

News and views

## Addressing ethnic disparities in drug abuse treatment in the clinical trials network<sup>☆</sup>

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Ethnic minorities have significantly higher rates of unmet needs for treatment of substance use disorders and are often underrepresented in clinical trials and treatment research. The NIDA Drug Abuse Treatment Clinical Trials Network (CTN) was established in 1999 to conduct research in a wide variety of community based treatment programs across the United States (Hanson et al., 2002). Through its size and scope, the CTN provides a unique opportunity to address a variety of underserved populations, and in particular to evaluate access to and effectiveness of treatments for ethnic minorities. Through June 2006 (when the CPDD symposium on which this article was based was conducted), the CTN portfolio included 22 randomized clinical trials, two large-scale surveys and one quality improvement study. Over 7000 individuals have been randomized to treatment in these protocols; of these, 42% have been women, 47% non-Hispanic European American, 20% Hispanics, 25% African American, 1% native American/American Indian, and 7% multirace or other.

Beyond seeking to reduce barriers to all CTN studies and attending carefully to recruitment and retention of women and individuals who are members of ethnic minority groups across studies, the CTN has sought to address the issue of ethnic disparities through multiple strategies. These have included (1) formation of special interest groups composed of both researchers and community providers that have focused on research and clinical issues specific to women and ethnic minorities, (2) conducting protocols developed specifically to meet the needs of special populations (e.g., substance-using women with PTSD, opioid-dependent adolescents), (3) adapting existing protocols to meet the need of special populations (e.g., adapting an existing protocol evaluating motivational interviewing for Spanish speaking substance users), and (4) conducting secondary analyses of existing datasets to examine issues related to differential access to treatment, retention, or treatment response among members of ethnic minority groups. In June 2006, a CPDD symposium, organized by Carmen Rosa of NIDA, was conducted; it included four presentations on ongoing CTN activities addressing ethnic disparities using a range of these

strategies. Kathleen Carroll described a protocol developed specifically to address retention in treatment among Spanish-speaking substance users. Ray Daw described the special issues raised in clinical research among American Indian communities and an example of a CTN protocol that was adapted in one site so it could be implemented among American Indians in the context of a tribal treatment center. Kathryn Magruder summarized results of a secondary analysis evaluating rates of retention among ethnic minorities in clinical research using data from multiple completed CTN trials. Lawrence Brown described a secondary analysis of a CTN survey study on national practices regarding the availability of specialized treatments for sexually transmitted diseases, including HIV and HCV, in drug abuse treatment and emphasized the extent to which services are available for ethnic minorities. Finally, Dr. Lula Beatty summarized how these efforts correspond to NIDA and NIH's efforts to address health disparities among ethnic minorities. The public databases of the CTN trials will be available at <http://www.nida.nih.gov/CTN/Data.html> as studies are completed and published.

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**1. MET-S: the first multisite randomized clinical trial of behavioral therapies conducted in Spanish (Kathleen M. Carroll, Samuel A. Ball, Steve Martino, Yale University School of Medicine; Jose Szapocznik and Lourdes Suarez, University of Miami)**

Substance abuse is a significant problem among Hispanic Americans, who represent the largest ethnic minority group in the United States. The 2004 National Survey on Drug Abuse indicated that 35% of Hispanics 12 years or older have used illicit drugs in their lifetime and 40% have used alcohol (Substance Abuse and Mental Health Services Administration (SAMHSA), 2004). National data on rates of treatment utilization suggest that Hispanics are less likely than Whites and African Americans to receive treatment services when needed and that those services are often delayed when they are available (Wells et al., 2001). Compounding the disparities in treatment access and utilization among Hispanics is the underrepresentation of monolingual Spanish-speaking patients in clinical and research samples (Wells et al., 2001; Williams et al., 1996). A major barrier to participation in many research studies by monolingual Hispanics is the inability to read consent forms or complete study assessments that are written in English as well as lack of Spanish-speaking clinicians (Derose and Baker, 2000). Thus, clinical trials that require proficiency in oral or written English exclude a sizable proportion of the Hispanic population. To date, no study has addressed the extent to which the addition of empirically supported therapies to standard treatment approaches improves treatment retention and outcome among Hispanic adults, and in fact very few single site studies have been conducted primarily with Hispanic adult substance users.

To address the underrepresentation of Hispanics in clinical trials of substance use treatments, the CTN implemented the first ever multisite trial of treatments for monolingual Spanish speakers. The Spanish MET trial is an adaptation of a completed CTN trial that com-

pared motivational enhancement therapy (MET) (Miller and Rollnick, 1991) with counseling-as-usual in the first month of outpatient treatment in five community-based sites across the country (Santa Fe, NM; Denver, CO; Miami, FL, New York, NY; Portland, OR). Briefly, in the original (English) version of this trial individuals seeking treatment for any substance use disorder were randomized to receive either three individual sessions of manual-guided MET or three sessions of the standard individual counseling offered at the participating sites (Ball et al., 2006; Carroll et al., 2002, 2006). Clinicians were drawn from the clinical staff of the participating sites (all of which already offered treatment in Spanish and hence had experienced bilingual staff on hand) and were randomized to be trained in and then implement MET or to continue to use the standard counseling approach in that clinic.

As described in more detail elsewhere (Suarez-Morales et al., *in press*), a number of challenges emerged in implementing the trial. These included first, translating the treatment manual and worksheets, IRB-approved consent forms, and a large number of assessment instruments into Spanish. This required not only careful translation and back-translation procedures, but also review by local staff at the participating sites to assure that the translations encompassed the variety of nationalities and regional differences in Spanish language use across the participating sites. Second, recognizing that simply delivering a treatment in Spanish, even by Hispanic clinicians, did not necessarily render it culturally appropriate, the bilingual MET trainer/supervisors and clinical supervisors worked throughout the trial to facilitate effective implementation of MET, using a system which provided regular review of session audiotapes by both national expert trainers and local supervisors, with regular feedback to the clinicians.

Finally, the trial raised multiple complex issues related to human subjects protection. Most of the participants were immigrants (85%), and many were in the country illegally. The vast majority had not participated previously in clinical research and participants were

largely not aware of the rights or federal protections governing clinical research. Hence, special attention was given to the issues of language and unfamiliarity with research procedures throughout the study, in particular during the informed consent process. For example, the consent forms were translated into Spanish and were read aloud to the participants to assure they understood all the procedures involved in the research and their rights as participants. Because full literacy in Spanish was not a study requirement, some participants had difficulty with reading and responding to some of the self-report assessment instruments and it was often necessary for the research assistant to read the questions aloud to the participant while the participant filled in the appropriate responses on his or her own copy. For this reason, the assessment battery was also comparatively brief (compared with previous multisite trials) to enhance engagement and to allow sufficient time for rapport building (Suarez-Morales et al., *in press*).

Data collection for the 463 individuals randomized to treatment for this study is now complete and outcome analyses are ongoing. In general, treatment retention in the trial was comparatively high across conditions with 61% of the sample completing all three sessions offered. Products from this trial will not only include important process and outcome data on the effectiveness of MET and standard treatment in this population, but also a wealth of clinical materials appropriate for use with Spanish speaking populations (treatment manuals, multiple validated versions of validated assessments translated into Spanish).

**2. Strengthening research to address health disparities among American Indians (Ray Daw, Executive Director, Na'nizhoozi Center, Inc.)**

Tribal communities and researchers agree that substance use and related health problems are major issues that continue to face American Indians (Jones, 2006). Whereas epidemiologic research with American Indians has increased over the past decade, numerous issues with regard to effective clinical

research remain. American Indians living in the United States are a very diverse ethnic group with nearly 600 federally recognized tribes. Many American Indians are living on rural reservations, but a majority now lives in large metropolitan areas like San Francisco, Los Angeles, Phoenix, Minneapolis, and Chicago. Unlike other ethnic-racial groups living in the United States, American Indian tribes are political entities which have sovereignty, which in turn changes the very nature of the relationship between the United States government (and funding mechanisms) and American Indian tribes.

Indigenous research is complicated by cultural, social, and spiritual differences as well as ongoing acculturation affecting tribal people in positive and negative ways (Strickland, 2006). Knowledge, acquisition of knowledge, and what constitutes knowledge also differs from tribe to tribe. There remains longstanding distrust of non-tribal researchers that compound implementation of needed studies to develop effective prevention and treatment practices that are adapted to the tribe-specific context. These differences create barriers for researchers who do not have previous experience with tribal communities. The NIDA Native American Workgroup has described three improvements needed in drug abuse research: (a) identifying indigenous models of healing that enhance protective factors, (b) addressing adaptation of non-indigenous models of prevention and treatment, and (c) inclusion of indigenous researchers and clinicians in research design and study (Volkow, 2005).

Moreover, historical trauma experienced by native people has not only negatively impacted the overall health of American Indians, but has created distrust of research and involvement of non-tribal institutions within their communities (Warne, 2006). Poverty on tribal lands has existed for generations and continues to take its toll on inhabitants of the reservations. Most tribal reservations have high unemployment rates and poor socio-economic conditions.

Cultural dissonance is best addressed by increasing American Indian identity. This is an important protective factor, as substance abuse or misuse is not

condoned within the indigenous belief system of all tribes. Consequently, tribal communities have been shown to have higher rates of abstinence, when compared to other ethnic groups in the United States. Structural poverty that exists with tribal communities and many urban families is another area that can be positively changed. Education, vocational training, jobs, housing, economic development, and transportation are considerations for development of resilient communities and families.

Na'nizhoozhi Center (NCI) is part of the southwest node of the CTN, by partnering with the University of New Mexico's Center on Alcoholism Substance Abuse and Addictions (CASAA). NCI has implemented the Job Seekers Workshop protocol, which was developed to improve job interviewing skills for people with substance abuse problems and was identified by NCI as a priority for implementation in meeting a critical need of the people served by NCI with a population that is heavily American Indian and very rural. This study is examining and comparing, with an American Indian sample, the effectiveness of Job Seekers' Workshop, a three session, manualized program designed to train participants in the skills needed to find and secure a job, relative to a job interviewing videos (JIV) intervention, a single session 40 min video presentation designed to teach people the skills to find and secure a job. NCI originally was one site in the multisite trial, but has since been designated as a separate study site due to the need for cultural adaptation.

The CTN experience and challenges with this protocol has required adaptation of the protocol to the indigenous language of the population. Since the sessions are in an indigenous language, this has required fidelity monitoring of the protocol in that language. Particular challenges included those associated with (a) adaptation of the protocol to integrate the cultural identity of the NCI staff and participants into the day to day implementation of the study, and (b) the process of obtaining approval from the tribal HRRB for conducting research with members of the tribe. Once these challenges were addressed, protocol implementation was successful,

with comparatively high rates of enrollment and follow-up. The partnership of NIDA-CTN and NCI, has demonstrated that research protocols can be adapted for special populations. American Indian research can be accomplished by teaming with experienced American Indian clinicians and agencies to address the challenges of IRB and tribal-specific culture and conditions.

### **3. Participant factors related to study retention of minority subjects in drug abuse treatment research: evidence from the Clinical Trials Network (Kathryn M. Magruder, Barbara C. Tilley, Scott W. Miller, Bichun Ouyang, Kathleen T. Brady, Medical University of South Carolina)**

Successful recruitment and retention of minority research subjects is critical to the NIDA-CTN and addictions research in general. Much has been written concerning recruitment of minority subjects in research projects; however, very little attention has been given to retention of minority subjects. Differential attrition by minority subjects can be as limiting to interpreting final results as poor initial recruitment of minority subjects. For this reason, it is imperative to study factors influencing minority subject retention in research.

The focus of this report is on retention of study subjects in CTN studies trials and the role that race/ethnicity plays. Our aim is to determine if CTN study retention rates differ by race/ethnicity taking other participant factors and clustering within study into account. The specific aims of this secondary data analysis are to: (1) examine differences in study retention rates for under-represented minority participants relative to Caucasian non-Hispanic participants; and (2) explore factors that account for differential retention rates.

Participants who were randomized to the studies were categorized as retained or not retained based on completing the final study visit (per protocol specification). Note that a study visit and a treatment visit did not necessarily occur simultaneously, so completing the final study visit did not mean that the partici-

pant was retained in treatment. Included in this analysis are data from the first six clinical trials whose databases were locked. These studies included two medication trials (Amass et al., 2004; Ling et al., 2005), four behavioral trials (Petry et al., 2006; Peirce et al., 2006; Carroll et al., 2006; Ball et al., 2006), and a feasibility study of using telephone enhancement to improve participation in continuing care (Hubbard et al., 2006). In these studies, 1910 participants were enrolled and randomized, and thus eligible for inclusion in this secondary analysis of retention across trials. Because less than 10% of the participants were from race/ethnic groups other than Caucasian, African American, or Hispanic, we excluded those reporting other races/ethnicities. This left 1737 participants in the analysis dataset; of these 52% were Caucasian, 36% were African American, and 12% were Hispanic. For these participants, the following person-level data, common to all protocols, were abstracted: race/ethnicity, gender, age, and primary drug of abuse.

Overall, 72.3% of participants who were randomized in the studies were classified as retained in the study (range 59–82% by study). Preliminary multivariable analyses showed that there was a significant effect of primary drug of abuse on retention. There was no effect for gender. There was a significant race by age interaction. The interaction indicated that older African Americans and Caucasians were more likely to complete the study than their younger counterparts. There was no effect of age for Hispanics. In addition, there was a significant effect of primary drug of abuse on retention, with heroin, methadone, or opiate users more likely to be retained, while poly-drug users were least likely to be retained in the trials.

Future analyses will examine the role of protocol attributes in minority retention. For example, do attributes, such as the nature of the intervention, the duration of the trial, visit intensity, or monetary gain differentially influence race/ethnicity groups to remain in a study? Additionally, we will analyze the role of program factors in minority retention. Examples of such factors include organizational

characteristics (e.g., percent minority participants served, urban/rural location, funding sources) and staff characteristics (e.g., percent minority staff, percent female staff). By fully understanding the influence of personal, protocol, and programmatic factors that influence minority participants to remain in drug abuse treatment studies, we will be in a position to improve study retention rates, resulting in greater confidence in the interpretation of study outcomes for minority participants.

#### **4. Relationships between the availability of infection-related services and availability of services tailored for subpopulations in substance abuse treatment programs in the NIDA Clinical Trials Network (Lawrence S. Brown, Steven Kritz, John Rotrosen, R. Jeffrey Goldsmith, Edmund Bini, James Robinson, Donald Alderson and the Infections Study Team of the National Drug Abuse Treatment Clinical Trials Network)**

Human immunodeficiency virus (HIV), hepatitis C virus (HCV), and sexually transmitted infections (STIs) are major causes of excess morbidity and mortality in the United States. Persons with a history of a substance use disorder represent a major vehicle of transmission of these infections, especially among women and many communities of color. This presentation was a secondary analysis of data from the infections and substance abuse study, specifically assessing the availability of infection-related services in treatment programs with and without substance abuse services tailored for sub-populations subject to significant disparities in healthcare access and quality. The infections and substance abuse study examined associations between services provided for HIV/AIDS, hepatitis C viral infection, and sexually transmitted infection at substance abuse treatment programs in the CTN (Brown et al., 2006). This report used data from the survey of treatment program administrators. Program administrators provided information about substance abuse services targeted for women

and minorities and the availability of eight infection-related services: provider education, patient education, risk assessment, counseling, medical exams, biological testing, treatment, and monitoring.

Treatment program administrators from 269 of 319 (84%) substance abuse treatment programs responded. Substance abuse treatment services tailored for women, African Americans, and Latinos were available in 71, 34, and 39% of the treatment programs, respectively. HIV infection services were more prevalent than infection services for HCV or STI. Irrespective of the infection, non-medical services were more prevalent than medical services. Treatment programs offering substance abuse treatment services for African Americans, Latinos, and women were also more likely to offer infection-related health services. This information suggests that treatment programs with substance abuse treatment services tailored to women and communities of color should also be considered as a unique health care setting for providing access to infection-related health services to these populations who suffer significant healthcare disparities.

#### **5. Summary and discussion (Lula Beatty, National Institute on Drug Abuse)**

Eliminating health disparities is a priority goal of NIDA and NIH. In 2000, NIDA developed its Health Disparities Strategic Plan which was last updated in 2004 (<http://www.drugabuse.gov/StrategicPlan/HealthStratPlan.html>). The plan outlines directions and initiatives for research, research infrastructure, and outreach and dissemination and, more broadly, serves as a framework and impetus for initiating new efforts to better address drug abuse research needs of racial/ethnic minority populations as need and opportunity arise. It should be noted that there are few overall significant differences by race or ethnicity in drug use and addiction. There are disparities, however, in the consequences of drug use by race/ethnicity with persons from certain racial/ethnic minority populations experiencing worse outcomes (e.g., greater



rates of HIV/AIDS in African Americans and Hispanics associated with drug use).

Essential to the successful implementation of any health disparities research agenda focused on improving drug abuse prevention and treatment in racial/ethnic minority populations is the inclusion of racial/ethnic minority populations in research studies and clinical trials. Without adequate knowledge of the factors that influence each population group's access and responsiveness to treatment and interventions, disparities will persist and, in some cases, widen. Recent literature suggests that the successful recruitment of racial and ethnic minority populations into health research is determined by asking the desired group members to participate (Wendler et al., 2006, Hussain-Gambles et al., 2006) and the investigators' belief that minority inclusion is important (Williams and Corbie-Smith, 2006).

The CTN has adopted a planned, thoughtful model to ensure that inclusion is viewed as important and critical to the clinical trials research undertaken and that racial and ethnic minority populations are asked to participate in the research in a manner appropriate to their culture, gender, and circumstances. The multiple strategies described in the CTN projects above, namely the formation of a special interest groups, the development of specific protocols, the adaptation of protocols, and the conduct of secondary analysis, provide a strong foundation and model for research in this area, where inclusion is not an afterthought.

These studies also demonstrate approaches that can be used to gain meaningful participation or valid information about racial/ethnic minority populations and drug abuse treatment and services. It becomes clear that each racial or ethnic group may require recruitment and retention tactics that reflect their unique histories, culture and drug abuse related needs. For example, Carroll highlights the barriers posed by language beyond sheer comprehension (e.g., ability to give consent), and describes how MET was adapted and made culturally appropriate for Spanish-speakers. It was not a straightforward easy translation task. Although final results of the protocol were not

yet analyzed, participant retention was impressive.

Daw eloquently describes the particular challenges encountered in including native Americans in clinical trials. There are over 600 tribes, each of which has sovereignty with the United States (hence, working with native American tribes can be compared to conducting international work.) He describes the factors that must be acknowledged if one is to intervene effectively with native Americans including historical trauma and poverty. The Job Seekers Workshop intervention protocol, adapted for native Americans and tested at the Na'nizhoozhi Center, emphasizes the benefits of exploring interventions aimed at making changes at the structural level. Addressing the unemployment and underemployment that disproportionately affects native Americans may provide the support needed for participants to sustain sobriety.

Magruder et al. provided information on how well racial and ethnic minority subjects were retained in CTN studies. Data from six studies in the CTN suggested that participation rates varied by race and age, and that other factors, such as type of drug use, were also important in retention. Although it is not clear why these rates vary, asking the questions brings the field closer to understanding the factors that affect racial/ethnic minority recruitment, attrition, and retention.

Dr. Brown et al.'s study explored the availability of infection (e.g., HIV, HCV) services and substance abuse treatment programs and services tailored for special population groups. Differences were found by group. When tailored treatment programs were available, infection related services were also more likely to be available. This type of analysis suggests that when the needs of particular groups are considered, the breadth of services needed will be recognized and provided. The field will be greatly enriched by the careful deliberation and scope of issues addressed by the CTN in the development of protocols for racial/ethnic minority populations. It is hoped that future studies will allow them to expand their research to include other groups, such as Asian Americans and Pacific Islanders and to explore even

more closely the factors that account for variability in recruitment, attrition and retention within the groups.

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