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Increasing Ethnic Minority Participation in Substance Abuse Clinical Trials: Lessons Learned in the National Institute on Drug Abuse's Clinical Trials Network

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Abstract

Underrepresentation in clinical trials limits the extent to which ethnic minorities benefit from advances in substance abuse treatment. The objective of this article is to share the knowledge gained within the Clinical Trials Network (CTN) of the National Institute on Drug Abuse and other research on recruiting and retaining ethnic minorities into substance abuse clinical trials. The article includes a discussion of two broad areas for improving inclusion— community involvement and cultural adaptation. CTN case studies are included to illustrate three promising strategies for improving ethnic minority inclusion: respondent-driven sampling, community-based participatory research, and the cultural adaptation of the recruitment and retention procedures. The article concludes with two sections describing a number of methodological concerns in the current research base and our proposed research agenda for improving ethnic minority inclusion that builds on the CTN experience.

Keywords

recruitment; retention; ethnic minorities; clinical trials; research participation

According to the U.S. Census, ethnic minorities will constitute more than 50% of the population in the United States by the year 2042 (U.S. Census Bureau, 2008). Past research reveals that various ethnic groups respond differently to substance abuse treatment (Marsh,

Cao, Guerrero, & Shinn, 2009). Ethnic minority participants in some interventions have better outcomes than Whites (Covey et al., 2010; Montgomery, Burlew, Kosinski, & Forcehimes, in press; Winhusen et al., 2008); however, ethnic minority participants have worse outcomes than Whites in other interventions (Calsyn et al., 2009). Therefore, the underrepresentation of Ethnic Minorities in clinical trials impedes the development of effective treatments to reduce health disparities in substance use (Shaya, Gbarayor, Yang, Agyeman-Duah, & Saunders, 2007). Both recruitment and retention are essential to increasing ethnic minority participation in clinical trials. However, previous research demonstrated that ethnic minorities are less likely to be included into clinical trials (Kennedy et al., 2010; Maculuso et al., 2005) and more likely to withdraw prematurely than Whites (Areal, Alvidrez, Nery, Estes, & Linkins, 2003; Moreno-Black et al., 2004).

Yancey, Ortega, and Kumanyika (2006) recently described the limited research on the effectiveness of recruitment and retention strategies for specific target groups as a shortcoming in the current knowledge base. The objective of this article is to address this gap in two ways. First, the article focuses on two broad approaches in the existing literature for increasing ethnic minority inclusion—community involvement and cultural adaptation—and also illustrates these approaches with case studies from the Clinical Trials Network (CTN) of the National Institute on Drug Abuse (NIDA). The second contribution is the presentation of a research agenda on recruiting and retaining ethnic minorities into substance abuse clinical trials that builds on the knowledge gained within the CTN and other existing research.

The next section provides a background of the literature on the inclusion of ethnic minorities in clinical trials. The discussion of community involvement and cultural adaptation and the related case studies follow the background section. The article concludes with two sections describing several methodological concerns and our proposed research agenda for improving ethnic minority inclusion in substance abuse clinical trials.

Background

Even the limited available substance abuse research makes a strong case for examining treatment effects within specific ethnic groups because of ethnic differences in the factors related to substance use. Some meaningful ethnic differences are due to the unique experiences of members of a particular ethnic group in this society. For example, cultural or subcultural factors result in ethnic differences in drug histories (Shillington & Clapp, 2003), specific drugs used (Moselhy & Telfer, 2002), health consequences of substance use (Iguchi, 2005), patterns of treatment engagement and retention (Campbell, Weisner, & Sterling, 2006; Jackson-Gilfort, Liddle, Tejada, & Dakor, 2001), and more broadly, cultural attitudes about mental health treatment (Buser, 2009). In addition, cultural differences in the relation of both spirituality (Strada & Donohue, 2006) and acculturation (Epstein, Botvin, & Diaz, 2000; Hahm, Lahiff, & Gutterman, 2003; Klonoff & Landrine, 2000; Strada & Donohue, 2006) to substance use attitudes may also influence treatment response. Moreover, African American and Hispanic youth are more likely than White youth to be referred to treatment from the criminal justice system (Iguchi, 2005; Shillington & Clapp, 2003). All these issues raise questions regarding the generalizability of findings on evidence-based treatments (EBTs) conducted on White samples to specific ethnic minorities.

National attention on ethnic minority underrepresentation in research can be traced back almost 2 decades. The National Institutes of Health (NIH) issued its first mandate to include women and ethnic minorities in research in 1994 and followed up with amendments in 2001 (National Institutes of Health, 1994, 2001). In 2000, NIDA released its first Health Disparities Strategic Plan and recently updated the plan for 2009–2013. The NIDA Strategic

Plan aims to use research to understand, address, and treat drug abuse and addiction among ethnic minorities. Ethnic minority recruitment and retention in clinical trials are both critical to enacting the NIH mandate and the NIDA Strategic Plan.

The Surgeon General also addressed the underrepresentation of ethnic minorities in research in a 2001 report (U.S. Department of Health and Human Services [USDHHS], 2001) that identified two specific shortcomings for clinical trials. First, the Surgeon General's report expressed concern that ethnic minorities are generally underrepresented in clinical trials. Second, the report noted that even studies that include ethnic minorities typically fail to examine the treatment effects for ethnic minorities separately. For example, the Surgeon General reported that not a single study listed in the 1995 American Psychological Association (APA) Task Force on Empirically Validated Treatments (Chambless et al., 1996) analyzed the outcomes separately for ethnic minority participants (USDHHS, 2001). A decade later, another APA Task Force examined EBTs (American Psychological Association, 2006) and again concluded that the generalizability of findings regarding EBTs to ethnic minorities remained understudied. Nevertheless, some progress has been made in this area (Miranda et al., 2005; Muñoz & Mendelson, 2005). Scholars have begun to endorse the importance of examining the findings for specific ethnic minorities (Areal et al., 2008; Starr & Kenner, 2005; Tonigan, 2003). However, few studies are available in the substance abuse literature that either report the outcomes for specific ethnic minority groups (Burge et al., 1992; Montgomery, Burlew, Kosinki, & Forcehimes, in press; Robles et al., 2004; Szapocznik, Prado, Burlew, Williams, & Santisteban, 2007) or describe racial or ethnic differences in outcomes (Amaro et al., 2007; Covey et al., 2008; Winhusen et al., 2008).

Despite the general consensus that ethnic minority participation in clinical trials is essential to developing more effective treatments for ethnic minorities, ethnic minority inclusion is a formidable challenge for researchers. For example, the federally funded principal investigators in a survey by Durant, Davis, St. George, Williams, and Blumental (2007) reported that they were significantly less likely to meet their recruitment goals for African Americans, Latinos, or Asian Americans than their goals for White participants. Clearly, more research is required to develop strategies to address the inclusion barriers reported in previous work.

As background for developing a research agenda to improve ethnic minority participation in substance abuse treatment research, we reviewed the literature on effective strategies for ethnic minority inclusion into substance abuse trials from 2000 to the present in two databases: PsycINFO and PubMed. For each ethnic group, we cross-tabulated both recruitment and retention search terms with research and clinical trials.

Much of the available literature focuses on barriers to inclusion. Recent reviews by Mason (2005) and Yancey et al. (2006) suggest that the ethnic minority barriers fall into the following categories: personal factors (e.g., especially cultural distrust), social factors (e.g., travel expenses, child care, inflexible work schedules), and factors related to the research procedures themselves (e.g., lengthy consent documents, insufficient outreach, inconvenient times and locations, use of Internet). Substance abuse adds additional barriers to either recruitment (e.g., concerns about social, legal, or employment consequences of disclosing one's substance use) or retention (e.g., stigma, relapse, ongoing legal involvement) (Magruder, Ouyang, Miller, & Tilley, 2009).

Fouad (2009) argued that enough attention has been devoted to identifying the inclusion barriers. Consequently, she argues for redirecting future efforts away from documenting barriers to developing a comprehensive plan to use the available information to increase

ethnic minority inclusion. Accordingly, the focus of this article is on effective inclusion strategies.

The CTN

The CTN has proven to be a rich platform for testing the effectiveness of substance abuse treatments. The CTN evaluates substance abuse treatments in larger effectiveness trials. Some large samples collected in multisite randomized clinical trials include adequate samples of ethnic minorities to conduct secondary analyses using smaller sample techniques to evaluate the efficacy of the interventions for specific ethnic minority populations.

As of February 2011, the CTN had enrolled 2,700 (22%) African American, 2,071 (17%) Latino, 179 (1%) American Indian/Alaska Native, 56 (<1%) Asian/Pacific Islander, and 1,575 (13%) other/multirace participants into 30 clinical trials. Overall, the CTN retention rates for ethnic minorities have been similar to the retention rates for Whites (Burlew et al., (2011)). However, the recruitment rates have varied widely across trials. A comparison of the trials with higher (*Motivational Incentives for Enhanced Drug Abuse Recovery: Methadone Clinics* [25% White] [Pierce et al., 2006] and *Brief Strategic Family Therapy for Adolescent Drug Abusers* [34% White] [Robbins et al., in press]) and lower (*A Pilot Study of Osmotic-Release Methylphenidate in Initiating and Maintaining Abstinence in Smokers with Attention Deficit Hyperactivity Disorder* [82% White] [Winhusen et al., 2010] and *A Two-Phase Randomized Controlled Clinical Trial of Buprenorphine/Naloxone Treatment Plus Individual Drug Counseling for Opioid Analgesic Dependence* [91% White] [Ling et al., 2009]) proportions of ethnic minorities reveals several lessons. The first (and, perhaps, most important) lesson is that the trials with higher rates of ethnic minorities included community treatment programs (CTPs) that enrolled higher numbers of ethnic minorities. Those CTPs have both the advantage of being able to recruit from their natural caseloads and more experience with working with ethnic minorities. Conversely, those sites with lower numbers of ethnic minorities in their natural enrollment streams may be forced to recruit outside their natural recruitment streams to include ethnic minorities in clinical trials. Moreover, such CTPs may find it necessary to train their staff to be effective with populations outside the groups they have served in the past or to collaborate with CTPs that already serve these groups.

The second lesson refers to the finding that the two trials with the lowest ethnic minority enrollment were medication trials, whereas the trials with the higher numbers of ethnic minorities were behavioral trials. This pattern suggests that it may be more difficult to recruit ethnic minorities to medication trials than to behavioral trials. The third lesson is that the two trials with the lowest numbers of ethnic minorities had more stringent eligibility criteria. The inclusion criteria for one of these studies not only limited the participants to those using prescription opiates but also required individuals to satisfy two specific restrictive criteria: meeting diagnosis for attention-deficit/hyperactivity disorder (ADHD) and smoking more than 10 cigarettes per day. The lower numbers of ethnic minorities in these trials suggest that utilizing some of the strategies described later to ensure the inclusion of ethnic minorities may be even more important in medication trials or in trials with restrictive eligibility criteria.

Increasing Inclusion With Community Involvement

This section describes a set of community outreach strategies utilized within the CTN and elsewhere that reflects the diverse approaches to community involvement. One set of strategies, community outreach, takes the research team out into the community. Another set of strategies actually includes community representatives in a variety of roles on the research team. This section also includes two case studies that demonstrate two types of

community involvement—respondent-driven sampling (RDS) and community-based participatory research (CBPR).

Community Outreach

Several researchers have demonstrated the efficacy of community outreach for recruiting ethnic minorities. Although Kennedy reported moderate success in using mailed letters, flyers, and mass media to recruit African Americans (Kennedy et al., 2010), the available evidence suggests that community outreach may be more efficient than those methods. Okuyemi et al. (2007) calculated that the cost per randomized African American participant recruited into an intervention for light smokers was only \$27 for community outreach methods (e.g., sending representatives to community activities). Conversely, because of the low yield, the cost per randomized African American was much higher for more traditional appeals such as posting announcements on billboards (\$120), advertisements in newspapers (\$1,208), and advertisements on mass transits (\$940). Research estimating time spent on recruitment instead of dollars reveals this same pattern in an area other than substance abuse. Specifically, Cabral et al. (2003) compared the efficiency of community outreach approaches to more traditional methods for recruiting African American and Latino participants into a lung cancer study. The average time required per participant enrolled with a combination of community outreach strategies (i.e., presentations at community events, distributing flyers or letters at health fairs or to churches, community and housing centers, employers, and physicians who serve large numbers of ethnic minorities) was less than 1 hour per enrollee, compared with 18.6 and 11.4 hours for random digit dialing and mass mailings from the health care system, respectively.

Community Involvement on the Research Team

Fostering community involvement with the research team can be another approach used to improve recruitment of ethnic minority individuals. The history of exploitation from researchers has shaped how ethnic minority communities view research (Shavers, Lynch, & Burmeister, 2000) and influences researchers' ability to engage community members in research activities. Therefore, involving community members at any level takes time and requires a great amount of trust building.

Community involvement can vary from limited, narrowly defined roles such as the use of community representatives to recruit (e.g., RDS) to community representation in the decision making at all stages of the research (CBPR). The literature includes many examples of community representatives who perform very specific roles on the project but have only limited involvement in the decision making. Some narrow roles include serving on a community advisory board (Dancy, Wilbur, Talashek, Bonner, & Barnes-Boyd, 2004; Reed, Long, Foley, Hatch, & Mutran, 2003), agreeing to serve as the "public face" of the project to enable the program to capitalize on one's influence in the community (e.g., minister, political figure) or celebrity status (e.g., prominent athletic figure, media personality). Despite the intuitive appeal of these strategies, we are unaware of any research on the efficacy of these strategies for recruiting ethnic minorities into substance abuse clinical trials.

Enlisting the support of existing community and social service organizations to recruit and retain participants is another form of community involvement. Alvarez, Vasquez, Mayorga, Feaster, and Mitrani (2006) described an impressive model for enrolling African American women into a behavioral study focusing on HIV medication adherence and substance abuse recovery. The research team began by identifying and contacting the appropriate administrators of organizations in the target communities. If the contact with the administration was successful, the research team also established relationships with staff and

client representatives who became informal recruiters. Using this approach, Alvarez et al. (2006) identified and contacted 14 organizations and ultimately recruited 46 participants from 9 of these organizations.

The evidence is quite promising for RDS, another approach to involving community members. In RDS, study participants agree to recruit within their own social networks. The underlying assumption of RDS is that peers can recruit participants more effectively than either community outreach workers or other research staff. In RDS, the research team offers incentives to early waves of recruits referred to as “seeds” to recruit additional participants from their social networks. Robinson et al. (2006) demonstrated the effectiveness of RDS over targeted sampling for recruiting African American injection drug users in a trial implemented in three U.S. cities. Two other studies successfully used RDS to recruit African American and Latino drug users (Frost et al., 2006; McKnight et al., 2006). However, none of these studies were recruiting participants into a clinical trial. The CTN case study discussed later on RDS illustrates the use of RDS to bolster recruitment into a clinical trial.

Case Study 1: RDS

Lexington–Richland Alcohol and Drug Council (LRADAC) was one of 11 sites participating in a randomized controlled trial comparing the efficacy of osmotic-release methylphenidate versus placebo for ADHD in adolescents with ADHD and a substance use disorder. The eligibility criteria for the study were particularly restrictive. For example, along with substance use, eligible participants were required to be between the ages of 13 and 18, to meet criteria for ADHD in accordance with the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; *DSM-IV*; American Psychiatric Association, 1994) by scoring above a cutoff on a *DSM-IV* ADHD symptom checklist, and to be willing to participate in a medication trial. Adolescents who had concurrent bipolar diagnoses or who required other psychotropic medication were excluded.

The two original recruitment strategies were (1) clinic referrals from existing referral sources (e.g., juvenile justice, social services, and schools) and (2) passive recruitment strategies (e.g., posting flyers within the community and on billboards and buses, announcements in newspapers and radio public service announcements). During the first year of the study, only 5 African Americans were recruited with the two original recruitment strategies. When these two strategies proved unsuccessful, LRADAC sought approval from their institutional review board (IRB) to implement a RDS recruitment approach. The IRB approved the proposed revision once LRADAC added statements to the informed consent form explaining the voluntary nature of the RDS, the procedures for referring any interested individuals to the research team, and the incentives. Eventually, the research team gave flyers to interested participants (seeds) to distribute to peers. The seeds instructed interested peers to contact the research office by telephone or in person to be considered. If a peer consented to participate, the seed received an incentive of \$10.

Although recruitment was initially slow, LRADAC eventually exceeded the study’s recruitment goal after the RDS component was added. The fact that 46% of the volunteer seeds were African American suggests that African Americans are willing to recruit from their social networks. Moreover, the fact that African Americans represented 50% of the final sample suggests that this method is promising for recruiting African Americans into clinical trials and other types of research.

Several concerns have been raised regarding whether RDS has some of the same potential problems with sample selection as snowball sampling. One concern is the representativeness of the sample. Several researchers have reported promising results in studies that calculate the probability of selection post hoc to evaluate the validity of RDS-derived population

estimates (Gile & Handcock, 2010; Heckathorn, 1997, 2002). A second but related concern is that a few seeds may have a disproportionate influence on the final sample. However, as a safeguard against that possibility, a limit can be placed on the number of referrals from any one seed. Moreover, it should be noted that RDS at least addresses the potential for bias, whereas many clinical trials utilize convenience sampling, an approach that does not necessarily even consider the issue of bias.

CBPR

CBPR is an example of the most inclusive approach to community involvement. In a CBPR partnership, all partners have the opportunity to participate in each phase of the work, including assessment of community needs, design, implementation, analysis, interpretation of results, ownership of data, and dissemination of results (USDHHS, 2011; Wallerstein & Duran, 2006). The partnership is based on two fundamental CBPR principles: equitable involvement of all partners and the recognition of the unique strengths of different partners. The research team may have more expertise on the scientific procedures, whereas the community members may be the experts on community needs and on accessing participants in a specific community. A CBPR approach is consistent with recommendations by African American and Latino community representatives consulting with federal representatives about inclusion of ethnic minorities in research (Grady et al., 2006). These community representatives recommended the formation of true partnerships between the researchers and community organizations as a means of addressing the community distrust of researchers.

Emory University researchers used CBPR to assess the feasibility of developing and implementing a culturally adapted faith-based HIV intervention for African American women (Wingood, Simpson-Robinson, Braxton, & Raiford, 2011). Consistent with CBPR principles, the Emory researchers first reached out to partner with New Birth Missionary Baptist Church, a church with strong community ties and an HIV ministry. Emory and New Birth shared in all decision making, including study design, designing effective recruitment and retention protocols, and implementation of the faith-based intervention. Together, university and church representatives conducted focus groups with potential participants, selected the appropriate intervention, selected and trained facilitators, and implemented a two-session HIV risk reduction intervention. Eventually, 44 of the 52 (85%) eligible women agreed to participate. Wingood et al. did not report the number who completed the follow-up assessments. However, the authors did report that 92% completed the two-intervention sessions.

Case Study 2: A CBPR Approach to Recruiting and Retaining Navajo Participants

The Southwest Node of the NIDA CTN used a CBPR approach to evaluate a job training protocol designed to increase employment among substance-dependent participants. The academic researchers of the Southwest Node partnered with Na'nizhoozhi Center, Inc. (NCI), a community treatment program in Gallup, NM, to implement the project. On the basis of the principle of equitable involvement of all partners, NCI representatives were full partners on the research team from the beginning. To ensure the ongoing involvement of the community partners, the academic researchers traveled lengthy distances to hold joint weekly planning meetings. The partnership modified a job training protocol used earlier in other sites in the CTN and developed a research plan compatible with community norms.

The partnership of academic researchers and NCI representatives then submitted the project to the Navajo Nation Human Research Review Board (NNHRRB, 2007). Anyone interested in conducting human subject research in the Navajo community must meet a series of requirements (www.nnhrrb.navajo.org) established by the NNHRRB. These requirements are very consistent with a CBPR approach. The first step requires the researcher to present

and gain support from appropriate local community leaders to implement the project. The second step is to partner with at least one local program representative. Ultimately, NNHRRB approval, a requirement for conducting research in this population, increases participation by communicating the support of community leaders for the project.

On the basis of the CBPR principle that each partner has unique strengths and, consequently, can make different contributions to the partnership, NCI assumed responsibility for several specific tasks. NCI hired research assistants from the community to implement the research who were fluent in both Navajo and English and fully understood the Native American worldview. Also, Navajo staff edited assessment instruments to ensure that they were culturally appropriate.

The use of the term *relatives* for research participants conveys the type of relationship established between NCI and the community. Accordingly, NCI also assumed a leadership role in recruitment. NCI posted flyers that described the project and provided contact information in visible areas of the clinic. In addition, NCI partners introduced the project to counseling staff and asked counselors for referrals. Finally, clinic staff identified and referred potential participants to study staff during treatment team meetings and/or chart reviews. Ultimately, the project recruited and randomized 102 participants.

The design included follow up assessments at 1, 3, and 6 months after enrollment. The community partners helped the team to design procedures for collecting follow-up data that were likely to be successful in that community. First, research assistants contacted participants in both study arms regularly (not just for assessment appointments) by phone, letter, or in person to maintain rapport and encourage continued research study participation. Second, study participants could choose to complete their follow-up assessments either at the clinic or at some other location in the community. In addition to collecting the typical locator and tracking information, cell phone numbers were particularly helpful for maintaining contact. Finally, the team utilized a graduated compensation schedule. Specifically, participants received \$20 for the 1-month follow-up assessment, \$30 for the 3-month follow-up, and \$40 for the 6-month follow-up. In addition, any participant completing all three follow-ups received a \$40 bonus for study participation. Thus, participants who completed all three assessments earned \$130.

The retention rate for the follow-up was exceptionally good. In fact, the follow-up rates were 98% at 1, 3, and 6 months, which exceeded the corresponding rates of 88%, 82%, and 81%, respectively, for the original study conducted in traditional sites (Svikis et al., in press). One might wonder whether the high retention rates in the Navajo nation are primarily due to the stability of the population perhaps in a confined geographic area. Instead, however, the treatment and research were implemented in a border town next to the reservation. Finding the participants for follow-ups sometimes entailed driving to sites as far as 2 hours away in bordering states including Arizona and Colorado. Therefore, the retention rates are unlikely to be attributable to population stability and more likely attributable to the involvement of the community representatives who were able to educate the research team on the most effective way to retain research participants in the study.

Several researchers have mentioned the tension between a concern with internal validity and promotion of external or ecological validity (Glasgow & Emmons, 2007; Wallerstein & Duran, 2010) inherent in a CBPR approach. For example, if the community representatives are equal partners, the researcher may need to alter the design, and even the project, in significant ways to accommodate the interests of the community representatives. Another concern is the extent to which the treatment outcomes ultimately reflect the efficacy of the intervention versus the wraparound activities associated with the CBPR approach.

Obviously, such questions regarding the mechanisms of change can be examined empirically. However, Hohmann and Shear (2002) have argued that the aim of a CBPR approach is not limited to whether Treatment A works better than Treatment B. Rather, researchers using a CBPR approach are more interested than other researchers in understanding how the treatment works or does not work for a particular population, under what circumstances, and why. To achieve those aims, the CBPR researcher is interested in examining the effects of some of the factors (e.g., community input) ordinarily referred to as *noise* (or threats to external validity). Compared with traditional researchers, CBPR researchers place more emphasis on understanding the relationship between the situation or social context in which that treatment is being implemented and the outcomes. For that reason, CBPR researchers frequently explore questions not typically explored in treatment outcome research, such as the influence of people external to the treatment relationship on enrollment, client participation in treatment, and treatment outcomes. Hohmann and Shear have added that interdisciplinary teams that include qualitative researchers are essential for addressing these questions.

Cultural Adaptations to Increase Inclusion

The available research on cultural adaptation primarily focuses on treatment outcomes or program retention rather than recruitment or retention in clinical trials. However, although Bernal and colleagues defined cultural adaptation as “the systematic modification of an evidence-based intervention to consider language, culture, and context in such a way that it is compatible with the client’s cultural patterns, meanings, and values” (Bernal, Jimenez-Chafey, & Rodriguez, 2009, pg 362), some evidence, albeit limited, suggests that cultural adaptation will improve the research recruitment and retention procedures as well. Resnicow and colleagues (Resnicow, Soler, Braithwaite, Ahluwalia, & Butler, 2000) designed their conceptualization of cultural adaptation primarily for treatment interventions; however, their approach can be applied to the modification of recruitment and retention procedures as well. The Resnicow conceptualization includes two levels of cultural adaptation: surface adaptation and deep structural adaptation. The surface adaptation involves changes in observable and superficial aspects of a target population’s culture, such as language, music, foods, or clothing. Conversely, a deep structural approach would examine whether the recruitment and retention procedures can be modified to be more consistent with the cultural norms of the target population.

A recent meta-analytic review suggests that clients with perhaps the greatest need for accommodations (i.e., low-acculturated, non-English-speaking adults) received the greatest benefit from cultural adaptations (Griner & Smith, 2006). The limited research available on the cultural adaptation of the inclusion procedures addresses ethnic matching as well as other approaches to modifying the recruitment and retention procedures to be more appropriate for the target community.

Ethnic Matching

Most research on matching the client and provider on race or ethnicity, a surface adaptation, has examined the effect of ethnic match on treatment outcomes or program retention. The findings in these studies have been inconsistent (Weekes, 2010). For example, provider–patient ethnic match improved outcomes but was more important for the less acculturated and foreign born in a recent study on the effectiveness of a brief intervention on alcohol use for Latinos (Field & Caetano, 2009). However, neither gender nor ethnic match was related to treatment outcomes or retention in a sample of drug-using African Americans (Sterling, Gottheil, Weinstein, & Serota, 2001). Weekes (2010) reported that the effect of ethnic match varied across cultural groups. These findings highlight the complexity of ethnic matching and the importance of considering its effect within ethnic groups.

Although prevention researchers have advocated for ethnic match in prevention research (Kumpfer, Alvarado, Smith, & Bellamy, 2002), we are unaware of any published studies examining the relation of ethnic match to the recruitment of participants into substance abuse treatment clinical trials specifically. However, studies in areas other than substance abuse suggest that this issue is more complicated than simply ethnic match. For example, ethnic matching of interviewer and participant did not influence the willingness of African American psychiatric patients to agree to a research interview (Thompson, Neighbors, Munday, & Jackson, 1996). However, Moorman, Newman, Millikan, Tse, and Sandler (1999) found that both African American and White women were more likely to agree to enroll in a breast cancer study if approached by a same-race recruiter.

Several specific questions remain about the relationship of ethnic match to recruitment. The first question is whether ethnic match obviates the need for other training. A study by Larkey et al. (2002) addresses that question. Specifically, Larkey et al. found that Latino lay advocates called *embajadoras*, trained in recruiting Latinos, had higher rates of recruitment into the Women's Health Initiative, a large-scale prevention program, than untrained Latino recruiters.

Second, the diversity within the major ethnic groups included in the *NIH Guidelines for the Inclusion of Women and Minorities* raises questions in defining when the recruiter and potential participant are matched. For example, is a pair that includes a Cuban recruiter and a Mexican participant matched or unmatched? This issue deserves more attention in future research.

Cultural Adaptation of Procedures

Both surface and deep structural approaches have been utilized to modify the procedures to fit the target group. Along with ethnic match, another commonly used surface adaptation strategy is to approach potential participants in their native language or to translate recruitment materials and consent forms into their native language. Language has been demonstrated to be a barrier to research participation especially among non-English speaking groups (O'Sullivan & Lasso, 1992). However, beyond ethnic match and language, the existing research does not support the recruitment benefits of several other surface adaptation strategies, including the addition of health information about the target group on flyers or brochures (Kiernan, Phillips, Fair, & King, 2000), the insertion of either a picture of the ethnic minority researcher, or the inclusion of a culturally sensitive letter stressing the need for more research on the target ethnic group in the mailing (Satia, Gallanko, & Rimer, 2005). Together, these findings indicate the limitations of addressing surface changes instead of combining surface with deep structural changes.

Although limited, a few deep structural examples are available for recruitment and retention. One example is the CBPR approach described earlier that included a community partnership and NNHRRB endorsement before approaching individual participants. Several other projects exemplify a deep structural approach by redesigning interventions not simply to be appropriate for recruiting in a familiar setting but also for implementation by lay professionals who already have a relationship with the target group. The Black Barbershop Health Outreach Program illustrates that barbershops can be a viable site for health promotion among African American males (Releford, Frencher, & Yancey, 2010). Victor et al. (2009) conducted a trial in which they trained barbers not only to recruit participants but also to actually conduct the intervention—hypertension screens. The Black Barbershop Health Outreach Program is currently conducting and evaluating an intervention in a 50-city tour to recruit and conduct health screens to African American males in barbershops. In a test of this approach at beauty salons, Johnson, Ralston, and Jones (2010) evaluated a health intervention in two African American beauty salons. The cosmetologists not only recruited

participants but also conducted an intervention that increased their clients' fruit and vegetable intake.

Besides the Spanish MET study conducted within the CTN, Amaro, Arévalo, Gonzales, Szapocznik, and Iguchi (2006) reported that only two randomized clinical trials (Burge et al., 1992; Robles et al., 2004) had been conducted that specifically targeted adult Latino substance users. Both were plagued with low treatment entry and retention problems. The case study discussed in the following section is based on a clinical trial that evaluated the efficacy of a version of motivational enhancement therapy (MET) that is culturally adapted to be more appropriate for a Spanish-language population (Carroll et al., 2009). However, the focus of this article is on the modification of the recruitment and retention procedures in that study to be more appropriate for the target group.

Case Study 3: A Culturally Tailored Approach to Recruiting and Retaining Spanish-Speaking Participants

The CTN Spanish MET study is believed to be the first Spanish-language multisite substance abuse trial in the United States (Carroll et al., 2009). The team adapted the MET intervention focusing on surface level changes, such as conducting sessions in Spanish and providing materials in the native language. In addition, however, the team made deep structural changes throughout the trial to maintain high recruitment by utilizing strategies consistent with the cultural norms and sensitive to the cultural context at each of the five sites where the study was conducted. Because the purpose of the study was to examine the efficacy of MET, the various recruitment strategies utilized in the trial were not quantified across sites. However, some common recruitment and retention strategies were included across sites. These are described in the following text.

The adaptations began even before the implementation of the protocol. First, the research team carefully chose sites that served large populations of Latinos and sites with Spanish-speaking staff. To address the fact that at least 55% of the Latino adult population has only limited English proficiency (U.S. Census Bureau, 2003), recruitment materials (e.g., recruitment flyers, informed consent forms) were translated into Spanish. Bilingual staff at local sites reviewed these translated materials for appropriateness rather than ignoring variations in regional dialect. In addition, research assistants at each site were hired who demonstrated at least minimal Spanish fluency on a test developed for the study (Suarez-Morales et al., 2007). The recruitment materials referred potential participants to a bilingual research assistant who was responsible for explaining and answering any questions about the study.

During implementation, other strategies were added to ensure adequate study enrollment. Research assistants were prepared to read the consent forms and allocated additional time to read assessment materials to participants with limited literacy skills. The team scheduled research appointments at flexible times, including evening times for those who worked long hours in agriculture (Suarez-Morales et al., 2007). Because 85% of the study participants were immigrants, many of whom were in the country illegally (Carroll et al., 2009), some were concerned that their participation might jeopardize their (illegal) immigrant status or pending court cases (Suarez-Morales et al., 2007). Legal status information was obtained anecdotally by the research assistant; however, the research team was instructed not to ask direct questions about immigration status, given the understandable mistrust in this population of individuals in higher authority or positions of power. Instead, the research team trained research assistants to emphasize how confidentiality would be maintained in the study, to clarify the rights of participants to withdraw from the study, and to describe clearly the information that might be shared with the courts (i.e., verify court-mandated

attendance but not information gained from research assessments; Suarez-Morales et al., 2007).

The research team implemented other recruitment strategies to increase the visibility of the research in the Latino community. Study coordinators created partnerships with the court system to obtain referrals from parole officers. A representative responsible for community outreach distributed information about the research at Latino community events. Public service announcements were broadcast on Spanish radio or TV stations. Eventually, 538 individuals from five community treatment agencies agreed to be assessed for eligibility, and 405 met study criteria and were randomized into the study.

Some strategies used to enhance recruitment facilitated retention as well. For example, previous research also indicates that addressing language barriers lowers Latino dropout rates in research (O'Sullivan & Lasso, 1992; Sue, Fujino, Hu, Takeuchi, & Zane, 1991). Hence, the use of Spanish-language materials and research staff fluent in Spanish improved study retention. In addition, the study team implemented several other strategies specifically for enhancing retention. First, the research team reduced participant burden by limiting the length of the assessment battery, scheduling research assessments before or after counseling sessions, scheduling sessions outside of normal business hours, and meeting with participants in public places at the participant's request. The latter two strategies were especially helpful for participants who expressed concerns about attending sessions at the clinic because of local sentiments against illegal immigrants (Suarez-Morales et al., 2007). In addition, it was not uncommon for participants to visit their country of origin for extended periods. In those instances, research staff conducted follow-up assessment sessions by telephone. The retention rates for the study were quite good: 82% at termination and 92% and 82% at the 1- and 3-month follow-ups, respectively.

The issues that arise from adapting recruitment and retention procedures include some challenges similar to those of adapting evidence-based treatments for use in minority communities. These issues include determining the cultural factors that should be addressed and selecting the best strategies for adaptation without jeopardizing the fidelity of the original intervention (Castro, Barrera, & Steiker, 2010).

Methodological Concerns

Yancey et al. (2006) pointed out two concerns with the current knowledge base. First, much of the existing research is descriptive. In addition, Yancey et al. argued that the designs for evaluating ethnic minority recruitment and retention strategies should be, but are not, just as strong as the designs used to evaluate treatment outcomes. Our review identified several specific methodological shortcomings limiting the quality of the evidence. The first shortcoming is that the designs in many existing studies omit a basis for comparison. For example, Areal et al. (2003) described a promising protocol that increased ethnic minority recruitment rates by collaborating with community agencies. However, the evidence would be more convincing if the study had compared recruitment outcomes at sites using this approach with outcomes at similar sites using a standard approach. Future researchers may find it more feasible to conduct studies that compare the recruitment and retention rates to similar sites using traditional recruitment or retention methods than studies that compare individuals exposed to different methods. Moreover, studies that embed recruitment or retention questions in treatment outcome studies may be more practical than separate studies on recruitment and retention.

Our review suggested that the common use of multiple recruitment strategies in the same study is a second methodological shortcoming. This pattern is understandable for increasing recruitment as the general consensus is that studies with higher retention rates use multiple

strategies. For example, Okuyemi et al. (2007) combined several strategies to obtain good recruitment rates when enrolling participants into an intervention for light smokers. Similarly, Carroll and colleagues (2009) used several retention strategies simultaneously in their MET study. That approach, however, makes it difficult to evaluate which specific strategies are effective. Future research designs must disaggregate the strategies to identify which ones work. Again, treatment outcome studies flexible enough to permit research on recruitment questions (e.g., staggering the introduction of specific strategies into the recruitment procedures) and meta-analyses may be more feasible than separate studies on recruitment.

The tendency to combine ethnic groups for data analyses is a third methodological concern. Because different ethnic groups bring different concerns and experiences to the research experience, assuming without further research that effective strategies with one ethnic group are appropriate for other groups may be unjustified. Even the limited available evidence argues against combining ethnic groups for analyses. For example, the Spanish-language MET study demonstrated the advantage of addressing confidentiality differently when recruiting immigrant groups worried about deportation. They also found that translating the materials into the primary language of the target group improved retention (Carroll et al., 2009). These strategies may not be as important for other ethnic groups who are American citizens or English speakers. Our literature review identified only limited research comparing effective recruitment and retention strategies by ethnic group. The available research suggests that ethnic minority groups respond similarly to social marketing campaigns (i.e., mass mailing, mass telephone calls, and media [TV, radio, newspaper, magazines, newsletters, brochures, flyers, public service announcements, specialty publications to a target group]). However, African Americans respond better to community outreach but Hispanics respond better to referrals from friends, family, or other participants (UyBico, Pavel, & Gross, 2007). The literature on the retention of minority participants is less clear. Moreover, in addition to racial/ethnic subgroups (e.g., Mexican vs. Cuban), considering both age (Magruder, Ouyang, Miller, & Tilley, 2009; Szapocznik et al., 2007; Warden et al., 2009), gender (Jackson-Gilfort et al., 2001), and acculturation (Suarez-Morales et al., 2007) may be important for designing effective recruitment efforts. For example, previous research demonstrates that younger Blacks (Magruder et al., 2009; Szapocznik et al., 2007; Warden et al., 2009)—and especially younger Black males (Jackson-Gilfort et al., 2001)—may be especially hard to retain in research. Clearly, more research on effective strategies for specific ethnic groups and subgroups is needed.

Finally, some terms used to describe strategies are quite broad (i.e., outreach, cultural adaptation, community based). However, the actual strategies are themselves frequently quite specific. This practice may lead to conclusions about the effectiveness of a broad group of strategies on the basis of the evaluation of a very specific variation of that strategy. For example, we described several very different approaches to adapting the recruitment procedures to the culture of the target group. The modification of the recruitment materials did not increase recruitment (Kiernan et al., 2000; Satia et al., 2005). However, adapting the procedures by recruiting in settings where the target group naturally gathers, such as barbershops and beauty salons, was more successful (Johnson et al., 2010; Releford et al., 2010). It would obviously be incorrect to make a broad conclusion that cultural adaptation is or is not effective on the basis of those studies. Instead, it would be more appropriate to focus research on identifying which cultural adaptation strategies work and which do not.

Research Agenda for Improving Ethnic Minority Inclusion Into Clinical Trials

The underrepresentation of ethnic minorities in clinical trials coupled with research suggesting ethnic differences in treatment response both signal the need for more research aimed at identifying effective recruitment and retention strategies for ethnic minorities.

Fouad (2009) proposed a set of recommendations to address the participation of ethnic minorities in clinical trials. The recommendations include the following: (1) research funding to cover the increased costs of recruiting a diverse sample; (2) appropriate policies and regulations to ensure future studies have sufficient statistical power to permit sound inferences about the outcomes for ethnic minorities; (3) insurance coverage for participant costs in clinical trials; (4) strategies to increase representation of minority investigators; (5) support mechanisms for participants in clinical trials; and (6) public awareness campaigns regarding the benefits of participation in clinical trials. Despite the focus on recruitment, several of these strategies (e.g., increasing insurance coverage, increasing the number of minority investigators) can improve retention as well. Although these recommendations contribute substantially to developing a plan to recruit and retain ethnic minorities, inclusion in substance abuse clinical trials specifically raises some unique issues. Therefore, our research agenda differs from the Fouad (2009) recommendations in two ways. First, the focus is on substance abuse. Second, because the current research base is both limited in scope and variable in quality (Yancey et al., 2006), the focus is on research instead of the other broad issues (e.g., policy, public awareness campaigns) in the Fouad recommendations. Accordingly, we offer the following recommendations for a research agenda for substance use clinical trials.

(1) More Research Aimed at Identifying Effective Inclusion Strategies for Substance Abuse Research

As Fouad (2009) indicated, the available knowledge base has emphasized the identification of barriers. We agree with Fouad's recommendation that more emphasis be placed on identifying effective recruitment and retention strategies rather than describing the barriers. Future researchers should emphasize the development and testing of empirically supported recruitment and retention strategies to overcome the barriers. As stated earlier, embedding the research in other clinical trials may be more efficient than separate studies evaluating recruitment and retention strategies.

(2) Improve the Quality of the Research

The quality of the research evaluating recruitment and retention strategies should be just as strong as studies of other research topics. Several methodological shortcomings in the current research have been described. These include the absence of comparisons in the research designs in too much of the current research, the simultaneous inclusion of multiple strategies inhibiting conclusions about the effectiveness of specific strategies, and a tendency to combine ethnic groups for analyses. We encourage researchers to strengthen future research by addressing these design issues.

(3) Further Evaluation of the Three Strategies Used in CTN Studies

Three promising strategies used in the CTN were described earlier. The strategies include RDS, a CBPR approach, and the cultural adaptation of the recruitment and retention procedures. Research on the efficacy of these strategies for increasing ethnic minority inclusion is very limited. Although the evaluation of these strategies was not the focus of the CTN studies, the promise of these strategies in the CTN clinical trials argues for more research designed to evaluate these specific strategies and to identify any modifications that would maximize the effectiveness of the strategy.

(4) Research on Other Strategies

The available evidence suggests that several other strategies not included in the CTN case studies are worthy of further examination. These strategies include community outreach (Okuyemi et al., 2007), matching the recruiter and the potential participant on ethnicity

(Moorman, Newman, Millikan, Tse, & Sandler, 1999), using recruiters experienced in working with the target population (Larkey et al., 2002), training recruiters to work more effectively with the target group (Paskett, DeGraffinreid, Tatum, & Margitic, 1996), the media (Okuyemi et al., 2007; Paskett et al., 1996), and the Internet (Im & Chee, 2005; Wingood et al., 2011). In addition, some novel strategies deserve more attention including the use of lay professionals to recruit and even implement interventions in highly frequented settings such as barbershops (Releford et al., 2010), beauty salons (Johnson et al., 2010) and churches (Corbie-Smith et al., 2010). Finally, incentives have proven useful for retaining participants in substance abuse clinical trials (Brigham, Winhusen, Lewis, & Kropp, 2009). However, questions remain about the effectiveness of incentives for recruiting and retaining ethnic minority participants and about the effectiveness of various incentive schedules (e.g., graduated) for substance abuse clinical trials. The stigma associated with substance use may require some of these strategies to be modified to be effective in substance abuse clinical trials. Therefore, more research is required on potential adaptations of these strategies for increasing ethnic minority inclusion in substance abuse clinical trials.

(5) Identifying Effective Recruitment and Retention Strategies for Specific Ethnic Groups

Although multiple ethnic groups are underrepresented in clinical research, ethnic differences in the barriers (e.g., language, concerns about immigration status) suggest that the effectiveness of specific strategies may vary across ethnic groups (UyBico et al., 2007). Moreover, whenever feasible, future studies of recruitment and retention strategies should be designed to examine within-group differences such as age (Magruder et al., 2009), gender (Jackson-Gilfort et al., 2001) and acculturation (Suarez-Morales et al., 2007).

Summary

The underrepresentation of ethnic minorities in clinical trials is a barrier to reducing health disparities in substance abuse. The limited knowledge base is clearly insufficient for providing guidance to researchers on promoting inclusion. This article describes lessons learned from the CTN to improve recruitment and retention. The first lesson is that researchers conducting clinical trials in sites with low numbers of ethnic minorities, researchers conducting medication trials, and researchers implementing clinical trials with stringent inclusion criteria all may need to consider adding strategies to include ethnic minorities. The second lesson is that community involvement (e.g., community outreach, RDS, CBPR), and the cultural adaptation of the recruitment and retention procedures all appear promising for improving recruitment and retention of ethnic minorities. The third lesson is the need for additional research on recruitment and retention with stronger designs. Finally, on the basis of the CTN experience and the available literature, we proposed an agenda for future research.

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