

PHASE 1 OF THE GIRLS HEALTH ENRICHMENT MULTI-SITE STUDIES (GEMS): CONCLUSION

This special supplement to *Ethnicity & Disease* presents the background and rationale, methodology, feasibility, and results of 4 separate interventions that were pilot-tested in Phase 1 of the Girls health Enrichment Multi-site Studies (GEMS) research program. The ultimate aim of the interventions was to prevent obesity in African-American girls. Four field centers, a Coordinating Center, and the National Heart, Lung, and Blood Institute were involved in a unique collaboration to generate and share ideas related to recruitment, formative assessment, and the standardization of some aspects of data collection while each field center designed and implemented a different intervention. Outcomes for recruitment, participation, and behavioral change were generally very favorable, particularly for the two field centers that have progressed to test their interventions in full-scale randomized trials in GEMS Phase 2. The intervention development and pilot study phase also provided many lessons about the importance of trust, openness, and community acceptability in implementing undertakings of this type. Given the paucity of evidence for effective strategies to prevent obesity overall and in high-risk populations, GEMS is an important step forward in developing well-grounded strategies for improving nutrition, physical activity, and weight status in African-American girls. (*Ethn Dis.* 2003;13(suppl1):S1-88–S1-91)

Key Words: African American, Girls, Obesity, Prevention, Nutrition, Physical Activity, Interventions

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INTRODUCTION

This special supplement to *Ethnicity & Disease* presents the background, rationale, methodology, feasibility, and results of four separate interventions that were pilot-tested in Phase 1 of the Girls health Enrichment Multi-site Studies (GEMS) research program.¹ The ultimate aim of the interventions is to prevent obesity in African-American girls. As if to underscore the urgency of this research program, the alarming reports of the 1999–2000 National Health and Nutrition Examination Survey (NHANES) data on obesity trends in the US population^{2–4} were released just as this supplement went to press. The NHANES data updates show that the prevalence of obesity (body mass index [BMI] ≥ 30) in the US adult population, already considered to constitute an epidemic in the early 1990s, actually increased from 22.9% to 30.5% between 1990 and 1999–2000.² The problem of obesity in Black women worsened, with half (49.7%) of Black women ages 20 years and older classified as obese and 77% classified as either overweight or obese (BMI ≥ 25). Moreover, there are signs that the trend of increased obesity in Black women was particularly steep: an increase of 11.5% in Black women compared to 4.4% and 7.2%, respectively, in Mexican American and White women and increases of 7.0% in Black and White men and 5% in Mexican-American men. Class 3 obesity (BMI ≥ 40) occurred in 15.1% of Black women in 1999–2000, a prevalence that was three times greater than in White and Mexican-American women and an increase of 7.2 percentage points over the prevalence of Class 3

obesity in Black women in 1988–1994.² In the 1999–2000 Behavioral Risk Factor Surveillance System data, Class 3 obesity was especially common in Black women without a high school education.⁴

Unfortunately, the trends in children and adolescents were even more alarming than those in adults. Increases in overweight in children (≥ 95 th percentile of the sex-specific BMI-for-age growth charts) during the past decade have followed the steep trajectory seen between 1980 and 1990.³ The prevalence of overweight in females in 4 age groups between birth and 19 years was 11% to 15.5%, with a notably higher prevalence in Black females (approximately double that in White females) except in the 2 to 5 year age range. In girls, ages 6 to 11 years, (which includes the range targeted for obesity prevention in GEMS), the prevalence of overweight was 11.6%, 22.2%, and 19.6% in non-Hispanic White, non-Hispanic Black, and Mexican-American girls, respectively. Overweight prevalence increased by 10 percentage points in Black girls as well as Black boys.³

THE CHALLENGE

How does one approach research on a public health problem that is epidemic in character when existing evidence provides few definitive leads for an effective solution?^{5–7} The answer can only be that such research must be approached even more carefully than if the situation were less urgent, given the added importance of finding solutions that will work and the added complexity of conducting research while the situation is still unfold-

ing. In this vein, GEMS Phase 1 represented a groundbreaking effort by the National Heart, Lung, and Blood Institute (NHLBI) and cooperating investigators at 4 US universities to initiate a rigorous program of research on ways to curb the upward trends in obesity in a population that is at especially high risk of obesity development.¹

As described in the Introduction,¹ the 4 universities participating as field centers in GEMS were located in different regions of the country: University of Memphis in Memphis, Tennessee; Baylor College of Medicine in Houston, Texas; Stanford University in the East Palo Alto-Oakland, California area, and the University of Minnesota in Minneapolis. In the GEMS model, these field centers were involved in a unique collaboration together with the NHLBI Division of Epidemiology and Clinical Applications and a Coordinating Center based at George Washington University. The uniqueness of the collaborative model was that study-wide activities focused on the generation and sharing of ideas related to recruitment, formative assessment, and the standardization of some aspects of data collection while each field center designed and implemented a different intervention.⁸

The ultimate aim of GEMS is to evaluate relatively long-term (2 year) interventions on eating and physical activity attitudes and behaviors of pre-adolescent African-American girls and their parents or caregivers with the objective of preventing excessive weight gain during the pubertal transition. In Phase 1, formative assessment activities were conducted to guide and enhance intervention development, particularly with respect to cultural appropriateness. In pilot testing, several specific aspects of field center performance were targeted for evaluation: success in recruiting and engaging the targeted number of study participants, adequacy of intervention delivery, acceptability of the intervention to participants and staff, intervention adherence, and quality and com-

pleteness of data collected. While recognizing that changes in BMI would not be appropriate outcomes for preventive interventions lasting only a few months (differentiated from treatment studies in which the expectation of significant short term BMI changes would be reasonable), the NHLBI sought clear evidence, even in these short-term pilot studies, that key behaviors in the pathway to obesity prevention were favorably influenced by the interventions. In addition, although not an explicit objective, GEMS Phase 1 constituted an evaluation of the utility of this type of collaborative process itself in which investigators who were actually conducting separate projects work in a conjoint manner on certain aspects of planning and implementation with facilitation from an outside coordinating center.

The articles in this supplement⁹⁻¹⁴ provide detailed accounts of the rich experience that GEMS Phase 1 gained in addressing the several challenges outlined above. Following are some highlights of lessons learned during the process of generating these results.

WHAT DID WE LEARN?

In the “big picture” the GEMS Phase 1 outcomes can be categorized into those that are tangible, ie, the specific study results and decisions to progress (Memphis and Stanford) or not to progress (Baylor and Minnesota) to Phase 2, and the intangibles that did as much or more to enrich our thinking about what we were doing and how to go about it. With respect to the ability to recruit, retain, and collect data from pre-adolescent African-American girls and their parents/caregivers, these studies were—with one exception—a resounding success, even a model for what can be done when one takes the appropriate measures for reaching populations that are sometimes labeled as “hard-to-reach.” The one study that did not meet participation goals¹¹ had an intervention

approach that was different in many respects from the approaches at the other 3 centers. The Baylor approach involved a summer camp followed by Internet-based instruction and also, therefore, specifically targeted a higher income population than did the other 3 field centers. Given the difference in location as well as other variables among field centers, it is impossible to isolate the factors driving the Baylor results. However, the clear indication that more exploratory work is required to increase the likelihood of success with the Internet-based approach is in itself a very informative finding. Other overall lessons about recruitment and participation focused on the locality-specific nature of what works or even what can be attempted and to the extremely cost- and labor-intensive nature of this type of prevention research—perhaps over and above the costs associated with recruitment for studies to treat medical conditions that already exist.

The tangible results for behavior changes are summarized in Table 1, using a qualitative notation of + or – to indicate whether results observed during the 12-week period of pilot testing were in the expected or desired direction (using the baseline-adjusted follow-up difference in the treatment vs the control groups) or, in the case of weight concerns, in an adverse (–) or acceptable (+) direction. The intent here is to summarize rather than meta-analyze. The data underlying the results presented in the table can be found in the respective field center main results reports.¹¹⁻¹⁴ Simplistically, there are many more (about twice as many) plus signs vs minus signs in the table, suggesting that the majority of indicators assessed were favorably affected and had consistency across field centers. One set of findings that stands out is that changes in efficacy and expectations were opposite the desired direction in many cases. Improved self-efficacy and positive outcome expectancies are thought to be key mediators in the behavior change pro-

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Table 1. Directions of baseline-adjusted follow-up differences in the Treatment group compared to the Control Group†

	Baylor	Memphis Parent-Targeted	Memphis Child-Targeted	Minnesota	Stanford
Body composition					
Body mass index	-	+	+	-	+
Waist circumference	-	+	+	-	+
Physical activity					
Physical activity from noon–6 PM (CSA counts per minute)	+	+	+	+	+
Minutes of moderate-to-vigorous physical activity from noon–6 PM	-	+	+	+	+
Self-reported physical activity, GEMS Activity Questionnaire (GAQ)	+	+	+	+	+
Dietary intake					
Total energy intake per day (kcal)	+	+	+	+	-
Percent of energy from fat (%)	+	+	+	+	+
Fruit, juice and vegetable servings	+	+	+	-	
Sweetened beverages servings	+	+*	+	+	
Water servings	+	-	+	-	
Media use					
Girl's television, videotape and video game use					+
Total household television use					+*
Ate breakfast with the TV on					+
Ate dinner with the TV on					+*
Psychosocial variables					
Physical activity preferences	+	+	+*	+*	+
Sedentary activity preferences		-	+	+	
Physical activity self-concept		+	+	-	
Positive expectancies for physical activity		+	-	-	
Self-efficacy for physical activity		-	-	-	
Physical activity home environment				-	
Low-fat food practices		+	-		
High-fat food practices		+	-		
Sweetened beverage preference	+				
Self-efficacy for healthy eating				-	
Parent encouragement for healthy eating				+	
Healthy choice behavioral intentions				+*	
F&V snack availability				-	
Body image/Weight concerns					
Body shape dissatisfaction				+	+
Overconcern with weight and shape		+*	+*		+*
Weight concerns—unhealthy behaviors		+	+	-*	
Weight concerns—moderate behaviors		+	+	+*	

* Statistically significant treatment vs control difference at a level of $P < .05$.

† Empty cells indicate a construct not targeted by the intervention or not measured at that field center, or not reported. A plus sign (+) indicates a treatment minus control difference in the desired direction and a minus sign (-) indicates a difference opposite to the desired direction, except for Body image/Weight concerns where a plus sign (+) indicates an acceptable direction and a minus sign (-) indicates an adverse direction.

cess and amenable to improvement by interventions. Yet, it might be that self-efficacy, or the perception of one's self-efficacy, can actually decrease initially as a person gains a fuller appreciation for the difficulty of adhering to lifestyle change. This has important implications for the content and duration of interventions that will ultimately prove efficacious.

Less tangible than the objectively measured outcomes, but also important for success in obesity prevention research with African-American girls, were lessons about collaboration and cross-cultural interactions. Several aspects of the development and conduct of these studies underscored and expanded our understanding of the importance of trust and openness when working cross-

culturally and across social-class lines. The need for trust and openness among investigators became important as we struggled to learn about and address cultural and contextual issues.⁹ The need to establish trust with community representatives as well as parents was evident during the recruitment planning and implementation process.⁸ Also, with respect to openness, we learned that the

need for “double consciousness” in the African-American community (ie, participating in society from both African-American and mainstream perspectives that are both valid but not necessarily congruent) may mean that responses in focus groups or interviews reflect only some of the relevant attitudes about a particular issue.⁹

From a reality-testing perspective, there may be no better teacher of acceptable research practices applicable to African-American girls than the parents of the girls. Whether or not parents were the focus of the intervention, all that we were able to accomplish or not accomplish was mediated through the willingness of the parents to become engaged in the intervention in order to facilitate their daughters’ participation. In particular, eligibility criteria, comparison group conditions, or logistics that seem unfair, inadequate, or too burdensome to parents were or could be problematic, if not in a small, short-term study then clearly in a longer term study. In considering Phase 2, even the things that worked in the pilot study were scrutinized for how they worked, in order not to miss cues or take too much for granted about what would be required for full and sustained participation.

NEXT STEPS

While the public health community goes forward to take the best available actions to curb the epidemic of childhood obesity based on what is already known,¹⁵ we must recognize that the evidence base for obesity *prevention* is small and, for some age-, ethnic-, or socioeconomic status groups is non-existent.²⁻⁴ Clearly there are things that

need to be done and done right away based on common sense,¹⁶ but how to do them—particularly when having to keep pace with an ever changing and increasingly complex food and physical activity landscape—is currently educated guesswork.

Given a problem of this magnitude, GEMS is a small but important step. As we face the current dismal statistics about the recent increasing trends, it is particularly rewarding that GEMS is already underway, so that we can now expect at least some initial answers within a few years. Two field centers have already begun to test promising interventions in full-scale randomized trials, and the two other field centers are mining the rich Phase 1 data base for insights from which to formulate new strategies.

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