facing the biggest challenges from HIV/AIDS and (2) Fund research that can develop innovative ways to reach the highest risk populations, who are frequently hard to reach and help because they have many stressors in their lives. Haiti has the highest adult HIV prevalence in the Caribbean, which in turn has the second highest regional prevalence next to sub-Saharan Africa. As in other resource-poor countries, the chronicity of the epidemic and the higher morbidity of Haitians living with HIV have been linked to contextual factors (i.e., living conditions, alcohol use, nutritional deficiency, male-female inequality, cultural norms of social behavior and between sexual partners that make prevention difficult) and the lack of psychosocial interventions necessary to support biomedical scale-up in ARV treatment. While many countries like Haiti are aggressively involved in ARV scale-up, their populations continue to lack the emotional, physical and socioeconomic means to use whatever help and prevention information that is accessible. Most

significant is the neglect of HIV-related alcohol and drug risk reduction infrastructure in high seroprevalence resource-poor countries like Haiti. For example, although alcohol use has been implicated in the high rate of intimate partner violence in Haiti, its use coincident with risky sex has been very understudied at both the individual and social levels and has remained untargeted in prevention efforts.

These gaps in multi-level psychosocial interventions necessary to support ARV scale-up are not unique to Haiti, motivating a number of special initiatives by the National Institutes of Health, as represented by the NIAAA RFA competition, which was conceived by Dr. Kendall Bryant, NIAAA's Coordinator of AIDS and Alcohol Research. A majority of grant recipients from this competition focused on developing social venues for their study or intervention, such as bars, in order to better understand how the use of alcohol and sex interact with a social situation to increase risk. Understanding the context of risk where people actually live has increasingly become a focal point of public health research, especially when target populations are hard to reach and disadvantaged. However, in the effort to design more ecologically astute interventions, public health researchers have sometimes neglected the clinical venue as a vehicle for not only understanding these issues but also for best intervening, particularly in countries organized to fight the HIV epidemic on a clinic and medical model. This return to understanding clinical venue is increasingly important as antiretroviral treatment is becoming simpler, more available and accessible and HIV testing more acceptable with less stigma. HIV is becoming much more of a chronic disease, in which a clinic is much more likely to have frequent contact with an HIV-infected individual or even one at risk

Consequently, a distinctive aspect of the CBSM-A adaptation for this project is the focus on clinical venue as the point of prevention leverage in integrating an Enviro-Psycho-Social framework to reduce HIV transmission among those living with the infection. As the public health profession looks to innovative alternative venues for reaching populations and overcoming socioeconomic barriers, it is essential to not bypass existing structures of trust and expertise in these countries that are often anchored in the medical model of health care delivery, particularly for their urban populations. GHESKIO has played this role in Haiti and has recently been mandated by the Haitian government to become a conduit for model HIV/AIDS programs to 25 private and public hospitals and health clinics throughout the country, as part of their national scale-up against AIDS, malaria and TB. Thus, this

project may have potential value in replication throughout Haiti and for other highly stressed, resource-poor countries whose scale-up efforts are already clinically organized with considerable social trust.

The project builds on our earlier work in developing intervention models for VA patients with HIV and substance abuse problems, which sought to differentiate the effects of treatment from factors outside of treatment in their daily living situation. This has become increasingly important as advancements in antiretroviral treatment have transformed HIV into a more chronic disease, thus elevating the importance of self-management and coping skills and enviro-psycho-social support in adhering to treatment recommendations. The project also adapts the enviro-psycho-social model developed by NIAAA's VA Cohort Study (VACS), which investigated HIV as a chronic disease in alcohol-using, low-income clinic populations having multiple health and social support problems. The clinical venues of the VA and GHESKIO systems of HIV/AIDS care have a number of shared characteristics which motivated our approach. Both are clinical venues organized along a treatment-training-research model of integrated care, with a patient population that is typically sicker with multiple health problems and risky behaviors.

The study will include 160 male and 160 female HIV-positive adult Haitian alcohol users, randomly assigned to CBSM-A and a Health Promotion Comparison (HPC), which will serve as our time-matched control condition. The primary purpose is to test the influence of contextual factors, informed by Moos and Finney framework<sup>[40,41,23,42-44]</sup> and the NIAAA VACS study and to determine whether CBSM-A can be effectively adapted to reduce HIV transmission risk for a mostly low income population of HIV-positive adult alcohol users in Haiti. We will evaluate if CBSM-A improves our primary outcome associated with HIV sexual transmission risk and our secondary outcomes associated with Alcohol and Other Drug (AOD) use, utilizing primary HIV care services and psychosocial health. We will also examine how putative theoretical variables of IMB theory mediate effects on safe sex outcome (e.g., information, motivation, behavioral intentions and behavioral skills).

The study may also be seen as fulfilling the intent of the NIAAA funded VACS, which was "intended to provide a platform for developing an integrative approach to research that allows for translation of alcohol and AIDS research into clinical practice"<sup>[45]</sup>. Finding better ways to address EnvPsySoc moderators, which this project proposes to enable in Haiti, has been identified by Kazdin<sup>[46]</sup> as essential to tailoring treatment

and is likewise emphasized by O'Leary *et al.*<sup>[47]</sup> for HIV prevention in crisis-ridden populations. CBSM-A is also adapted to include the following components specified to be important in a CDC meta-analytic review of HIV transmission risk reduction<sup>[48]</sup> being guided by behavioral theory, specifically focused on HIV transmission behaviors, provision of skills building (e.g., demonstrating correct condom use), practice in coping or problem-solving skills, role-playing safer sex communication, delivered in clinical settings in an intensive manner (10-20 h) and inclusion of issues related to coping and medication adherence. In addition, we chose to adapt CBSM for HIV-positive AOD users because it is the only intervention for this population that has been shown to be effective in reducing sexual risk behavior in Haiti and that also enhances HIV medication adherence and health care participation. Another core element of the adapted CBSM (CBSM-A) is its usefulness to coping with EnvPsySoc stressors, which are increasingly recognized as potentially significant moderators of intervention effects among HIV-positive AOD users, particularly in resource-constrained environments<sup>[49]</sup>.

## CONCLUSION

The focus on alcohol use and other stimulants has become even more urgent in relationship to HIV prevention as new, genomic-related research has emerged on biological susceptibility and HIV infectivity<sup>[50,51]</sup>. In particular, stimulants have recently been shown to enhance sexual desire<sup>[27]</sup> and the infectivity of HIV<sup>[28]</sup>. Recent research, particularly on illicit stimulant abuse, has emphasized behavioral interventions that can help build or regain sensitivity to positive reinforcers of healthy behavior<sup>[27,52,53]</sup>. In particular, genetic polymorphism or variance in the serotonin/dopamine regulatory systems has been tied to distortions in the reward system of the brain and morbid, repetitive behavior patterns frequently associated with substance abuse. Failure to adhere to safe sex practices and to benefit from risk reduction efforts may be related to neurobiological problems known to be prevalent among HIV-positive AOD abusers.

In the case of alcohol abusers, alcohol influences the complex decision-making process to engage in risky acts<sup>[54]</sup>. The degree of alcohol intoxication is associated with more risk behavior, as is a history of chronic alcohol use<sup>[54]</sup>. Alcohol use and HIV progression also compromise information processing, executive functioning and emotion regulatory functions that may be important in adhering to safe sex practices<sup>[54]</sup>.

Alcohol also compromises adherence to health care recommendations, particularly ARV medication adherence<sup>[54,55]</sup>. In a population sample of PLWH, over half reported alcohol use in the previous month and nearly 20% reported “heavy” or “frequent heavy” alcohol use<sup>[56]</sup>. Regarding adherence to safe sex practices, recent literature<sup>[54,57-59]</sup> indicates that current or recent alcohol use is associated with (1) Behaviorally high levels of sexual impulsivity and frequent unsafe sexual activity; (2) Deficits in self-management, social skills and problem solving; (3) Risk-producing social interaction that invite relapse, transient sexual relationships and coerced or survival-oriented sex; (4) Residence in the inner-city where HIV and AOD abuse and related activities are pervasive.

HIV exploits biological vulnerability through psychosocial opportunity, such as risky behavior and nonadherence to treatment regimens. These behaviors occur for a variety of psychological, social and economic reasons that ultimately stress the personal and interpersonal resources of the individual. The development of CBSM-A has been guided by the need to intervene in this trajectory and to investigate what our next steps should be to fight the epidemic in places like Haiti and also the United States. The HIV epidemic in ethnic minority and female populations, especially in resource-rich countries like the U.S., has exposed the complex nature of risk and disease like few others, revealing that these populations at risk for HIV, especially those with AOD problems, are living in a developing country context.

However, the most neglected variable in HIV prevention interventions may be biology<sup>[49]</sup>. For example, increasing biological research indicates that women face a unique biological vulnerability to HIV because of the female genital tract. And yet, very few women know this and even fewer HIV interventions include this perspective of biological vulnerability in their strategies for women-or their male partners. While HIV biomedical science has firmly entered the genomic era, HIV behavioral prevention is still struggling to integrate applicable findings into intervention content and research. Cohen *et al.*<sup>[50]</sup> have been explicit that the spread of HIV-1 has been heterogeneous and that infectiousness of the index case and susceptibility of the host determine transmission risk, which largely pivots on exposure to those with acute infection and the total viral load of other pathogens such as STIs, especially HSV-2. What is unclear is whether HIV interventionists are attempting to ensure that their study participants are informed of these new facts of biological vulnerability.

A next step for investigators would be to investigate how to effectively interpret and communicate such findings to clients and community stakeholders and develop a participatory methodology for involving the target audience in the 21st century science that HIV is a retrovirus, not a germ and that knowing one’s vulnerability in the time of genomic HIV/AIDS prevention is to know at least as much about the HIV footprint in the human body as carbon footprints and climate change. Most participants in HIV behavioral prevention programs may still be emerging without knowing that the body is an ecosystem and HIV is a species in it. Indeed, many HIV behavioral interventionists themselves may not yet conceive of HIV as a “quasispecies,”<sup>[61]</sup> as recently elaborated<sup>[60,62]</sup>. Their research is further delineating the founder genes of the HIV viruses that permit infection to establish itself in the processes between transmission and seroconversion. Now that the biomedical field has established its own genomic beachhead, the information component of HIV prevention interventions may become increasingly important. How to communicate these developments and whether it makes a difference in behavior will need to be investigated in future HIV prevention research. This is particularly true for HIV-positive populations as ARV treatment shifts from primarily a secondary prevention strategy to one utilized in preventing transmission of the virus.

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