

# GIRLS HEALTH ENRICHMENT MULTI-SITE STUDIES (GEMS): NEW APPROACHES TO OBESITY PREVENTION AMONG YOUNG AFRICAN-AMERICAN GIRLS

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The Girls health Enrichment Multi-site Studies (GEMS) is an obesity prevention research program sponsored by the National Heart, Lung, and Blood Institute (NHLBI), targeting young African-American girls. Expert groups have suggested that the high prevalence of obesity in African-American women could be a contributing factor to their excess morbidity and mortality from cardiovascular disease compared to women from other ethnic groups. To address the issue of obesity and its origins in African-American women, the NHLBI Growth and Health Study (NGHS) was initiated to investigate factors related to the development of obesity and associated cardiovascular disease risk factors in a cohort of young African-American and White girls, aged 9 and 10 years. Findings from NGHS, and the realization that obesity had become a major public health problem, subsequently led to a 2-phase, 7-year collaborative obesity prevention research program, the Girls health Enrichment Multi-site Studies (GEMS). Initiated in 1999, Phase 1 of GEMS was conducted collaboratively among 4 participating field centers, a coordinating center, and the NHLBI project office to conduct formative assessment research and to pilot test, over a 12-week period, interventions that might be effective in reducing the rate of weight gain in African-American girls, aged 8–10 years. Over a 2-year period, Phase 2 of GEMS will test the interventions that appear most promising in preventing excessive weight gain in young African-American girls. The experiences of the GEMS pilot studies will help guide future intervention research for obesity prevention beginning in childhood. This report describes the background and rationale for the GEMS initiative. This journal supplement describes the experiences of the GEMS Phase 1 program. (*Ethn Dis.* 2003;13[suppl1]:S1-1–S1-5)

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## INTRODUCTION

The Girls health Enrichment Multi-site Studies (GEMS) is a 2-phase multi-site research program created to develop and test interventions to prevent obesity in African-American pre-adolescent girls. Phase 1, from 1999–2002, was a developmental phase in which to form a collaboration among the field centers, coordinating center, and the National Heart, Lung, and Blood Institute (NHLBI) project office, to conduct formative assessment studies to fine-tune the interventions and measurements, and to carry out pilot studies of 12-week interventions in a small number of African-American girls assigned to treatment and control groups using a randomized design and common measurements of key outcomes. During Phase 2, from 2002–2006, field centers with promising Phase 1 results will test their interventions over a 2-year period in full-scale trials of 260 or more participants per center. The GEMS initiative was a new approach to obesity prevention research and intervention development built upon prior NHLBI activities and initiatives aimed at addressing the public health problem of obesity. This paper describes the prior NHLBI activities, the public health problem of obesity, and the rationale for the various elements of the GEMS program.

## DISPARITIES IN OBESITY AND CARDIOVASCULAR DISEASE

Racial disparities in cardiovascular disease have been a public health concern for more than two decades. In 1980, the National Heart, Lung, and Blood Institute convened the National

Black Health Providers Task Force, which recommended an examination of the epidemiology of coronary heart disease in Black populations.<sup>1</sup> At the ensuing conference, it was noted that Black women had substantially higher mortality rates from coronary heart disease (CHD) compared to White women.<sup>2</sup> Black women also had higher prevalence rates of hypertension and diabetes compared to White women.<sup>3</sup> It was suggested that one of several possible reasons for the increased CHD mortality and unfavorable CHD risk factor levels was the approximately 2-fold higher prevalence of obesity experienced by Black women, compared to White women. Although the second National Health and Nutrition Examination Survey (NHANES II) found no significant difference in mean body mass index (BMI) between Black and White girls aged 6–11 years (17.6 vs 17.0 kg/m<sup>2</sup>, respectively), significant differences in mean BMI were observed in the 12–20 year age range (22.2 kg/m<sup>2</sup> for Black girls vs 21.4 kg/m<sup>2</sup> for White girls).<sup>4,5</sup>

## NHLBI GROWTH AND HEALTH STUDY (NGHS), AN EXAMINATION OF OBESITY DEVELOPMENT

Shortly after the conference on CHD in Black populations, the NHLBI Growth and Health Study (NGHS), a biracial observational cohort study, was initiated to specifically examine the issue of obesity development. It was generally agreed that the etiology of obesity is multifactorial.<sup>6</sup> Diet, physical activity, psycho-social factors, socioeconomic status, family environment, and genetic influences are all associated with obesity and with behaviors related to obesity.

However, the precise relationship of these factors to each other and to obesity development was unknown, especially among Black populations. In 1987, NGHS enrolled 2379 Black and White girls, age 9 and 10, to examine factors associated with obesity development and their racial differences, as well as associated cardiovascular disease (CVD) risk factors. Participants were recruited from 3 field centers from a broad range of socioeconomic backgrounds and income levels in each racial group. The overall goal of NGHS was to identify critical modifiable factors predisposing Black women to obesity, so that results from this research could ultimately guide future intervention studies aimed at prevention.<sup>7</sup>

Results from NGHS showed that at baseline (ages 9–10 years) Black girls were taller, heavier, more sexually mature, and had higher BMI compared to White girls.<sup>7</sup> At baseline, Black girls as compared to White girls had higher intakes of energy and percent of energy from fat, lower levels of physical activity, and viewed more TV.<sup>8</sup> TV watching was directly associated with obesity, more strongly in Black girls than in White girls.<sup>8</sup> Physical activity level was inversely associated with obesity, both cross-sectionally and longitudinally in both Black and White girls.<sup>8,9</sup> It was also observed that socioeconomic status was strongly and inversely related to obesity in White girls, but not in Black girls.<sup>10</sup> However, the relationship between energy intake and obesity in NGHS was unclear. Cross-sectionally, caloric intake from fat, but not caloric intake *per se*, was directly associated with obesity in White and Black girls, respectively.<sup>8</sup> These relationships did not persist longitudinally.<sup>11</sup>

Racial differences in attitudes and behaviors, and their associations with obesity, were also examined in NGHS. Although lower levels of satisfaction with physical appearance were associated with higher levels of obesity in both Black and White girls, Black girls were

much less dissatisfied than White girls. Perceived social acceptance was lower with increasing obesity in White girls, but did not differ in relation to adiposity in Black girls. Examination of 11 eating practices commonly targeted in weight reduction programs (eg, eating while doing other sedentary activities like watching TV, eating large portions, eating when not hungry, and eating alone) demonstrated that caloric intakes were higher in girls who frequently engaged in these eating practices, compared with girls who did not.<sup>12</sup> Black girls were more than twice as likely as White girls to engage frequently in these behaviors. Higher household education level was associated with less likelihood of practicing these eating behaviors.<sup>12</sup> Taken together, these results indicate a need for special efforts to be made among Black populations to foster healthy eating habits and regular physical activity, and to develop effective interventions designed to reduce behaviors that may lead to obesity.<sup>13</sup>

## **OBESITY, A PUBLIC HEALTH PROBLEM**

Obesity was becoming a more prominent public health issue in the 1990s because of increasing population weight levels. Reports on national secular trends from the NHANES II showed that the prevalence of overweight ( $\geq 95$ th percentile BMI of National Health Examination Survey [NHES], 1963–1970 is the reference population) in Black girls aged 6–11 years, increased from 11.3% in 1976–1980 to 16.2% in 1988–1991, while the rate among White girls increased from 6.4% to 10.2%.<sup>14</sup> For adolescents aged 12–17 years, the prevalence rates in Black girls increased from 10.4% to 14.4%, and in White girls, from 5.3% to 8.4%.<sup>14</sup> Data from NGHS from 1987 to 1996 (with the NGHS cohort of girls aging from 9 to 19 years) demonstrated that the prevalence of over-

weight doubled ( $\geq 95$ th percentile BMI of NHES 1963–1970 reference population), from 18% to 37% in NGHS Black girls, and from 8% to 18% in NGHS White girls.<sup>15</sup> By the mid-1990s, it was clear that obesity was a critical public health problem, and was the only major CVD risk factor that was not improving during this time.

Obesity in childhood is not benign, and is likely to confer future elevated risk for CVD. Weight tracks strongly from childhood to adulthood,<sup>16</sup> such that an overweight child is likely to be an overweight adult, with the attendant elevated risk of high blood pressure, dyslipidemia, and impaired glucose tolerance/diabetes.<sup>17,18</sup> As in adults, obesity in children is associated both cross-sectionally and longitudinally with single and multiple CVD risk factors.<sup>19</sup> Obesity in childhood and adolescence is associated with impaired glucose tolerance and type 2 diabetes, high blood pressure, dyslipidemia, and other disorders, such as sleep apnea.<sup>19</sup> In addition, psychosocial consequences of obesity have been reported, including lower self-esteem and more behavioral problems among obese, compared to non-obese, children and adolescents.<sup>19</sup> Therefore, given the high (and increasing) prevalence of obesity, the pressing need for obesity prevention in childhood is evident.

## **DEVELOPMENT OF AN OBESITY PREVENTION INITIATIVE**

In 1997, a Special Emphasis Panel was convened to advise the National Heart, Lung, and Blood Institute on critical areas of research for CVD prevention in children and adolescents. Among several concepts for initiatives that were reviewed, obesity prevention for African-American girls was considered a high priority. The focus was on African-American girls because other ethnic groups with high rates of obesity,

such as Hispanics, had lower mortality rates from heart disease and diabetes, compared to Whites or African Americans.<sup>20</sup> The Special Emphasis Panel discussed several elements that would form the core components of such an initiative, including the research question, target population, effect size, intervention, feasibility, and measurement issues.

### Obesity Prevention: Population and Effect Size

The most fundamental focus of the initiative, obesity prevention, was chosen for several reasons. First, the prevalence rate of obesity is very high and continues to increase. Efficient primary prevention efforts can be delivered in group or community settings when targeted toward widely prevalent conditions in which lifestyle behaviors play an important role. Due to the high prevalence rate of obesity, clinical treatment of the condition in individuals is too burdensome for the healthcare system.

Second, weight loss treatments, although successful in the short-term, tend to exhibit a high degree of recidivism over the long-term, particularly when intervention ceases.<sup>21</sup> The problem of long term weight loss maintenance has raised further interest in research on obesity prevention.<sup>22,23</sup>

African-American girls were chosen as the target population because the underlying goal was to address health disparities, and the trend of accelerated weight gain in African-American girls had begun to emerge.<sup>14</sup> African-American women were experiencing high rates of both obesity and mortality from CVD, and childhood was an obvious time for a prevention intervention. In addition, efforts focused on African-American girls as compared with other ethnic minorities because of the availability of ten years of NGHS data to guide specific design elements for obesity prevention trials. For example, data from NGHS showed that Black girls began gaining body fat at a faster rate than

White girls, starting at age 12.<sup>11</sup> Therefore, in order to be effective, obesity prevention interventions should be delivered to African-American girls younger than 12 years. The age range of 8–10 years was chosen for GEMS for this reason.

One of the important elements considered was the effect size: to what degree can the incidence of obesity be reduced? If the rate of obesity development in Black girls could be attenuated to equal that of White girls, as observed in NGHS, obesity development in Black girls would be reduced by 30%. With a continuous outcome (more efficient than a categorical outcome in behavioral trials), reaching the goal of equalizing the rates of obesity between Black and White girls would require that BMI be reduced by an average of at least .75 kg/m<sup>2</sup> over a period of 2 years. This magnitude of effect size was specified in the initiative.

### Intervention and Measurement Issues

An important element of the initiative was to encourage testing a long-term intervention. Obesity prevention efforts, the goal of which is to decrease the trajectory of obesity development, may need to be long term before the intervention's effect on BMI is discernible, as the effect is expected to accumulate incrementally over time. Further, the reduction of life-long exposure to adverse lifestyles in order to reduce disease risk requires healthful behavior to be maintained long-term.

Whereas most intervention experience was in the area of obesity treatment, often for the purpose of improving CVD risk factors such as hypertension, dyslipidemia, and diabetes, there were very few studies in which the research objective was to prevent obesity. These included a small number of studies in adults,<sup>24–26</sup> a pilot study in African-American girls and their mothers,<sup>27</sup> and some school-based studies.<sup>28–30</sup> In contrast, more than 1000 randomized

controlled weight loss trials in adults were reviewed by the Expert Panel for the Obesity Clinical Guidelines,<sup>23</sup> and more than 30 studies of weight loss interventions conducted in children were reviewed by Epstein et al.<sup>31</sup> Most published studies were conducted in White populations, with very limited experience in weight loss interventions with African Americans. The Special Emphasis Panel strongly recommended that any initiative incorporate a formative assessment and pilot phase to help refine interventions, choose and fine-tune measurements appropriate for African-American girls, and assess feasibility.

Due to the paucity of prior studies on conducting lifestyle interventions in African-American pediatric populations, no one intervention would be known *a priori* as the best to use in a traditional multi-center trial with a single common protocol. It was therefore decided that several separate studies would be funded, with each one developing and testing a separate intervention. The initiative also specified that the interventions should be based on behavioral theory and have a theoretical framework.

The use of common measurements for key variables of interest enabled comparisons across studies, and was a key concept of the program.

## INITIATIVE: DECREASING WEIGHT GAIN IN AFRICAN-AMERICAN PRE-ADOLESCENT GIRLS

### Two-Phase Program

In 1998, a Request for Applications (RFA) from NHLBI solicited applications for a 2-phase, 7-year program of several studies encompassing a developmental phase, followed by full-scale randomized trials. Phase 1 would allow approximately 2–3 years to conduct formative research and needs assessment, including focus groups, interviews, and surveys, which would inform more precisely the design and development of the

interventions, as well as the measurements; to prepare a protocol and manual of operations; and to conduct pilot studies with a clinical trial design that included random assignment to a 12-week active intervention or control group. The purpose of the pilot studies was to demonstrate the ability to recruit and deliver an intervention that was acceptable, to take high quality measurements, to achieve high retention rates and good adherence, and to evaluate the interventions on hypothesized behavioral mediators of excessive weight gain. The pilot studies would provide the experience and data to enable the investigators to refine and make changes to promising interventions and measurements, which then would be used for subsequent full-scale trials. During Phase 2, over a 4–5 year period, the centers would perform full-scale randomized controlled trials of their 2-year interventions, with BMI as the primary outcome.

### Collaborative Program

Although each field center was expected to develop and pilot test its own separate intervention, the investigators were requested to develop several common eligibility criteria, a single primary outcome, key measures in the areas of diet and physical activity, a statistical analysis approach, along with a common protocol and manual of operations. Because of this substantial collaboration, a coordinating center was also solicited. The purpose of the collaboration was not only to enhance comparability of results and ensure high quality data collection, but also to create a synergy during protocol development, as the best strengths and experiences contributed by investigators across several centers are pooled together to create a collective expertise with more significant breadth and depth than is usually found within a single center. The RFA also encouraged women and individuals from minority groups to apply as principal investigators.

### Birth of GEMS

Four field centers and a coordinating center were selected after a standard National Institutes of Health (NIH) peer review process of applications, and funding for Phase 1 began in August of 1999. Although not originally part of the requirements, it was decided after the selection of the centers that a subsequent external peer review would be conducted prior to Phase 2, in order to evaluate the success of Phase 1 and plans for Phase 2. A set of “criteria for success” was developed and externally reviewed to help form a framework to evaluate the success of Phase 1. This entire process—the Phase 1 developmental and formative assessment work, pilot study, and criteria for success—helped provide the data needed to decide which interventions were most promising, and had sufficient justification for Phase 2 grant applications.

### CONCLUSION

The GEMS program is proceeding during this time when the need for obesity prevention has become a critical public health priority.<sup>32</sup> The risk reduction potential for an obesity prevention intervention targeted toward adults is clearly illustrated by a recently published trial demonstrating that a behavioral weight loss intervention reduced the incidence of diabetes by 58% over 3 years.<sup>33</sup> The results and experiences from these four pilot studies should provide much-needed information to guide future research in obesity prevention interventions in African-American girls, an understudied population. This journal supplement describes the experiences of the GEMS Phase 1 program, including formative assessment approaches for intervention development, the collaborative study design, results of the individual pilot studies from the 4 field centers, and recruitment challenges. Reliability and validity characteristics of the measurements used to assess behav-

iors, attitudes, and practices of 8- to 10-year-old African-American girls will be published elsewhere. The results from the GEMS pilot studies will help guide future intervention research for obesity prevention beginning in childhood, therefore advancing the ultimate long-term goal of reducing health disparities by decreasing mortality and morbidity from cardiovascular disease in African-American adults.

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