

COLLABORATIVE PLANNING FOR FORMATIVE ASSESSMENT AND CULTURAL APPROPRIATENESS IN THE GIRLS HEALTH ENRICHMENT MULTI-SITE STUDIES (GEMS): A RETROSPECTION

Objective: The Girls health Enrichment Multi-site Studies (GEMS), Phase 1, developed and pilot-tested interventions to prevent obesity in African-American preadolescent girls. This article describes the collaborative planning process undertaken to take full advantage of formative assessment activities for improving contextual relevance and cultural appropriateness.

Design: Working group activities were designed to stimulate awareness and reflection among group members and, through them, among other field center investigators and staff about developmental, cultural, and contextual issues for formative assessment.

Setting: Telephone, Internet, and face-to-face interactions across GEMS field centers in Houston, Texas; Memphis, Tennessee; Minneapolis, Minnesota; and Palo Alto, California.

Participants: Investigators and staff involved in intervention development.

Main Outcome Measures: The utility of the process was judged from feedback by participants and field center principal investigators about the contribution of the collaborative effort to improving the perceived relevance and cultural appropriateness of formative assessment data collection and interpretation.

Results: A working bibliography was compiled. A detailed matrix of programmatic, child, family, and contextual issues related to ethnicity, socioeconomic status, general health and lifestyle, food, physical activity, and body image/weight control was completed. Additional guidance was derived from a workshop that involved scholars with expertise in aspects of African-American culture, child development, and family processes.

Conclusions: This process improved the breadth and depth of GEMS formative assessment activities by increasing the appreciation of the complex structural, contextual, and personal forces at play. A similar process may be useful to other investigators when attempting to develop culturally appropriate interventions. (*Ethn Dis.* 2003;13[suppl1]:S1-15-S1-29)

Key Words: Cross-cultural, African American, Obesity, Prevention, Program Planning, Nutrition, Physical Activity

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INTRODUCTION

The National Heart, Lung, and Blood Institute (NHLBI) sponsored the Girls health Enrichment Multi-site Studies (GEMS) to develop and test interventions to prevent obesity in African-American preadolescent girls,¹ building upon insights gained through the NHLBI Growth and Health Study.²⁻⁵ As described elsewhere in this special issue,⁶ the original impetus for GEMS was an interest in addressing health disparities affecting minority populations with a focus on the high susceptibility of African-American girls and women to obesity. The need for a focus on this problem has been underscored by the recent, population-wide

trends of increasing obesity in US adults and children.⁷

The rise in obesity in African-American girls has been particularly steep, with trends crossing over to yield a prevalence rate that now exceeds the rate in non-Hispanic White girls.⁸ Childhood and adolescent obesity confers increased risk of developing diabetes, cardiovascular disease and other health problems during the maturational years. The upward trend in obesity in African-American girls exacerbates the longstanding problem of excess obesity in African-American women,⁹ by setting the stage for an even higher prevalence of obesity and related comorbidities among African-American women in the future.^{10,11} GEMS was developed because of the urgency of addressing the problem, the general lack of evidence about how to effectively prevent childhood or adolescent obesity, and the particular lack of models for obesity prevention in African-American females.⁶

GEMS Phase 1 included extensive formative assessment activities to determine the best approaches to obesity prevention interventions with African-American girls prior to full scale trials in Phase 2. Formative assessment, which may involve a variety of qualitative and quantitative data collection techniques,^{12,13} is conducted before an intervention program is developed to obtain detailed information about the people for whom and the context within which the intervention will be designed. Such formative assessment is a crucial element when developing health interventions and choosing evaluation components,

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particularly when designing interventions for specific or diverse cultural groups or when there is a limited knowledge base regarding effective intervention models. In keeping with the intent of the RFA,¹ GEMS formative assessment activities focused primarily on intervention content and delivery issues but also explored the acceptability of various strategies for recruitment, retention, and data collection. This article describes the collaborative process among the 4 GEMS field centers of planning formative assessments related to intervention development and, more specifically, to the environmental, familial, and cultural contexts for interventions on eating and physical activity behaviors in African-American pre-adolescent girls. The collaboration on formative assessment addressed the common challenges (ie, the complexity of programming for obesity prevention in maturing girls and in the African-American community) and attempted to create a synergistic, multi-site process that would enrich the ability of the field centers to address cultural and contextual issues in obesity prevention in African-American girls.

Field center-specific formative assessment activities and results are discussed elsewhere,¹⁴⁻¹⁷ and will be forthcoming (N. Sherwood, personal communication; V. J. Thomson, personal communication). Here we present a retrospective examination of the formative assessment planning process itself.

This type of retrospection, although not commonly included in the methodological reports from intervention studies, helps to articulate some of the specific content areas relevant to nutrition and physical activity interventions in African-American girls. It also begins to highlight some of the sensitive and often ignored aspects of cross-cultural and culture-specific programming that may affect the researchers and health professionals who are involved in such activities, eg, the management of emotional investment, trust and insecurity,

professional cultural barriers, and the particular need for researchers who work with minority populations but who are not members of the ethnic group in question to learn to be comfortable in the uncomfortable situations that often arise in cross-cultural interactions.

BACKGROUND

The GEMS field centers were located in Houston, Texas, Memphis, Tennessee, Minneapolis, Minnesota, and Palo Alto, California. Unlike most multi-center trials, in which the goal is for all field centers to agree to implement the same intervention, the goal in GEMS was to explore several different approaches by supporting each field center in the development and testing of a distinct intervention. Thus, different interventions were to be tested in different types of African-American communities. Table 1 summarizes the field center specific study populations and proposed intervention approaches and objectives. Three of the 4 centers focused on girls in low income communities entirely or in part and one, which required the payment of summer camp fees and access to the Internet from a home computer, targeted girls from middle-income families. By design, the study population at all centers was to be pre-adolescent (peri-pubertal), 8- to 10-year-old, African-American girls.

Formative assessment approaches used by the different field centers are shown in Table 2. Most field centers used a combination of qualitative and quantitative techniques, specifically, focus groups and questionnaires with variations based on investigator preference as well as differences in the type of intervention proposed. Some centers had previously performed substantial formative research related to their interventions and were using the formative assessment to shape and refine previously

tested approaches, while others were developing completely new interventions.

METHODS

Working Group Membership, Objectives, and Timeline

A Formative Assessment Committee was convened under the auspices of the GEMS Multi-site Steering Committee with a voting member from each field center, the coordinating center, and the NHLBI. An African-American woman investigator with specific expertise in the relevant cultural appropriateness issues (SKK) was appointed as committee chair and named as a non-voting member of the Steering Committee to provide a direct reporting line to that group. By virtue of having been selected for funding, all GEMS field centers were expected to have considerable experience in conducting studies in children and with African Americans. The RFA encouraged participation by African-American female investigators, and there was an implicit expectation that African-American female investigators or staff would be directly involved in collection of the formative assessment data at each field center. However, the membership of the Formative Assessment Committee as such was left to the discretion of the principal investigators and the interest of field center team members in participation. In addition, participation in formative assessment planning of all field center investigators with relevant interests and expertise was encouraged, and some field centers had 2 or 3 members on the committee. The 8 regular field-center participants (the authors of this article) were all women investigators or staff and included 4 African Americans.

The committee's main objectives were to facilitate identification of the primary influences on the eating and physical activity practices of African-American girls and of the most effective methods to intervene to promote

Table 1. Girls health Enrichment Multi-site Studies (GEMS) Phase 1 field centers and intervention approaches

Principal Investigator and Institutional Affiliation	Study Population and Eligibility Criteria	Type of Active Intervention Proposed	Behavioral Objectives
Tom Baranowski, PhD Children’s Nutrition Research Center Baylor College of Medicine	8-year-old African-American girls residing in Houston, Texas. Eligible girls had a BMI above the 50th percentile of the CDC 2000 growth standard. Access to the internet was required. Socioeconomic status level: middle	4-week summer camp program for the girls followed by internet-based program for the girls and their parents	<ul style="list-style-type: none"> ● To increase consumption of fruit, 100% juice, and vegetables and thereby decrease the girl’s dietary energy density ● To increase water consumption to 5 or more glasses (12 oz) per day and decrease the girl’s soft drink and sweetened fruit flavored beverage consumption ● To increase physical activity to 60 minutes of moderate-to-vigorous physical activity per day
Robert C. Klesges, PhD Center for Community Health, University of Memphis	8- to 10-year-old African-American girls residing in Memphis, Tennessee with BMI above the 25th percentile of the growth standard. Willingness of a parent or caregiver to enroll was required. Socioeconomic status level: diverse	After school weekly group programs held in community centers—one version of the program involved girls directly, and the other worked directly with parents	<ul style="list-style-type: none"> ● To increase the frequency of moderate to vigorous physical activity ● To decrease the frequency of sedentary behaviors ● To promote enjoyment and self-efficacy in physical activity ● To increase consumption of water and decrease consumption of sweetened beverages ● To increase consumption of fruits and vegetables ● To promote nutrition-related healthy behaviors such as the recognition of natural satiety levels, portion control and the selection of healthy snacks
Mary Story, PhD Division of Epidemiology, University of Minnesota School of Public Health	8- to 10-year-old African-American girls residing in Minneapolis and St. Paul, Minnesota with BMI at or above the 25th percentile of the CDC 2000 growth standard. Socioeconomic status level: low	After school program 2 days per week, held in schools, and a parent involvement component	<ul style="list-style-type: none"> ● To increase the frequency of participation in sustained, moderate-to-vigorous intensity activities ● To decrease time spent engaging in sedentary activity ● To promote enjoyment, physical competence, and self-confidence in a range of physical activities and thereby increase interest and motivation for continued involvement in physical activity ● To decrease consumption of high fat foods ● To increase consumption of fruits and vegetables ● To decrease consumption of sweetened beverages ● To promote the adoption of healthy weight-related eating practices (eg, reduce irregular eating times and meal-skipping, situational eating such as eating while watching TV, consuming large food portions, and snacking when not hungry)
Thomas N. Robinson, MD Center for Research in Disease Prevention, Stanford University School of Medicine	8- to 10-year-old African-American girls living in East Palo Alto and Oakland, California areas with BMI >50th percentile of the CDC 2000 growth standard or at least one parent or guardian with a BMI ≥25 kg/m ² . Socioeconomic status level: low	Dance classes offered after school in local community centers and a home-based TV reduction program with parents and children	<ul style="list-style-type: none"> ● To engage girls in culturally-relevant dance classes as a way of increasing physical activity ● To reduce television, videotape, and video game use at home

healthy weight gain in this population. Although the autonomy of field centers implementing their respective formative assessment plans was to be preserved,

the Formative Assessment Committee was charged with recommending core issues for inclusion in formative assessments at all field centers and with de-

veloping a standardized protocol to assess these issues. Consideration was given to collaborating on the process of translating and applying formative as-

Table 2. Girls health enrichment Multi-site Studies (GEMS) Phase 1 field center formative assessment approaches

Field Center	Formative Assessment Approaches
Baylor College of Medicine	<ul style="list-style-type: none"> ● Focus group discussions with 8- and 10-year-old girls and their mothers ● Child and parent questionnaires ● Interviews with directors and staff of summer camps ● Consultations with web-site designers
University of Memphis	<ul style="list-style-type: none"> ● Focus groups with <ul style="list-style-type: none"> ○ girls ages 8 to 10 alone ○ girls ages 8 to 10 with a parent ○ girls ages 12 to 15 ○ boys ages 12 to 14 ● Child and parent questionnaires ● Key informant interviews with child health experts and community leaders
University of Minnesota	<ul style="list-style-type: none"> ● Child- and parent-targeted intervention feasibility studies ● Separate focus groups with 8- to 10-year-old girls and their parents ● In-depth interviews with community leaders and youth workers ● Child and parent questionnaires ● Card-sort interviews with girls to assess food and physical activity preferences ● Environmental assessment of the neighborhoods/communities
Stanford University School of Medicine	<ul style="list-style-type: none"> ● Interviews with girl/parent dyads ● Separate focus groups with 8- to 12-year-old girls and parents ● Interviews with community leaders and community workers ● Dance feasibility studies ● TV reduction feasibility studies

assessment results to intervention development and of building a common theoretical model to support this process. However, beyond the clarification that all interventions were to be guided by adaptations of Social Cognitive Theory,¹⁸ the adoption of a common model or process for intervention development was not pursued because of the importance of preserving the individuality of the interventions across field centers.

Formative assessment activities took place through a series of regularly scheduled conference calls ($N=14$) during October 1999 through June 2000 and through face-to-face meetings held in conjunction with Steering Committee meetings. Communications were facilitated by a Formative Assessment Committee listserv maintained by the GEMS Coordinating Center. As described below, Formative Assessment Committee activities culminated in a face-to-face

workshop that included consultation with outside experts. Written minutes were kept of all teleconferences and meetings.

Planning Resources and Tools

In the aggregate, committee members had a wealth of relevant knowledge and experience. Areas of expertise included the conduct of lifestyle interventions generally, studies with preadolescent girls, qualitative research, cross cultural research and interactions, cultural adaptation of interventions, child development, parenting, and family relations, African-American culture, and research in African-American communities. Participation by the NHLBI staff provided direct knowledge of the NHLBI Growth and Health Study findings about the 10-year natural history of weight gain in African-American girls beginning in pre-adolescence.² Ap-

proaches used to share and augment the common expertise were as follows:

Bibliography and Core Issues

Each field center was asked to list up to 10 references they viewed as particularly pertinent background reading to inform their GEMS formative assessment activities and intervention development. These lists were compiled into a working bibliography and discussed by the committee. Each field center was also asked to summarize the key content areas from their formative assessment plans into a short list of core issues. These lists were then distributed and discussed by the committee to clarify domains and issues considered important by the various field centers and also to identify issues of mutual interest. Several investigators also circulated formative assessment protocols from other studies in minority populations as additional examples of topics and approaches.

Matrix

The committee chair (SKK) drafted a matrix to facilitate the organization of information on cultural and contextual issues and as a tool to support further discussion and prioritization of core issues. The matrix was based on this investigator's previously developed conceptual framework (see Figure 1), checklists, and models for describing cultural influences on weight status^{19,20} and cultural influences in weight control programs for African-American women or other cultural groups. These conceptualizations draw upon several theoretical constructs from disciplines such as sociology, social psychology, and anthropology, for use in specific situations.^{19,20} The matrix (see Table 3) included columns prompting for programmatic, child, family, and environmental variables (ie, contextual variables that were important to assess but not necessarily modifiable by either the intervention program or by participants) and rows for ethnicity, socioeconomic status, content variables such as food, physical ac-

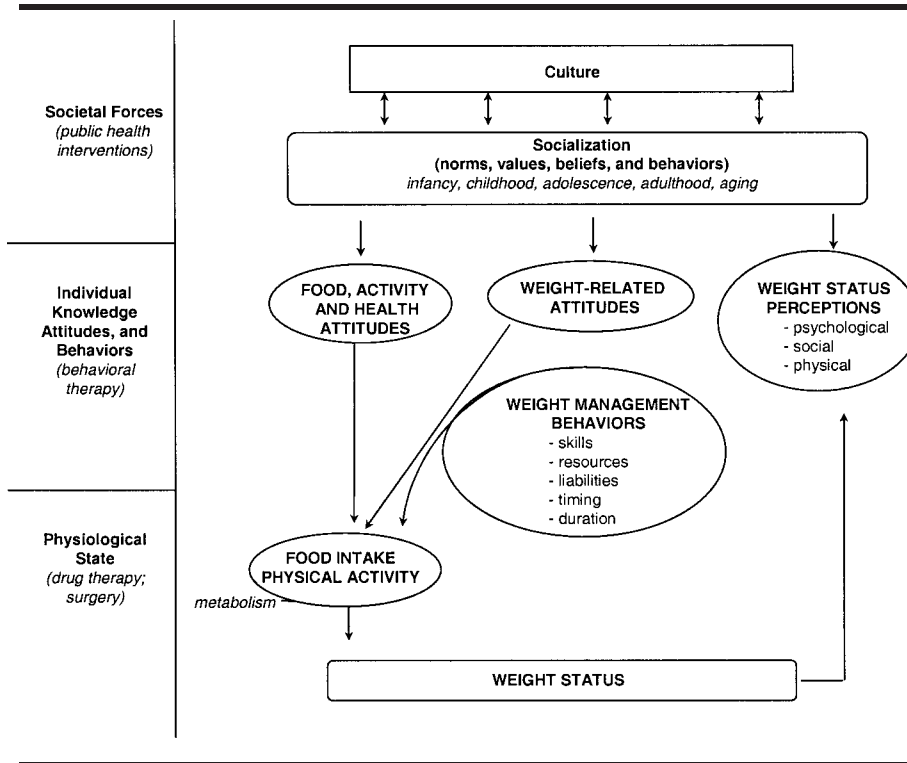


Fig 1. Levels and types of cultural influences on weight status. Reprinted with permission from Kumanyika SK, Morssink CB¹⁹

tivity, weight control, general health lifestyle and psychosocial factors, smoking, alcohol, drugs, and implementation variables such as programmatic interactions, setting, and format. Cell entries related to potentially important variables at each intersection were guided by the committee members' personal and professional knowledge and experience as well as information from relevant literature sources. This matrix was used as a reference point for planning formative data collection and was further refined during the initial months of committee deliberations. Cell entries in the original matrix were revised and expanded during an iterative process that extended over several weeks and included reflection and discussion within as well as across field centers. This matrix guided the field centers in ranking priority issues to consider as core variables for assessment across field centers; these rankings were then compiled into a master short-list and further refined and adju-

dicated through a consensus-oriented discussion process.

Workshop

Discussion of the value of a formative assessment workshop took place early in the planning process, but the idea did not gel sufficiently at that time to justify the use of resources for investigator and staff travel for this purpose. As planning progressed and some formative assessment data had been collected, the perceived need for a workshop and ideas of what it could add to enhance the process became much stronger. A formative assessment workshop was ultimately convened to strengthen and facilitate the ability of those designing interventions to understand and incorporate cultural factors in the intervention. This workshop ultimately took place at the end of the planning process because of the lead time needed to plan for it once the decision had been made to go forward.

In developing the workshop, it was agreed that scholars with relevant expertise would be invited as consultants, with an implicit expectation that these scholars would be African-American. Committee members nominated and circulated literature citations for candidates who could potentially address topics of interest (eg, conducting programs with African-Americans families, youth development issues relevant to the design of intervention programs, unique youth developmental issues for girls who are African-American, and general cultural appropriateness issues). For pragmatic reasons, the Steering Committee requested that priority in selecting consultants be given to individuals with intervention research experience (even if this experience did not directly involve nutrition or physical activity) rather than to inviting basic social science or African-American studies researchers.

Three consultants participated in the workshop.¹ In advance of the workshop, these 3 individuals were provided background information that included descriptions of the intervention approaches proposed by the field centers, the working bibliography, and some questions of particular interest to Formative Assessment Committee members. The one-day workshop agenda allowed time for didactic presentations from each consultant followed by brief presentations from each field center highlighting formative assessment results to date. Time was also allowed for discussion, with each consultant asked to lead a discussion about issues in his or her area of expertise.

RESULTS

The Formative Assessment Committee process was collegial and collaborative,

¹ Collins Airhihenbuwa, PhD, Professor of Biobehavioral Health, Pennsylvania State University; Geraldine Brookins, PhD, W K Kellogg Foundation; and Barbara Guthrie, PhD, RN, Associate Professor, University of Michigan School of Nursing.

Table 3. Influences on weight gain of preadolescent African-American girls: matrix of potential core domains and variables for formative assessment

	Program Variables	Child Variables	Family Variables	Environmental Context*
Ethnicity	<ul style="list-style-type: none"> — Cultural perspectives of investigators and staff — Programmatic assumptions 	<ul style="list-style-type: none"> — Ethnic diversity within self-defined African-American population — Caribbean — Hispanic — Afrocentric — Bi-cultural — Interracial experiences — Religion (Christian, Muslim, Adventist, other) — Religious participation — Worldview — Ethnicity-specific social activities — Significance of racial identity — Interest in learning more about African heritage 	<ul style="list-style-type: none"> — Ethnic diversity within self-defined African-American population — Caribbean — Hispanic — Afrocentric — Bi-cultural — Interracial experiences — Religion (Christian, Muslim, Adventist, other) — Religious participation — Worldview — Ethnicity-specific social activities — Significance of racial identity — Interest in learning more about African heritage 	<ul style="list-style-type: none"> — Ethnicity of neighborhood — Ethnicity of school children and staff (eg, predominantly African American; % White; % Hispanic) — General climate for race-relations in area
Family	<ul style="list-style-type: none"> — Directly involved — Not directly involved — Type of family involvement 	<ul style="list-style-type: none"> — Directly involved — Not directly involved — Pattern of interaction with significant adults and with siblings 	<ul style="list-style-type: none"> — Household composition — Sisters — Brothers — Mothers — Fathers — Extended family — Intrafamilial interactions and parenting style — Cohesiveness — Age of mother — Health status of household members — Usual summer and holiday activities — Seasonal activities — Motivation 	<ul style="list-style-type: none"> — Household composition — Sisters — Brothers — Mothers — Fathers — Extended family — Interactions — Competing priorities — Family health: life events — Location of extended family base (ie, another city or same city) — Working status (employment)
Socio-economic status	<ul style="list-style-type: none"> — Peer staff — Professional staff — Participatory action model — "Social class" of program — Literacy level 	<ul style="list-style-type: none"> — Low — Middle — Mixed — Child's discretionary spending — Living arrangements (living with someone temporarily) 	<ul style="list-style-type: none"> — Presumed biological child, ie, genetic predisposition — Motivation for enrolling — Primary caretaker in family — Role of the father — Marital status — Working status — Upwardly mobile — 2nd generation middle class — Mixed — Frequency of eating out — Computer availability in the home — Mobility/transience — General literacy level — Transportation issues — Own or rent house or apartment — Stability (how often moved) — Own car 	<ul style="list-style-type: none"> — Type of neighborhood of residence (eg, inner city; suburb) — Access to food — Access to physical activity — Economic conditions; layoffs; etc — Marriage or divorce — Computer availability (outside of the home) — Safety of the neighborhood (objective vs perceived measure of ambient hazards)

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	Program Variables	Child Variables	Family Variables	Environmental Context*
Program Content: <i>General Health Lifestyle and Psychosocial Context</i>	<ul style="list-style-type: none"> — Content — Assumptions — Health vs obesity 	<ul style="list-style-type: none"> — Learning style — Personality and interests — Level of health motivation — Concepts of health — Health literacy — Information sources — TV in bedroom — Media usage and habits — Perception of obesity — Concepts of health — Usual eating pattern — Attitudes/interest — Food preferences and food ideology — Peer interactions — Food allergies — Eating out and where — Frequency of eating out — Snacking (what? where? when?) — Usual activity pattern — Weight status — Body image re physical activity — Activity preferences and role perceptions — Physical skills — Health problems (eg, asthma) — Access to physical activity resources — Discretionary time — Sedentary behavior — Current weight management behaviors — Already obese — Previously obese — At risk of obesity — Mixed — Attitude toward smoking — Dieting predisposition — Body image/attractiveness — Physical activity as a social activity — Perception of healthy weight — Priorities of weight and size — Perceived importance of weight and size — Public performance as a motivator — Sedentary behavior 	<ul style="list-style-type: none"> — Education level — Work status — Food insecurity issues — Learning style — Health-oriented family — Prevention-oriented family — Aspirations for child — Health literacy — Information sources — Media habits — Perception of obesity — Concepts of health — Family meal pattern and food ideology — Food preferences — Family meal content — Skills/predispositions of food shopper or preparer — Raised in the South — Health lifestyle — Eating out: where and how often — Recreation patterns and activity lifestyle — Activity preferences and role perceptions — Attitudes about children's activity — Access to physical activity resources — Logistical flexibility — Discretionary time — Sedentary behavior — Mother/father obese — Number of obese in household — Personal body image — Body image aspirations re the child in the program — Perceived safety — Pattern of transportation (close distances) — Physical activity as a social activity — Public performance as a motivator — Sedentary behavior — Perception of healthy weight — Perceived importance of weight and size 	<ul style="list-style-type: none"> — General health promotions in the community or in the environmental context of program participants — Current media promotions for children — Competing opportunities — Extant fad diets — School meals — Neighborhood food stores and restaurants — TV programs and ads — Food supply trends — Peer interactions — Holidays; vacations — Opportunities — Secular trends (eg, skateboarding) — School and community programs — Holidays; vacations — Objective safety — Perceived cultural milieu — Magazines; TV; other media/information and entertainment sources — Pregnancy of mother involved in intervention
Program Content: <i>Food</i>	<ul style="list-style-type: none"> — Approach to dietary modification — Counseling: <ul style="list-style-type: none"> — Didactic — Experiential — Themes — Specific activity, eg, dance — "Lifestyle" activity — Approach to counseling <ul style="list-style-type: none"> — Didactic — Experiential — Themes — Music — Parental involvement 	<ul style="list-style-type: none"> — Usual eating pattern — Attitudes/interest — Food preferences and food ideology — Peer interactions — Food allergies — Eating out and where — Frequency of eating out — Snacking (what? where? when?) — Usual activity pattern — Weight status — Body image re physical activity — Activity preferences and role perceptions — Physical skills — Health problems (eg, asthma) — Access to physical activity resources — Discretionary time — Sedentary behavior — Current weight management behaviors — Already obese — Previously obese — At risk of obesity — Mixed — Attitude toward smoking — Dieting predisposition — Body image/attractiveness — Physical activity as a social activity — Perception of healthy weight — Priorities of weight and size — Perceived importance of weight and size — Public performance as a motivator — Sedentary behavior 	<ul style="list-style-type: none"> — Family meal pattern and food ideology — Food preferences — Family meal content — Skills/predispositions of food shopper or preparer — Raised in the South — Health lifestyle — Eating out: where and how often — Recreation patterns and activity lifestyle — Activity preferences and role perceptions — Attitudes about children's activity — Access to physical activity resources — Logistical flexibility — Discretionary time — Sedentary behavior — Mother/father obese — Number of obese in household — Personal body image — Body image aspirations re the child in the program — Perceived safety — Pattern of transportation (close distances) — Physical activity as a social activity — Public performance as a motivator — Sedentary behavior — Perception of healthy weight — Perceived importance of weight and size 	<ul style="list-style-type: none"> — Extant fad diets — School meals — Neighborhood food stores and restaurants — TV programs and ads — Food supply trends — Peer interactions — Holidays; vacations — Opportunities — Secular trends (eg, skateboarding) — School and community programs — Holidays; vacations — Objective safety — Perceived cultural milieu — Magazines; TV; other media/information and entertainment sources — Pregnancy of mother involved in intervention
Program Content: <i>Physical Activity</i>	<ul style="list-style-type: none"> — Explicit ? — Cultural appropriateness to girls and families in study 	<ul style="list-style-type: none"> — Physical activity as a social activity — Perception of healthy weight — Priorities of weight and size — Perceived importance of weight and size — Public performance as a motivator — Sedentary behavior 	<ul style="list-style-type: none"> — Activity preferences and role perceptions — Attitudes about children's activity — Access to physical activity resources — Logistical flexibility — Discretionary time — Sedentary behavior — Mother/father obese — Number of obese in household — Personal body image — Body image aspirations re the child in the program — Perceived safety — Pattern of transportation (close distances) — Physical activity as a social activity — Public performance as a motivator — Sedentary behavior — Perception of healthy weight — Perceived importance of weight and size 	<ul style="list-style-type: none"> — Opportunities — Secular trends (eg, skateboarding) — School and community programs — Holidays; vacations — Objective safety — Perceived cultural milieu — Magazines; TV; other media/information and entertainment sources — Pregnancy of mother involved in intervention
Program Content: <i>Weight Control</i>	<ul style="list-style-type: none"> — Explicit ? — Cultural appropriateness to girls and families in study 	<ul style="list-style-type: none"> — Physical activity as a social activity — Perception of healthy weight — Priorities of weight and size — Perceived importance of weight and size — Public performance as a motivator — Sedentary behavior 	<ul style="list-style-type: none"> — Activity preferences and role perceptions — Attitudes about children's activity — Access to physical activity resources — Logistical flexibility — Discretionary time — Sedentary behavior — Mother/father obese — Number of obese in household — Personal body image — Body image aspirations re the child in the program — Perceived safety — Pattern of transportation (close distances) — Physical activity as a social activity — Public performance as a motivator — Sedentary behavior — Perception of healthy weight — Perceived importance of weight and size 	<ul style="list-style-type: none"> — Opportunities — Secular trends (eg, skateboarding) — School and community programs — Holidays; vacations — Objective safety — Perceived cultural milieu — Magazines; TV; other media/information and entertainment sources — Pregnancy of mother involved in intervention

Table 3. Influences on weight gain of preadolescent African-American girls: matrix of potential core domains and variables for formative assessment

	Program Variables	Child Variables	Family Variables	Environmental Context*
Program Content: <i>Smoking</i>	— Explicit?	— Perceived safety — Pattern of transportation (eg, walking to school) — Structured vs unstructured activity patterns — Current behavior — Individual predisposition	— Smokers at home — Anti-smoking influences in family life	— Regulatory climate — Secular trends — Exposure — Contextual factors for juvenile access to drugs and alcohol
Program Content: <i>Alcohol or drugs</i>	— Explicit?	— Current behavior — Experiences in family — Experiences with peers — Attitudes based on experiences with sexuality and perceived relationship to weight status	— Drinkers or abstainers in home — Attitudes towards drinking and related counseling in children — Attitudes towards sexuality, sex education, and perceived relationship to weight	— Experiences with sexuality and perceived relationship to weight status
Program Content: <i>Interactions</i>	— Who interacts with children and family members, and how, including age, sex, and ethnicity of program staff	— Interactions with other children in program — Interactions with staff — Interactions with family members — Primary or through parent only — Familiarity with setting — Perceptions of setting — Convenience of setting — Prior or current experience with any type of program participation	— Interactions with other parents or family members in program — Planned or incidental to program content — Primary vs through child only — Familiarity with setting — Perceptions of institutional setting — Convenience of setting — Permit access to home — Prior or current experience with any type of program participation	— Mix of participants who attend — Interactions among participants or between staff and participants outside of the program context — Other things that happen in the setting
Program Content: <i>Setting/format</i>	— Cultural/psychosocial distance from participants — Contact pattern — Other connotations of setting — Home visits			

* Considered immutable unless directly targeted in the intervention.

except for the underlying constraints on idea-sharing associated with the requirement that each field center develop a unique intervention. With respect to tangible outcomes, the planning process yielded the bibliography provided here as an Appendix, the comprehensive matrix of potential formative assessment domains shown in Table 3, and a set of questions for assessment of content around selected core issues (Table 4). Less tangible but perhaps the most critical outcome of the process, were the ideas and concepts generated by the workshop. Each of these results is discussed below.

Bibliography

Of a total of 40 possible citations for the bibliography (ie, each field center was asked to submit up to 10), 35 were submitted, with only 3 citations appearing on more than one list. The resulting 32 items are listed in the appendix. As expected, the list included citations from prior work of the respective investigative teams as well as citations from the NHLBI Growth and Health Study.

Matrix

The entries in Table 3 highlight the need to consider ethnic diversity within the African-American community, the multiplicity of family lifestyle and interaction variables that may be relevant, and the numerous socioeconomic variables of potential interest particularly given the focus, for 3 of the 4 field centers, on African-American girls in low income communities. The fourth column emphasizes the influence of variables in the environmental context, most of which were either not targeted or only partly addressed in the interventions proposed. The programmatic variables identified for consideration reflect issues relevant to obesity development among children in general and particularly those identified in the NHLBI Growth and Health Study as of special relevance to African-American girls.³⁻⁵ Not all topics shown on the matrix were

Table 4. Girls health Enrichment Multi-site Studies (GEMS) Phase 1 core formative assessment questions related to intervention development

Issue To Be Addressed	Comments	Specific Wording To Be Used To Lead Into Topic, With Possible Probes
1. Intervention content related to general health	Ask in a neutral manner to avoid assumption that weight is viewed as health-related; ie, assess whether weight, food, or activity come up spontaneously when health is discussed and if so, how.	<i>What makes a person healthy?</i> Possible probes, if needed: — Where does weight fit in? — Where does food fit in? — Where does physical activity fit in?
2. Intervention content related to food intake	Try to elicit with respect to both home, school, and other settings.	<i>Describe what you eat during a typical day during the week.</i>
3. Intervention content related to physical activity	Try to elicit preferences for recreation while also getting a sense of level and type of obligatory activities.	<i>What types of activities do you usually do when you are not in school?</i>
4. Intervention content related to body image	This question may have overtones of sexuality; possible alternative wording is “good looking”; use of silhouettes in assessing body image is optional.	<i>What makes a girl attractive?</i>

incorporated into focus group protocols. For example, the prompts related to sexuality and substance use were intended as reminders of psychosocial and environmental context issues that might arise during interactions with preadolescent girls or their parents but were not directly addressed. The rows in the matrix for program content also included aspects of cultural appropriateness that relate to staffing, interactions between staff and participants, and acceptability of the program and venue to the participants.^{19,20}

Taken together, the prompts in Table 3 serve to point out issues that might be overlooked by investigators focusing narrowly on a particular intervention objective or approach or those less familiar with African-American or low income communities. All of the issues have general relevance to designing obesity prevention programs for children, and some require in-depth consideration of special issues for girls and for African-American girls. Some of the items on the matrix were assessed in focus groups or with questionnaires. Others were noted as issues to be incorporated or assessed in other ways (eg, by inclusion of certain psychosocial assessments in the GEMS data collection protocol).

Core Items for Study-wide Formative Assessment

The study wide formative assessment protocol outlined a set of primary questions to be incorporated into focus group data collection with girls in the GEMS age range (Table 4). These questions both assured that all field centers assessed these core issues and also enhanced the potential comparability of the resulting focus group data across field centers. Principles underlying the design of these questions were to keep them open-ended and neutral, to avoid introducing assumptions or eliciting biased responses, and to leave the follow up questions or probes up to the judgment of the study team at each field center, as appropriate to the different programmatic foci of each center. The questions were framed for incorporation into focus groups with children in the GEMS target age range. Field centers could opt to develop similar questions for use with parents. The manner in which these questions would be incorporated was left open. However, one additional understanding that grew out of these discussions was that a cultural and gender match of data collection staff to respondents was important (ie, staff conducting formative assessments would be or would include African-American

females, or males for the center that conducted a focus group with boys).

Workshop

All interested field center investigators and staff were invited to attend the workshop, although actual participation was limited by cost and logistics. All 4 GEMS field center principal investigators and most Formative Assessment Committee members attended. Approximately half of those participating in the workshop were African-American. Workshop presentations and discussions were shaped by several factors: the background information provided to the consultants; the particular expertise they had to offer and the perception of how that expertise related to GEMS formative assessment objectives and process; the formative assessment findings across field centers as presented at the workshop; the knowledge and interests of workshop participants, many of whom had limited or no prior involvement with Formative Assessment Committee process. Key perspectives and insights from the workshop deliberations, highlighted in Table 5, related to bridging differences in cultural perspectives and world views (the focus of Dr. Airhihenbuwa’s presentation), to African-American mother-daughter relationships and other famil-

Table 5. Highlights of key perspectives and insights from GEMS Phase 1 formative assessment planning workshop

Western Cultural Perspective

— Many of the core cultural perspectives of African Americans arise from other than western cultures that include some qualitatively different perceptions and values when compared to western culture.²¹ Most fundamentally, the premium value on linear logic in western culture differs paradigmatically from the more encompassing values embraced by other cultures. Moreover, western cultures, even western scientific definitions of cultures, promote a hierarchical view in which the recognition and value for other cultures is limited. Hence, many individuals from western cultures may have great difficulty in understanding other cultures. Those who have substantial, albeit often superficial, understanding of other cultural perspectives, may still have difficulty accepting these other cultural perspectives “in their own right.” This difficulty becomes even more evident in the unbalanced power context that characterizes almost all provider-client relationships, particularly in situations where providers have a western cultural orientation and clients do not.

Bridging Cultural Differences

— Given that one’s cultural perspective defines what seems normal and comfortable, attempting to bridge cultural differences requires “becoming comfortable with being uncomfortable” (as phrased by Dr. Airhihenbuwa). The amount of effort required or discomfort associated with such attempts to bridge cultures differs among individuals.

Historical and Contextual Influences on African-American Family Interactions

— In the case of African Americans, culture includes a reflection of experiences of discrimination and a history of oppression, and these cultural influences shape communication patterns. Communications with authority figures or in groups may reflect traditions among African Americans about what can be safely or appropriately said in various circumstances. Parent-to-child communication may be indirect.

— Certain common cultural patterns have contributed to the resiliency of African Americans, and these patterns are reflected in the values, beliefs, and familial relations of African Americans. Various social forces, including issues related to Black men, reinforce family patterns where motherhood becomes a centrality, with mothers as preferred role models for girls, girls’ views of adulthood as linked to the circumstances of their mothers and important roles of “fictional kin” (sometimes referred to as “other mothers” or “play mothers”) in child-rearing.

Perspectives of African-American Girls

— African-American girls, as with people in general, reconstruct the societal images to which they are exposed to fit their own realities. It is thus of critical importance to reflect on the realities of African-American girls with respect to their age, generation, and social circumstances when developing the GEMS interventions. The importance of verifying and refining assessments of these perceptions of reality and their implications by going back to the initial respondents or similar respondents was stressed, eg, having African-American girls as advisors for intervention development.

Double-consciousness

— A survival strength of African Americans is the ability to navigate in multiple worlds without power in any. This is associated with “double consciousness,” or having to develop valid ways to participate in dual culture.²² As an example, the aspirations of African-American mothers for their daughters may be a mixture of wanting them to participate fully in society and derive benefits and also wanting to protect them from harm in the society at large where this implies racism or a low value for African-American life or beauty.

Distrust

— Many African Americans may have true ambivalence about certain aspects of participation in the mainstream US society, whether based on racial or class experience. This ambivalence extends to participation in research, whether as subjects or members of the research community. Fears about being disadvantaged in healthcare situations and research settings transcend social class lines and may be apparent in middle- or high-income African Americans. Such fears are validated by a wide variety of studies, including studies demonstrating discriminatory attitudes and behaviors of health professionals.²³ However, while these fears can be documented by fact, some may reside below the surface of the consciousness of the client and may be difficult to uncover and elicit even in focus groups. For example, there may be a norm of silence about such fears, particularly among those of higher socioeconomic status, making expression of them a taboo. For this reason, investigators were advised to be wary of obtaining too consistently positive a picture on issues where some negative reactions might also be expected. In addition, focus groups, by their nature as time limited, artificial, and semi-controlled group interactions may provide relatively superficial reactions about some deeply-rooted, sensitive issues.²⁴ This particularly holds true when focus groups are conducted from a relatively applied (eg, as in formative assessment conducted to specifically inform intervention development), qualitative research perspective.

Framing Questions

— In cases where there are fundamental differences in perspective, questions framed from one perspective (eg, that of the investigator) may incorporate latent assumptions that constrain and decrease the validity of responses by those with a different cultural perspective (eg, that of the study participant). As an example, an investigator who is a member of a cultural group that publicly holds the value that being overweight is negative and being thin is positive (whether he/she shares that perspective or not) may have difficulty framing sufficiently broad or unbiased questions about body image to elicit the complete spectrum of body image attitudes in cultural settings where views of being overweight are a mixture of positive and negative.

Study Design Issues

— The randomized, controlled trial designed from outside of the community is difficult to implement effectively in settings where potential participants expect or want a community-based, client-oriented approach. This applies particularly to the formulation of control group conditions. Recognizing the need to work within specified research objectives and scientific principles, the more there can be clarity and acceptance of the community needs and values, the more likely whatever is developed will be well-received and sustainable. For example, given the cultural centrality of mother-daughter relationships for African Americans, an approach that emphasizes strengths, assumes that parents want the best for their daughters, and aligns the program with the goals of these parents and girls or with community agencies in the broader sense will be successful.

ial interactions (the focus of Dr. Brookins' presentation), to the importance of listening to and involving the girls themselves in the research development (the focus of Dr. Guthrie's presentation), and to how research can be affected by cross cultural communication patterns and by the socio-cultural history and sociopolitical climate affecting the African-American community (emphasized by all 3 consultants as well as participating investigators).

Indicative of the effect of the workshop in creating true moments of cross-cultural interaction among those present was that not all of the discussion was "comfortable." This was particularly noticeable in the less than desired degree of fluidity in the open-ended afternoon session. Evident in reactions to the morning presentations and in the discussion in the afternoon was the difference in perspective of the African-American researchers versus those who were not African-American. Those who had grown up with a Black experience, including the consultants and GEMS investigators or staff, often spoke from a "we" perspective when discussing issues in the Black community. Several offered personal disclosures of experiences with discrimination or feelings of distrust to validate the information being presented for their colleagues and also to demonstrate that some aspects of the Black experience transcend social class lines and affect African-American professionals as well as clients. An apparent side effect of this identification with these cultural perspectives was some polarization of the discussion along "insider-outsider" lines,^{25,26} ie, in which the "expertise" that can only be gained through a lived experience as an African American was viewed as important apart from one's professional credentials and experience.

Although the workshop was considered worthwhile and successful overall, satisfaction with the outcomes was not uniform. Positive reactions included a sense of validation in that approaches already planned appeared to be on the

right track and reinforcement of the importance of paying attention to certain factors of which one was already aware. Negative reactions included feeling put on the defensive and feeling emotional stress due to the sensitive nature of the subject matter. Participants apparently had varying expectations about what the workshop would provide and different responses to the experience of discussing African-American cultural and social perspectives in this forum. For example, one (White) participant commented:

"The meeting was not what I was expecting. I had expected presentations and dialogue focusing on current social science research findings and theoretical and historical perspectives regarding African-American families, parenting styles, and development and cultural issues of pre-adolescent and adolescent African-American females and implications for our interventions. While this information was not presented to the extent that I had expected, the meeting did reinforce key concepts such as what Collins (referring to Dr. Collins Airhihenbuwa) said on the importance of being comfortable with being uncomfortable when working with populations of color. For me, the meeting raised issues of the undercurrent of trust and mistrust present both at the community level and the research community."

Finally, there was a general sense that the workshop was "too little, too late." Had the workshop been conducted earlier or for a longer duration, the ambitious agenda, intended to cover didactic presentations of general information and hands-on level discussion about how to incorporate certain knowledge or sensitivities into intervention design, might have been more spread out, doing more justice to each objective. A more relaxed schedule might have allowed time for participants, several of whom had not previously met, to feel more comfortable

with each other or to digest information or feelings (eg, of discomfort with discussions about racial issues) that were new to them. More time would also have allowed for more discussion and small group interactions, to work out issues as they arose.

DISCUSSION

Cultural factors are social or group variables whose influences are easy to overlook because they are insufficiently specified within models of individual behavior change, although they are clearly implied in these models.^{18,27} It is generally agreed that formative assessment is a critical step in the development of culturally appropriate health interventions.²⁸ However, the understanding of how to identify and account for cultural influences in developing and implementing weight management^{19,29-31} or other health lifestyle change programs^{28,32} is still early in its development and is not well-grounded in the more extensive literature on culture or culture and health.³³⁻³⁵ This is true both in general and particularly in the unique circumstances posed by randomized trials.³⁶ Available reviews and conceptualizations of cultural or ethnicity-related issues in the obesity and related lifestyle change literatures have helped to describe what the salient cultural variables supposedly are or to elaborate the rationale for culturally sensitive programming.^{19,20,27,29-31,33,34,37} However, with respect to implementation, there is relatively little specific guidance as to how to approach the task of formative assessment and no existing standard for evaluating the quality or validity of formative assessment or its translation into components of culturally appropriate interventions. By observation, the process of adapting programs for cultural appropriateness has been largely intuitive and empirical, drawing on the prior knowledge and instincts of the investigators, staff, and in some cases community members involved.

This descriptive article from GEMS Phase 1 is a case study of how investigators at 4 research centers collaborated on formative assessment planning. The starting point for and boundaries around the activities, although not unlike the situation in many other health behavior change studies, should be kept in mind. The process was time limited and not completely open-ended. The general approaches to be undertaken for both formative assessment and intervention were determined based on the content of the RFA, the funded applications, the developmental work that went into those applications, and the attendant budgetary and logistical framework that had been established. Also, this was collaborative planning for distinct projects rather than for a single program to be developed for multi-site implementation.

The collaborative planning activities involved the generation of ideas about—literature to be tapped (eg, for the bibliography), the universe of domains and topics that should be considered for assessment (ie, using the matrix), and the core content to be assessed (ie, priorities emerging from our collective reading of the relevant literature). The selection of articles for the bibliography (Appendix 1) reflected the convention in research of building upon one's prior work. However, the list also demonstrated recognition of the breadth of literature that can potentially be brought to bear on this type of task. Included were theoretical papers on cultural sensitivity, interventions in other minority populations, body image literature, prior intervention studies of both food and physical activity related behavior change, as well as literature from Black sociology. Literature from the root disciplines of sociology, anthropology, and to some extent cultural psychology was not included in the bibliography, but this is not entirely surprising. The structural and conceptual dichotomy between these disciplines and the discipline of clinical or behavioral

psychology, which dominates in the health domain, may limit the interest in or ability of health professionals to do a deep reading of texts from these root disciplines.

The other activities undertaken during planning, ie, using the matrix in Table 3 to guide brainstorming and information seeking, and working to identify core issues for standardized assessment (Table 4) prompted for a comprehensive consideration of issues and structure in order to link the formative assessment plans to cultural and contextual factors influencing African-American girls. The results may provide tools for further exploration and elaboration or ideas for how these tasks could be approached more systematically.

The workshop was successful in the anticipated ways, ie, providing numerous insights about relevant cultural and contextual issues, but also in some unanticipated ways with respect to attitudes and perceptions of the investigative team. The issue of how investigators or professionals relate to situations in which one's ethnicity (or in other settings gender) becomes a criterion of relevance with respect to "expertise," a key theme in the workshop discussion, was not anticipated but is certainly a critical one, and it deserves further comment.

"Insider-outsider" dilemmas potentially occur in situations in which membership in a group (or the possession of expertise) is based on unalterable characteristics, eg, ethnicity. In such cases, an outsider can never become an insider and, to be effective, must find an acceptable role and identity in the process in question that neither depends on insider status nor apologizes for outsider status. This is often done in collaboration with insiders who are working in liaison roles.³⁸ By contrast, in groups for which membership criteria can be acquired, an outsider can sometimes become an insider over time or the reverse, ie, can sometimes lose insider status over time (eg, because of language or place of residence). Whether this occurs will

depend on the nature of the group membership. For example, given our thinking about social mobility, the pathway whereby professionals with middle or upper income roots would become insiders in lower socioeconomic status communities is difficult to imagine. However, insider knowledge about low socioeconomic status communities may be retained by professionals with origins in such communities, particularly if they retain sufficient contact with less upwardly mobile friends or relatives.

Although beyond the scope of this article, one could engage in much broader reflection as to variables for which direct knowledge and lived experience could be potentially beneficial in augmenting professional knowledge and experience: being female (eg, having been a girl at some point) and being a parent of a girl, or an African-American girl, in the GEMS target age range, with respect to GEMS, or having been overweight as potentially relevant to the design or delivery of obesity treatment programs. A generally applicable and important caveat is that being an insider as such (eg, being or having been a member of the group in question) does not automatically confer full and sentient cultural competence. Rather, insider status refers to the specificity of the cultural grounding, which differs for those who are cultural outsiders. Another important caveat is that most insiders (of a cultural entity such as ethnicity, profession, gender), cannot see or be cognizant of their cultural biases, especially when the subjectivity about the matter is seen as a strength. Therefore, diversity in project teams is an important tool recognizing that a balance of power will be difficult to achieve in a racially stratified society.

To the extent that immutable criteria of membership or expertise are acknowledged (which is the implication of cultural competence discussions), this threatens the principle of merit on which participation in scientific endeavors is based. These issues have been dis-

discussed in detail in the literature on community development and in anthropology.^{25,26} The intention here is only to demonstrate that the types of issues encountered in the workshop can be understood on the basis of terminology and concepts that have been worked out in other disciplines and to suggest that these frameworks from other disciplines might help us to understand and handle some of the issues that are encountered in cross cultural programming.

The rationale for ethnic diversity in study populations has been well described. However, the professional significance of ethnic diversity in investigative teams is not a common topic of discussion. Again, by observation, the mandate for cultural congruency in nutrition and health services delivery³⁹⁻⁴¹ has not been extended to health research, perhaps because the professional culture of expertise is much stronger in research than in practice. The usefulness of having cultural congruency of formative assessment data collection staff with respondents was recognized in GEMS and the specification in the RFA encouraging African-American women investigators implied that this was advantageous. However, the reasons for wanting to involve African-American staff or investigators were not made explicit. Reflecting back on the workshop, it might have been very beneficial to have these types of issues made more explicit, for all concerned. Cultural self-awareness is an absolute first principle in any cultural competence exercise, a prerequisite to acquiring knowledge of and skills for working with other cultures.³⁹⁻⁴³ For example, not all participants in the workshop were prepared for or pleased with what evolved. Although a group process that stimulates cultural self-awareness is probably always uncomfortable for all who are involved, it may be particularly uncomfortable if a person is taken by surprise, since the preparation for this can only be personal, not professional.

CONCLUSIONS

Two specific recommendations can be made based on lessons learned in the GEMS formative assessment planning process. One is to encourage appropriately framed, open discussions of diversity issues at the investigator level, perhaps at meetings of professional societies as well as study-wide meetings of multicenter trials, a trend that is already in evidence.³⁶ Inviting the direct participation of sociologists and anthropologists to these discussions would enhance access to the relevant knowledge and conceptualizations from these disciplines. The American College of Epidemiology has provided a thoughtful statement of principles that addresses some relevant issues.⁴² The “insider-outsider” issues are the most sensitive because they raise the tension of expertise based on life experience versus credentials or merit. Questions that need to be asked include: What is the effective blend of professional knowledge with life experience and cultural knowledge? How does the role of the insider differ from that of the outsider? How can insiders and outsiders work most effectively together? What are the implications from a personal perspective (feeling marginalized) or from a professional perspective (not owning the requisite expertise)? How does one address the perception that insiders are automatically more “expert” because of their life experience? Can an insider avoid the imposition of personal biases based on inherently subjective life experience of those on the inside? What professional issues does dual consciousness raise for minority investigators?

The other recommendation is for the continued development of conceptual frameworks in which cultural components are clearly articulated, to reduce the reliance on empiricism and support the evaluation of quality and validity in this aspect of intervention development.⁴³ There are numerous studies of culturally adapted programs that have

high drop out rates, disappointing effect sizes for outcomes or null results, or even significant results contrary to expectation.²⁹ Thus, the importance of gaining a better sense of when these initial stages of intervention development are optimal relates directly to the need to strengthen culturally adapted interventions.

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APPENDIX

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