A New Model for Developing and Executing Culturally Appropriate Behavior Modification Clinical Trials for African Americans

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Past clinical trials addressing behavior modification for cardiovascular disease (CVD) prevention have not been culturally appropriate for African Americans. This supposition is borne out by the continued challenges researchers face not only in recruiting and retaining African Americans in clinical trials, but also in achieving the desired outcomes among this population. Investigators have limited resources to develop culturally appropriate CVD prevention trials. The scientific literature reveals 2 models for implementing culturally appropriate interventions applicable to CVD prevention among African Americans; however, these models are not easily applied to the clinical trial setting. We propose a new model for developing a culturally appropriate clinical trial. The clinical trial is a function of the investigator's cultural framework, meaning that an investigator will have more difficulty designing clinical trials appropriate for use with cultures other than his or her own, a definite limitation when attempting to effectively reach diverse populations. Differences between the cultural frameworks of most clinical trials and African Americans' cultural frameworks lead to intrinsic biases, limiting the ability of African Americans to achieve the desired outcomes for any particular trial. An African-American participant's degree of immersion in traditional African-American culture, or acculturation, influences the magnitude of these biases. Investigators must be aware of, and attempt to mitigate, such biases so that the trial's potential for success is equitable across ethnic groups. In addition, investigators must understand how to effectively address relevant biases of African Americans without challenging their ethnic identity. Steps to decrease biases are described. (*Ethn Dis*. 2002;13:279–285)

Key Words: Behavior Modification, African American, Clinical Trials, Culturally Appropriate

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Introduction

Modifying behavior is an important first step in the management of many cardiovascular disease (CVD) risk factors.[1,2] Numerous studies have demonstrated that risk factors for cardiovascular morbidity and mortality, such as obesity, diabetes mellitus, and hypertension, can be successfully reduced with the appropriate behavioral interventions.[3–5] However, in many of these studies, African Americans are consistently less successful at achieving the desired outcomes.[6,7] For example, a review of weight-loss trials sponsored by the National Heart, Lung, and Blood Institute (NHLBI) showed differential outcomes based on race.[6] Mean weight loss averaged 2.2 kg less in African-American women compared to European-American women after 18 months of follow up in the Trials of Hypertension Prevention, and 2.7 kg less after 36 months of follow up in the Hypertension Prevention Trial. In both studies, the differences seen in weight loss for African-American men compared to European-American men were similar to those seen in women.

To eliminate or prevent these differences between ethnic groups, it is imperative to understand the reason(s) for the imbalanced outcomes. A potential reason for the lack of optimal success may be a decreased biologic response to various behavioral interventions. However, feeding studies such as the Dietary Approaches to Stop Hypertension (DASH) suggest that an equal, or even greater, effect on blood pressure can be achieved when comparing African Americans and European Americans who consume the same dietary pattern.[8] Data from other behavior interventions, such as exercise trials examining changes in insulin sensitivity, suggest that changes in insulin sensitivity are similar for European and African Americans for a given amount of exercise.[9,10] In clinical trials where the adoption of the desired behavior is well controlled, as in feeding studies, there appears to be no differential effect of the intervention based on ethnicity. Therefore, there is little evidence to support the notion that African Americans do not achieve optimal outcomes because of a decreased biologic response to the behavior intervention.

Another potential explanation for the lack of success in achieving the desired behavioral outcomes may be psycho-social factors that influence both adherence to an intervention, and the maintenance of healthy behaviors by African Americans in the clinical trial setting. Evidence suggests that culture can be a substantial influence on most aspects of daily behavior. Culture is defined as a highly specific pool of information, categories, rules for categorization, inter-subjective meanings, collective representations, and ways of knowing, understanding, and interpreting stimuli, as a result of a common history.[11,12] For African Americans, the influence of culture on health behaviors and attitudes goes far beyond food preferences to include historical perspectives on participation in clinical trials, attitudes about clinical trials, and beliefs about what a healthy lifestyle entails.[11] Historically, African Americans' prior experiences with clinical trials have not been positive, and knowledge of these events can negatively affect current willingness to participate.[13,14] For many African Americans, cultural attitudes to-

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ward clinical research include the belief that research is purely experimental, with no perceived benefit for themselves or their community.[13] As an example of how cultural perceptions influence ideas of what is healthy, cultural beliefs about body image for many African-American women include a preference for a body image larger than that preferred by European-American women.[15] This preference may cause African-American women to desire a larger body habitus, and to be less likely to comply with recommendations for weight loss that they may perceive to be excessive. With such a large domain of potential influences, culture can directly affect the number of African-American participants recruited, their degree of adherence to study protocols, and their acceptance of a lifestyle intervention.

Because of the influence of culture on African Americans' perceptions of health and clinical trials, clinical investigators should consider giving special attention to the cultural appropriateness of the clinical trial. Cultural appropriateness is defined as the concept of being congruent with the cultural framework of the target population, presenting no significant disagreement with the cultural value system. Application of this concept may reduce or eliminate potential cultural barriers to achieving the desired outcome. In this context, "culturally appropriate" is synonymous with "culturally sensitive." Many recommendations for implementing culturally appropriate interventions have addressed specifically the delivery of public health programs.[11,16–18] However, as previously mentioned, many African Americans perceive clinical studies promoting behavior change differently than public health programs, which traditionally have no recognizable experimental groups or perceived risk to the participants. A systematic approach to designing culturally appropriate clinical trials for African Americans would decrease cultural barriers, thus allowing for equivalent outcomes for all groups. The following is a review of the literature and a proposed model for systematically improving the cultural appropriateness of clinical trials with behavioral interventions.

REVIEW OF CURRENT LITERATURE

There are few guidelines available to help investigators develop culturally appropriate behavior modification trials targeting African Americans. Most efforts for attempting to make a clinical trial culturally appropriate only deal with improving recruitment and/or retention. An increasing body of literature is devoted to culturally sensitive strategies for recruiting and retaining African-American participants in clinical trials.[19–22] However, improvements in recruitment, while important, do not necessarily translate into adherence to study protocol, or to recommended behaviors.[6] The challenges involved in recruiting African-American participants are very different from the issues surrounding the retention of the same participants.[23] Pressures to increase the enrollment of African-American participants can lead to the recruitment of participants who are unlikely to adhere to the study protocol, or to return for study measurements. In addition, certain aspects of the study may be a deterrent to continued participation, even for potentially adherent participants. Retention and adherence should be thought of as a product of the cultural appropriateness of all aspects of the research project. Difficulties with the recruitment, retention, and adherence of African Americans are probably symptoms of the larger, systemic problem of a lack of cultural sensitivity.

A broader approach to improving cultural sensitivity in clinical trials has been undertaken by others, primarily in the fields of psychiatry/psychology and nursing. Several models and recommendations derive from these disciplines.[17,24–29] Rogler proposes pretesting specified data collection instruments to improve the cultural sensitivity of mental health research. The pretesting includes using back-translation methods, and providing bilingual participants with language options for responding.[25] Chavez and Oetting recommend that researchers confront their own prejudices, consciously fighting to oppose the societal inclination to categorize other groups as "different." They also recommend that researchers consider the limitations of their instruments and data sets to avoid "over-generalizing."[27] Campinha-Bacote and Padgett put forth a model of culturally competent nursing research that includes cultural awareness, cultural knowledge, cultural skill, and cultural encounters, designed to train nursing researchers to view cultural competence as an ongoing process, rather than an end-point.[24] While these models and recommendations are helpful, they do not adequately address or apply to some of the specific clinical factors that must be taken into account when conducting a trial aimed at risk reduction, behavior modification, or prevention of CVD. For example, many of the outcome measures used in cardiovascular research require more burdensome or invasive procedures than those used in psychiatric research, with some even having potentially serious implications (eg, repeated blood draws, 24-hour blood pressure monitoring, cardiac catheterization). For certain ethnic groups, this may negatively affect willingness to enroll or to provide study measurements. Other issues with possi-

ble cultural implications not considered in these models include the appropriateness of materials used for education, mode of delivery of the education, and type of motivation provided for health behavior change.

The aforementioned models are general guidelines that attempt to apply across ethnic groups. Global guidelines for cultural appropriateness are a worthwhile starting point; however, the research community needs to focus separately on individual ethnic groups in order to address the varying and explicit culture of each group. The cultural context for studying African Americans and their health is very unique, and includes historical, societal, and environmental influences.[11] Because of these unique experiences, some techniques for improving cultural appropriateness among other groups would not apply to African Americans. For example, a general consideration in improving the cultural sensitivity of a research study is language.[25,30,31] While English is the first language for most African Americans, other ethnic minorities, such as immigrant Mexican Americans, may speak very little English. Therefore, back-translation may not be considered an issue for researchers with a solely African-American sample. This does not imply, however, that issues of communication have no relevance for African Americans.

The measurement of acculturation is another cultural sensitivity technique that does not apply in its traditional form to African-American populations. Acculturation refers to the adoption of values, beliefs, language, customs, and mannerisms of the larger society—usually by members of a minority ethnic group. The level of acculturation directly influences a person's cultural perspective, such that highly acculturated individuals should have cultural perspectives similar to those of members of the dominant culture.[32] Therefore, when attempting to design an intervention culturally appropriate for an ethnic minority, it is necessary to understand the level of acculturation of the target sample; however, acculturation must be measured differently for African Americans compared with other ethnic groups.[32] Acculturation in African Americans is not a function of an individual's level of educational attainment, or ability to speak English, as it is for foreign immigrants; rather, African-American acculturation is related to the individual's degree of immersion in mainstream American culture vs traditional African-American culture.[32]

Perhaps the primary consideration when delineating culture-specific guidelines for African Americans should be the effect of history on this population's current health status and beliefs. Historical events involving research and the medical establishment in the United States, such as the Tuskegee syphilis experiments, are unique to African Americans.[33] Focus group and survey data have demonstrated that these events are considered when African Americans make decisions about participation in clinical research, or when seeking health care.[13,14,34] Investigators must not only be aware of these events, but also understand their effects on the thought processes of African Americans, particularly as these effects relate to current health status and beliefs.[35]

Two models exist for designing culturally appropriate interventions that are applicable both for African-American populations, and to CVD prevention. Kumanyika and colleagues describe cultural components that are potential factors in dietary and weight change for African-American women.[16] The underlying premise in this model is that cultural factors influence the behavior change process, and if an individual is in harmony with his or her cultural context, then behavior changes will only be adopted if they do not cause any sustained cultural discomfort. Some cultural factors that might influence behaviors related to diet and weight loss include support networks, attitudes toward obesity and exercise, and expectations of the individual's relationship with a counselor or weight loss group.

Resnicow describes a model for understanding cultural sensitivity from a public health perspective, for use with disease prevention interventions.[11] In this model there are 2 dimensions of cultural sensitivity, termed "surface structure" and "deep structure." Surface structure deals with the topical characteristics of a target population and affects the acceptance of the intervention by the target population. For African Americans, surface structure would refer to items such as "soul food" and body image preferences. A weight loss program incorporating healthy soul food items into the intervention would address a surface structure issue for African Americans, thereby making the program more acceptable. Deep structure can be viewed as the rationale for surface structure, as it deals with the cultural values that serve as the foundation for superficial characteristics or preferences. Deep structure includes the ways in which ethnic populations differ with respect to cultural values, and how these cultural values potentially influence health behaviors. While the degree to which a program appeals to a given population is a function of the surface structure, the actual impact or efficacy of the program is a function of the deep structure. As in the above example, the use of low-fat soul food recipes may be attractive to African Americans participating in a weight loss intervention; however, if other facets of the intervention contradict cultural values that affect health (eg, family support, or the role of religion in health), then the intervention is less likely to be effective. To determine these elements, Resnicow proposes using exploratory focus groups and pre-testing the materials and messages with the target audience.

There are 2 potential limitations to using these models for designing cultur-

ally appropriate lifestyle modification clinical trials. First, these models were designed for public health programs, and consequently are less suitable for the clinical trial setting. Although both public health programs and CVD prevention trials utilize similar types of interventions, it would be difficult for investigators to apply these models to other areas of the clinical trial. For instance, in a clinical trial it is necessary to include consideration of recruitment strategies for African-American participants, issues of data collection, informed consent, data reporting, and staff composition. Since most of the recommendations presented in the models are related primarily to the intervention, additional constructs need to be developed to guide investigators in non-intervention areas.

Second, the prescribed use and scope of the exploratory focus groups may not provide the most useful information regarding the target group's culture. The recommended scope of questioning assumes that the participant has some valuable experience with the disease process, or with areas of the intervention. This assumption may be incorrect. Using exploratory focus groups, many investigators have sought advice from participants about potential behavior change interventions, even when the participant has no prior documented experience with successful behavior change.[36–38] Based on our own experiences with a community advisory board, even insightful suggestions regarding behavioral interventions can have limited applicability within the confines of a scientific protocol. Also, limiting focus group questions to perceived acceptance of the intervention design or delivery provides little opportunity to consider the potential effects that permanently adopting a behavior change will have on the daily lives of the participant. Simply seeking feedback from participants on interventions or health messages fails to take advantage of their real expertise as owners of their culture.

PROPOSAL OF A NEW MODEL

A new model for a culturally appropriate lifestyle modification clinical trial incorporates both viable aspects of the 2 prior models and new constructs. When an investigator designs a clinical trial, one of the goals is for participants of diverse backgrounds to have an equal opportunity to achieve the desired outcome as a result of adopting the recommended behavior(s), leading to a high level of internal validity. Another goal is to have high external validity, which can be achieved by recruiting and retaining a diverse, representative sample, thus improving the generalizability of study results. However, because the clinical trial is traditionally a function of the investigator's cultural framework, an investigator will have more difficulty designing clinical trials appropriate for use with cultures other than his or her own, a definite limitation when attempting to effectively reach diverse populations, more specifically, in this case, African Americans. In most instances, there is an inherent difference between the cultural framework of the investigator (and, consequently, the clinical trial) and the African-American participant. The biases of the clinical trial influence the action and reaction of individuals within the study setting, particularly affecting the ability of African Americans to participate and achieve the desired outcome in the clinical trial.

The differences between the cultural frameworks of the clinical trial and those of African Americans form the basis for biases. In this model, bias is defined as a set of beliefs and preconceived ideas derived from perceived differences between cultures, or from an ethnocentric viewpoint. Bias refers to an inherent property of the differences between cultures, not a premeditated act of racism. Based on these definitions, the presence of bias can only limit successful outcomes for those who are not a part of the dominant culture, and the absence of bias indicates that there are no major cultural barriers to achieving a successful outcome. As defined by this model, each individual holds biases, including the investigator and the potential participant.

A key modulator of bias for African Americans is acculturation. African Americans' level of immersion in the traditional culture, or their lack of acculturation into mainstream culture, influences the magnitude of bias, such that those who are less immersed in traditional African-American culture would be assumed to have less bias. It is further supposed that highly acculturated African Americans will have a cultural framework more similar to that of mainstream culture, when compared with traditional African Americans, thus causing less incongruence between the frameworks of highly acculturated African Americans and the clinical trial. The assertion that, in the areas of health beliefs and practices, the cultural frameworks of highly acculturated African Americans are more similar to those of the majority culture than to those of traditional African Americans, is supported by an increasing body of literature. Several studies have been published on acculturation and its relationship to health behaviors for African Americans, including tobacco use and cigarette smoking, food-related attitudes and eating disorders, knowledge of AIDS transmission, and depression.[39–43] Abrams et al[42] provided evidence that, among college-aged African-American women, the prevalence of anorexia and bulimia is related to degree of acculturation, such that African-American women exhibiting these disordered eating behaviors were more likely to be highly acculturated. In a study of cigarette use among African Americans, 70% of smokers were noted to be highly traditional in their cultural orientation, whereas non-smokers were more acculturated. More than 25% of a sample of 520 African Americans held beliefs about a government HIV/AIDS conspiracy targeted to the Black com-

munity. African Americans holding this belief tended to be more traditional and less acculturated. Understanding the target population's level of acculturation should allow investigators to estimate the magnitude of bias that the cultural framework of the clinical trial may cause for African-American participants. Understanding acculturation leads to an appreciation of cultural heterogeneity or within-group cultural variations of African Americans, thereby limiting the potential for stereotyping.

Investigators must work to decrease the biases of behavior modification clinical trials so that potential achievement of the desired outcome is equitable for all groups. These biases are addressed by understanding that significant differences exist between African Americans and European Americans, even though African Americans are a part of the American society and popular culture. Investigators must seek to understand these differences, appreciating the fact that African Americans seek to maintain a unique identity and to avoid cultural discomfort.[16] For example, attempting to motivate African-American participants in a weight loss intervention by using the promise of a "slimmer" body size may not be the most appropriate incentive because of cultural differences in body image perception.[15,44] However, incentives that focus on health benefits, such as increased mobility and a reduced cardiovascular risk, have been shown to be helpful in producing weight loss without any significant changes in body image perception.[45]

Understanding and appreciating cultural differences must be accomplished while addressing the relevant biases of African Americans. Addressing the biases of African Americans, while not challenging their cultural framework, may allow the adoption and propagation of important health behaviors. For example, some African Americans view certain health-related behaviors as being relevant only to European Americans. Instead, African Americans should be persuaded that no ethnic group has ownership of, or the exclusive right to, any healthy behavior. If, for example, an African American woman swims for exercise, it does not make her less African-American. However, researchers must recognize the potential cultural barriers caused by a recommendation for behavior change, such as suggesting swimming as an exercise for African-American women. In this particular case, it would be necessary to consider the fact that, various hairstyles and hair care techniques are relatively unique to African Americans and are considered a part of being African-American. For African-American and European-American women, the length of time and effort involved in hair care and styling is generally very different. The increased length of time and effort required to restore one's hair to its previous form after swimming may be a major deterrent to African-American women's adoption of this behavior. Because differences in hair care and styling are a source of bias, recognition of these differences, and suggesting strategies helpful in maintaining one's ethnicity while adopting this new behavior, may improve the likelihood of this behavior change being permanently integrated into the lifestyle.

Addressing the biases of African Americans, while not challenging their cultural framework, may allow the adoption and propagation of important health behaviors.

These biases can be detected through the use of focus group methodologies. Focus group methodology allows for the exploration of topics that are potentially sensitive and complex. Using focus groups also allows for direct examination of the pertinent issues.[46] However, rather than focusing on details of the intervention, questions should relate to issues of culture. Limiting questions to focus on the intervention does not help to uncover the deep structures mentioned by Resnicow,[11] and can lead to the potential limitations previously mentioned. The focus group discussion should be an opportunity for the investigator to learn about potential cultural differences without the limitations of a questionnaire. Using this method of questioning also allows the investigator to understand some of the unique, cultural biases held by African Americans, thereby elucidating avenues for potential interventions directed at decreasing these biases.

To understand the larger context in which statements of cultural beliefs are made, it is necessary to assess the composition of the focus group. The assessment should include standard demographic measures such as gender, education, income, and age. The assessment should also include a measure of the group's acculturation level. Income and education are related to health behaviors for African Americans[47,48]; however, acculturation has been shown to account for a larger percentage of the variance than income and education combined.[49] Because acculturation is a modifier of the cultural framework, as previously described, it is important to consider its role in the results of the focus group discussion.

Once the information is gleaned, the cultural variables that emerge should be mapped to possible areas of interaction with the clinical trial process. Every process within the clinical trial must be considered. Each step should be examined to determine whether it could be a potential source of bias, which could lead to decreased success for African-American participants. Alternative procedures or protocols that decrease biases should be proposed. Subsequently, a pilot group of African-American participants that is representative of the target population should evaluate the clinical

trial process in an objective manner. Participants can be presented with several variations of materials, activities, or recommendations, which vary by level of cultural appropriateness. Acceptability and feasibility are the outcomes of interest. This includes willingness to enroll, completing screening procedures, understanding the informed consent process, adopting study recommendations for behavior change, regular attendance, and adhering to study protocol. Frank discussions about the potential implications for African-American participants are necessary to fully appreciate the evaluations.

POTENTIAL LIMITATIONS

The proposed new model may seem to assume that non-African-American investigators have little experience or insight into the culture of African Americans, thereby creating more bias than if the investigators were African-American. This is obviously not true in all instances. Many non-African-American investigators will have significant experiences and knowledge regarding African-American culture. Many may even appreciate some of the perceived cultural differences, working *a priori* in the design of the clinical trial to reduce potential bias. However, it should be noted that this indirect knowledge will not be an adequate substitute for the daily permanent experiences of the collective African-American population. Therefore, even for the most enlightened non-African-American investigator, foregoing important information-gathering steps on African-American culture will yield less than satisfactory outcomes.

This model may also appear to assume that African-American investigators could potentially forego this process, since the cultural frameworks for the investigators and target population are similar, thereby eliminating the bias. Although African-American investigators can claim the daily permanent experience of African-American culture, potential for bias still exists. Given the diversity within the African-American culture, and the fact that each person has his/her own level of bias, African-American investigators may vary from the African-American target population with respect to level of acculturation, generating biases similar to those that other investigators may bring to clinical trials. As the constructor of a clinical trial, the African-American investigator has already overcome one potential cultural bias—trust in medical research. Another source of potential bias is the likelihood that the investigator practices many of the health-related behaviors that he or she is asking others to adopt, especially in the setting of CVD prevention. Therefore, having more African-American clinical investigators, while being part of the solution, is not the only key to improving the cultural appropriateness of clinical trials.

CONCLUSION

In an effort to improve the outcomes of African Americans in behavior modification clinical trials, we have proposed a new model to assist investigators in applying the concept of cultural appropriateness to this type of study. The basis of this model is the influence of bias, generated by differences in cultural frameworks between investigators and the study population, on the achievement of behavior change, and on successful outcomes of clinical trials. Investigators must understand potential biases and address them, without challenging the cultural framework of African Americans. Using focus group methodologies can be helpful in determining potential biases, and in discovering avenues to implement strategies to eliminate these biases. However, it is important that the structure of the focus group be flexible enough to capture African Americans' views of their culture, without making assumptions about their knowledge or perceptions of behavior- related interventions. This process might be helpful in improving the recruitment, retention, and adherence of African Americans in behavior modification trials, leading to higher levels of internal and external validity. Validation of this construct is required, and the initial steps toward this are underway. Ultimately, understanding the effectiveness of such a model will require randomized clinical trials comparing standard and culturally appropriate lifestyle modification methodologies for clinical trials.

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Design and concept of study: Ard, Carter-Edwards, Svetkey
Acquisition of data: Ard
Data analysis and interpretation: Carter-Edwards
Manuscript draft: Ard, Carter-Edwards, Svetkey
Acquisition of funding: Svetkey
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