SUMMARY REPORT

Site Specific Approaches

Prevention or Management of Pediatric Obesity

July 14-15, 2004

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Sponsors

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PREFACE

The Workshop on Site Specific Approaches to the Prevention or Management of Pediatric Obesity was held on July 14-15, 2004, in Bethesda, Maryland. The following report summarizes the presentations and discussions from this workshop. The workshop program booklet is a companion document available on the NIH website (http://www.niddk.nih.gov/fund/other/management_pediatric_obesity/Abstract.pdf); slide presentations for many of the speakers complement information presented here and may be accessed at http://www.niddk.nih.gov/fund/other/conferences-arch.htm.

Pediatric obesity continues to be recognized as a widespread problem of public health importance. The reflections presented at this workshop on lessons learned from completed studies, emerging lessons from ongoing studies, or studies currently in the formative/developmental stages are instructional for future directions in site-based research for the prevention of overweight and obesity in childhood.

Major research trials reviewed include interventions targeting high-risk groups of Hispanic, Native-American, and African-American children who tend to be disproportionately affected by obesity. Across various studies discussed, among issues highlighted were the merits of tailored behavioral change intervention strategies that are developmentally and culturally appropriate and the value of local advocates or champions to support, promote, and sustain the intervention.

Enhanced home/family and community involvement for obesity prevention was a recurring theme, with emphasis on the influence and potential of parents as role models for appropriate dietary intake and physical activity behaviors. Participants discussed novel uses of media, the Internet, and community-based participatory research and lessons that may be learned from other areas such as drug use prevention and smoking cessation research.

Suggested areas for future research directions and priority areas for prevention of inappropriate weight gain in children were discussed at some length. Among the areas identified are the needs for the following:

- Objective physiological and biological outcome measures.
- Smaller scale innovative studies (pilots) and efficacy studies with longer follow-up.
- Prevention interventions that begin at younger (pre-school) ages.
- Multi-site/trans-site study design.
- Progressive environmental change combined with the need to sequence so environmental change can facilitate behavioral change.
- Approaches to improve recruitment, retention, and involvement of families.
- Formative research that includes community involvement and readiness.
- More intensive interventions (including more vigorous physical activity).

In aggregate, the presentations and discussions summarized here suggest there are opportunities and needs for additional research in various sites where children and adolescents spend time, including the school, home, faith-based sites, preschool childcare centers, and various other community access points.

Lessons learned from this workshop were subsequently considered in the development of a trans-NIH initiative led by the National Institute for Diabetes and Digestive and Kidney Diseases. A request for applications (RFA-DK-04-013) invited grant applications for research interventions to be conducted with children and adolescents. The receipt date for these applications was January 24, 2005 (see http://grants2.nih.gov/grants/guide/rfa-files/RFA-DK-04-013.html).

On behalf of the workshop planners and sponsors, I am grateful to the invited speakers and participants who shared their analyses and provided a very insightful and enthusiastic discussion. It is a pleasure to be able to share this information with a broader audience in the hope that it will stimulate new thoughts and help generate additional meritorious research proposals.

Robert Kuczmarski, DrPH
Director
Obesity Prevention and Treatment Program
National Institute of Diabetes and
Digestive and Kidney Diseases
National Institutes of Health

SUMMARY REPORT

Welcome and Introduction to the Workshop
Robert Kuczmarski, DrPH, *Director, Obesity Prevention and Treatment Program, Division of Digestive Diseases and Nutrition (DDDN), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), Bethesda, MD*

Dr. Kuczmarski convened the workshop by first expressing his appreciation for their support and planning of this meeting to the Chair and Planning Committee member, Dr. Ken Resnicow, University of Michigan School of Public Health; to Dr. Wendy Johnson-Taylor, Division of Nutrition Research Coordination, NIH, and Dr. Barbara Linder, Division of Diabetes, Endocrinology, and Metabolic Diseases (DDEM), NIDDK, both members of the Planning Committee.

Dr. Kuczmarski also expressed his appreciation to the other members of the Planning Committee (Dr. Gilman Grave, National Institute of Child Health and Human Development (NICHD); Ms. Robin Hamre, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC); Dr. Lynne Haverkos, NICHD; Dr. Van Hubbard, Division of Nutrition Research Coordination, NIH, and NIDDK; Dr. Linda Nebeling, National Cancer Institute (NCI); Dr. Charlotte Pratt, National Heart, Lung, and Blood Institute (NHLBI); Dr. Martina Vogel-Taylor, Office of Disease Prevention, Office of the Director, NIH; and Dr. Susan Yanovski, DDDN, NIDDK). Dr. Kuczmarski thanked the many NIH offices, centers, and institutes and the CDC for co-sponsoring this meeting and the speakers and attendees who had made time in their busy schedules to participate in this important discussion. In addition to the groups represented by Planning Committee members, other sponsors were the Office of Behavioral and Social Sciences Research (OBSSR), Office of the Director, NIH, and the U.S. Department of Health and Human Services (DHHS), the Federal Department under which the other groups are organized.

Leading up to this workshop were a series of meetings including the following:

- March 2004, a research roundtable on **policy and environmental influences** on young children's eating and obesity: building the evidence base; sponsored by the Robert Wood Johnson foundation (RWJF), addressed eating and weight patterns, with a focus on food environments to promote healthy choices.
- May 2004, a meeting on national evaluation and measurement of school monitoring and physical activity; sponsored by RWJF, examined efforts to evaluate **school policies** on food and soda sales and physical activity standards.
- May 24-26, 2004, a national workshop on Obesity and the Built Environment: Improving Public Health Through Community Design; sponsored by National Institute of Environmental Health Sciences (NIEHS), NIH; addressed **built environments** and access to food and physical activity and influence on obesity.
- June 2004, a meeting on **clinical health care strategies** to address childhood obesity, with emphasis on ethnically diverse, low-income communities; sponsored by RWJF.
- June 22-23, 2004, a workshop on Modifiable Environmental and Behavioral Determinants of Overweight Among Children and Adolescents; sponsored by NIDDK, focusing on how to design studies to measure **exposures** to these **determinants**.

Dr. Kuczmarski noted that Dr. Terry Bazzarre is the RWJF representative and can supply information from these meetings.

Purpose and Goals of Workshop. Dr. Kuczmarski stated that the current workshop would differ from these earlier meetings. For this workshop, the purpose was to provide a forum for experts to focus on and discuss state-of-the-art **prevention or management intervention approaches**, looking at future research needs and opportunities, innovative research and novel ideas, lessons learned from other areas, and potential combinations of sites or modalities. All together, these meetings are intended to assemble the elements involved in addressing the problem of the obesity epidemic in children and youth.

This workshop will further inform the NIH Strategic Plan for Obesity Research (http://www.obesityresearch.nih.gov) and assist in the development of an FY 2005 trans-NIH Request for Application (RFA) initiative. Dr. Kuczmarski explained that the primary target audience of this workshop is the NIH staff members present who will author and recommend funding for future initiatives resulting from the presentations, discussions, and summary report.

Site Definitions. Basically sites, according to Dr. Kuczmarski, are places where children and adolescents spend the majority of their time and/or where they can be reached for prevention or management interventions. The Surgeon General's Call to Action identified five key settings: families and communities, schools, health care settings, media and communications, and worksites. The first three—families, communities, and schools—seem to be natural sites for interventions because they are where children spend a lot of time. Although health care sites are another possibility, Dr. Kuczmarski explained that NIH already has a dedicated initiative for the primary care setting (http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-04-020.html), and thus would not focus on this site in the workshop. Media and communications are sites that hopefully can be used better, and even though most children do not spend time at worksites, their parents do and mechanisms can be developed to reach the children through the parents. (Please see abstract book, page 21, for further definitions of sites, at http://www.niddk.nih.gov/fund/other/management_pediatric_obesity/Abstract.pdf).

Realizations. Dr. Kuczmarski said that individual workshops and even individual funding initiatives could have been sponsored for each of these sites, but he realized that, given the known challenges of the macro-environment, continuing to emphasize research in isolation in the micro-environments was not reasonable. For example, NIH has substantially funded school-based studies that have affected knowledge and behaviors, to some extent, but have not had a large, significant impact on the intended outcomes or endpoints of body mass index (BMI), body weight, body composition, and so forth. Dr. Kuczmarski suggested that thus there are opportunities for trans-site approaches to integrate and reinforce interventions in schools by involving the gatekeepers at home and in the broader community.

Secondly, because overweight has a multi-factorial etiology, single intervention strategies cannot be expected to affect outcomes or research endpoints in more than a portion of responsive people in the group exposed to a particular intervention. One size may never fit all. Third, Dr. Kuczmarski recommended cross-disciplinary research using interdisciplinary approaches to enhance synergism across sites. His fourth realization was that much can be learned from approaches used by other disciplines, from interven-

tions for other health conditions such as smoking cessation and drug abuse, and from novel community programs currently being developed.

Fifth, perhaps more pilot studies are needed to obtain better efficacy data in order to ensure that the time is right to design approaches for larger trials for validation of the effectiveness of an intervention. Pilot studies also allow for exploration of more innovative and novel approaches. They tend to be lower cost so more trials can be done, enabling a higher throughput. Pilot studies also can have a higher impact and reward because greater risks may be taken to try different approaches. Sixth, for children, the focus must be on prevention or there will continue to be successive generations of overweight and obese adults. Dr. Kuczmarski said that treatment cannot be ignored, of course, but it generally does not occur to an appreciable extent outside of the primary care setting. Control and management, however, can be a part of research in the non-primary care sites, and thus this wording was chosen for the workshop's topic.

Dr. Kuczmarski noted that this would be a fast-paced meeting for which the speakers were asked to emphasize the most important messages they wished the group to take home. Sampling designs and so forth of the individual studies would not be mentioned in detail. The goal was to review the studies to identify remaining research challenges, opportunities, and future directions. The speakers would be emphasizing elements of successful interventions and recommending promising approaches to be developed, and they would also note approaches that in their opinion perhaps should not be encouraged further. They would be asked to describe translation barriers, requirements for long-term post-intervention maintenance, and constraints to prevention or management interventions. Speakers would be recommending other disciplines that need to be involved. They also would be highlighting the influences of childhood eating disorders and psychosocial dysfunction; the roles played by parents, guardians, peers, mentors, and role models; the part played by integrated cross-site research, social marketing, and elements of community-based participatory research (CBPR); and the role of change in an individual, change in a site, and synergy of these two domains.

The second day of the workshop would be devoted primarily to a general discussion based on a set of guiding questions and reactions to the first day's presentations. Dr. Kuczmarski concluded by introducing Dr. Ken Resnicow, the Workshop Chair.

Ken Resnicow, PhD, *Workshop Chair and Professor, Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, MI.*

Dr. Resnicow welcomed what he termed the "all star cast" in health promotion expertise. As Dr. Kuczmarski had said, previous meetings, at which most of those present had been speakers or attendees, had looked at the problem of childhood obesity from the viewpoints of theory, intervention approaches, and so forth. Today, the focus would be on sites. Some of the speakers were invited because they had conducted definitive clinical trials in a specific site or for a specific behavior. Some of these trial results were less encouraging than the investigators had hoped. Dr. Resnicow stressed that although one can always conclude more research is needed, or if only this or that had been done the expected effects would have occurred, the goal of the workshop was to open up our thinking and consider new ideas and approaches. Dr. Resnicow added that some people were invited because they are not currently a part of the obesity research field. For example, Dr. Pentz,

University of Southern California, has conducted innovative work outside of diet and physical activity, on substance use, in particular. She will contribute expertise and lessons learned from other areas.

Dr. Resnicow asked the group to keep in mind the question, "What benefit can be derived for science, for investigators, possibly for any age, in this framework of site?" As part of this question, he asked that they think about the differences and relevance between cluster randomization versus individual randomization within a site. How does the site affect design issues such as power and data analysis, intervention modality, and outcomes? Dr. Resnicow reminded the group that their answers to these questions and others that would be discussed were key to the workshop's intended goals of NIH-funded studies through RFAs, a trans-NIH initiative, and perhaps a publication.

SESSION 1

School Based Intervention Studies

SESSION 1: School Based Intervention Studies

Moderator: Howell Wechsler, EdD, MPH, *Acting Director, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, GA*

Dr. Wechsler opened the session on school-based sites by noting that children spend more than 1,000 hours a year for at least 12 years of their lives in school.

CATCH: A Coordinated Approach to Child Health
Larry S. Webber, PhD, *Professor, Department of Biostatistics, Tulane University School of Public Health and Tropical Medicine, New Orleans, LA*

Dr. Webber explained that about 20 years ago, NHLBI took the bold step of requesting applications to deliver, implement, and evaluate school-based health education programs specifically targeted at cardiovascular risk factors in children. The resulting program was originally entitled the Child and Adolescent Trial for Cardiovascular Health (CATCH). After the trial ended, the name was changed as part of the dissemination phase of this intervention. Since it seemed important to keep the CATCH logo, CATCH became a Coordinated Approach to Child Health. Although CATCH was not specifically targeted to reduce obesity, Dr. Webber stressed that schools remain a logical choice for influencing healthful behaviors in children. The school is an important social institution with a great deal of influence on the behavior patterns and lifestyles of children.

CATCH is a school health education program designed to prevent sedentary behaviors, poor dietary choices, and tobacco use through environmental and individual changes in elementary schools. CATCH had a small, not statistically significant or meaningful effect on its original intention to change serum cholesterol levels; however, the program was very successful in working with change in both the institution's environment and in individual behaviors related to developing healthy lifestyle choices.

Dr. Webber noted that when CATCH was originally designed in the mid-1980s, risk factors for type 2 diabetes were not a concern. Today this is an important rationale for designing school-based intervention and prevention programs for children. The original rationale for the program was the high prevalence of cardiovascular disease (CVD), its early onset among adults, and the potential for modifying lifestyle-related risk factors in children to prevent CVD in adulthood. The CATCH trial was the first large, multi-center trial to integrate the school, the child, and the family, using ethnically diverse populations in four different areas of the United States (California, Louisiana, Minnesota, and Texas). School was the unit of randomization, which was another unique feature in designing trials more than 20 years ago. It was subsequently learned that the school presents a number of design issues related to power and sample size and identification of different sources of variation that make the evaluation of these trials complicated. Dr. Webber added that, however, an important feature of the CATCH program was that due to the longevity of the study, the investigators were able to implement and evaluate multiple phases of the trial and bring the trial to its logical conclusion. He stressed that this longevity is needed to fully evaluate a school-based health education program; a 2-year trial duration is not long enough.

Components of Original CATCH Study.
Dr. Webber briefly reviewed the original CATCH study. The CATCH intervention consisted of four

logical components for a school environment: classroom curriculum, physical education (PE), school food service, and the family. The CATCH trial began in 1987, with a long pilot and feasibility study, in which the parameters to be measured were designed and the interventions developed. The main trial, in which 96 schools were randomized to three different treatment arms, ran from 1991-1994, with a tracking and follow-up period of 3 years after the intervention ended (1994-1997). In the follow-up, risk factors were measured in children and variables and risk behaviors in children were assessed to learn what the long-term implications of the trial were. From 1998-2000, the CATCH schools were evaluated against 12 unexposed schools to determine what parts of the CATCH trial were retained by the schools 5 years after the intervention ended. Finally, a very long-term follow-up on homocysteine and diet parameters, as well as physical activity behavior, was conducted from 2000-2002 to evaluate the original third-grade students in the CATCH trial who were then seniors in high school.

The CATCH physical education component involved participation in PE, if not daily, multiple times a week. Creating an enjoyable, active environment was an important target. The goal was for there to be moderate to vigorous physical activity about 50 percent of class time. New equipment and new games were provided to give students as many choices as possible.

The classroom curriculum was experiential and hands-on. It required a great deal of training of the schoolteachers and on-site help. Dr. Webber said that another important lesson learned was that teachers were not going to pick up and implement an unfamiliar curriculum. CATCH was designed as a longitudinal cohort study, following a group of children over time. A concern identified early on was that 1 year of experience with each teacher in each grade was inadequate to enable a teacher to feel comfortable with the curriculum. Now the curriculum is well developed, published, and focuses on areas expected to make it enjoyable for the students.

The family program had two components. One was activities developed for the child and parent or guardian to do together at home in order to integrate the parents or guardians into what the children were learning in the classroom. The second component was school health fairs, which were called family fun nights. Parents and children came to school and participated in healthy eating and physical activities.

Dr. Webber stated that the fourth component of CATCH, the Eat Smart School Food Service Program, was, in some ways, a big success. It was also the most difficult component to implement. The food service workers had 30 years' experience cooking foods in school. Getting them to change their cooking and purchasing techniques was a challenge. The goal was to provide children with lower overall fat, lower saturated fat, and lower sodium meals, while still meeting U.S. Department of Agriculture (USDA) guidelines for essential nutrients and maintaining student participation. School system cafeterias are reimbursed based on the number of students who purchase the school lunch, so student participation is critical. Part of the complexity was that implementing Eat Smart involved the district level, because the district negotiated the contracts and did a lot of the purchasing; the school cafeteria manager level, because this person coordinated how foods were prepared in the cafeteria; and the individual cooks and servers level, because they had to help promote the selection of the healthier products. The Eat Smart program also required a great deal of training and time. It was developed by setting small targets from

the 32 Eat Smart guidelines. The cafeteria was asked to implement the guidelines one or two at a time. Dr. Webber stressed that, as with the school curriculum, a 1-year program would have been insufficient. CATCH fortunately had 3 years to work with the cafeteria people.

Results of Original CATCH Study. Reviewing the CATCH program's successes, Dr. Webber pointed out that in the PE classes, there was a clear difference in the increased percent of time devoted to moderate to vigorous physical activities (MVPA) in the intervention schools versus the control schools. Individually, by fifth grade (baseline was third grade) children in the intervention schools were reporting more minutes of vigorous activity. By eighth grade, 3 years after the active intervention ended and after the children left the elementary schools and moved on to middle schools, there was a slight diminishing in this difference, but it was still statistically significant. At baseline, dietary fat intake was well above the recommended 30 percent of calories from fat and there were no differences between the groups. By the end of the active intervention phase, there was a clear difference and by the end of eighth grade, 3 years after the intervention ended, even though the difference diminished, it was still statistically significant.

Dr. Webber said that institutionalization proved to be very difficult. Five years after the intervention ended, interviews with teachers, physical education specialists, and cafeteria workers showed there were some residual effects from the CATCH program. Approximately a third to a half of the schools still had some remnants of the CATCH program in place.

Overall, Dr. Webber pointed out that as an intervention CATCH reduced fat and saturated fat in school lunches, increased moderate to vigorous activity, improved individual students' behavior, and, most importantly, demonstrated that these effects persisted over 3 years even though there was no continued active intervention (Luepker RV et al. 1996. JAMA 275(10):768-776; Nader PR et al. 1999. Archives of Pediatrics & Adolescent Medicine 153(7):695-704).

CATCH as a Dissemination Model. Dr. Webber stated that, as a dissemination model, CATCH is significant because it has been possible to take the research and use the interventions in other schools. The Department of Defense Education Association has implemented CATCH in schools overseas. CATCH has been integrated with the Hearts N' Parks program. There are State-wide initiatives in several States, with Texas taking the lead here. About 4,000 schools nationally are implementing some parts of the CATCH program. In Louisiana, the Rapides Foundation, a private foundation, funded a very specific CATCH dissemination in six schools. At the end of 3 years, there was an increase in moderate to vigorous physical activity in PE class and a reduction in the percentage of calories from fat through the school food service. All of the CATCH materials have been modified and updated to use 21st Century themes and are available from a national distributor.

In explaining why CATCH was adopted by schools after the research phase, Dr. Webber stressed that it was because CATCH was well studied and well documented—an important factor in presenting the results from any future studies. It was compatible with the school environment. Almost all elementary schools have physical education, food service, and health education guidelines. In general, it was not complex. It was an add-on, a modification, rather than a replacement of what already existed in the schools. It was not expensive. Finally, there was an early impact of the intervention, particularly in physical education class, and that is important to schools.

Lessons Learned. Lessons learned, according to Dr. Webber, included that institutionalization is difficult. Compliance over time was less than what the study investigators had desired, possibly because the intervention and training phases were not long enough. There was somewhat better compliance in the school cafeteria over time, so training the managers and the food service workers had a more lasting effect. This was probably due to the fact that these personnel do not change schools as frequently as teachers do. For a program to be institutionalized, it has to be cooperative, collaborative, and fit in with the school, the school district environment, and what the national norms are.

Another difficulty was maintenance of the classroom curriculum because teacher transfer is high and accountability has changed since the middle 1980s. Schools are highly accountable now for standardized test scores, rankings, and national norms, and this requirement has precedence over health education. Teachers, concerned with academic subjects, lack time for a new curriculum. Fortunately, the popular CATCH Activity Box for PE class is easy to use. It has gone through extensive developmental periods and is adaptable for use by a classroom teacher if a PE specialist is not available.

Based on his experiences with CATCH, Dr. Webber presented the following recommendations:

- Training is essential. There was never enough training time for school personnel.
- Materials and strategies need to be developed to allow school districts to take over training.
- District-level personnel must be identified as champions and trained in order to maintain programs within schools. There has to be a champion at the district level who wants to continue these projects if the intervention is going to have an impact school-wide.
- Schools must devote resources for regular staff development in health education programs, and such programs must become a priority as part of an important national health agenda.
- Research studies must be long enough to prepare for and encourage institutionalization. A primary reason for the success of the CATCH trial was that the process could be studied over almost a 10-year period.

SPARK Programs for Physical Activity Promotion
James F. Sallis, PhD, *Professor, Department of Psychology, San Diego State University, CA*

Dr. Sallis presented information on two studies: SPARK (Sports, Play, and Active Recreation for Kids) and M-SPAN (Middle School Physical Activity and Nutrition). Dr. Sallis said that SPARK, an elementary physical education program, complements CATCH in several ways. SPARK was a much smaller study of seven schools randomly assigned to three conditions and with a focus on physical education in order to evaluate this factor closely. One arm was usual PE taught by classroom teachers, which is common around the country in elementary schools. A second arm involved training classroom teachers to implement an active curriculum, and a third was assessing how well the curriculum worked if implemented optimally by physical education specialists. The program was delivered in the fourth and fifth grades to approximately 2,000 students.

The 30-minute PE class was designed to teach children skills and enhance motivation to seek out and engage in physical activity. The class time was divided into two segments. The first part was health-related

fitness activities that could be done by one or two people after school with a minimum of equipment such as a jump rope. The students were taught to distract themselves with mental games while they walked and jogged so as not to become bored. The second part of the class was skill-related activities such as age-appropriate team sports that were modified to make them more active, to include all the children, and to make the sports more fun for everyone, not just the physically adept. There also were weekly classroom-based self-management health-education workshops to promote physical activity out of school and after the program. Dr. Sallis explained that a detailed curriculum for the teachers and a scripted teacher guide was used in the study and in the dissemination phase. Staff development was provided and there was on-site consultation and follow-up, critical components for adherence to the program.

SPARK Evaluation Results. To ensure that children actually enjoyed the SPARK lessons, 13,000 evaluations of different lessons were done. Dr. Sallis said the conclusion was that the students liked the activities. Through direct observation, it was shown that quality of instruction was improved. The teacher was actively instructing, demonstrating, or promoting activity 40 percent of the class time in the control group, 60 percent in the group of trained teachers, and 80 percent in the PE specialists group. Dr. Sallis explained that California guidelines call for spending 100 minutes a week in PE, but the control group was spending only 30 minutes a week. After teachers were trained and felt comfortable teaching PE, they increased the total to 65 minutes per week. The PE specialists achieved 80 minutes per week and doubled the amount of time spent in moderate to vigorous physical activity. Dr. Sallis stressed that although specialists always do the best, the trained classroom teachers did far better than the untrained teachers. He added that PE should be optimized but other strategies also are needed because even given the best case, PE class will never provide the total amount of physical activity that children require.

Dr. Sallis provided data showing that SPARK also provided for overall gain in skill improvement (22.7% in the PE specialist group and 18.1% in the trained teacher group versus 12.6% in the control group). The study investigators believed that as the children became more active, they would also be getting fitter. From the fall to the spring of 4th grade, the girls ran the mile-run in fewer seconds, again with the PE specialist group doing the best. Over the summer when they had 6 extra hours a day in which to be active, girls in all the groups slipped back, a trend that Dr. Sallis felt warranted further study. In the fifth grade, they improved again. Data on boys and sit-ups over a 2-year period followed a similar pattern.

Interestingly, on the critical issue of the importance of standardized testing and the time devoted preparing for these tests that Dr. Webber had mentioned, test scores collected in the SPARK study showed that even though the SPARK students were spending much more time in PE class, in many cases they performed better on academic achievement tests. This was especially true for the students in the trained classroom teachers group. They did significantly better than controls in three out of eight comparisons.

Dr. Sallis said that process evaluation of the self-management component showed there was no overall effect on physical activity outside of school, but only about 65 percent of the self-management lesson components were implemented. Student participation in self-management, based on points earned for physical activity, was related positively to BMI changes in the boys.

SPARK Sustainability Studies. The International Life Sciences Institute and the Childhood Obesity Prevention Initiative conducted a sustainability study of SPARK in the dissemination phase. Approximately 300 schools had been trained in the intervention for more than 1 year prior to the mail survey conducted independently at the University of South Carolina. Dr. Sallis said that of the teachers in the 111 schools that completed the survey, almost 80 percent reported using SPARK currently, 75 percent had used it more than 2 years, and approximately 52 percent of the schools reported that at least half of the teachers in their classes were using SPARK. Trained classroom teachers continued to use SPARK up to 4 years later. Dr. Sallis pointed out that ensuring adequate equipment and principal support and promoting teacher physical activity may enhance sustainability of health-related PE programs such as SPARK.

M-SPAN and the School Environment. Moving on to M-SPAN, Dr. Sallis explained that the aim of this study was to determine what could be achieved by only changing the school environment—the least studied component of school health. There was no curriculum included in this intervention to increase students' energy expenditure (kcal/kg) at school and decrease fat intake and maintain the changes post-intervention. He noted that Dr. John Elder and Dr. Thom McKenzie, also of San Diego State University, were co-Principal Investigators (PIs) on this study.

Dr. Sallis said he would primarily address the physical activity component of the study. M-SPAN was an ecological approach, meaning the study was intended to identify the times and places for physical activity at school, to identify policies that hinder and facilitate activity, and to provide social and physical resources that, in essence, would create more opportunities for physical activity at school, changing the school environment. Twenty-four middle schools, grades six to eight, from nine school districts were randomized. Student populations were very diverse. Forty-three percent of students were ethnic minorities, 39 percent received free or low-cost meals at school, and 36 percent arrived by bus. Five training sessions for physical educators were conducted over 2 years to help the teachers become more efficient in providing physical activity. Overall, there was a 20 percent increase in physical activity in PE classes without changing the frequency or duration of classes. Although boys were more active to begin with, there was an effect size of 0.98 in increased moderate to vigorous physical activity for boys in the intervention schools versus the 12 control schools. The effects were less dramatic for girls but the controls changed very little.

Policy Change Goals. A key goal of M-SPAN was to facilitate policy changes promoting physical activity throughout the day, not just in PE class, but especially after lunch and after school. School committees met to plan policy changes such as improving the playing fields, opening play areas to students instead of prohibiting students from going to the play areas, assigning faculty to supervise student activity, and expanding the lunch period to allow time for eating and activity. Volunteers were recruited to come to school and supervise activity. Policy goals were shared with other schools through a newsletter.

Dr. Sallis explained that the study was assessed through direct observation, a method named SOPLAY. Although the effect size was modest and not statistically significant, the intervention had the desired effect of increasing activity at school for both boys and girls. For an unknown reason, the controls also increased physical activity during this period. In studying why the intervention was not more effective, the investigators looked at the relationship

between changes in student activity levels and levels of supervision of, for example, after school and after lunch periods. They found a correlation of 0.43 (i.e., when supervision increased, so did physical activity). The problem was that in 4 of the 12 intervention schools, there was a decline in supervision. There were practical barriers to bringing in volunteers to do this supervision at some schools.

Nutrition and the Environment. Dr. Sallis briefly reviewed the nutrition component of M-SPAN. The intended environmental change of reducing fat content of foods in all food sources at the schools was not accomplished. Major barriers were money-related. Food service is self-supporting, so there was a disincentive to try new foods. In addition, there is a very low reimbursement for school lunches, which limits opportunities for trying new things or improving the quality of foods. Then, of course, there is nothing easier than selling sugar and fat to children.

Lessons Learned from M-SPAN and SPARK. Overall, Dr. Sallis found from M-SPAN that health-related PE interventions can be effective in secondary schools. Programs to increase physical activity throughout the school also can be effective, but implementation difficulties must be overcome. Dr. Sallis' group is now disseminating the SPARK elementary program and the M-SPAN program for physical education and active recreation outside of PE class.

Dr. Sallis pointed out that the CDC Community Guide recommends enhancing active physical activity in PE. He listed several continuing challenges to carrying out that recommendation. First, funding and incentives for evidence-based physical education are needed with the goal of diffusion. Obtaining acceptance and use of classroom behavior change curricula by teachers is difficult, but critical. For example, the SPARK self-management curriculum was very structured, but teachers did not understand behavior change. They thought that not teaching facts was a waste of time and thought it unbelievably repetitive to set goals more than once. A big issue was that they did not understand the importance of setting weekly goals. Finally, a great deal of time and effort is required to change school policies. The M-SPAN intervention was 2 years, and investigators felt they were just getting started when the study ended.

Planet Health

Karen Peterson, DSc, *Associate Professor, Department of Society, Human Development, and Health, Harvard School of Public Health, Boston, MA*

Dr. Peterson recommended that, in thinking about prevention and control of overweight and obesity, the prevention paradigm be expanded from the traditional classification framework of prevention as primary, secondary, and tertiary with a clinical outcome. She suggested that the alternative classification framework of the WHO (World Health Organization) approach that focuses on level of intervention was more appropriate because obesity is a chronic and multi-factorial condition (WHO. 2000. WHO Technical Report Series No. 894. Geneva: WHO).

WHO Framework. Briefly summarizing the WHO approach, Dr. Peterson explained that there are three levels of intervention: the universal or public health level, the selective prevention level, and the targeted prevention level. At the universal or public health level of prevention, the focus is on the population at large and the sociocultural and physical environment. For obesity, the aim would be to reduce mean BMI and decrease incidence and prevalence. This is a very cost-effective approach when prevalence is high,

which it appears it is or will be very shortly. Dr. Peterson said that the selective prevention level is the level most consonant with the workshop. At this level, high-risk groups are identified by age or life-stage or other risk-factor characteristics (e.g., genetics, socio-demographic, and so forth) and the focus is to develop successful and sustainable programs and policies that ultimately change outcomes, such as BMI curves, in the high-risk populations in such settings as schools, worksites, and clinics. The targeted prevention level focuses on management protocols.

Overview of Planet Health. In securing funding for Planet Health from NICHD, Dr. Peterson said that the investigators had to repeatedly go back to the school systems and talk with the teachers, which may have provided a number of advantages in developing their intervention model. Middle school students (6th-8th grades) were selected as the subjects for Planet Health based on prior experience with DASH (Dietary Approaches to Stop Hypertension) that indicated self-reports were unreliable in children below the sixth grade. Another reason for the choice was that this would be the last time to work with children before they entered high school. Ten ethnically diverse public schools were matched and randomly assigned as intervention and control groups (5 intervention schools and 5 control (delayed intervention) schools). Obesity was defined as a BMI and triceps skinfold over the 85th percentile. Planet Health began in the Fall of 1995 and ran through the Spring of 1997.

Interdisciplinary Curriculum. Dr. Peterson stated that an aspect of Planet Health that is unique and contributed to its success is its interdisciplinary curriculum that was incorporated into the existing school structure and core curricula. In the preliminary conversations with teachers in the school systems, investigators learned that nobody wanted to displace the current health curriculum; thus, the Planet Health interdisciplinary curriculum evolved. This curriculum incorporated four basic health messages into four different subjects (math, science, language arts, and social studies) and was taught by regular classroom teachers. PE teachers taught micro-units (5-minute units) that focused on activity and inactivity. A major advantage of the interdisciplinary curriculum was that it was designed to meet the curriculum frameworks required by the departments of education.

The behavioral messages were targeted to reduce TV viewing to less than 2 hours per day, increase moderate and vigorous activity, increase consumption of fruits and vegetables to five or more per day, and decrease consumption of foods high in fat and, especially, saturated fat. The targets were based on Healthy People 2010 objectives and guidance from DASH that focused on both sides of the energy balance equation.

Dr. Peterson stressed that what definitely worked in Planet Health was that the students repeatedly were exposed to the four basic messages. In the intervention schools, there were 16 lessons scheduled in each of 2 years for a total of 32 lessons. Thus students heard each of the four messages four times a year. For example, in algebra they heard about eating fruits and vegetables, then they heard about saturated fat, then they graphed their TV viewing, and so forth. Assessments demonstrated that, on the average, approximately 80 percent of those lessons were delivered. Dr. Peterson emphasized that Planet Health was a very feasible model in terms of support of teachers. Teachers attended four training workshops taking up only 2 hours a year and received three wellness sessions donated by the community. Some on-line training was also available.

Dr. Peterson said that weight status per se was not included in the curriculum, a decision that may be a factor in what works and what may not work about Planet Health. The concern, at the time (mid-1990s when prevalence was lower), was about safety. It was thought that discussing weight status would raise a lot of questions and possibly engender disordered eating behaviors.

Results. At the end of the 2 school years, the odds ratio for girls in intervention schools was 0.48 for reduction in obesity (Gortmaker et al. 1999. Arch Pediatr Adolesc Med 153:409-418). However, remission odds also were greater in girls (2.4). Boys' and girls' TV viewing was reduced by about half an hour per day on the average. In analyses of what behaviors might have mediated the effect, it was found that television viewing had an independent association and attenuated the overall intervention impact in girls. Girls also increased their dietary intake of fruits and vegetables.

Dr. Peterson asked if researchers have the luxury of designing interventions that are specific for certain racial/ethnic groups or, in some settings, must interventions always be responsive to a multicultural group. For example, in Planet Health, there was a much greater reduction in the odds of obesity among African-American girls, which might suggest the intervention should target this group in a dissemination phase.

In another analysis of Planet Health, the one ineffective intervention site was dropped in calculating results. The study then showed an odds ratio of 0.31 for the intervention's effect on girls and a borderline effect on boys.

Dr. Peterson said that several papers have been written on the Planet Health cohort. One such paper examined how the intervention's effect on TV viewing might change other variables such as fruit and vegetable consumption (Thomas TN et al. 2003 APHA Annual Meeting A#70572). The presentation suggested that reduced exposure to television viewing may result in reduced exposure to other things on TV and this might cause children to choose more healthy foods.

As mentioned earlier, there was a concern about safety in Planet Health. A recent analysis showed that girls in the intervention group who did not report maladaptive weight control practices (i.e., vomiting, laxatives, diet pills) at baseline, when followed over time, were half as likely as girls in the control group to adopt those methods (Austin B et al. 2004. Submitted). Dr. Peterson said the study group is embarking on some qualitative research to investigate why this difference might have happened.

Replication and Dissemination Phases. Planet Health has about a 15-year timeline from 1992 to the end of its current dissemination phase in 2007. From publication of the efficacy results to the adoption of Planet Health by Blue Cross/Blue Shield (BCBS) in Massachusetts took 5 years (1999 to 2004). Dr. Peterson stated that this successful translation from the research phase to the community was attributable in large part to the Harvard Prevention Research Center's collaborative infrastructure. She pointed out that translation can move relatively quickly if there is continuous and ongoing funding for such a collaborative infrastructure. Dr. Peterson expressed her appreciation to CDC for their role in funding the Center.

Dr. Peterson explained that the replication of Planet Health as the 5-2-1-Go! program was funded under the Massachusetts Partnership for a Healthy Weight, which was funded by a CDC initiative, headed by Ms. Robin Hamre, to reduce youth overweight and related chronic diseases. Massachusetts was one of three States that had a pilot intervention. Because the Massachusetts Department of Public Health must work within a social ecological framework for behavior change, the Department combined the individual-level Planet Health curriculum with application of the environmental-level School Health Index (SHI), which had never previously been used and evaluated in this particular way. The study group's randomized design included 13 urban, suburban, and rural middle schools and both public and parochial schools. 5-2-1-Go! was conducted from the Fall of 2002 to the Spring of 2004. Currently data are being edited and excellent results are expected. Previously, an actigraph sub-study validated Youth Risk Behavior Surveillance System (YRBSS) activity items for CDC. Dr. Peterson noted that the validation study used 24-hour recalls, which are comparison measures, as criterion measures; however, there should be some longitudinal data from accelerometers, pre- and post-intervention, coming from this sub-study.

Initially, there were not plans to evaluate the 5-2-1-Go! replication of Planet Health combined with SHI. However, recently Dr. Peterson was asked by the Massachusetts Department of Public Health to conduct a RAP qualitative study of the program. On a very fast track, the study group is conducting in-depth interviews and focus groups with personnel at various levels of administration and with teachers to try to identify some of the challenges that the school systems are going to face when they scale-up for the impending BCBS implementation phase and when they move from the randomized controlled trial setting (with all the assistance from the study group) to dealing with the four components of Planet Health on their own. BCBS is investing $7 million to control pediatric overweight in Massachusetts, $2 million of which is going to a total of 100 schools over the next 2 school years to implement the Planet Health curriculum, the School Health Index policy/environmental change, and Healthy Choices, which is another before- and after-school program conducted by the Massachusetts Department of Public Health.

Surveillance Data. Dr. Peterson emphasized the importance of linking NHANES and CDC surveillance data with locally collected data of estimates of prevalence and incidence and with data from trends in organizational settings such as schools. As an example, she presented unpublished longitudinal data from the ongoing Cambridge Public School Surveillance System. The data were part of Dr. Juhee Kim's doctoral dissertation and were presented at the 2003 annual meeting of the American Public Health Association (APHA). Every April, the PE teachers in the school system measure weight and height. The teachers have received training consistent with CDC surveillance protocols. Dr. Kim created four 1-year cohorts beginning with 1999-2000. She found, in a diverse sample of all children in the Cambridge Public Schools between kindergarten and grade 8, that 19.2 percent were overweight (BMI $\geq$ 95th percentile) and 17.6 percent were at risk of being overweight. The average annual incidence between 1999 and 2003 was 4 percent per year overall. Remission was 15 percent.

A slide from Dr. Kim's study of 1-year changes in weight status (April to April) by baseline weight showed that 90 percent of those in this age group whose BMI was between the 5th and 85th percentile remained at that healthy weight 1 year later. In the

overweight group (BMI ≥ 95th percentile) 85 percent remained at the overweight level, but, interestingly, about 14 percent remitted to the at-risk level. Dr. Peterson reminded the audience that remission in Planet Health odds was 2.4, which was the primary reason the intervention had an effect. In the at-risk of overweight group (BMI between 85th and 95th percentile), only 56 percent remained at the baseline level, 18 percent became overweight, and 26 percent remitted to healthy weight. Dr. Peterson said this remission to healthy weight may be an artifact of the growth curves, but it may also have affected the Planet Health results. There is a normal shifting of percentiles as weight velocity reduces and height velocity peaks at this age. Dr. Peterson added that this study by Dr. Kim raises interesting questions for researchers. It points out what can be learned from surveillance data and also that it is worthwhile to implement monitoring of children in schools.

Lessons Learned. In conclusion, Dr. Peterson adapted a concept from a recent paper by Drs. Stover and Bassett in the American Journal of Public Health (Stover G and Bassett MT. 2003. AJPH 93:1799-1801) to answer why and how Planet Health as an intervention model was successful. She listed the following lessons learned:

- Why does it work?
  - Role of TV in mediating change in diet and activity behaviors
  - Optimizing growth and development
  - Age, gender, and cultural appropriateness
  - Relative importance of individual and environmental influences.
- How does it work?
  - Partnership and participatory approaches
  - Adoption and sustainability
  - Program evaluation
  - Monitoring overweight.

PATHWAYS: A Randomized Trial for the Primary Prevention of Obesity in American Indian Children
Benjamin Caballero, MD, PhD, *Professor and Director, Center for Human Nutrition, The Johns Hopkins University, Baltimore, MD*

Dr. Caballero noted that PATHWAYS was heavily influenced and based on CATCH and SPARK; however, PATHWAYS had some unique characteristics, particularly in the dietary intervention and the physical activity intervention, from which lessons can be learned. PATHWAYS was a randomized, school-based trial for primary prevention of obesity in American Indian children. Its primary aim was to evaluate a comprehensive, culturally appropriate primary prevention program for obesity using percent body fat as the outcome variable, not BMI. Secondary aims were to assess the efficacy and safety of each of the program components and to identify constraints to these types of programs in the school environment and the surroundings of the daily life of children. NHLBI funded the program and a number of universities participated—Arizona, Johns Hopkins, Minnesota, New Mexico, and North Carolina.

The PATHWAYS schools represented a wide range of conditions and climates. Some were very isolated schools, some were completely urban and reasonably well equipped with nice playgrounds, and some were

very poor such as the Rosebud Reservation in South Dakota, which is one of the poorest areas in the country. In some, obviously, there were difficulties in implementing physical activities during the winter. The following seven American Indian communities participated in this study:

- White Mountain Apache Tribe, Arizona
- San Carlos Apache Tribe, Arizona
- Gila River Indian Community, Arizona
- Tohono O'odham Nation, Arizona
- Navaho Nation, New Mexico, Arizona, and Utah
- Sicangu Lakota Tribe, South Dakota
- Ogalala Lakota Tribe, South Dakota

Dr. Caballero stressed that the support of Tribal leaders and of the Indian communities is essential to overcome constraints and gain approval of research-oriented studies in these populations.

Measurements. An important characteristic of the study design, according to Dr. Caballero, was that the unit of analysis and sampling was the school, not the children. Various measurements were used to compare and evaluate control and intervention groups in the various schools. There was a single cohort, starting at third grade and continuing for 3 school years through the fifth grade. After baseline measurements of the 1,705 children, the schools were randomized into intervention and control groups. The study used cluster randomization, stratified by field center using median percent body fat of each school as the cut-off. Percent body fat was measured using a population-specific equation based on weight, skinfolds (triceps, scapula), and bioelectrical impedance (resistance, reactance). The equation had been previously evaluated by deuterium oxygen dilution in this same population (Lohman et al. 2000. Intl J of Obesity 24:982-988). The other measurement, besides the main outcome variable, was dietary intake.

Dr. Caballero explained that other study measurements included physical activity measured by accelerometers, by a physical activity questionnaire, and by the SOFIT (System for Observing Fitness Instruction Time) observation protocol and measurement of knowledge, attitudes, and behaviors. Dietary intake was measured by direct observation at the school and by 24-hour recall, but only at the end of the study because they could not reliably measure 24-hour recall in children at the end of second grade when the baseline measurements were done.

Study Design. The target for the intervention was based partly on the CATCH concept, as Dr. Caballero had mentioned earlier, but the study group also did extensive formative research, applying ethnographic techniques, before starting the intervention. During the feasibility phase, structured interviews were conducted with teachers to identify the priority risk factors for obesity in the eating and physical activity behaviors of the subject population. Findings were that school meals included higher fat foods and not enough fruits and vegetables and children drank whole milk or high-sugared drinks. Also, there was not enough physical activity at school. The intervention was adapted to address these particular issues.

As in the CATCH study, the four components of PATHWAYS were a classroom curriculum, a school food service intervention, a physical activity component, and a family component. The developers for the intervention included a number of American Indians from the different participating Tribes, which

Dr. Caballero stressed was necessary in designing a culturally appropriate intervention. Because of this participation by the Tribal members, cultural values, interests, and constraints of the different communities were addressed along with the key scientific elements common to interventions. The study demonstrated that it is possible to create a consistent and acceptable program for a number of different American Indian cultures, in spite of the many differences among Tribes and their different traditions. For example, the aims of the classroom curriculum included introducing and supporting the other three components, reclaiming American Indian traditions associated with a healthy lifestyle, and promoting healthy eating habits. Dr. Caballero said that many things regarded as part of traditional Indian culture, such as fried bread, were really introduced by the white man; whereas, actual Indian traditions in many communities promote good health. An example is the Apache tradition of being very active or walking a long distance every day; the current trend of being sedentary is part of the westernization of their lifestyle.

Classroom Curriculum. The goal of the classroom curricula was primarily to introduce and support dietary intervention components, such as the introduction of new foods and other changes in the school lunch menu. Children in the third grade would then understand and be privy to this information, and when the changes occurred for the whole school, these children were in the privileged position of being able to explain to all the children why these changes were important. The teacher-delivered curriculum consisted of two 40-minute lessons per week, 12 weeks per year. There also was a general health education component.

Dr. Caballero said that study leaders, in conducting the extensive teacher training required, faced many of the same issues described for CATCH. He added that one of the constraints that will be seen in any school program is the tremendous competition among extracurricular activities. Teachers showed the trainers they already had 10 to 15 prevention packages to teach—prevention of sexually transmitted disease, prevention of smoking, prevention of child abuse, prevention of alcoholism, and so forth. The PATHWAYS packet first went to the top and then to the bottom of the stack. Dr. Caballero stressed that motivating the teachers to be concerned about a particular issue for the health of the children is an important part of the training for an intervention.

Dietary Intervention. Dr. Caballero stated that one cannot deliberately promote a reduction in caloric intake in any school. There are guidelines from the school breakfast and lunch programs that require a certain amount of calories be available to children. Within that constraint, some of the things that can be done are reduction of the energy base by reducing total and saturated fat intake and consumption of sweetened drinks and low-nutrient, energy-dense foods and by introducing and increasing consumption of healthier foods such as fruits and vegetables, thus providing adequate calories and the essential nutrients for normal growth. If successful, it is possible that children will spontaneously reduce their total energy intake and obtain their energy from foods that are healthier.

Physical Activity. The physical activity program took some elements from SPARK, but added American Indian games that were traditional to different Indian communities. The goal was to have a minimum of three PE sessions a week of 30 minutes each and two 5-minute exercise breaks a day.

Family Involvement. Dr. Caballero said that the goal of the family involvement was primarily to create, at home, a supportive environment for the child. This component consisted in having the children engage their parents at the school through family fun nights by sharing with them some of the practical aspects of the healthy changes and explaining to them the importance and reasons for some of the changes that were occurring. For example, children were going home and demanding low-fat milk instead of whole milk, and parents obviously wanted to know why this was happening. Parents came to the school and tasted the new healthy foods and learned how to prepare the foods that had lower fat content and so on. The family fun nights started with an annual kick-off event and included snack packs, workshops, and year-end events.

Results. At the beginning of the study, the average age of the children was 7.5 years, and it was 10.5 at the end of the study. The percentage of boys and girls was approximately equal. More than 30 percent of the children were above the 85th percentile at baseline, and a large number were above the 95th percentile. Dr. Caballero noted that clearly this was not a pure primary prevention to prevent children from becoming obese. Many already were obese. This population had a higher BMI than most groups of children in the country. Since PATHWAYS used the school average as the unit of analysis and some schools had in excess of 50 percent of their children who were obese, this obviously was important in influencing and in understanding the outcomes in those schools.

Body Fat. The results at follow-up showed no difference between the intervention groups and the control groups in BMI, triceps skinfolds, or scapular skinfolds. Dr. Caballero stated this essentially was a negative study in the sense that it did not produce any difference in the intervention group after 3 years of intervention. The main outcome was percent body fat, which was 40 in both groups, indicating no effect of the intervention on the final outcome. There were no real changes in body fat from baseline through the third, fourth, and fifth grades in the intervention or control groups.

Dietary Intake. There was some change in the dietary intake, just as in CATCH. From baseline through the fifth grade, there was a progressive difference in the percent of calories from fat. The goal was 30 percent of calories from fat. Dr. Caballero reported that the intervention group achieved a successful and significant 28 percent compared to 32 percent in the control group. There was a similar difference in absolute values in grams of fat, for which the goal had been 22 grams. By study end, the intervention group was at 22 grams; the control group was at 25 grams. In the 24-hour diet recall, there also was a significant difference in calories of approximately 260 kilocalories per day between the intervention and control groups. Dr. Caballero said there was certainly some reporting bias because the children in the intervention group had been exposed to education that probably let them know how to answer many of the questions. A 24-hour recall of after-school dietary intake showed the same significant difference (approximately 195 kilocalories), but again this may not be accurate since it certainly was not reflected in percent body fat.

Food Service. In terms of the 13 food service guidelines, Dr. Caballero reported that the percent of these that were implemented increased each year. He explained this component extended over about 2 1/2 years because the last year was cut short in order to conduct the large amount of measurements needed

at the end of the study. One constraint was that schools had 5-year contracts to buy whole milk; changing these contracts to make them for 1% milk took a serious political effort. As mentioned earlier, there were also Federal reimbursement requirements to purchase certain types of foods and not others, which partly explained the difficulty in removing butter or fats from the serving line or less use of these in food preparation. In spite of these constraints, the intervention groups achieved a reasonably good level of implementation of the guidelines.

Physical Education. Dr. Caballero noted that CDC recommends 60 minutes of moderate to vigorous physical activity per day for adults to maintain energy balance. Although there is not firm empirical evidence for children, the consensus is that children need to do the same. Since the PATHWAYS minimal goal was three PE lessons a week and its maximal goal was five a week with an average class duration of 32.8 minutes, the children would need a lot of additional physical activities to meet the 60 minutes a day goal to just maintain energy balance. Dr. Caballero pointed out that the physical activity intervention goal for populations that have high levels of obesity needs to be carefully considered.

In the PATHWAYS study, there was no difference overall between the intervention and control groups in terms of physical activity. Dr. Caballero explained that this was because the disparity among sites was very great. Some sites did have a positive difference. In one site, on the other hand, the control was slightly more physically active on average than the intervention. Some parallel competing activities at the sites may also have affected the results. In terms of food choices and physical activity behaviors, there were some significant effects, particularly related to knowledge. A physical activity questionnaire showed a significant effect but the accelerometers, which were an objective measurement, did not.

Summary of Results. Dr. Caballero presented the following summary of the PATHWAYS intervention:

- No effects on percent body fat, anthropometry.
- No effect on physical activity level measured by TriTrac accelerometer, but a significant effect by questionnaire.
- A significant effect on food service intervention, particularly in reduction in percent calories derived from fat.
- A significant effect on several components of knowledge.

Lessons Learned. Dr. Caballero stated that one lesson learned from PATHWAYS was that, in some communities, the percent of children who are already overweight or severely obese in terms of BMI may be so high that specific strategies ought to be implemented. There has been an effort to avoid targeting obese children for fear of stigmatizing them and because of concern over increasing unhealthy eating behaviors. Dr. Caballero said he has not seen evidence of the latter in young children. He emphasized that it may be necessary to develop a creative approach to provide an intense, clinical intervention at an institutional level where there is a large proportion of children who already have an excessive BMI.

(See the following websites for additional details about PATHWAYS: http://www.cscc.unc.edu/path (administration, committees, publications); http://hsc.unm.edu/pathways (study materials).)

Bienestar: A School-Based Diabetic Control Program
Roberto P. Treviño, MD, *Director, Bienestar Health Program, Social and Health Research Center, San Antonio, TX*

Dr. Treviño began his presentation by explaining that Bienestar is Spanish for "well-being." Bienestar is a diabetes prevention program, so the primary endpoint is blood glucose. The secondary endpoint is the risk factors associated with diabetes. A study by Dr. Frank Hu in the New England Journal of Medicine, published in 2001, reported that 91 percent of all the cases of diabetes were the result of such modifiable risk factors as high saturated fat intake, low fiber intake, sedentary lifestyles, and overweight (Hu F et al. NEJM 2001; 345:790-797). Measurement of these four risk factors was the outcome for Bienestar. Dietary intake was measured by a 3-day, 24-hour dietary recall. A Harvard step test, heart-rate monitors, and measurement of heart rates after the exercise test were used to measure fitness. Overweight was measured by BMI and percent body fat.

Bienestar targeted mostly low-income communities. Subjects were 85 percent Mexican American and 15 percent African-American. Dr. Treviño said that the children in these communities already had all four risk factors for diabetes. He added that Bienestar focuses on intervention at an early age because for these children, diabetes does not start at the age of 30 when the adult patient comes to the doctor with a blood sugar of 140 or 180. It starts at the age of 9 when these risk factors are present.

Dr. Treviño explained that the study selected the fourth grade because the children are pre-pubertal and between this period and puberty, there is a physiological change that mimics diabetes. Bienestar targets these fourth graders because of biological and behavioral changes that start occurring. Around this age, children have an increase in blood sugar levels, body fat, and insulin levels (Bogalusa Heart Study 1977; 10 State, Tecumseh and NHANES Studies, 1981, Eco Food & Nutr). The goal is to identify and intervene with them when these initial abnormalities start happening to ensure that, as they go through the physiological change state, they do not develop abnormal levels. Not only does children's biology change in the fourth grade, or at 9-years-old, but studies also show that between 6 and 11 years of age they have an increase in their sugar intake and a decrease in fruit and vegetable intake (NHANES 1990 J Am Diet Assoc). Also, several large national studies have shown that their physical activity starts decreasing around the age of 9 (NHLBI Growth and Health Study 2002 NEJM).

Bienestar is based on social cognitive theory. The aim is to change the four social systems that have an influence on children's health behaviors—their classroom health class, their after-school care, their home, and their cafeterias. There are structured curriculums presented in about nine manuals, everything is bilingual, and materials are in color. The objectives are to decrease saturated fat, increase fiber, increase physical activity, and prevent obesity. These four messages are consistently repeated throughout the four arms of intervention. Dr. Treviño stated that the children hear the same messages so many times that eventually there is evidence of some behavioral changes, although the aim of the program is not to change behaviors, attitudes, or knowledge. The aim is to change the biological marker, which is blood sugar, because this is what will cause blindness, amputations, and dialysis.

Classroom Health Class. The Bienestar curriculum consists of 13 lesson plans implemented in health class once a week during the first semester of the school year. The lesson plans are all related to diabetes. The plans are written at a third grade level, use very simplistic terms, and use many cartoons. The children learned about diabetes and how to prevent it. They also learned about how some carbohydrates are related to diabetes and how some can protect against diabetes. The same is true for fats. They also learned about the importance of exercise.

Physical Activity and the Health Club. Continuing his description of the program, Dr. Treviño said there are 32 physical activity components tailored to the third and fourth grades. The classroom PE intervention took place four times a week and included moderate to vigorous physical activity components. The health club met after school (3 to 4 p.m.) 32 weeks of the year and used the arts to teach what glucose is, what an insulin level is, what the pancreas does, and so forth. The arts program included theatrical plays, puppet shows, music, dancing, and songs. There was a lot of physical exercise. Children had the opportunity to play, jump around, and role play. Dr. Treviño explained that Spanish dancing can burn close to 600 calories in half an hour. Attendance rate at the health club was 65 percent.

Food Service. There are six lesson plans for the cafeteria staff. These are bilingual and written at a sixth grade level with a lot of pictures because many of the cafeteria staff are entry level persons who have only received limited educations. The Bienestar curriculum was implemented during the workers' morning break from 8:30 to 9 a.m. each day, so attendance was very high, from 85 to 90 percent. This curriculum also emphasized the carbohydrates and fats that can protect against diabetes and those that are prone to lead to diabetes. The staff were encouraged to use more mono- and polyunsaturated fats and to increase the amount of fiber in the diet. The messages were positive ones. The study group members visited the cafeteria once a week to ensure that healthy foods such as fruits and vegetables were available and that children were eating them. Peer pressure was also used by having patrol children go up and down the aisles between the tables.

Outreach to Parents. Dr. Treviño described the components aimed at the parents. Initially, there were health education classes where parents would come and sit down in the classroom and a nutritionist, doctor, or nurse would talk. Attendance rates were very low, only 7 percent. With more experience, the study group switched from a lecture medium to a dance and a theatrical play performed by the children. The attendance rate at that meeting was 68 percent. All the parents wanted to come and see their children perform. Dr. Treviño stressed that using children to educate their parents is probably one of the best vehicles. Children are very powerful mediators as change agents. Another event was a cooking class and a play where the parents became the actors. They were given little necklaces or collars and became insulin, body fat, or muscle. They formed a circle (a cell) and a glucose (husband) grabbed an insulin (wife) and pulled her inside the circle. This represented a normal state. Then two rows of parents held hands and were asked to do the same thing. This was difficult to do and represented the insulin-resistant state. These simple role plays were useful in helping the parents understand and recognize the importance of these issues.

Initial Results. The whole Bienestar program consisted of 93 lesson plans and each child, on the average, had 45 encounters with the program (S&HRC 2001-

2002). There was a lot of positive reinforcement. Initiated in 1991, for three consecutive years when blood sugar cutoffs were above 110, every year that a child was identified with an abnormal blood sugar level at the beginning of the school year, 9 months later the child's blood sugar had been lowered without medication, just through the four arms of the Bienestar program running during those 9 months (Garcia. 2003. Diabetes).

Extended Study. Based on the success of the initial 3-year program, Dr. Treviño said the study group applied for a grant to do cluster randomization in 13 schools with the intervention and with 14 schools as the control. There were approximately 700 children in each arm. In late August when school started, there were 17 children in the intervention group with abnormal glucose levels and 25 children in the control group, which was also receiving some intervention through basic recommendations and referrals to doctors. By May, blood sugars in the Bienestar arm had been lowered by 40 mg/dl and by 23 mg/dl in the control arm (S&HRC 2001-2002). None of the children had been on medication. Dr. Treviño pointed out that a decrease of 40 mg/dl blood sugar is about a 32 percent decrease in blood sugar, whereas the most potent drug available, Metformin, can only lower blood sugars by 28 percent. Metformin is also more expensive and has side effects. Dr. Treviño added that for the children who had normal blood sugar (below 110) at baseline, the incidence of those whose glucose rose above the normal range by May was 1.4 percent in the Bienestar group compared to 3.2 percent in the control group (Trevino R. 2003. Diabetes).

Lessons Learned. In terms of how Bienestar is able to reverse hyperglycemia and also prevent hyperglycemia, Dr. Treviño stated that, after 9 years experience with the program, it is thought the most powerful agent for modifying the biological markers is the increased physical activity. Based on the Harvard step test, Bienestar improved fitness levels, whereas the children in the control group followed the trend of most U.S. children, which is a decrease in fitness level (S&HRC 2001-2002).

Dr. Treviño suggested that BMI may be the wrong measure to use in these intervention studies and may be the cause of the poor outcomes being reported. He presented a slide showing that BMI and body fat took different directions (S&HRC 2001-2002). Even though Bienestar did not modify significantly the percent body fat, there was a decrease in body fat compared to controls even though BMI did not show a difference.

Another thing that was surprising was that Bienestar children consumed more calories. However, these calories were mostly from monosaturated and polyunsaturated fats and fiber. Dr. Treviño stated that children in this age group are developing and need their high-calorie intake, which is fine as long as they are kept physically active.

Dr. Treviño said that another incentive that helped to modify biological markers was that when children came to the health club and when they ate all their fruits and vegetables in the cafeteria, they were rewarded with play money. At the end of the school year, there was a tiendita (a little store), where the children could buy a variety of sporting goods—hula hoops, gloves, and so forth.

Cost Analysis. Dr. Treviño reported that the cost of each encounter with a child in the Bienestar program was approximately $4.20. As an internist, he is paid $48 by Medicaid for each encounter with a patient. Bienestar was able to increase fitness, increase fiber

intake, lower blood sugar, and prevent high blood sugar. The United Kingdom Prospective Diabetes Study (UKPDS) showed that, even with all the free medicines in the world, people progressed to complications such as blindness, amputations, and dialysis (UKPDS 2000).

Future Directions. When the study group revisited the children who had received the intervention in the fourth grade, when they were in the fifth and sixth grades, it was discovered that they had begun to equilibrate. Even the positive results seen at the end of the fourth grade were starting to wash off. Dr. Trevino suggested that the fourth-grade level may be too late. Intervention needs to take place at an earlier age. Bienestar is now written for kindergarten through the fifth grade and is being published by McGraw-Hill. Hopefully, this will have an impact downstream.

Another important fact noted by Dr. Treviño was that many of the children who are overweight and at risk for diabetes and other obesity-related diseases are Latino, African American, and Native American. Because of this ethnic/cultural disparity and the fact that only about 3 percent of the audience were from these populations, he recommended that NIH make a special effort to fund minority researchers not just studies in which the subjects are minorities.

All Other School Studies + STOPP-T2D

Ken Resnicow, PhD, *Professor, Health Behavior and Health Education, University of Michigan School of Public Health, Ann arbor, MI*

Dr. Resnicow noted that he would be briefly reviewing a range of school-based studies organized into three basic groups: multiple risk factor intervention trials for which obesity was an outcome but not the primary focus; obesity-specific trials such as PATHWAYS; and diabetes prevention programs such as Bienestar. If time allowed, he would also speak a little about synthesis.

Multiple Risk Factor Studies Without and With Obesity as an Outcome—First-Generation Studies. Eight U.S. and six international studies were classified as multiple risk factor studies for which obesity was an outcome but not the primary focus. Dr. Resnicow said these studies belong to what could be termed the Wynder and Berenson era stemming from work that came out of the 1980s. Like the earlier studies that were driven by smoking prevention and cardiovascular disease, there was a series of studies in the early 1990s, culminating in CATCH, for which lipids was the main outcome with adiposity as a secondary outcome. These were dominated by social cognitive theory. There was also substantial parallel work influenced by the initial Know Your Body (KYB) studies by Dr. Wynder.

Results. The only first-generation study that had a positive BMI effect was one at Stanford. There were relatively limited effects on skinfolds. Dr. Resnicow cautioned the group that these early studies did not use the more rigorous unit of analysis and other covariate adjustments that, for the most part, would have decreased or attenuated the treatment effects. Four of the European studies were large, randomized trials. By and large, the effects of these studies were null. Where there were effects, they often were short-term and, if the proper unit of analysis had been used, the effects would likely have been null. A number of studies named adiposity as a primary outcome. Overall, these first generation obesity-specific studies had little if any effect.

Obesity-Specific Trials—Second Generation Studies. Dr. Resnicow explained that the list of second-generation studies were selected because the designs were very rigorous (cluster randomized, proper adjustment for intracluster correlations) and/or they took a novel intervention approach. For example, PATHWAYS and Planet Health were named second-generation obesity prevention studies because of their methods and their intervention approach. Dr. Tom Robinson's pilot study in reducing TV viewing time was included because the intervention was novel. A United Kingdom study to decrease consumption of "fizzy" drinks also was included.

Results. Again, a Stanford study showed an effect on adiposity. The African-American girls in Planet Health also had positive effects. Dr. James' "fizzy drink" study had paradoxical effects. The primary message of this intervention was not to drink sweetened beverages, but they also included diet drinks because a goal was to increase consumption of water. Overall, mean BMI did not change, nor did BMI z-scores change. However, there was a significant intervention effect on the prevalence of overweight. Interestingly, while the main outcome showed a lower use overall of carbonated drinks, the use of diet drinks increased significantly. Thus, while there was no effect on consumption of sweetened drinks and water, there was an effect on obesity prevalence. Dr. Resnicow said this raises issues from other studies such as M-SPAN, SPARK, CATCH, and PATHWAYS that did not necessarily have the adiposity effect expected but did have powerful behavioral effects.

Diabetes Prevention Studies. Dr. Resnicow noted that Dr. Treviño's Bienestar study is the most rigorous of the current diabetes prevention studies. There is also a pilot study, the Zuni Pueblo High School Study in New Mexico led by Dr. Ritenbaugh, which also raised an interesting paradox. This quasi-experimental study involving one intervention school and an Anglo comparison school has similar components to the other studies discussed: a Youth Fitness Center during lunch and after school; a food service intervention to increase consumption of fruits, vegetables, water, and diet beverages and decrease consumption of fats and sweetened beverages; a 9-week diabetes-related curriculum; and school-wide posters, announcements, displays, and a public service announcement over the local radio station.

Results Raise Questions. There was no effect on BMI or glucose, but there was an effect on fasting and on post-challenge insulin. Dr. Resnicow said these results again raise issues about how to interpret and apply these mixed physiological (and behavioral) effects that, in some ways, are the opposite of the Bienestar study. He asked how this outcome information can be used within and across studies. Gender differences are another question to be discussed. As an example, he asked if the Planet Health study were done again, would an effect again be found only in African American girls—or not? Possibly, but the issue remains on how to apply these interaction effects down the line and make sense of them. Dr. Resnicow pointed out that the successful second-generation studies that would be reviewed by Dr. Story in more detail tended to have more focused messages as outlined by Dr. Treviño.

STOPP-T2D STANDUP. This is one of three current large studies. GEMS (Girls Health Enrichment Multi-Site Studies) and TAAG (Trial of Activity in Adolescent Girls), both sponsored by NHLBI, are the other two, which will be reviewed by other speakers. Dr. Resnicow pointed out that Dr. Barbara Linder, NIDDK, is the program administrator for STOPP-T2D (Studies to Treat or Prevent Pediatric Type 2

Diabetes). The study within STOPP-T2D is called STANDUP, which represents Schools Tackle Activity Nutrition Diabetes and Prevention, with a little poetic license for the Up. It is the prevention arm of the STOPP-T2D. An attempt has been made to make this study a little different from CATCH, SPARK, and M-SPAN.

There are seven study sites and a coordinating center, each with their own Principal Investigator. Initiated in winter of 2003, Dr. Resnicow said that several pilot studies have been conducted. In the fall of 2004, all seven sites will work together on a pilot study in one school. Next fall, another pilot study is planned, and then the full trial should begin in the fall of 2006, although some changes are possible before then. Like CATCH, the full trial will involve approximately 100 middle schools, 16 per site. The cohort will begin with sixth graders and last for 2 years through the seventh grade with a follow-up in the eighth grade. There will be a major kickoff event and the study will include a variety of incentives.

Dr. Resnicow remarked that conceptualizing an outcome for diabetes was very interesting. The following troika was chosen and will be analyzed in a couple of ways: BMI (≥ 85th percentile); insulin (≥ 30 uU/ml), and glucose (≥ 100 mg/dl). In reviewing the other studies to design the new study and choose the outcome, the main question was: What will it take to achieve the ambitious outcome and prevent type 2 diabetes? The study developers knew they wanted a multi-level intervention that included greater duration and intensity of physical activity, more comprehensive food service change, integrated social marketing and behavioral strategies, and an interactive, individually tailored, behavioral change intervention. These last two items have not been in prior studies at the intensity level planned for STOPP-T2D. There will be a major social marketing campaign, which was considered to be one of the elements that was in previous studies on a lesser level and needed to be enhanced. The campaign will be conducted by a contractor. An SBIR (small business innovation research) mechanism has also been added that will provide an interactive DVD game for children to use in tailoring their own goals and behavioral outcomes based on their baseline physiologic measures.

Dr. Resnicow presented a detailed slide of the theoretical and conceptual model for the study based on the intervention components, teacher/staff mediating variables, environmental and psychosocial mediators, and targeted behaviors. It was decided that to reach the desired physiologic effect, five to nine servings of fruits and vegetables would be needed along with decreased fat, an increase in water, and at least 20 to 25 minutes of moderate to vigorous physical activity three times a week.

Food service goals will be directed at three channels: the National School Lunch Program (NSLP); non NSLP, non-vending machine foods and beverages; and vending machines. The goals are ambitious and the designers have taken prior generation studies' food service interventions and raised the bar structurally and behaviorally. There will be several creative mechanisms used.

Dr. Resnicow explained that the PE intervention goals were set at the upper limit of the other studies' best results. This will be a five-unit program of 5 to 12 activities and will satisfy State-mandated requirements. Skill attainment is progressive with students expected to attain the goal in three out of the five units. Key people will administer this intervention, which aims for students to achieve an average heart

rate of ≥ 140 bpm, measured by a heart rate monitor, for 70 percent of the classes, and a heart rate of ≥ 140 bpm at least 50 percent of the classroom time.

The behavioral and social marketing program has several goals. The primary aim is to promote positive changes in students' physical activity and dietary behaviors in and out of school. There will be three main elements: school-wide communications; school-wide events, contests, and activities; and the Health Action Team. The campaign will focus on five messages and three mediators. Dr. Resnicow commented that this is an area where the study is unique in that, based on an interest in self-determination theory, they plan to measure intrinsic motivation and try to enhance it with strategies such as the DVD game. Other potential novel alternative behavioral activities may include a pedometer challenge, Take 10! (Dr. Kohl's project), video and broadcast messages, point-of-purchase advertising, before- and after-school PE programs, newsletters for parents/teachers/cafeteria workers, and school-wide contests such as a water bottle top collection. The Health Action Team, planned to get local buy-in for the program, will be formed early in the school year and will help deliver some of the activities.

Finally, the SBIR component is planned as an individual behavior change intervention, particularly to engage those who are at high risk or who already have type 2 diabetes. This is an attempt to work a chronic disease model into a primary prevention trial. The children's baseline glucose, insulin, and BMI will be measured. Using the game approach that Dr. Thomas Baranowski successfully used in Squire's Quest, children who need to reduce their risk factors will build individual targets and behavioral change strategies based on their level of risk. For example, there is a DASH diet to maintain normal weight and a DASH diet to lose weight. This second-level of intensity built into the program is expected to be fun, motivational, and effective.

Dr. Resnicow said they are still working on the best way to involve parents, other family members, and the community. He noted that Dr. Mary Story's presentation would address multiple channels to do this.

Creating a Healthy School Environment

Howell Wechsler, EdD, MPH, *Acting Director, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, GA*

Dr. Wechsler explained that CDC's School Health Index (SHI), which is being widely implemented in hundreds of schools, is basically a self-assessment and planning tool for schools. It uses a community organizing approach, in which the school community itself decides what the intervention will be. Dr. Wechsler stated that SHI can be packaged and readily disseminated. It offers an approach that may stimulate ideas about new directions to promote physical activity and healthy eating at the school site.

When SHI was initiated in 2000, it addressed physical activity and nutrition issues. In 2002, a smoking component was added. The latest edition also addresses safety issues such as unintentional injury prevention and violence prevention. Other critical health issues will be added, such as asthma, which soon will be included, and hopefully by 2006, prevention of sexual risk behaviors. Dr. Wechsler said that there is an online version of the latest edition because so many topics are being added, that it was thought this would more easily enable selection of particular issues (http://apps.nccd.cdc.gov/shi). For example, if a

school is funded just for obesity prevention, the administrators can click on nutrition and physical activity to obtain a tool that focuses just on those topics.

SHI Approach. Dr. Wechsler explained that there are two pillars behind the School Health Index. First, it is an interactive tool to help schools implement the recommendations from CDC's School Health Program guidelines (http://www.cdc.gov/MMWR). He added the guidelines were built on NIH-funded research in which many of those present had participated. The second key pillar is the Coordinated School Health Program model pioneered by CDC. The model is based on the premise that there are many different sectors of the school community that can influence health behaviors, and therefore, to be effective, these components need to be organized to work together to reinforce positive health messages and to maximize the resources that, unfortunately, will always be scarce. Again, the approach is based on research practices and policies recommended by experts. There is a structured process based on the CDC guidelines that leads to informed decision-making at the site. It emphasizes multiple changes across multiple components of the school environment. Most importantly, the Coordinated School Health Program is a community-organizing approach for self-improvement that promotes a sense of ownership of implemented changes.

Dr. Wechsler listed the following possible team members: principal and assistant principal, physical education teacher(s), school food service manager, health education teacher(s), classroom teacher(s), school nurse, school coordinator; school psychologist, school social worker, parents, students, community-based health care and social services providers, community health organization representative (e.g., American Cancer Society), and local health department staff member. All are key players in the school setting, particularly parents and outside community-based persons and, especially at the secondary school level, the students themselves. Dr. Wechsler pointed out that the team does not have to consist of all these people. Sometimes there are only two or three persons at the table; other times, the school will bring in many types of participants, which is most likely to be a richer experience and have the most impact.

Format. The SHI format is simple, consisting of two tools—one for elementary schools and one for secondary schools. Eighty percent of the items are the same. Each tool has eight self-assessment modules that follow the Coordinated School Health Program model and then funnel into the School Health Improvement Plan, where scores from the modules can be improved.

The School Health Index addresses a gamut of issues. For example in Module 1 on school policies and the environment, there are areas such as a school health committee, use of physical activity as punishment, daily recess in elementary schools, adequacy of physical activity facilities and student access to them, fundraising and healthy eating, and so forth. The organizing committee is asked "Does the school have a representative committee that meets at least twice a year and oversees school health and safety policies and programs?" There is a four-point scoring scale so that schools can see themselves making gradual, incremental improvements and not feel that the task is hopeless, that they could never make it. There is a scorecard for each module listing scores for each of the items in the module and with an average score for the whole module. An overall scorecard lets the school committee compare the eight modules and see where they are and are not doing well. This helps them prioritize areas on which to work.

Dr. Wechsler explained that there are three fundamental planning questions to help assess the school's strengths and weaknesses. They are encouraged to congratulate themselves on their strengths, as well as list and prioritize areas where they need to improve, along with possible actions to change the scores in these weak areas. They are helped with the prioritization process by considering factors such as importance of the weakness and the time, cost, commitment, and feasibility of the proposed corrective action. Through this process, the planning committee identifies their top three or four priority changes for the coming school year. It is recommended that they select some short-term, more easily accomplished changes and some long-term, more difficult systematic changes. Based on this scoring and planning process, a School Health Improvement Plan is devised. This plan details, step-by-step, what will be done, by whom it will be done, and when it will be done. It is a simple, basic plan similar to other types of school improvement plans they do as part of education reform.

Current Use of SHI. CDC has reports from at least 46 States and from Canada where schools are using SHI. Dr. Wechsler said there is heavy usage in some localities and States (i.e., in Texas, more than 90% of Austin schools and more than 50% of Houston schools; in Missouri, 300 schools; in Montana, 66 schools). There is a Spanish version the University of Arizona will take into Mexico next school year. The online version receives more than 3,000 hits per month. Overall, SHI is by far the most highly demanded item on school health that CDC produces.

Dr. Wechsler presented a couple examples of the use and effectiveness of SHI. The Education and Health Departments in DeKalb County, Georgia, are promoting it by providing schools that complete the planning process with grants from $500 to $5,000 to implement the changes they identified. The number of schools receiving the grants increases each year. Samples of concrete, solid changes that have taken place include hiring a physical education teacher for the first time, developing a walking club and other wellness programs for staff, adding innovative activities to the PE program, installing fitness stations on campus, and adding healthy choices to vending machines. In Michigan where the Departments of Education and Health offered grants to implement changes, 10 schools in 2001-2002, 15 in 2002-2003, and 29 schools in 2003-2004 did so. Sample changes here included adding another lunch line and moving healthy choices to the front of the line, offering a salad bar every day, increased PE time, opening of gym for after-school use, and daily fitness breaks in classrooms.

The School Health Index is being used for many other purposes. In Maine, it is a source for evaluation instrument items. Indiana, Louisiana, and Ohio use it as criteria for award programs. At various universities (e.g., Purdue, Morehead State, Georgia State, Southeastern Louisiana, Florida), SHI is the basis for curriculums on teacher programs that require a course in health education; teachers go to schools as part of the course and help the schools implement the School Health Index. Dr. Wechsler added that SHI also is being integrated into the education reform-based school improvement plan required of schools, which hopefully means that the approach will be institutionalized.

Evaluation. Some of the Health Departments and Education Departments are basically just issuing narratives of what the schools are doing, pre- and post-SHI, and reporting how their School Health Index score improved. Others have developed new indices

of the school health environment and are showing how that has changed after using SHI. Two prevention research centers have done studies.

Dr. Lillian Cheung, at the Harvard Prevention Research Center, and her team conducted a 2-year qualitative study of nine schools on what exactly happened in the school setting and what nutrition and physical activity changes were made in the school as a result of completion of the SHI. The schools (six from New England and three from a Midwest school district) were categorized by the amount of outside facilitation that was brought in to help with the process. The study has not been published yet, but Dr. Wechsler presented some preliminary information. Examples of results from where there were moderate facilitation activities included a student health fair, subsidized membership to a health club for staff, a staff wellness day, and reducing the number of days French fries were served in the cafeteria and placing vegetables first in the lunch line. In-depth, individual interviews with school staff asked them to describe the factors that were perceived to facilitate the actual implementation of the action plan. Not surprisingly, the support from the school administration was a major factor. If there is a shared value in the school community about health, then SHI seems to be a tool that can get them over barriers and make actual change possible. Without this setting, then change is probably not going to happen. Other factors included regular team meetings throughout the year and protected time for the team to work together, team cohesion and maintenance of motivation, and a small grant for the school.
Dr. Wechsler noted that the study at the University of Arizona used SHI as an impetus for policy change in a very interesting setting, 13 schools along the Mexican border. Not surprisingly, the process and the participation varied in the different schools. Some dramatic, powerful, and exciting changes have been made. On the other hand, longer term, larger changes that had been anticipated have been stalled, largely because of issues that have thwarted dissemination of a lot of other interventions—high staff turnover and challenges in terms of time and resources. Intermediate changes that were made included ending sale of unhealthy snacks after school, replacement of a soda vending machine with one selling bottled water and sports drinks, establishment of walking groups before school and during recess, hiring PE teachers and developing a new PE curriculum, and increased utilization of community resources.

Lessons Learned. Dr. Wechsler emphasized that the CDC School Health Index is focused on the real world and is about effectiveness. He did not see how it could be used in an efficacy trial. It is a process, not a package, and the process will be different in every school community, with one consistent similarity—the process will be slow. It also will be generally uneven and disorganized and more often than not, it will fail. Dr. Wechsler stressed that this is how change happens in the real world. It is not an ideal situation as is found in a randomized control trial supervised by a team of Ph.D.s. However, SHI is based on research. It is based on disseminating insights from the best minds in the country on what are the best policies and practices to make a difference. Most importantly, it is based on community ownership, and that is why CDC thinks this is the type of intervention that must be considered and that will lead to lasting change. He also stressed that the intervention will only be as strong as the community and the champions in that community who advocate for these changes, because, again that is what happens in the real world.

Discussion With Session 1 Speakers

Facilitator: Howell Wechsler, EdD, MPH, CDC

Dr. Susan Yanovski, Co-Director, Office of Obesity Research, NIDDK, commented that the data on attitudes and behavior change and so forth from the CATCH study, which is considered a successful program, is primarily from self reports. She asked Dr. Webber if there were any objective data from the long-term follow-up except for no BMI change and some observations of increased physical activity. She was particularly interested in anything that showed a change in fitness or a change in cardiovascular risk factors.

Dr. Webber answered that in addition to the lack of change in BMI, there was no statistically significant change in serum cholesterol, which was the primary outcome variable. The evaluation took place at two different levels—one for behavioral change and one for the two environmental components, school food service and physical education class. For behavioral changes in children, there were self-reports from 24-hour recalls collected at third grade (baseline), fifth grade (end of the main trial), and at eighth grade (at the end of 3 years of tracking). There is also data from the end of twelfth grade, as well. There was also a questionnaire, entitled the Self-Administered Physical Activity Checklist (SAPAC), which began with the San Diego group and then was worked into CATCH. At the second level of assessment, there was a nutrient analysis of the school lunches from one week's worth of menus and recipes at third grade, fifth grade, and for the institutionalization study. At fifth grade, the analysis showed a reduction to 30.2 or 30.3 percent calories from fat and very close to 10 percent of calories from saturated fat in the intervention schools and a slight reduction to about 32 or 33 percent in control schools. This was a much more objective measure. In addition, in every semester from third grade through fifth grade, there was an assessment of moderate to vigorous activity during PE class using SOFIT. An immediate change was seen in the number of minutes of moderate to vigorous activity after one semester of the intervention and this, importantly, was maintained through fifth grade. Five years after the children were in fifth grade, the study group went back to look at institutionalization in the intervention and control schools, as well as some unaffiliated schools. There was a reduction in the difference between the schools, but there were some residual effects that have been reported in various papers. They found that basically the difference had to do with such characteristics as teacher transfer or lack of teacher transfer. Dr. Webber concluded that, in terms of the environment, the measures could be considered objective. In terms of individual behaviors in children, the measures were subjective.

Dr. Yanovski commented that the goal is to have changes in health over the long term. This may not mean changes in BMI, depending on the length of the intervention and what is being studied. She stressed that, however, in order to move the field forward, it was important to have objective measures rather than relying on self-reported attitudes and behaviors. Her concern was that children learn what expected attitudes and behaviors should be and that is what they report. Dr. Webber agreed and noted that this was discussed in the primary outcome variable paper for CATCH. He added that BMI and obesity, however, were not objectives of CATCH. Dr. Treviño agreed that it is important to have physiologic and biologic measures if there are to be greater impacts in the communities.

Dr. Matthew Gillman, Harvard Medical School, asked if there are data about cost effectiveness of the interventions as a whole, as well as of different components. For example, even with limited resources and difficulties with implementation, if food service changes, as an environmental intervention, were done on a regional, State, or USDA basis, there might be a substantial return on the dollars spent. On the other hand, given the many barriers discussed, efforts involving school teachers educating students to change their individual behaviors might be less cost effective. He asked if studies have been done or if there was information in existing datasets about cost effectiveness of the interventions and components to indicate which ones are the more cost-effective strategies. If not, Dr. Gillman would recommend that cost-effectiveness analyses be included in subsequently funded projects.

Dr. Webber responded that CATCH did not have any official cost-effectiveness studies, and they did not collect cost data. CATCH did not supply foods to the schools or give them money to purchase particular foods or to implement change techniques such as defatting ground beef. Changes had to be done within the existing budget guidelines of the school food service. One of the things learned was that schools are great economic sources in the community. For example, if a large school district says, "I now want a hamburger patty that's 5 percent lower in fat," vendors will find a way to do this because a great deal of their income comes from the school food service. There are not data on the number of visits to schools for training and on-site support that were needed to get school food service workers to meet the guidelines. It might be possible to go back and obtain such data.

Dr. Peterson contributed that Planet Health was evaluated for its cost effectiveness. The analysis was published in November 2003 in *Obesity Research*, along with an editorial calling for more such research. In the evaluation done, Planet Health was estimated to cost school systems $14 per student per year. The curriculum costs only $39; the additional cost was for staff time and so forth. The analysts then looked at costs from medical care and productivity losses that could be related to adult overweight, projecting prevention of overweight in approximately 2 percent of adult females and 4.1 quality adjusted life years. They found savings in medical and other societal costs.

Dr. Wechsler added that CDC's Division of Adolescent and School Health has a full-time economist on its staff who is looking for cost-effectiveness studies because these are powerful and critically important when talking with legislators and foundations. The Division of Nutrition and Physical Activity also has economists. CDC could do a study on Planet Health because the program had excellent documentation of costs and outcomes. Dr. Wechsler offered the analytical services of his division's economist to work with other study groups with similar outcomes and well-maintained data to translate their information into an economic analysis.

Dr. Treviño agreed that cost needs to be a part of effectiveness and efficacy. To implement the Bienestar program in all the San Antonio elementary school districts would cost close to $500,000, which is very expensive. On the other hand, it is estimated that there are approximately 5,000 children in those schools with undiagnosed diabetes. Studies have shown that in the healthcare setting, $13,000 would be spent on each of these diabetic children. The cost for these children would then be $72 million. The

issue then is whether to spend $500,000 early on or $72 million downstream. Dr. Treviño added that, ironically, the Texas Department of Health is more willing to pay $60,000 for each dialysis patient every year than to spend $120 a year for each child for a health textbook. Although this is difficult to understand, it is reality. He emphasized that more cost-effectiveness studies are clearly needed to substantiate the cost-benefit of early intervention in overweight and obesity.

A participant asked if the dietary targets of current interventions are the right ones. Although fruits and vegetables have been shown to have effects on cardiovascular disease and cancer, there is little evidence of their having any effect on weight change. In young adults, probably the best dietary approaches to preventing obesity and insulin resistance are fiber and dairy products. There are also questions about concentrating on total fat or saturated fat. Some of the inefficacy of dietary approaches may not be the intervention approach, but the targets of the intervention.

Dr. John Elder, San Diego State University, had a similar question. Most of the interventions seem to be based on social cognitive theory, whereas positive effects seem to be derived primarily from the environmental changes such as aggressive changes in the PE curriculum or reducing fats in the food service without even telling the children about this. He raised the issue of how relevant social-psychological theories were, especially when the term "school-based interventions" implies an environmental setting of classrooms and playgrounds and gymnasiums and cafeterias, in which, there are, of course, teachers and students. Dr. Elder suggested as a matter for discussion that interventions such as the School Health Index may be more relevant in this setting.

Dr. Resnicow remarked that he had made a similar suggestion at a meeting in New Mexico about 2 years ago. He agreed that there needed to be a serious discussion about the use of current theories in general. Dr. Thomas Baranowski has reported that only 9 percent of variance can be accounted for by current theories. Dr. Resnicow stated that part of the current difficulty with interventions is the measurement issue and part is use of the wrong theory. The current idea that 100 percent of the variance will be captured with our psycho-social measures is mistaken on many levels. His personal opinion is that 50 percent of the variance in health behavior is due to unpredictable, random, small and large events that cannot be captured with any of the current measures. Interventions can only make the ground fertile, so when a random event occurs, the seed may take place. With a few exceptions like self-determination theory, it is quite possible that current theories have lost their usefulness for interventions for large public health issues in general.

Dr. Peterson commented that for Planet Health, social cognitive theory was useful in structuring the curriculum and behavioral change theory was helpful in building skills and motivation. The study developers applied a concept based on behavioral change theory by linking satisfactory and unsatisfactory behaviors such as choices between reducing inactivity versus increasing activity. Dr. Peterson said she, therefore, was not ready to abandon behavior change theory. Regarding measurement, changes in TV viewing could be effectively measured.

Dr. Sallis suggested that, rather than dismissing psycho-social theories, it might be that interventions were in the wrong sequence. Children were being asked to make choices in an environment that made those choices difficult and sometimes impossible. For

example, following a lesson on nutrition education in which children are told to choose fresh fruits and vegetables, they go to the cafeteria where the only choice is between hamburgers and hot dogs. In such a situation, psycho-social interventions cannot be effective. Then when the children arrive home, they are told to stay inside where it is safe, eliminating the choice to be active, and to sit down and eat foods other than fruits and vegetables. From an ecological point of view, if first healthy choices are made easier and available, then teaching children skills and decision-making should be more effective. Dr. Sallis recommended that this is the direction that needs to be taken in the future.

Dr. Gilman Grave, NICHD and the initial Project Officer for Planet Health, stated that he was disappointed when only the girls showed an effect in the reduction of TV viewing component. Did the boys stop watching as much TV, too, and if so, why was there no effect on their obesity? He also asked if Planet Health planned to always conduct the analysis by boys versus girls or was this a post-hoc decision.

Dr. Peterson responded that in any research team, there are always different voices supporting different approaches. The stratified analysis of boys and girls was selected based on the difference between girls' and boys' developmental trajectories and when the periods of incidence for overweight tend to occur. At baseline, the girls were between the ages of 11 and 13. The average age of menarche would be at 12, which is also the average age of peak height velocity. Peak weight velocity precedes this by about 11/2to 2 years. Taking advantage of these critical periods of behavioral and biologic adaptation, the study was designed to be implemented as the girls came off peak weight velocity into peak height velocity. Dr. Peterson said she would like to look at the boys 2 years after the study ended to see if that would be where they potentiated biologically. She stressed that she felt very strongly that it was important to assess obesity in such a stratified manner because of the different developmental and maturation trajectories. In answer to his first question, she said that the boys, like the girls, did reduce their TV viewing by half an hour a day and there was no significant effect on their weight.

In response to Dr. Grave's asking if other screen time such as DVD, CD, video games, and instant messaging was included in the 5-2-1 Go! intervention, Dr. Peterson answered that it could be. The initial Planet Health data were published in 1999 and covered a period in the mid-1990s when children watched approximately 4.5 to 5 hours of TV a day. The screen time is slightly higher today and is about half and half TV viewing and computer usage. The Planet Health curriculum has not been changed yet so it still emphasizes TV viewing. A decision was not made to intervene with computer use; however, 5-2-1 Go! has more detailed evaluation measures that would enable analyzing other screen time. Dr. Peterson said they also looked at reading and homework time and can assess changes in those over the course of the trial.

In response to questions from Dr. Debbie Young, University of Maryland, regarding funding of dissemination of the interventions and sustainability evaluations, Dr. Webber said that research funds for dissemination are very difficult to acquire, so there is not a lot of data yet regarding dissemination of CATCH. Texas has done a great deal of dissemination, and there is a little data on this, and trainings also have occurred throughout the Nation, in different pockets, as well as at military-based schools in Germany and in Japan. CATCH did have funding to collect pre- and post-data on menu and recipe use and on use of

SOFIT in one school district in Louisiana that showed that, at the end of 3 years, there were changes in the desired directions. There was adherence to fat guidelines for school lunches and to increased minutes of moderate and vigorous physical activity with SOFIT. From 1987 through 2000, CATCH was funded by NHLBI. All the funding for dissemination has come from other sources such as the Texas Department of Health, foundations, and so forth. Dr. Webber agreed that evaluation of sustainability was essential to know how well the interventions last, but not all of these sources were interested in or required extensive evaluation. He added that what makes dissemination possible without research funding is the providing of attractive materials and promoting the materials through a national distributor, because schools are an enormous economic source. They buy schoolbooks all the time and are looking for health materials, particularly for elementary schools, that are easy to use and do not require a lot of preparation of lesson plans on the part of the teacher.

Dr. Resnicow remarked that there is an interesting parallel in tobacco research. In the mid-1980s, the National Cancer Institute issued an RFA on diffusion of school-based tobacco prevention programs. They funded randomized studies testing different diffusion strategies. Dr. Resnicow suggested this could be a mechanism for obesity interventions, but he did not think the field was ready for it yet. There appeared to be two viewpoints being expressed by the meeting participants. Some were saying, "Show me the physiologic effects before I'm going to call this intervention effective." Others were saying, "We had strong behavioral and environmental effects, which make these effective programs, and people are adopting them." Until there is consensus on what determines whether an intervention is effective or not, it was unlikely that NIH would fund testing diffusion strategies. Dr. Resnicow also noted that in the 1980s and early 1990s, there were two interesting mechanisms to diffuse programs. One was funded by the U.S. Department of Education that provided Federal money to train teachers and disseminate programs. The other was funded by CDC for programs that had been shown to work. Unfortunately, these mechanisms apparently no longer exist.

Dr. Young expressed concern about disseminating materials without testing to see how they will be used in the real world and whether or not they will be effective there. Schools need to invest their limited resources where they will have the most impact.

Dr. Sallis commented that there will always be discussion about how much evidence is necessary to decide a program is effective. For example, CATCH and SPARK demonstrated that their physical activity components were better than the usual PE classes in the schools, which should justify disseminating them rather than staying with the status quo. There can be an insistence that it be demonstrated that they also work in a diffusion phase, which CATCH has done and SPARK has done to some extent. Dr. Sallis suggested that the issue is one of getting into a situation where a lot of school districts say, "We want to adopt this, but we need to make sure it's going to work here, so we need to do a study first," which is not feasible. Each and every school district cannot pre-test a program to see if it works in their district. Dr. Sallis agreed that there definitely is a need for diffusion research to make the case that evidence-based programs can be effectively implemented. While some dropoff is expected from the most controlled trials, a serious effort is needed to move programs that have shown effectiveness and are better than what exists now from the laboratory into practice. Given the current incidence and the growing trend in

overweight and obesity among children and adolescents, there will be a tremendous public health cost as a result of waiting until every piece of evidence is lined up. Dr. Sallis stressed that the focus of discussion needed to be on deciding where the boundary should be drawn between the need for more efficacy/effectiveness testing and for willingness to use the best of what is available and for which we have some positive evidence. Granted, it would be good to be able to show that each of these programs has an effect on BMI or body fat. However, each program is only a piece of the solution. Even the best school programs may not be enough, in themselves, to have that impact. This does not mean they are not valuable as long as they show they do what they are intended to do—change dietary intake and physical activity. In changing energy balance, they are contributing to an overall effect that has to be supported by family programs and community programs. Dr. Sallis emphasized that there needs to be a complete package.

Dr. Young pointed out that CATCH was an expensive study that included a high level of research rigor. She suggested that a real-world effectiveness trial, perhaps along with some dissemination at the same time, could have identified and addressed difficulties prior to proceeding to a full institutionalization phase and ensured better results.

Dr. Peterson commented that the NCI 5-A-Day program is a valuable source of data on process implementation evaluations that is receiving increasing attention in the literature. NCI and 5-A-Day have taken a lead in seeking information on what worked in delivering various interventions in schools. CDC also has a model program site. Dr. Peterson stated that process evaluations are important to learn about dose and fidelity implications, about replications, and about age and gender appropriateness. The project director and co-Principal Investigator of the Prevention Research Center has a paper in press describing Planet Health within a community-based participatory research framework. Dr. Peterson noted that one of the important elements of the project was that the study group worked with the teachers throughout the process, and a key point in the article is assessment of whether teachers found the curriculum viable. Dr. Jill Carter, the lead author of the Planet Health curriculum, is a teacher.

Dr. Treviño stated that in 1991, Bienestar was in one elementary school, working with 40 children. In 2004, it is in 94 elementary schools in 6 school districts, working with 7,000 at-risk children. He noted that from 1 school to 94 elementary schools over a 13-year period is a very slow growth rate. The reason for this slow growth is that Bienestar is considered more of a medical intervention than an educational intervention. Ninety-four percent of the children targeted have all the risk factors for diabetes. Sixty percent of these children have family members with diabetes. In May 2005, fasting capillary glucose will be measured in all these children, and fitness tests will be conducted. When working with sick children, such measurements are necessary for accountability and to assess change. Bienestar will not go into another school district with the intervention unless it is able to measure these at-risk children and produce results. Dr. Trevin_o stressed that there is always a fine balance in making such decisions. For Bienestar, it was felt that it was better to work with 10 school districts and hopefully lower blood sugars by next May rather than take the intervention to 1,000 school districts and possibly produce no effect.

Dr. Mary Ann Pentz, University of Southern California, commented that individual behavior change theories are the cornerstone for building curricula and so forth in interventions involving policy, particularly in school and community environments. Her group is conducting the Tobacco Prevention Program (TOPP) trial in approximately 20 middle schools in 4 districts in California. TOPP has a tobacco policy intervention component. At baseline, less than 10 percent of the teachers and less than 4 percent of the students knew there was a school policy on tobacco and drug use. When TOPP built a curriculum aimed at changing the school environment, they found that students' awareness increased, compliance increased, and support of the policy increased and this, in turn, drove behavior change in tobacco use. In other words, school environmental change interventions are not passive interventions. Dr. Pentz asked if others had built awareness of school policy into interventions. She also asked if those building DVD-based interventions had a counterpoint to offset an outcome similar to that of passive TV watching. Dr. Pentz had come across a Swiss study published in 2004 showing an adverse effect of electronic game-playing on the outcomes for overweight.

Dr. Resnicow responded that the University of Michigan is creating an interactive DVD and has grappled with the important issue of using DVDs and computers in interventions. The total dose of DVD time will probably be 15 to 20 minutes per week in the classroom, not in PE, which is time when the students would be sedentary anyway, so this should not add to the problem of inactivity as it might if it took 14 hours a week to play the game.

Dr. Peterson mentioned that there is an emerging technology being financed by Sony that should be on the market very soon that requires that the player move in order to play the interactive games. This is another technique that could be used in an intervention.

Dr. Bazzarre, Robert Wood Johnson Foundation, presented the group with several issues. Everyone recognizes the complexity of the issues. Obesity must be reduced somehow, and BMI is the indicator currently used as the outcome measure. Dr. Bazzarre noted that the current interventions report a lack of impact on BMI, but there is evidence of behavior change—children eat the healthier foods and are more active. He suggested that the reason an effect is not being seen on BMI is that the dietary changes (more fruits and vegetables, less fat and saturated fat) are not impacting energy balance. Given the difficulty of measuring energy intake in children, perhaps the interventions are actually successful. Similarly, where there have been significant increases in activity, perhaps that energy expenditure simply has not been a sufficient dose to alter BMI. More needs to be understood about energy balance—intake and expenditure—and what are sufficient intervention doses for diet and physical activity. He added that using BMI as a measure may also be hampering assessment of the interventions' successes.

Another issue is whether the environment is fully supportive of the intervention. If not, this may be another reason there is behavior change but more impact on outcomes is not seen. Dr. Bazzarre suggested that research is needed to learn how to assess, and if required, effectively change the environment to be more supportive. Finally, as part of the ecological

model, families probably have not been well engaged in these studies. Diet or activity patterns at home may be undermining the interventions' potential effects on BMI.

Dr. Resnicow added that in focusing on essential nutrients for the next generation of interventions, whole grains, milk, and water need to be included. He also pointed out that teaching about energy balance may be more of a challenge than discussing reducing TV time and consumption of fizzy drinks. His group has engaged a social marketing contractor to come up with a framework and tangible, captivating ways to teach energy balance from a behavior change approach.

Dr. Caballero reminded the group that, contrary to adults, children need to be in positive energy balance. This creates additional difficulties; one cannot just promote controlling energy balance. Furthermore, if the intervention program includes physical activity change, children may need to consume more energy to maintain energy balance. Dr. Caballero pointed out that inevitably behaviors will have to be introduced to enable children to consume more energy if they are to grow normally and maintain energy balance in the face of more exercise and consumption of healthier, lower-energy dense foods. Under-nutrition is unlikely in an obese adult who is trying to lose weight. For children, concentration on reducing energy balance runs the risk of negatively affecting their growth.

Dr. Bazzarre added the comment that this underscores the potential importance of a higher dose of physical activity to help shift the distribution of body fat and lean body mass without impairing growth.

Dr. Webber recommended that studies start with children younger than 8-years-old. Dr. Treviño supported this recommendation by citing information from a paper published in the Journal of Clinical Investigation in 1979 that indicated fat cell size starts to increase between the ages of 2 and 9, increasing up to a certain point and then triggering cell number proliferation (Knittle JL et al. The growth of adipose tissue in children and adolescents. Cross-sectional and longitudinal studies of adipose cell number and size. J Clin Invest. 1979 Feb; 63(2):239-246). Once this happens, the fat cells do not go away; the best that can be accomplished is to shrink the cell size in adulthood. Dr. Treviño stressed that interventions are needed when these biological events are happening in the early years of a child's development.

SESSION 2

Home, Other Underutilized Sites, and Novel Modalities

SESSION 2: Home, Other Underutilized Sites, and Novel Modalities

Moderator: John P. Elder, PhD, *Professor, Graduate School of Public Health, San Diego State University, CA*

The GEMS Phase 1 Program: Four Pilot Studies
Eva Obarzanek, PhD, *Acting Leader, Prevention Scientific Research Group, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute, NIH, Bethesda, MD*

Dr. Obarzanek stated that GEMS (Girls Health Enrichment Multi-Site Studies) was initiated to address obesity prevention in the high-risk group of African-American girls during puberty, a critical period when fat deposition occurs and accelerates. She stressed that GEMS was called a healthy behaviors study, not an obesity study. Dr. Obarzanek noted that the issue of addressing obesity in children and adolescents and achieving a desired outcome without stigmatizing them remains a difficult one. GEMS is a two-phase program. Phase 1, the developmental phase, was 3 years in duration, consisted mostly of formative research, and culminated in the conduct of four pilot studies in preparation for the current 4-year Phase 2's full-scale trials. Phase 1 took place from 1999-2002; Phase 2 began in 2002 and will be completed in 2006.

For additional details on the GEMS pilot studies, Dr. Obarzanek recommended the following references: Kumanyika, SK, Obarzanek E, Robinson TN, Beech B (guest editors). Winter 2003. *Ethnicity and Disease* 13(1) Supplement 1; Baranowski T, Klesges LM, Cullen KW, Obarzanek E (guest editors). May 2004. *Preventive Medicine* vol. 38, Supplement; and Story M, Smyth M, Sherwood N, Obarzanek E (guest editors) ,September 2004 *Obesity Research*, vol. 12 Supplement.

Eligibility Criteria and Measurements. GEMS' four separate 12-week intervention pilot studies were conducted at four field centers supported by a coordinating center. The studies were designed to be collaborative and consisted of common elements in order to compare results and improve the synergy involved with the collaboration. Eligibility criteria and common key measures (height, weight, 24-hour recalls, physical activity) were similar. At least two centers used the same instrument for various psychosocial measures. Although the four centers shared common elements each had their own intervention.

Dr. Obarzanek explained that Phase 1 goals were to assess feasibility, acceptability, and potential of the interventions. Specific objectives were to assess the recruitment experience, the follow-up rates for study-wide measurements (i.e., would the children return for measurements), adherence to intervention components, and behavior changes in the expected directions, especially for diet, physical activity, and the psychosocial measures. As pilot studies, sample size was small, so there was really no power to obtain statistical significance as will be done with the full-scale studies.

The eligibility criteria were similar, but not exact, among the four field centers. All children were African-American girls, ages 8 to 10. The Minnesota and Memphis centers had a more expansive eligibility for BMI beginning at the 25th percentile, which included some lean, but not very lean, children. The Baylor center used the 50th percentile and above for the children as the cutoff, and Stanford added to this the alternative criteria of having one parent with a BMI ≥25 kg/m2.

The four centers agreed that the measure of obesity would be body mass index, easily measured with

height and weight, and they also included waist circumference. Dr. Obarzanek said that some of the centers also measured body fat from DXA (dual-energy x-ray absorptiometry). For dietary intake, the common measurement came from two 24-hour recalls. The primary dietary targets were to increase consumption of water, fruits, and vegetables and to decrease consumption of sweetened beverages, total calories, and calories from fat.

Physical activity was measured by accelerometers. For 3 days, counts/minute were recorded from 6 a.m. to midnight and minutes of MVPA (i.e., ≥3200 counts/minute) were recorded from noon until midnight. The girls also completed self-report questionnaires.

Dr. Obarzanek listed a number of psychosocial measures for diet and physical activity. Diet-related measures focused on the home environment and the availability of fruits, vegetables, and low-fat foods; home barriers to healthy eating; food preparation practices; and preferences for sweetened beverages. Physical activity-related measures were outcome expectancies for physical activity; self-efficacy for physical activity; physical performance self-concept (from the Harter scale); and physical activity preferences. Dr. Obarzanek reminded the group that, with a sample size of 35, there was not high statistical power for these pilot studies. Results for all four centers were based on indications of changes in the desired direction and were adjusted for baseline levels.

Baylor GEMS Intervention and Results. For their 12-week intervention, Baylor had a special 4-week summer day camp followed by an 8-week Internet component at home (with a new story each week) for the intervention group. The control group attended a 4-week standard summer day camp and then could log on to two monthly Internet programs at home. The control group Internet programs did not focus on enhancing diet and physical activity. Dr. Obarzanek noted that the day camp was very popular with the intervention group (92% attendance), even when a hurricane came through and flooded the whole area, requiring them to shut down. There was 48 percent compliance with the Internet goal of logging on at least once a week.

Baylor achieved an 89 percent follow-up rate for the girls returning for measurements at the end of 12 weeks. Dietary intake results from 24-hour recalls for the intervention group in comparison with the control group were a 232 kcal reduction in calories and 1.6 percent reduction in calories from fat, a 20 percent increase in fruits and vegetables, a 40 percent increase in water, and 20 percent decrease in sweetened beverages, showing that dietary behaviors changed in the desired direction. Physical activity results were mixed. Adjusted for baseline levels, the intervention group compared to the control group increased their counts/minute but had lower MVPA. BMI also differed slightly in the wrong direction with a 0.6 kg/m2 greater increase compared to the control group.

Minnesota GEMS Intervention and Results. Minnesota's intervention group held weekly sessions focused on eating a healthy diet and increasing physical activity and included two family nights. The control group had monthly sessions on self-esteem with a cultural enrichment program. Sessions were held after school at an elementary school. There was an 88 percent rate of attendance at the intervention sessions. At the 12-week follow-up, 98 percent of the 54 children in the study returned for the study-wide measurements. Changes in diet behaviors in the intervention group compared to the control group

were mixed. Calorie and fat changes were in the expected direction (-124 kcal and -1.1% fat), but not the fruits and vegetables (-16%) or the sweetened beverages (+11%). Water consumption increased 13 percent, which was in the desired direction. Physical activity changes were in the direction hoped for with an increase of 57 counts/minute overall and three additional minutes of MVPA. However, BMI increased 0.2 kg/m^2 more in the intervention than control group.

Memphis GEMS Intervention and Results. This center had two active interventions and a control intervention. Dr. Obarzanek explained that, since the literature was mixed as to whether the best targets were parents or children, the Memphis investigators decided to have an intervention for each. The girls' and parents' interventions had 90-minute weekly sessions, and the control intervention was monthly sessions on self-esteem. The venue was community centers in the evening. In the child-targeted intervention, 83 percent attended at least 80 percent of the sessions. Ninety-four percent of the parents attended at least 80 percent of their sessions. Memphis achieved a 100 percent return of their 60 participants for the follow-up measurements. For the girls' intervention, nearly everything changed in the hypothesized direction for the intervention compared to control groups. Calorie and fat intakes were reduced more (-242 kcal and -0.1%); fruits, vegetables, and water were higher by 20 percent; and sweetened beverages were reduced by 20 percent. Changes in the desired directions were also seen in the parent's intervention, except for water, which was lower than the control group by 18 percent. However, sweetened beverages were significantly lower by 49 percent. Physical activity, in both intervention groups, was in the desired direction, a positive 24 counts/minute and +4 minutes of MVPA for the children and a positive 32 counts/minute and +11 minutes of MVPA for the parents. In Memphis, BMI decreased 0.4 kg/m^2 less for both children and parents in the intervention groups compared to the control group.

Stanford GEMS Intervention and Results. Stanford offered a dance class 5 days a week in community centers after school. The sessions were 2 1/2 hours long with actual dancing for 45-60 minutes. The reason for this was that homework help was provided prior to the dancing. Dr. Obarzanek stated this could be called an environmental-type intervention. Part of their intervention was also to reduce television viewing at home so there were five home sessions over the 12-week period. There were also health education newsletters. The control intervention had monthly general health education lectures and also some health education newsletters that went to the parents and to the girls. Forty-six percent of the girls met the attendance goal of at least two dance classes a week. Stanford had a 98 percent follow-up rate from their 61 participants. Diet results were mixed and very small. There was an increase of 84 kcal and only a 0.3 percent decrease in fat compared to controls. Physical activity, however, did change in the desired direction with a +26 counts/minute and +7 minutes of MVPA compared to the control group. There were also 20 percent fewer hours per week of TV watching, and BMI was lower by .3 kg/m^2 compared to the control group. Although Stanford did not have a direct dietary intervention, it is expected that when children are dancing they are not eating and when they reduce their TV watching, they are less exposed to TV commercials for food and eat fewer snacks.

Summary of Results. In Dr. Obarzanek's overview of the GEMS results for the four pilot studies, the targeted BMI and healthy eating components had the following results:

- Baylor: All components were in the hypothesized direction, except for BMI and MVPA.
- Minnesota: BMI was not in the hypothesized direction; diet was mixed, as fruits and vegetables and sweetened beverages were not in the desired direction. However, physical activity was in the hypothesized direction.
- Memphis: everything was in the hypothesized direction, for both interventions, except for the parent target with water.
- Stanford: BMI, physical activity, percent fat, and TV watching changed in the desired direction, although calories increased slightly.

Dr. Obarzanek noted that not all psychosocial measures were included at each center. In general, results were mixed for changes in availability of foods, food preferences, and physical activity attitudes and preferences.

GEMS Phase 2. Dr. Obarzanek said that Memphis and Stanford are now testing their 2-year interventions in Phase 2. Memphis will continue their diet and physical activity intervention, combining the best of the features of the child- and parent-targeted interventions into one intervention. Stanford is continuing with their physical activity focus using the community center-based dance classes and the home intervention to reduce TV viewing. Diet intervention will be indirect. The primary outcome for both centers will be BMI at 2 years.

Lessons Learned. Dr. Obarzanek stated that a number of conclusions and lessons learned can be derived from the GEMS pilot studies. First, interventions can produce behavior changes in the desired direction in children. Community settings, which all of these studies used, offer an important venue for healthy lifestyle activities in children. The day camp was a particularly novel approach that should be developed further. The Internet intervention also needs developmental work. The log-on rate was low, but even as a weak intervention, the Internet is a viable medium because it has the potential for a broad application on a large-scale that can have a beneficial impact. All four centers learned that the family participation is very important. Families rated the family component highly, but attendance was poor, so methods need to be found to involve the family and caregivers and increase participation. Such activities as the children's performances described earlier might be good techniques.

Dr. Obarzanek noted that several barriers need to be addressed, including providing transportation for children to community centers and other outside school venues. The reason Stanford had a 2 1/2-hour session with only an hour of dancing was because they had to provide tutoring assistance with homework in order for the children to attend the session. Parents are concerned about academic achievement and are not always willing to let their children spend time on what they consider less important activities. Accommodating summer schedules is also important. For both intervention and recruitment, summer is a downtime. Finally, when parents are involved in an intervention at a community setting, child care must be provided.

Research Directions. Dr. Obarzanek recommended the following future research directions:

- Assess longer-term interventions.
- Test whether behavioral changes can reduce the excessive weight gain or prevent obesity.
- Identify key behaviors associated with weight control.
- Identify environmental and psychosocial factors that mediate behavior changes.

Family-Based Behavioral Interventions

Leonard H. Epstein, PhD, *Distinguished Professor of Pediatrics and Social and Preventive Medicine, University of Buffalo School of Medicine and Biomedical Sciences, NY*

Dr. Epstein explained that he would be speaking about family-based interventions, first discussing behavior modification; then the importance of including the parent as an active part of obesity treatment; next, new data on conjoint effects of family-based interventions; and finally benefits and challenges of family-based interventions. His emphasis would be on the family-based intervention used at the University of Buffalo School of Medicine.

Family-Based Behavior Modification. Dr. Epstein stressed that a family-based intervention really treats the parent and child together, not separately, with the parent receiving the same intervention as the child. This concept often is not what takes place in so-called family-based interventions. At Buffalo, treatments target the parent and child for both behavior change and weight loss. The eating program is the Traffic Light Diet. The exercise program is a lifestyle physical activity program. The hallmark of all of the treatments is the use of very strong behavioral treatment techniques to promote behavior change and positive parenting. These techniques include self-monitoring, social reinforcement, stimulus control, problem solving, and pre-planning.

The purpose of the first study that Dr. Epstein's group did, which was in the late 1970s, was to compare a behavior modification program with a nutrition education program to see if it was really necessary to do behavior modification in a family-based study on weight. The reason for this comparison was because behavior modification requires a different kind of training than most people have and it is more time-consuming, so if providing education alone worked equally, or nearly equally, that would be simpler and less expensive. Families with obese 6- to 12-year-old children were randomized to two groups. Both groups in the study received the same information and had the same level of contact; however, over the 8 months, the behavior modification group was still losing weight and, although the nutrition and activity education group lost some weight initially, it was not very much, and they then reached a plateau. An interesting finding in the study was that there was a 0.8 correlation of parent and child weight loss.

Dr. Epstein presented data on the odds ratios for obesity in young adulthood based on children's obesity in childhood and their parents' obesity (Whitaker RC et al. 1997. NEJM 337:869-873). At ages 1 to 2, if both parents are overweight, the child is 14 times more likely to become overweight in adulthood. At ages 3 to 5, the overweight child is 15 times more likely to become overweight in adulthood in comparison to thinner youth. The risk associated with parental

obesity decreases as the child gets older, but the obese child's risk, compared to the non-obese child, increases. A 2-year-old child with two overweight parents and other overweight siblings is living in a very risky environment.

The second study in Dr. Epstein's group looked at the role of including the parent in pediatric weight control. Approximately 80 families with 6- to 12-year-old obese children who had at least one obese parent were randomized into three target groups: a parent-plus-child (with both expected to make behavior changes and lose weight), a child-alone (the usual target, with the parent accompanying the child and being weighed but not directly targeted to change), and a non-specific control group who were measured and received education but neither the parent or child were directly targeted.

Ten years of data were collected for this study (Epstein L et al. 1994. Health Psychology 13:373-383). The final sample included more than 90 percent of the people initially randomized. Dr. Epstein reported that the parent-plus-child group lost weight and maintained the loss over the 10 years. The child-alone group lost a little weight over time, but the non-targeted control group gained weight and maintained that weight gain. Dr. Epstein pointed out that the children did not do as well as the parents in this study, which led the investigators to make some changes in working with the parents. The study has been replicated three times, so there are four studies with 10 years of data. There are three other research groups that have published at least 5-year outcomes that are very similar.

Dr. Epstein pointed out that when families are seen together, the parents do most of the talking. When children are seen separately, they then talk and say things they would not say with their parents present. Dr. Kelly Brownell did a treatment study of obese children with and without their parents (Brownell, Kelman, and Stunkard. 1983. Pediatrics. 71:515-523). When the parents and children were seen together, outcomes were not as good as when they were seen separately; however; seeing them together was better than not seeing the parent at all.

Another interesting study on childhood obesity looked at what happens if only the parent is treated, not the child at all, although the child is measured at intervals (Goldman et al. 1998 Am J Clin Nutri 67:1130-11135). Over the 18-month study, both the parent and the child lost weight, although the effect on the parent was greater. Dr. Goldman suggested that this technique of the parent serving as the change agent in the environment was less expensive and robustly successful.

The Parent as an Active Part of Obesity Treatment. At the University of Buffalo School of Medicine, researchers are assessing the relationship between parent and child weight loss. The first trial with the 10-year outcomes closely examined parent weight loss. These parents, who were also obese, arranged the eating and activity environments for their children and modeled eating and activity behaviors. To lose weight, parents rearranged the shared family environment to accommodate their required eating and activity changes. They bought different foods and were more active to lose their weight. In addition to changing the environment, they were modeling different behaviors.

To further determine if there was a relationship between parent and child weight change, Dr. Epstein's group combined data across three randomized trials with approximately 150 families (Wrotniak

BH, Epstein LH, Paluch RA, Roemmich JN. 2004. Arch Pediatri & Adolesc Med 158:342-347). The parents were divided into four groups based on who lost and maintained the most weight versus those who did not do as well. While the average loss across the four quartiles was close to 20 pounds maintained for 2 years, there was a significant difference in the BMI z-scores between the best group who lost about 30 pounds and the other three groups.

The children's BMI z-scores had basically the same relationship. The children whose parents were the most successful, also did the best. Dr. Epstein said that there has been some deterioration over time in these children that was not seen with the parents. He added that it is very hard to maintain these changes over time. Because they have done 2-, 5- and 10-year outcomes, his group has shown that the 2-year point is a good indication of the 5-year and the 10-year point. There seems to be some activity occurring in the first 2 years of an intervention that is important for long-term behavior change. Dr. Epstein's group just completed a trial of a parent-child intervention in which all the weight lost was maintained over 2 years. Data are not available yet for this trial, but he expects it to have an important impact on future studies.

Conjoint Effects of Family-Based Interventions. To understand the factors accounting for similar weight loss in the parents and children from the earlier study, at the 2-year followup, Dr. Epstein's group asked them about adherence to specific components of the intervention. Questions were asked about recording of food and calories, staying within the caloric range, daily weighing, using the food reference guide, meeting the activity goals, and parent modeling. Other question were about activity recording, eating less than seven red foods per week, daily weight graphing, nightly meetings, using praise, and planning ahead.

Hierarchal regression models were used to identify determinants of successful child and parent weight loss. Dr. Epstein explained that the hierarchal regression model provides for control of background variables and then allows for examining the additional benefits of adding new variables. To predict child percent overweight change over 24 months, the model's step 1, background variables, included child and parent gender, SES (social economic status), child and parent ages, parental BMI, and parental BMI change. Parental BMI change was the only one of these variables to significantly relate to the child's change.

Next the child's behaviors were added as variables in step 2 to see if something about their behavior helped in understanding the weight loss. Child behaviors included weighing and child pre-planning. Combined, these accounted for another almost 10 percent of the variance. In step 3, parent behaviors, which included parent praise for child behavior change and parent modeling, accounted for another 5 percent. Dr. Epstein stated that these are all theoretically quite relevant and what one might expect in thinking about how parents and children might interact to make behavior changes.

Looking at parent percent overweight change over the 24 months with the regression model, the background variable that predicts child change in weight also predicts the parent's change—parental BMI, especially the mother's BMI. Step 2 in this model combined child and parent behaviors. Self-monitoring was found to be critical, regardless of the accuracy of the self-recording by the child. Dr. Epstein pointed

out that a diet record from somebody on a diet will always reflect what the person has been told to do. The importance of keeping the record is not how accurate it is, but rather that doing so keeps the person aware of the need for behavior change. Parent modeling accounted for another 14 percent of the variance, indicating that parent modeling tends to relate both to child weight loss and parent weight loss. Even if parents are not trying to model, they are automatically doing it since in order to lose weight themselves, they must eat differently and be more physically active. In fact, the best result Dr. Epstein's group has had for parent and child weight loss together was when the parents and children exercised together.

Benefits of Family-Based Behavioral Treatment. Dr. Epstein repeated that family-based means treating both the parent and child. More than 20 years of research proves that family-based treatment is effective in treating obese youth. There is a concurrent treatment benefit for the obese parent. This type of intervention is more effective than treating each family member separately. Family-based interventions can be used to treat obesity and comorbidities in multiple family members, such as type 2 diabetes in the parent and obesity in the child, or type 2 diabetes in both the parent and child. Importantly, family-based treatment provides an opportunity to prevent obesity in the at-risk youth whose parent(s) is obese.

Challenges of Family-Based Treatment. Dr. Epstein explained that one reason investigators do not treat the parents and child directly is that doing so requires expertise in both parent and child treatment, and that is not easy to come by. Many people who treat children are comfortable with children, but not with parents, and most people who treat adults tend to be less comfortable with children. Family-based treatment may require a team who feel comfortable in treating the whole family. Also, two trained therapists are needed for concurrent sessions, thus increasing staff resources. At Buffalo, there is a parent group and a child group, each treated separately and then brought together for a family session, but all the educational interventions are done separately. Another possible challenge that has not been seen in Dr. Epstein's studies but that is often reported is that the parents may not be motivated to receive treatment for themselves; they consider the problem to be their child's weight. The reason he has not encountered this barrier may be because Dr. Epstein works in a clinical setting, not a community setting, and people come for treatment when recruitment is advertised through newspapers or through pediatricians. About half of the people who respond to the recruitment ads come to an initial screening session. At the screening session, they are told that the parent will be included as an active participant. In 20 years, only one family has declined to participate. Most parents appreciate getting help for themselves as well as help for their child. They understand the importance of changing the family eating and exercise environment. Finally, it may be more challenging to change behaviors of multiple family members than of one family member because of the many intra-family elements such as mom having to have ice cream, dad having to have steak, and the teenage brother, who has his own money, bringing food and sodas into the house.

Lessons Learned. Dr. Epstein's list of lessons learned included:

- Behavioral techniques improve pediatric weight loss.
- Including parents as active participants improves pediatric weight loss.
- Family-based weight control improves both the parent and child weight loss pool.

Future lessons will be learned from the next generation of studies that Dr. Epstein's group is beginning in order to identify factors related to concordance of change in parents and children. Is it modeling? Is it changes in the shared family environment? Is it the support that the child brings?

Media – VERB: It's What You Do!

Faye L. Wong, MPH, PhD, *Director, VERB Campaign, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, GA*

Dr. Wong explained that VERB is a CDC-funded paid media campaign to reach and activate youth 9 to 13 years of age (the tweens). The primary target age was selected because that is when youth begin to become independent of parents and begin to make decisions on their own. Secondary audiences are parents, teachers, and youth leaders. VERB's mission is to increase and maintain the number of tweens who are physically active in order to fulfill a vision of all children living a healthy lifestyle.

VERB is about building a brand (as GM, Ford, Coke, and Pepsi are brands) to sell physical activity. Unlike a commercial product, physical activity is an experience. VERB is a tween's brand for having fun, playing, and being physically active. For youth, physical activity is not about a rational need; it is an emotional desire. VERB does not just inform, and it does not preach. It creates affinity, a sense of belonging, and self-motivates.

VERB's integrated campaign components include marketing (mass media, public relations, and working with the entertainment industry), public and private partnerships, community events and community programming, and, research and evaluation. The program is based on formative research, testing, and evaluation. The campaign uses a surround strategy involving numerous channels to reach tweens. The bottom line is that VERB messaging is everywhere you find tweens—at school, in the community, and at home.

Marketing Strategy. The campaign strategy to create the brand, VERB, included generating brand awareness and affinity, providing opportunities for initiation of trial behaviors, and encouraging and reinforcing everyday play. Affinity means that when children see or hear about VERB, they recognize it positively and know that it stands for having fun, being "cool," being physically active, and being "for kids and by kids"—not something they are told to do by adults. Dr. Wong said that many children are not active because they have not been exposed to the many ways to be physically active—for example, swimming, playing basketball or soccer, or biking . If given an opportunity to try these or other physical activities, they might be introduced to a VERB that they like to do.

The VERB campaign created an ethnically diverse, true-to-the-brand campaign. CDC works with seven advertising and marketing agencies. Several target the multi-ethnic general market audience; others include an Hispanic-owned agency, African-American-owned agency, Asian-owned agency, and American Indian-owned agency. Each of these agencies are specialists in reaching their particular population market. Dr. Wong suggested that those interested go to http://www.cdc.gov.verb to see the current ads that encourage tweens to try new physical activities and play every day. The concept behind the VERB brand is that there are thousands of verbs in the dictionary that are all about action. What is the action

that moves you? What verb turns you on? Is it running? Is it swimming? Is it climbing? Is it hiking? What is the verb that motivates you? The initial ads were intended to spark interest and curiosity in what VERB isl; the current ads are focused on getting tweens to be physically active. For example, a recent ad aimed at multiethnic audiences and created in partnership with Venus Williams says, "Play your way. Play anytime. Play anywhere. It's not about playing by professional rules. It's not about being on the team. Go out in your backyard and play."

Partnerships. Dr. Wong explained that since VERB was a newly created brand and advertising is unlikely to be successful alone in motivating and sustaining youth to be active, partnerships are an important component of the campaign. The CDC team aggressively sought out partners to extend awareness of the VERB brand, elevate the value of the VERB brand, provide access to places for play and physical activity, reward tweens with prizes, and provide them with instructions on how to engage tweens in being physically active the "VERB way." VERB's win/win, best-in-class partnerships include online, mobile tour, retail, and community groups. Media partners include Disney, Cartoon Network, *Sports Illustrated for Kids*, Telemundo, Nickelodeon, and others. Celebrity partnerships include Venus Williams (tennis), James Blake (tennis), Tracy McGrady (basketball), Apolo Ohno (Olympic skater), Landon Donovan (soccer), and Donovan McNabb (football).

Other partners are sports leagues such as the NFL, WNBA, MLS, WTA, NHL, and USTA. All of these sports leagues share a common mission with VERB—to get children interested in being active. The leagues want to interest youth in their particular sport through engaging them in trying it and by helping them to develop the skills to be proficient or even join a team. Not only will these youth have opportunities to be active, they may become lifelong advocates who buy tickets and go to the games. Public and private sector partnerships with corporate America include the Sporting Goods Manufacturing Association, which is the trade group representing all the companies that sell athletic equipment, apparel, and so forth, and Wilson's, who has donated basketballs and other equipment for VERB community events.

Dr. Wong stated that the VERB campaign is a social marketing campaign that merges private sector commercial marketing strategies with public health. This is sometimes like merging oil and water because the private sector is about speed and returns on investment while public health systems, partner engagement, and behavior change move more slowly in the real world.

Community Events. In working with the public sector, Dr. Wong said CDC is trying to achieve two things. One, generated by the ads, public relations, and in-market community events, is to stimulate short-term excitement and trial behavior and provide incentives for tweens to be active; and the second, is to encourage an increase in the supply of opportunities for children to be active in their own communities. Media partners sponsor a number of added-value activities in support of VERB. For example, the Nickelodeon Wild and Crazy Kids show was brought to nine markets in high-dose communities. Channel One offered a school-based pedometer program, Make Every Move Count, which was highly successful. Community media partnerships sponsored a Harvest Moon Festival, and Tribal pow-wows had a VERB presence.

There are also national activity promotions. In 2003, for example, VERB claimed June 21st, the summer solstice, the longest day of the year, as the longest day of play. Community organizations across the country offered opportunities for youth to be active all day long in partnership with VERB and Radio Disney. Another was the Extra Hour for Extra Action (EHEA) promotion that was launched at the end of daylight savings time in 2003. The concept behind the promotion was to encourage tweens to use the extra hour gained to be physically active in fun ways. During the EHEA launch event at the Navy Pier in Chicago, a Guinness book of record was set for the number of basketballs bounced all at the same time. Another promotion is Anytime Doubletime—put two verbs together and you have a new game and new rules. Dr. Wong also described the VERB Anytour, a mobile in-market promotion. She said that the United States has been divided into six regions and, during the summer and fall of 2004, six large Anytour trucks will travel to communities across the country and set-up activity zones where children can come to try a variety of physical activities; they can experience VERB first hand. The tour is expected to reach 500,000 tweens in more than 80 cities.

Evaluation. CDC is conducting a longitudinal dose-response evaluation of VERB. There was a baseline telephone survey with 6,000 tween/parent pairs from April to June 2002, prior to the launch of the campaign. The pairs will be followed over several years. The year one follow-up was in 2003, and data collection has been completed for year two. Dr. Wong reported that year one results showed a very high awareness of the campaign nationally and in high-dose communities, six communities where there was an additional buy of local media on top of the national media buy. CDC also brought marketing and public relations events to the high-dose communities in year one. Among the nation's 21 million tweens, 74 percent recognized the VERB brand. Among the 74 percent, 90 percent understood that VERB is about having fun, going out to play, being active, and doing it your way.

CDC had not expected to see any behavior change in year one; however, a pattern of positive effects directly attributable to VERB was found surprisingly early in the campaign in three important groups—younger children, 9 to 10 years of age; girls 9 to 13; and tweens from household incomes of $25,000 to $50,000. For children 9 to 10, there was a median increase of 1.1 media-free-time physical activity sessions. For the 9- to 13-year-old girls, there were 0.7 sessions, and for tweens from the middle- and low-income families, 1.0 sessions. Dr. Wong noted that this is a rigorous dose-response analysis. Findings were more robust in the high-dose communities. Dr. Wong explained that Congress was so interested in the data that CDC had to release it in February, prior to publication in a peer-reviewed journal. A manuscript will be submitted shortly.

Lessons Learned. Dr. Wong stated that a major contributing factor for VERB's success is that it is a paid media campaign. Most public health campaigns must rely on public service announcements (PSAs). Production of a TV or radio spot is funded and then the agency must rely on donated media to place the message, which greatly reduces the coverage and impact. Oftentimes a PSA is run at 3:00 a.m., when most people are asleep. Dr. Wong stressed that CDC had the opportunity of Congressional funding for a paid media campaign. The VERB campaign purchased its media placements and delivered the ads through channels that were guaranteed to reach tweens such as Nickelodeon, Cartoon Network, ABC Disney, and tween/teen magazines such as *Teen People*.

Other factors included the following:

- A "can do" message, rather than a "don't do" or "should do" message.
- A multi-agency team that included general market and ethnic-specific agencies.
- Direct targeting of tweens with the message to get active.
- Creation of a "for kids, by kids" brand and campaign.
- An integrated marketing campaign that ties together advertising, marketing, public relations, public and private partnerships, and the community.
- Application of private sector marketing principles used by advertising agencies to sell products to children.
- Formative research and adherence to social marketing principles to understand the audience such as knowing they like to have fun, to play, to experience and discover new things, and to be with friends. These elements were built into the VERB brand.
- Concept and message testing to learn which messages resonated the most with tweens, were understood by them, and elicited positive responses.
- Strict adherence to being tween-centric throughout the campaign.
- Use of strategic partnerships.
- Always goal-focused—to increase physical activity.
- Process and outcome evaluation on a continuous basis to inform changes in strategies and tactics immediately.
- Willingness to take risks, be open, and be non-traditional.

Dr. Wong recommended the following resources for additional information about VERB:

For partners: http://www.cdc.gov/verb
For tweens: http://www.verbnow.com
For parents: http://www.verbparents.com
Online journal:
http://www.cdc.gov/pcd/issues/2004/jul/toc.htm

The Potential of the Internet as a Tool for Weight Management

Victor J. Strecher, PhD, *Professor and Director, Health Media Research Laboratory, Health Behavior and Health Education and Cancer Center, University of Michigan, Ann Arbor, MI*

Dr. Strecher, who builds web-based and other interactive media programs, primarily for adults, presented corollaries for children and demonstrated how such programs can influence behavior.

Internet as a Library. As an example of using the Internet as a library, Dr. Strecher presented a slide of the Kaiser Permanente website. Kaiser Permanente, which reaches 8.9 million members around the country, has an online weight management program that is essentially the equivalent of lots and lots of information from their pamphlets such as "Why Should I Pay Attention to My Weight?" "What is a Healthy Weight?" "What Affects Your Weight?" "How Do I Change?" What are the Tools for Changing?" "What Stage Am I In?" Although people can pick out from the library what is relevant or most needed for themselves, Dr. Strecher noted that there is nothing interactive about this posting of pamphlets on the Internet and it does not use the full power of the Internet. He explained that what has been found in the past is that often people circumvent the things

they need the most, especially children who have low skills to begin with. For example, children who need to improve their long-division skills avoid this subject in computer-assisted instruction programs for math skills.

Internet as an Advisor. A better usage of the Internet is that of an advisor or as an expert system. First, information is collected from the user. The information is then used to identify what the user needs; for example, that the student needs to learn more about long-division. The user receives a tailored message addressing him/her by name and the feedback about needing assistance with long-division. Dr. Strecher said that such feedback provides an important appraisal and supportive action. Then the user is provided with the information on long-division, not subtraction that he/she might have selected from the general library choices. Dr. Strecher noted that the majority of websites do not do this collecting of information and personalization, which they could do with a simple assessment and information processing and tailoring procedure. Dr. Strecher noted that tailoring is no longer difficult to do and can be done with a video as well as text. The video can focus on specific ways to relieve and prevent back pain for a person who drives a lot and specific ways for someone who lifts heavy objects. If a person needs a yoga exercise because of sitting at the computer for hours, a yoga instructor can appear and offer specific yoga exercises tailored to the type of pain that the person has and the type of activities he/she does.

Behavior Change Strategies Amenable to Online Interactive Programs. Most online weight management programs provide only education. Dr. Strecher pointed out that it has been known for 40 years that simple information transfer does not bring about behavior change. He listed the following behavior change strategies that can be tailored and incorporated interactively into online programs:

- Self-monitoring such as tracking habits by recording them.
- Stimulus control and creating new behavioral cues.
- Identifying and coping with triggers.
- Self-rewarding for behavior changes.
- Stress management such as learning meditation and relaxation techniques.
- Social support for positive reinforcement.
- Cognitive rehearsal of responses to high-risk situations.
- Challenge of irrational beliefs.
- Motivational and goal-setting assistance.
- Relapse/recycling prevention.
- Attributional retraining.

An advantage of web-based programs over clinical weight management interventions is that millions of people can be reached. Also, a physician can provide the newly diagnosed diabetes patient, for example, with a website URL where, in addition to reading or asking for a pamphlet about the disease, the patient can receive effective, interactive, personalized assistance in self-management strategies and even send his/her data back to the doctor in the form of an electronic medical record.

University of Michigan Online Health Advisor Program. Dr. Strecher next provided an example of an online weight management program developed at the University of Michigan. First the user selects a virtual guide, another example of personalization, who asks the user a series of questions, including gender, age, ethnicity/race, marital status, number of children, height and weight (so BMI can be calculated),

health conditions, eating and activity patterns, reasons for wanting to lose weight and expectations, previous behaviors and results in trying to lose weight, and assessment of the user's levels of motivation and self-confidence about losing weight. These are questions an expert in the area of weight management would ask. At the same time, based on the user's answers, the online program extracts any irrelevant questions, allowing the user to branch through only the questions needed. The result is collected data that is relevant to this individual. Dr. Strecher said that it is important for web-based programs to keep the user informed about where he/she is in the online questionnaire and how much time it normally takes to complete the questionnaire. At the end of the questionnaire, the virtual guide thanks the person for completing the questionnaire and provides him/her with information such as BMI, a listing of personal goals, and information to accomplish these goals based on the individual's personal habits, preferences, attitudes, and triggers.

The online program consists of more than 750 pages of text; however, the person sees approximately 10 pages. Dr. Strecher stated that on those 10 pages, the program can create more than $1x10^{30}$ different versions for an individual, very much as if a counselor were writing this out. In fact, users send emails thanking the author of the guide sent to them, which is not a person but a computer. The overall concept is that information is collected and processed to create feedback specifically relevant to an individual. The feedback offers new ways of looking at food and new ways of combining both food and physical activity to be aware of how they work together to affect weight. Tools are also provided. For example, if the person decides to eat a half cup of ice cream and take a walk, a tool can be used to calculate that it will take 20 minutes to burn off those calories. If the person decides to go bowling, it will take 75 minutes. The person can figure how much bowling it will take to burn the calories from eating half of a fried chicken (709 minutes), so the individual in managing his/her weight loss can identify trade-offs using this interactive tool.

Kaiser Permanente Trial. Kaiser Permanente wanted to run a randomized trial of the University of Michigan online weight management program to compare it with their user-navigated system. Response to an ad in their newsletters and online, offering this new weight management program, called Balance, received more than 4,000 answers in a couple of months. Kaiser noted that it had taken 10 years to get 4,000 people into their clinically based weight management programs. Because the Internet is available 24 x 7, people enroll in programs readily. Dr. Strecher also pointed out that the cost of such a program to the user is less than a quarter per person, which is much, much less than other weight management programs.

Responders were randomly assigned to the Balance tailored program and to the comparison program. The trial is ongoing. There were not significant differences in baseline characteristics between the Balance and the comparison group. Confidence levels were low, but equivalent. Motivation (7.3 out of 10) was again equivalent. Eighty-five percent of participants were women, the average age was 45 years, and, interestingly, 35 percent of those enrolled were African American.

Dr. Strecher reported that over time (3, 6, and 12 months) there was a statistically significant difference in weight loss of the tailored group over the user-navigated group. Motivation was on the lower side.

Dr. Strecher presented three ways of looking at exactly the same data on motivation and self-efficacy. In a cluster analysis, three different clusters emerge. There are people who have low motivation ("I don't really want to lose weight") and low self-efficacy; there were approximately 20 percent in the cluster. In looking at their motives for losing weight, they said, "My doctor wants me to do this. My family wants me to do this." Asked, "Do you want to do it?" their answer was "Not really." (Dr. Strecher referred the audience to Dr. Resnicow's work on intrinsic versus extrinsic motives.) These people were not really ready to change and did not lose much weight.

The largest group had high motivation but very low self-efficacy. They said, "I really want to lose weight but I can't." Dr. Strecher noted that children are similar to adults in saying "I'd like to do this. I just can't." Of course, this is where most people are with respect to behavior change. The majority of the program's effect was in that group, sometimes called "a learned helpless group." This is where the biggest differentials were. Then there was the group who said "I really want to lose weight and I know I can." These people, who were very skilled, did well with both the Balance and the comparison programs.

The African-American population in this study showed a statistically significant impact that was higher than among Caucasians. The study also collected data on out-patient visits during the trial and found a reduction in out-patient visits in both groups at 6 months and after 12 months. At 3 months, there was no reduction in out-patient visits, which was not unexpected. After 1 year, there was a 1.1 greater out-patient visit reduction in the Balance group versus the comparison group.

According to a path-analytic model, with all associations adjusted by baseline BMI, the tailored program influenced weight loss, which influenced self-reported health status. Also, the health status appeared to have a direct effect on both satisfaction with Kaiser and a reduction in out-patient visits. Dr. Strecher noted that this is based on preliminary data but this is the strongest pathway, by far, in the overall sustainability model.

Lessons Learned. Dr. Strecher stressed that the preliminary data indicates that the content of Internet-based programming is terribly important. His group is now building a program for children with asthma in inner-city Detroit. This will be a totally different kind of program than the one for weight management for adults. The children's program will be very visual, with lots of flash images. A rapper will provide the information. Although the program will differ in design, it will still collect information, process it, personalize it, and provide personalized, individualized, feedback to the children based on each child's specific needs.

Future Directions. Dr. Strecher recommended that future research directions for web-based interventions address such issues as content approaches, identifying who uses the program and how it is used, outcomes, why a program works or does not work, and the research challenges.

Take 10!® Program

Harold W. Kohl III, PhD, *Lead Epidemiologist and Team Leader, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, GA*

Dr. Kohl explained that he is now with CDC and no longer directly involved with the TAKE 10!® program, which is a very innovative approach to physical activity promotion conducted by the ILSI (International Life Sciences Institute) Center for Health Promotion in Atlanta, but he was pleased to be asked to talk about the program. He noted that in the earlier presentations about school-based programs, various elements had been discussed such as improvements in physical education, curriculum development (cognitive) and curriculum integration, after-school programs, and so forth. At the ILSI Center, researchers saw a niche in which to focus on curriculum integration, as Dr. Peterson and the people at the Harvard School of Public Health had done with Planet Health, except that the Take 10! approach was simpler. It looked at what a child's day might be like from 6 a.m. to 9 p.m. and when there might be opportunities for physical activity, such as after lunch and after dinner. In programs such as SPARK or CATCH, there might also be peak times for substantial physical activity. The researchers then asked what might happen if, instead of just relying on a single dose, they injected more of a lifestyle, repeated, shorter bouts of physical activity over time to raise the energy expenditure over a 24-hour period. It was thought that the energy expenditure might be equivalent to a traditional approach seen with active PE curriculums.

Program Design. Take 10! is basically designed to integrate 10-minute periods of physical activity into the school day combined with age-appropriate lessons of math, science, language arts, and social studies, relying on these standard curriculums to provide the opportunity for 10-minutes of physical activity. Dr. Kohl explained that the goal was not necessarily to increase knowledge or to achieve behavior changes outside the classroom. The single focus was physical activity. There was no intention to create a multi-focus intervention incorporating diet or behavior change or to improve on such programs as SPARK, CATCH, and Planet Health. The idea was just to identify how children could be physically active in a small niche of time while learning fractions or sentence structure.

Dr. Kohl stressed that Take 10! was not intended to replace PE classes. It was not skills training. It was designed to add 30 minutes a day of additional physical activity to complement and add on to other opportunities such as PE, intramurals, and after-school programs.

Materials. Using core academic objectives that were age- and grade specific, the Take 10! developers linked these objectives to physical activity cards that used unique cartoon characters and were fun to do. They developed a teacher manual, behavioral tools, and training video and conducted 2-hour in-service training sessions for teachers during their summer or winter break. Take 10!® Tracking Posters provided the prompting and monitoring important to motivate behavior change. Dr. Kohl emphasized that materials and lessons were all designed to be used by classroom teachers from kindergarten through grade 5 while pursuing their normal core academic objectives. The lessons were not meant to require a teacher to add something to her busy schedule, just to replace inactivity for activity. Lessons incorporating the 10-minutes of physical activity were also prepared for secondary curriculum objectives such as health, nutrition, character education, and PE.

Evaluation Methods. The program began in September 1999, and has continued. Funding for extensive process and outcome evaluation was not available. Initial efforts focused on teacher acceptance of something new and different. Dr. Kohl noted that to successfully get an intervention into schools and into particular classrooms, the teachers have to buy in. Materials funded by a grant were distributed free to random schools over four semesters. All teachers in the selected schools were surveyed and asked to participate in answering questions about the school and this type of program. The teachers provided information on school demographics; teacher implementation (how frequently used, acceptability), attitudes and behaviors of teachers, and on evaluation of materials (e.g., age-appropriateness, appeal of cartoon characters, understanding), energy expenditure, classroom behavior, and sustainability. Dr. Kohl pointed out that there was ongoing evaluation of materials as they were developed.

Through winter 2001, a diverse group of 175 schools had participated in the Take 10! program. The program was evaluated in various grades in four of these schools, which had a good mix of ethnicity and racial identity ranging from 33 to 65 percent African American, 53 to 15 percent Caucasian, and 4 to 15 percent Hispanic. An attempt was made to get a broad cross-section of schools in the evaluation samples. Many of the students in the schools participating in the early part of the program were on free and reduced meals. In the later sample, about half the students received these meals. Dr. Kohl said that an indicator of school quality is the percentage of parents who volunteer at the school. This ranged from 45 percent in the first group to 61-64 percent in the other three groups.

Outcomes of interest included frequency of use of the Take 10! program, types of use, and teacher impressions of "face and content" validity. Dr. Kohl noted again that teacher buy in is critical and these were teachers who were used to the traditional classroom where the teacher stands up front or moves around and the children are seated and quiet. Other outcomes were implementation characteristics by teacher experience and some initial data on energy expenditure.

Results. There were advances and changes in the program from the fall of 1999 through the winter of 2001. At the first evaluation, the median for implementation was about 50 percent of the teachers using the program one to three times a week. As improvements came along, this implementation rate increased to the majority using it between four and seven times a week. Overall, materials were rated highly for age- and grade-appropriateness. Dr. Kohl mentioned that earlier the comment had been made that interventions needed to begin with younger children. Take 10! began with the kindergarten through second grade; the other three grades were added later.

Dr. Kohl said that the most important aspect of the teacher implementation results may be in the daily timing of the activity. In the training sessions, teachers had been told that Take 10! was not designed to have a specific implementation time. It could happen first thing in the morning, when sleepy children get off the bus, as a transition between lessons in a particular class, at the end of day, or at various times. This gave teachers the leeway to implement the program when she or he needed to, for instance, when the students were losing interest in a lesson. This

freedom to use the program in accordance with their needs is reflected in the results of the daily timing of teacher implementation, which varied.

Energy expenditure was meant to be the result of meaningful physical activity of moderate intensity. Energy expenditure was estimated in a convenience sample in three schools with three various grades (1st, 3rd, and 5th) during planned Take 10! activities conducted by the volunteer teachers. Each grade did 8 to 9 Take 10! sessions in at least 1 of the 30 different kinds of activities, with 3 to 5 activities being the range in this group. The CSA Actigraph was used to estimate the physical activity or energy expenditure of randomly selected children. The rest of the students had pedometers. A consistent estimate was obtained in terms of intensity of the physical activity that was defined as moderate-intensity (> 3.5 METS (metabolic equivalents)) for each of the grades. Dr. Kohl stressed that the children were obviously not just standing up and stretching and then sitting back down. There was meaningful physical activity taking place. It was difficult, however, to determine just how vigorous the activity was given the physical constraints of the classroom.

Lessons Learned. Dr. Kohl stated that a single program is certainly not the solution to increasing physical activity among children and youth. What was learned was that design and implementation of a curriculum-integrated, classroom-based physical activity program for elementary school students across several ages and grades appears feasible. Such a program does not try to change a curriculum, but adds physical activity to the existing curriculum. Data suggests that it is possible to do this daily at an intensity (moderate) that provides some meaningful physical activity, as part of the 60 minutes per day that CDC considers important. The barrier of "no time" can be overcome. Initially, teachers protested that they absolutely could not do one more thing. Finally, the teacher training modules were able to make it clear that this would not take extra time. They would still be teaching the required math and language arts objectives but doing so in a slightly different way that would reduce inactivity and promote activity.

Other lessons learned are that schools are dynamic—not static—systems. For public health changes and environmental changes, teachers and students are consistently throughput. Teachers rarely remain in a school for a long time. Dr. Sallis had presented evidence from SPARK that a basic reason it is not being used is because the teachers who were the advocates are gone over time.

Future Directions. Dr. Kohl said that individual-based singular interventions may have limited use for the future. This means that the school environment, rather than the people, must be fundamentally changed. To do this, he recommended a "kitchen sink" approach to activity promotion. Dr. Kohl suggested creating a synergy of SPARK, CATCH, Take 10!, the best intramurals and interscholastic sports, and the best after-school programs to create a changed environmental setting. In such a setting, the principal would walk around, the teachers would have a walking club, and there would be adequate money for equipment and hiring of skilled PE teachers. Dr. Kohl concluded that interventions may come and go, but what is important is environmental change.

Exercise Interventions for Improvement of Body Composition in Youth

Bernard Gutin, PhD, *Professor of Pediatrics and Physiology, Georgia Prevention Institute, Medical College of Georgia (MCG), Augusta, GA*

Dr. Gutin stated his presentation would focus on: (1) the question of whether physical activity, without focusing on diet, can play a role in prevention; and (2) treatment of juvenile obesity and what dose of physical activity should be built into interventions. Dr. Gutin's group is currently conducting a cross-sectional epidemiology study for which they will complete the final data collection in July 2004. The model for the study, called Lifestyle, Adiposity, and Cardiovascular Health in Youth (LACHY), assesses lifestyle influences such as exercise, diet, and stress on adiposity, CVD risk factors, and predisposing factors. The study group expects to have some findings that will explain what type of fat (i.e., general, visceral) influences risk factors, the effects of fatness versus fitness, the influence of free-living physical activity, and the influence of diet and stress, along with other factors they will be assessing.

Effects of Physical Activity on Percent body Fat. The Georgia Prevention Institute measures body composition using DXA because this provides a three-compartment model, enabling them to look at bone mineral content (BMC), fat mass (FM), and fat-free soft tissue (FFST). Derived variables include bone mineral density (BMC/area), fat-free mass (FFST +BMC), and percent body fat (FM/total mass). Dr. Gutin said that today's presentation would focus on percent body fat.

The institute also uses magnetic resonance imaging (MRI) to measure visceral adipose tissue and subcutaneous abdominal adipose tissue across the abdominal area. In children, as in adults but in lesser degree, the child with more intra-abdominal or visceral fat usually has a poorer lipid profile, compared to the child with a lot of subcutaneous fat.

Cross-Sectional Data. Dr. Gutin noted that dieting can influence fat mass in obese people, but the institute is more interested in the effects of physical activity. Their cross-sectional studies and those from other groups have begun to suggest that vigorous physical activity (VPA) is more highly correlated to lower levels of percent body fat than is moderate physical activity. Dr. Gutin suggested this finding is important in designing preventive interventions. One possible mechanism for the effect of vigorous physical activity is because it increases protein turnover and synthesis, thereby increasing fat-free mass, which is a beneficial change in body composition. VPA is energetically expensive and thus causes the resting metabolic rate and the postprandial metabolic rate to be higher. The net result is that a child can eat more and get enough nutrition for optimal growth, an important factor in considering optimal lifestyle for children. Dr. Gutin stressed that children should be encouraged to eat more of the right foods, such as calcium to build bone, not encouraged to eat less. Without enough calcium, increasing amounts of physical activity do not lead to increased bone mass.

Experimental Design Data. Looking at cross-sectional data, according to Dr. Gutin, is only a beginning. For example, a child who has a hereditary predisposition to be overweight would probably do less vigorous physical activity, so the direction of causality is not so clear. Experimental designs in which the physical activity is controlled allow for clearer causal attributions. A meta-analysis reported in 2002 on obese youths (LeMura and Maziekas, Med Sci Sports Exerc. 2002 Mar; 34(3):487-96) showed favorable changes

in percent body fat in those who were most overweight at baseline and who did aerobic physical training of moderate intensity rather than higher intensity He reminded the group that this review was done with obese children, for whom moderate intensity training may be sufficient. When sessions were longer in duration and when strength training was included, they had better effects.

The study included in the meta-analysis (Gutin et al. 1999. Obes Res 7:208-214) included a 40-minute physical activity period—20 minutes on machines, 20 minutes on games modified to keep energy expenditure high, the typical ACSM (American College of Sports Medicine) catechism of 30 to 60 minutes, 3 or more times a week, at a percentage of VO_2 max of 50 to 70 percent; the duration of the program was 4 months. This routine worked well with the obese youth. There was good attendance and the youth achieved good heart rates measured by heart rate monitors, which provide continuous feedback to the children and the instructors. Not surprisingly, when the children stopped doing the physical training after the first 4-month period, their percent fat increased again. Dr. Gutin referred to physical activity as being similar to a prescription drug for a chronic condition—when taken, it has the desired beneficial effects, when stopped, the original problem returns. He recommended that interventions be long-term in order to achieve a long-term effect.

Next the study group examined two intensities with 13- to 16-year-olds in an 8-month intervention. The obese youth were randomized to a lifestyle education (LSE) group, a LSE and moderate-intensity physical activity group, and a LSE and high-intensity physical training group. Without going into all the difficulties encountered, Dr. Gutin stressed that doing a controlled study with this age group was challenging.

One goal was to hold energy expenditure constant in each individual at about 250 calories per session. That meant that the moderate group had to work longer each session to get to that goal. For overall results, the two physical training groups were combined and a criterion for minimal exposure to the physical training of 2 times per week was applied. The experimental group had a decline in percent body fat, and the lifestyle education alone group stayed about the same. For both the 4-month and 8-month programs, there were significant beneficial effects for visceral adipose tissue. Dr. Gutin stated that the data support the concept that physical training by itself, without a lot of emphasis on diet, can have beneficial effects in obese children.

Prevention of Adiposity. The meta-analysis described above showed that effect size is associated with baseline adiposity, so that you might not expect much of an effect in less obese youths. Dr. Gutin said that, while a number of studies in non-obese youths have found no significant effect of typical types of physical training programs, not all studies have had this result. In a study in California (Eliakim et al. Int J Sports Med. 2000 Jul; 21(5):332-7, children in a 5-week summer camp did 2 to 2 1/2 hours per day of physical training, 5 days per week. In the morning, they did academic work and in the afternoon, they exercised. Dr. Gutin reminded the group that 2 1/2 hours per day of physical activity is not an excessive strain for normal children. Results of the study showed no significant effect on percent body fat from skinfolds. On the other hand, abdominal adiposity measured with MRI showed significant beneficial training effects for subcutaneous and visceral fat. Given these results with a high dose of exercise, Dr. Gutin suggested that it would be interesting to do interventions with lower doses and see at what point one no longer sees a good effect.

APEX. The Adiposity Prevention by Exercise (APEX) study with 8- to 10-year old African American girls used 2-hour after-school sessions, 5 days a week. APEX was a 10-month intervention that took place in neighborhood schools rather than in the institute's own research gymnasium. Sessions included 30 minutes for a snack and to do homework plus approximately 80 minutes of physical activity including 25 minutes of skill instruction, 35 minutes of vigorous aerobic activity, and 20 minutes of strengthening and stretching exercises. The girls, who varied in adiposity, all wore heart rate monitors, which they liked. Dr. Gutin reported that results to date show significant favorable effects of the physical training on percent body fat, fat mass, and bone density.

MCG FitKid. Dr. Gutin next described the current MCG FitKid Project. Dr. Gutin pointed out that children today live in an obesogenic environment where vigorous physical activity is discouraged and unhealthy eating is facilitated. The primary hypothesis for MCG FitKid is that providing children with a "fitogenic" after-school environment will lead to less accretion of fat. The study began in the 2003-2004 school year. Eighteen schools were randomized to receive health screenings alone or to receive health screenings and the intervention. Subjects will be followed from the third through the fifth grades, with measurements taken at the beginning, midpoint, and end of each grade. A mobile unit (funded by NIDDK) goes to the schools and all the measurements are done in the unit, including blood pressure, cholesterol, and body composition by DXA. There are also cardiovascular fitness tests and measurement of psychosocial factors. The schools are providing grades and standardized test scores.

Dr. Gutin explained that even though MCG FitKid is focused on health, it has a 40 minute academic enrichment component that is coordinated with school personnel. The reason for this is that in the APEX study, a number of parents said their children had to drop out of the program because they were not doing well in school. Nutritional snacks are provided through the U.S. Department of Agriculture (USDA) program.

There are 80 minutes of skills and fitness, with a heart rate goal of 150 bpm for the vigorous activity component. Preliminary basic results for the first year in the third grade show a marginal significance in reduction of percent body fat in the intervention group and an increase in the control group. The difference for the intervention group is affected by the fact that some of the group never showed up for the intervention. For the children who had a 40 percent attendance rate, there was a more substantial and significant effect on percent change in body fat, and for the children who had an 80 percent or greater attendance record, the percent change was considerably more substantial and significant compared to the control group.

Anecdotal information indicates that it is important to have a long-term relationship with the schools. At MCG, medical students are taught health promotion and disease prevention and they go out and teach sixth graders in Augusta. Dr. Gutin reported that, over the last 30 years, more than 1,000 medical students have taught more than 70,000 sixth graders. Some of these former sixth graders are now legislators, parents, and principals and so the institute has an excellent image in the community. Another important factor is to maintain communication with both

the intervention and the control schools. The institute has an active advisory board made up of parents, principals, teachers, and school officials who are enthusiastic and helpful. Finally, anecdotal reports, many from teachers, are that children who have come through the FitKid Program are more fit, more confident, less clumsy, and take on leadership roles. A few of the parents have said that the program has also had a favorable impact on the whole family.

Lessons Learned. Dr. Gutin stated that promotion of vigorous physical activity in integrated trans-community interventions carries a positive message that emphasizes fitness, not obesity. Using regular schools, providing transportation home afterward, and providing the program for free are all important elements, particularly since they reduce barriers to participation for the lowest income children. Involvement of classroom teachers and also involvement of PE teachers whenever possible provides training in emphasizing vigorous activity for these people who know the schools and the students best.

Future Directions. Dr. Gutin offered various speculations. Given the focus on test scores, it is difficult to fit enough physical activity into the school day. Along with recommending more and better physical education classes and having recess periods or a Take 10! Activity, Dr. Gutin recommended using the large blocks of discretionary time after school, on weekends, and during vacation periods. He also suggested that integrating an academic enrichment component is attractive to the schools and to the parents.

Experimental studies have demonstrated that both obese and non-obese children can benefit from vigorous exercise without focusing on diet. Higher doses of physical activity elicit greater effects in some health outcomes. Dr. Gutin stressed that additional research is needed on dose-response. The institute is now doing a study on 20 minutes of vigorous activity per day compared to 40 minutes per day. Twenty minutes can fit into a PE class and can possibly provide good results with obese youth. Although at least an hour a day of moderate to vigorous physical activity, including aerobic and strengthening exercises, has been recommended for children, for those who are currently inactive and relatively overweight, benefits are attainable from less time and from lower intensities. These children need to gradually build up to the higher intensities and the longer durations. Dr. Gutin added that research is also needed on strategies to improve compliance and to increase parental involvement. He expressed the hope that his institute's efforts will contribute to greater numbers of fit, lean, and healthy youth in the future.

Latino Home and School Environments

John P. Elder, PhD, *Professor, Graduate School of Public Health, San Diego State University CA*

NHLBI funded Dr. Elder's project on environmental approaches to obesity prevention under a NIH-wide initiative that included NIDDK and other institutes. Dr. Elder explained that the specific research design is a two-by-two factorial design looking at macro-environmental interventions (i.e., school-based, community-based, and social marketing interventions) and micro-environmental interventions (i.e., family-based and home-based strategies) to prevent the onset of overweight and obesity in Latino primary school-aged children. Dr. Elder stated that the work of Dr. Sallis and Dr. Tom McKenzie, both of whom are co-investigators of the project, has been central to the design of much of the program's strategy. The micro-environmental intervention, which is largely a family-based intervention conducted through the

parents, primarily the mother, is based on the work of Drs. Len Epstein, Tom Robinson, and others. The purpose of the San Diego State University project is to determine how the environments interact, how effective a micro-environmental intervention is, how effective a macro-environmental intervention is, and then how effective is a combined micro- and macro-environmental approach, known as an integrated trans-community program.

Aventuras para Niños Design. Dr. Elder explained that the *Aventuras para Niños* program uses GIS (geographical information systems) and other environmental assessment procedures that do not focus on the individual, although outcome measurements will, of course, be based on individuals. The project is investigating the Latinos' social and physical environment, including grocery and convenience stores, restaurants, farmers' markets, vegetable trucks (which are frequently found in these largely Mexican immigrant communities), street vendors with pushcarts, billboards advertising food, recreation areas, and neighborhood characteristics such as housing density, traffic density, crime rates, and so forth. A major aspect will be to learn what is available in terms of healthy and not-so-healthy nutrition in the community, at the school, and in the home.

In the school, policy-level change will be an important element, trying to learn what can be done to change the entire school environment to improve the quality of the physical education program and add to the health curriculum in the classroom. Since the lunches in these schools are generally government subsidized, prepared in central kitchens, and adhere to USDA guidelines on 30 percent total fat, Dr. Elder said that not much can be done about these. However, the study is observing what the children actually eat from the lunches offered, what foods they prefer, and what advertising or provision of other foods, particularly junk foods, are available on school grounds.

The 12 schools in the study were selected based on at least 70 percent of the students being Latino, largely Mexican immigrants and Mexican-American children. Dr. Elder said there are not many other national roots in San Diego's Latino population. Located in southwest San Diego, the schools are in the communities of San Ysidro and Chula Vista on the Mexican border. Randomization was at the school level, so there is a two-by-two design, four cells, and three schools per cell. Analysis will be at both the individual and cluster (school) levels.

Secondary aims of *Aventuras para Niños* are to study micro- and macro-environmental mediators to see whether these are modifiable. A major interest is the impact of the community environment on physical activity and nutritional patterns, so community factors are geocoded to indicate the location of the school and the homes of the student participants in relation to restaurants, convenience marts, food vendors, fast food outlets, and so forth. For example, if a child has to walk past McDonald's on the way home from school, does this affect the child's eating patterns in comparison to a child who has a more suburban route home? Direct observation of the school and community settings using So-Fit and SOPLAY methods are also being used.

Promotoras. Dr. Elder explained that the intervention approach uses a *promotora* model, a tradition popular in Mexico and Mexican America as well as Latin America. *Promotoras* are lay health advisors who are recruited and trained. These women deliver the home intervention and tailor it to the family's specific home environment. Typically, they make an appointment

with the mother, deliver a newsletter, and sit down with her and go through the newsletter. They talk with the mother about the home environment and suggest things the mother might consider changing, based on the current newsletter's topic. This could be something to do with Game Boys and eating in front of the TV. It could be about the type and timing of snacking. It could be how to schedule homework vis-à-vis physical activity. Dr. Elder said that one of the things the *promotoras* have reported back to the investigators is that it is important not to be too critical of, for instance, TV watching, because a lot of these people use television to teach their children English and to improve their own English. Many people along the border learn English this way. The *promotoras* themselves are typically middle class, relatively bilingual, and have been in the United States somewhat longer than most of the women with whom they work.

Newsletters. The newsletters that are delivered and discussed during home visits are offered in either Spanish or English. Approximately three-quarters of the mothers choose the Spanish version. Topics are aimed at changing nutrition, sedentary behavior, and physical activity. An example might be rule setting such as how to set limits and stick to them and why one should do that; for example, setting limits on fizzy drinks. There are also profiles of people from the community. Specific ideas for activities and snacks are provided. An example might be a recipe for *licuado* (or fruit shake, in English), basically a mixture of low-fat milk, vanilla, and orange juice concentrate. The recipes are aimed at making snacks that are typical for the region healthy. There are also recipes for adults such as *ensalada de nopales*, cactus salad, which is a type of snack or lunch for adults.

School Components. At the school level, there are other macro-intervention components, including SPARK PE, Take 10!, peaceful playgrounds, the Start With Salad nutritional program, a walking school bus, and crosswalks. Dr. Elder said that they are trying to get more crosswalks put in as an environmental intervention. Peaceful playgrounds are an attempt to restructure the playgrounds, primarily by painting them and setting up play areas for games and for free form play. The children tend to gather in a small area in the playground and remain relatively inactive or shove each other around and get into fights. Hopefully, by painting the asphalt and laying out games such as hopscotch, the children will engage in more physical activity and free-form play.

SPARK PE has been well received by teachers. They are a little afraid of Take 10! The first order of any classroom is control. After that, comes learning. Many teachers are concerned that they will lose control if they use Take 10! but the teachers who have been brave enough to try it seem to really like it.

Dr. Elder said that while the meals conform to USDA guidelines, the children were not eating the salads and other healthy foods. In the Start With Salad program, cafeteria workers give the children stickers if they are caught eating salad or eating it first in their lunch. Dr. Elder reported that the walking bus idea was not successful. This was an attempt to get children to walk to school by having them walk in large groups with mothers to coordinate them. The idea interfered with mothers' schedules and their sense of safety. Instead, the mothers offered to help at noon and at recess to form walking clubs around the school grounds. The children in the walking clubs accumulate miles and receive rewards for 5, 10, and 20 miles.

Lessons Learned: Successes—Big and Small. The walking club has been a big success and has many participants. The *Start With Salad* stickers are popular, and salad consumption has never been higher, according to the cafeteria workers. The newsletter is also popular, and teachers are volunteering to edit this. Another preliminary success has been the tentative agreement by one city council to install more crosswalks near the school. Principals are at least passively supportive. As mentioned, the walking school bus was not effective. Walking is done on a solitary basis, or a mother picks up one or two, usually of course in an automobile and not by walking to school. There has not been full use of peaceful playgrounds yet. The teachers still need training on how to optimize the use of these.

Future Challenges. Dr. Elder stated that the program organizers want to get a little more aggressive with their macro-environmental interventions. They want to do counter marketing, particularly in relation to fast food. The promotoras are a little anxious about doing that. They are used to working mostly in homes and a little in schools but not at all in communities. The plan is to work with the promotoras slowly and build on successes. Another challenge will be to link up the micro- and macro-environments.

Discussion With Session 2 Speakers

Facilitator: John P. Elder, PhD, *San Diego State University*

In response to a question from Dr. Sallis about partners' contributions to VERB, Dr. Wong replied that there was very little interest from industry until VERB established equity and value as a brand. Then the sports leagues, such as the NFL and the National Soccer League, began to contribute prizes from their teams (e.g., a signed football, a hockey stick) for tweens to win as incentives for recording their activities on verbnow.com. There were not Federal dollars for these rewards. The leagues also contribute tutorial video clips to the website on how to throw a football, how to swing a tennis racket, and so forth. Children want to learn to master these skills. In addition, the Hockey League, for example, sponsors grassroots clinics where the children can come and learn from local hockey stars on the how to play hockey. Dr. Wong added that these are just a few examples of partner contributions.

Dr. Sallis remarked that he was glad to hear that the teams are supporting programs for the children to be active, not just sedentary spectators. Dr. Sallis then asked Dr. Epstein about plans for diffusion of his program, which had such excellent data. How could the program be introduced to clinics here and abroad since health care practitioners desperately need effective ways to help overweight children and adolescents?

Dr. Epstein explained that he is not a researcher in translation or diffusion. He primarily conducts efficacy trials, so he really did not have the answer. He has been surprised that so few people have come to him and said they want to do a translational trial to take

this program to another level. Dr. Epstein assured the group that he would gladly collaborate with translation researchers in such an effort.

Dr. Alice Ammerman, University of North Carolina at Chapel Hill, asked Dr. Gutin to describe how the MCG FitKid advisory board had been helpful to the program. Dr. Gutin explained that in the beginning the board had provided them with assistance in conducting formative research with the focus groups. After the first year of the program, they met and were enthusiastic about the program's results, even the members from the control schools. Pleased with the enthusiasm and support, the investigators then presented the board with the idea of addressing sexual maturation in the program. Boys and girls go through different developmental stages and it seemed from a scientific perspective that these changes might help explain changes in overweight. In order to be sensitive to the issue of "sex," they handed out envelope packets of diagrams and pictures to the board. The idea was that children would be given the envelope with directions and sent to a private area of the mobile unit to look at the diagrams, so they could say "I look like that." Someone would be nearby if the child needed help with the directions. The board members, although respecting their motives as scientists, reacted that adults and children, particularly in a traditional, conservative community, would see this as pornography, not education. Dr. Kohl said that the point of this incident was that the board saved them from an action that might have seriously undermined their success in achieving their other objectives, primarily what happens to body fat.

Dr. Wong responded to Dr. Resnicow's query about outcomes for VERB, particularly what was the most rigorous outcome they had achieved so far in the nine target communities and what would happen if the program were required to adhere to the standard of affecting BMI, or glucose, or insulin. Dr. Wong noted that as a national media campaign, VERB was reaching out to some 21 million tweens across the country. Through the community partnerships, they expect local groups to provide opportunities for children to be active. Dr. Wong explained that with a national telephone-based evaluation survey, it would not be possible to obtain measures of weight and height for the children interviewed in order to calculate BMI. The program designers have discussed trying to measure the level of physical activity by asking children to report their minutes of activity, but decided the data would be unreliable. Younger children, in particular, cannot conceptualize time to report it accurately. They also discussed giving out pedometers. The problem with pedometers was that the minute someone has one in hand, it changes their behavior, and there are many activities such as swimming for which a pedometer would not work to measure activity levels. Dr. Wong concluded that they do not see BMI or physical activity minutes as the appropriate measures for the campaign's effectiveness.

Dr. Wong added that, measurement barriers aside, she could not name a desirable outcome measure of VERB in relation to obesity rates; VERB alone cannot deliver lower rates of obesity. VERB is focused on only one behavior—inactivity—in one age group. Obesity, on the other hand, is a multi-faceted, multi-environmental problem affected by fast food outlets, vending machines, TV and video games, social customs, family socio-economic status, and even genetics. In the beginning, there was an effort to avoid any mention of obesity with VERB for these reasons. More accurately, VERB is now presented as a campaign that addresses a critically important risk factor

and intervention for obesity— youth physical inactivity. The campaign is being held accountable for achieving its goals to increase physical activity among tweens.

Dr. Terry Bazzarre, Robert Wood Johnson Foundation, commented that RWJF is funding a program through Health Partners to do a feasibility study of telephone-based counseling. The focus is on adults, and they found HMOs were readily signing up for the pilot program. Six months had been allocated for recruitment, but they were able to recruit more people than they needed in just 2 months. This suggested to them that there might be a great deal of interest from the clinical community in doing something to address childhood obesity. When RWJF investigated the feasibility of a similar telephone-based program with children, who talk on the phone all the time, they found there was virtually no interest in such a program amongst children. Reaching the children would have to come through mothers being engaged in such a program. Dr. Bazzarre added that over the last 18 months there has been a tremendous interest in trying to link clinical strategies for treatment of children with communities and schools. Since the University of Buffalo program appeared to be the gold standard, he asked Dr. Epstein what was needed to build bridges between the clinic and the real world and provide interested physicians, dieticians, and other persons with effective tools they can use.

Dr. Epstein answered that those who know how to translate the efficacy trials he conducts into real community interventions are needed to do this. He added that collaboration between basic scientists and such researchers would certainly advance the field.

Dr. Elder suggested that if the interventions to introduce new curricula or affect environmental change take hold, then they will facilitate their own maintenance and generalization. He pointed out that communities he has worked with in smoking prevention and cessation did not ask for these programs. However, community colleges were looking for timely curricula for English-as-a second-language (ESL) programs so a nutritional intervention was welcomed. Ten years later, the community colleges are still using the programs. Much depends on what the consumer wants.

Dr. Bazzarre stated that when RWJF funded the Active for Life program with Stanford, the national program office was surprised at how much effort was required and how many legal issues had to be resolved in preparing and testing a science-based program prior to seeing if people could do the intervention and to ensure the fidelity of the program. Dr. Bazzarre recommended that NIH invest in practical case studies to assess the amount of time and effort that is necessary before a research-based study can be made available in a community. The communication process and the legal issues are a real challenge that requires champions to overcome. Dr. Bazzarre emphasized that work such as Dr. Epstein's needs to be replicated to assure policymakers that the basic research data are robust enough to support changes in public policy regarding these environments. Collaborations between basic and translation researchers would hopefully accelerate acquiring an effective outcome measure and provide a policy vehicle for addressing the treatment issue.

Dr. Obarzanek responded that NICHD, along with other NIH institutes, is working on an initiative for obesity and weight control management studies based in pediatric practices to try to stimulate that kind of research. NIH wants some research studies on translation. Persons with primary care and pediatric

practices may have been thinking about these childhood overweight issues, and this initiative will provide an opportunity for them to participate.

Regarding translation, Dr. Kohl stated that CDC has 28-funded State obesity programs providing the opportunity for translation research through State and local health departments. In addition, the Steps to a HealthierUS initiative bypasses the State level and works with individual communities that can provide additional opportunities to generate translation research projects in the real world.

Dr. Mary Ann Pentz, University of Southern California, raised the possibility of having more than one standard for outcomes. In the drug prevention field, they have found that there are several appropriate outcomes and standards based on the population and the type of study being conducted. In most of her work in broad-based campaigns on drug abuse, changing preferences and attitudes are the appropriate outcomes, and the most proximal indicator to behavior change is changes in intentions. For obesity interventions that result in an up-and-down type of pattern, appropriate outcomes may be simply changing physical activity and time spent watching television. Using BMI as a measure may necessitate a longer course of study. Dr. Pentz pointed out that BMI changes anyway as children enter puberty, so increasing physical activity and decreasing inactivity may slow down the rate of obesity. Studies such as Dr. Epstein's might be considered sub-clinical studies where BMI is the appropriate outcome of interest.

Dr. Gutin contributed that in his studies, body composition is considered important. At times there have been changes in which bone mass has gone up in the intervention group which is the wrong direction for BMI but the right direction from the point of view of health. A study in Japan showed that athletes had a higher BMI than non-athletes. The athletes also had a lower percent of body fat. In other words, BMI may not be the best or only outcome measure, except for surveillance purposes since it is correlated with percent body fat. In individuals, however, BMI can be misleading. A variable that has not been discussed is waist circumference, which is easily measured and highly correlated to a lot of the outcomes that are measured by more sophisticated means. Australia has a program that uses waist circumference as an outcome. Dr. Gutin added that his study will have more data available on teenagers in a month or so, but he wanted to submit waist circumference for consideration.

A member of the audience asked Dr. Wong to comment on two issues. The first was that the VERB videos and stills she had shown were of role models who were lean and fit. How does VERB motivate children who are not lean and fit? Secondly, what are some of the successes/non-successes and pros and cons of working with industry partners? This is an out-of-the-box move for CDC that other researchers are interested in but struggle with deciding to try.

Dr. Wong stressed that the inventory of current VERB ads that could be viewed on http://www.cdc.gov/verb shows children of all sizes, all ethnicities, and all ability levels, including children with disabilities. She explained that given the time limitations for the presentation, she had shown only a couple of ads. For the industry partnerships, the program designers first consulted with CDC lawyers and reviewed CDC guidelines for public- and private-sector collaboration. The lawyers and the guidelines are concerned with implied endorsement, issues of exclusivity, and so forth. For example, one cannot seek out just one company so that only that company has an

association with a Federal campaign. Many things have been done to ensure compliance with Federal guidelines. A notice was placed in the *Commerce Business Daily* announcing that the VERB campaign, whose goal is to encourage and help children to be physically active, was seeking companies that had a common mission with VERB to come on board and work with the campaign. It was an open invitation to all companies, which avoided exclusivity. In addition, the designers made it a goal to pursue many companies within the same business sector such as companies that manufacture or sell sports equipment and apparel. Some companies were willing to work with VERB and some were not. The strategy was to find mutual interest areas and common goals and build a win-win partnership so that each could come away with some goals met. Dr. Wong agreed that this does involve risk-taking.

Dr. Debbie Young, University of Maryland, noted that with all the formative research and work with focus groups that was done up front, VERB still had a market segmentation that fell across racial and ethnic lines. For TAAG (Trial of Activity in Adolescent Girls), the study's ardent segmentation work found that the girls identified not by racial/ethnic lines, but by preppy girls, athletic girls, girly girls, and different kinds of categories. Dr. Young asked if that issue had come up or did the organizers choose to go with demographic characteristics? Dr. Wong answered the VERB ad agencies know kids and that all these factors are considered daily in creating ads, promotions, and materials that appeal to most tweens, identifying media channels for ad placements, and in selecting partners to bring events to communities.

SESSION 3

Community and Trans-Community Sites

SESSION 3: Community and Trans-Community Sites

Moderator: Diane R. Beth, MS, RD, LDN, *Nutrition Coordinator and North Carolina 5-a-Day Coordinator, Physical Activity and Nutrition Branch, Division of Public Health, North Carolina Department of Health and Human Services, Raleigh, NC*

Trial of Activity in Adolescent Girls: A Work in Progress
Leslie A. Lytle, PhD, RD, *Professor, Division of Epidemiology, School of Public Health, University of Minnesota, Minneapolis, MN*

Dr. Lytle said she would be discussing experience to date in developing the trans-community portion of the Trial of Activity in Adolescent Girls (TAAG) intervention and briefly mention issues about sustainability. TAAG is a current multi-center intervention trial in 36 schools/community catchment areas in six different areas across the country. The intervention is the result of an RFA issued by NHLBI in 2000. TAAG's primary aim is to evaluate the effectiveness of interventions linking schools to community organizations to reduce the age-related decline in MVPA in middle-school-aged girls. In addition to Dr. Lytle, research partners and principal investigators include Dr. John Elder, San Diego State University; Dr. Larry Webber, Tulane University; Dr. Tim Lohman, University of Arizona; Dr. Debra Young, University of Maryland; Dr. June Stevens, University of North Carolina (coordinating center); and Dr. Russ Pate, University of South Carolina. TAAG is a collaborative study with NHLBI. The NHLBI Project Officers are Drs. Charlotte Pratt and Jared Jobe.

In explaining why TAAG was planned as a trans-community intervention, Dr. Lytle pointed out that the field is obviously moving toward an ecological approach, believing that in order to see behavior change there needs to be a focus on multiple influences of behavior and the multiple contexts in which behaviors occur. In keeping with this, the RFA authors decided that, rather than a school-based physical activity intervention alone, a community-linked approach could not only increase the reach of the intervention but also increase its sustainability through having more community partners buying in and working together toward a goal. Another reason for working beyond just schools is that youth are active in places other than schools. In fact, TAAG baseline data showed that only 20 percent of MVPA time was spent in schools. About 45 percent was spent in the family or home area, and about 20 percent was spent in a community facility or at another outdoor venue.

Study Design. Dr. Lytle stated that TAAG has an ambitious study design. There are six field centers, each with 6 schools, and one coordinating center. The primary hypothesis of the study is that the intervention will reduce by half the decline in physical activity for girls as they move from sixth grade to eighth grade. The 36 schools were randomized into treatment and control groups. Effectiveness and sustainability of TAAG will be assessed through three cross-sectional samples. The 2-year intervention began in the spring of 2003 with sixth grade girls in the 36 schools after the completion of the baseline data collection. In the summer of 2005, the second cross-sectional sample of the eighth grade cohort will be completed. In 2006, the investigators will return to the same schools to assess the sustainability of the TAAG programs and goals by looking to see the degree to which the programs and partnerships developed are potentially influencing a second cohort of eighth grade girls.

TAAG's primary outcome measure is minutes of MVPA assessed by uniaxial accelerometers. Other assessments include physical fitness using a submaximal bicycle ergometer test (PWC-170), body composition (height, weight, triceps skinfold), types and context of MVPA using a 3-Day Physical Activity Record (3DPAR), psychosocial mediators and moderators, environmental variables, and physical activity in the PE class.

Four Components. The TAAG intervention has four components: health education, PE, promotions, and physical activity. A parallel set (i.e., can be used in classroom or PE class) of Health Education With Activity Challenges lessons was developed for the seventh and eighth grades. TAAG Physical Education, which resembles CATCH and SPARK, emphasizes offering more choices and targeting girls to be physically active during PE class. The TAAG Promotions component includes special events that encourage girls to be active and also a market segmentation. Finally, there are the TAAG Physical Activity programs. Dr. Lytle remarked that this fourth component most clearly demonstrates what TAAG is trying to accomplish with the school-community link.

TAAG as a Community Intervention. Dr. Lytle stated that community interventions can have several purposes. They may conduct community-based participatory research, perform locality development or social planning, develop community coalitions, build capacity, influence social capital, or build bridges between two community agencies that share a common goal. Dr. Lytle said that, like most community-based research, TAAG has many of these elements but does not neatly fit into any one of the categories. In the true sense, it is not a community partnership, because the investigators came to the community with a defined research goal and defined timeline. The hope is that, along the way, TAAG will build community capacity, social capital, and so forth, and, in particular, create linkages within communities to increase the sustainability of the TAAG program.

First, the schools and community stakeholder agencies were asked to embrace the idea that increasing physical activity opportunities for adolescent girls is a priority to which they need to pay attention. Second, they were asked to increase such opportunities within their organizations, increase the normative culture, and increase incentives so that girls will be more active. Third, they were asked to link together and partner with a university, a specific middle school, and a variety of other community stakeholders to find out how, together, they might accomplish the goal more effectively. Dr. Lytle stressed that obtaining agreement to this last request was the most difficult part of working with the community groups and schools.

Lessons Learned From Pilot Project. The pilot for the TAAG Partners for Physical Activity component was based on a participatory research model. One-on-one interviews, a technique from direct action community organizing, were held with members in the schools and in community agencies. Such interviews help to find stakeholders and identify the movers and shakers in the community. Those interested were brought together and presented with the TAAG needs assessment, based primarily on the TAAG formative assessment. Then, using a process-oriented approach, the stakeholders were guided to join together and build consensus on what they wanted to do within their partnership. Gaining ownership of the process was stressed to help them set their own goals and objectives. The initial plan included having university staff members serve just as facilitators for the process; however, the investigators found significant difficul-

ties with this idea. The primary problem was that the process was very, very slow. At 1 year into the pilot, two of the six field centers had not yet begun an after-school program. Dr. Lytle noted that, in retrospect, this was not surprising. According to the literature on community organization, the first phase of community building normally takes 18 to 24 months.

Other lessons learned were that some partnerships had difficulty in making decisions for the common good and often the agencies competed amongst themselves for university-supplied resources. It was also found that many of the community agency persons were not prepared to lead groups of adolescent girls in physical activities versus the audiences they were used to leading. For example, teaching an aerobics class for seventh graders is very different than teaching 35-year-old women. Other difficulties were that within the community-run programs, the girls often had large blocks of inactive time; there were discipline and supervision issues; and the staff-to-student ratio was inadequate for working with adolescents.

Basically, conducting the pilot was valuable and led to significant changes for the main trial. The organizers realized that, because of time constraints, they had to back away from a traditional participatory research approach and use a more university-driven approach. They developed a program for their partners that included physical activity programs, with clear directions and research goals, and an explicit timeline. They also reduced the size of the school/community planning groups because fewer people make decisions more efficiently. Several tools were developed to give to the community agencies to help them devise effective and efficient programs for girls. In general, the initial plan was modified so that university staff members were much more involved and had more responsibility to ensure there were increased opportunities for girls to be active through school/community-linked programs.

One-Year Results. Dr. Lytle reported that 1-year post-randomization, there were 74 programs across the 6 field centers, and nearly 14,000 attendees. The Health Education lessons have gone very well. PE teachers are beginning to adopt the TAAG philosophy. The schools and community agencies remain interested and committed to TAAG. Importantly, it appears that TAAG programming is influencing and bringing in a wide variety of girls, including those who were not on the intramural teams or in competitive sports. The girls particularly like dance and martial arts.

Lessons Learned. Dr. Lytle stressed that one of the most important lessons learned is that it takes a large amount of time to create linkages across community stakeholders. Both the schools and the community agency partners have severe limitations on the time they can devote to additional projects, and TAAG is very much an additional project. Coordinating schedules to find time to get together is difficult. School personnel are very busy from 8:00 a.m. until 3:30 p.m. which is exactly the time period when the community agency personnel like to meet. Also, it takes a lot of time for people to start to meld together and do creative problem-solving.

Another major lesson was learning about the competing responsibilities, needs, and motivators of these partners. Schools are under tremendous pressure to meet academic standards. Schools and community agencies have limited resources (including space, personnel, and money), and some community agencies may not have an incentive to have school children in

their facility. Having built a lovely community center, an agency does not want adolescent girls running around their facility unsupervised, and supervision, staff-to-student ratio, as mentioned earlier, is a frequent problem.

Other areas that can present barriers in linking community agencies and schools involve different payment systems, coordinating program registration, and compensating instructors. Logistics can be difficult in negotiating between two agencies that do not have structures to do that. Transportation is a huge issue. Formative data revealed that only 9 percent of children could get to a community agency venue by school bus; 51 percent had to be driven by car; only 28 percent could walk to the facility. Overcoming barriers to access is an ongoing problem.

Sustainability. Dr. Lytle emphasized that sustainability over time is an important concern in considering interventions that link schools and other community agencies. One of the specific endpoints of TAAG is institutionalization. Dr. Lytle added that TAAG's proactive efforts toward this goal are expected to be one of its major contributions to the field. Previous research on institutionalization of school-based programs comes from the CATCH Institutionalization Grant, the School Health and Tobacco Education Project, and the Smart Choices Diffusion study. In all of these past research programs, the key to program maintenance has been the identification, following the active phase of the intervention, of program champions who remain in the schools and take ownership of the program. TAAG is proactively working to identify such champions in the schools and community agencies during year two, to educate them about TAAG's programs and objectives, and to help them develop action plans for sustainability.

Challenges for Future Directions. Dr. Lytle cautioned the group to be aware of the challenges to be faced in trans-community interventions. Linkage between community agencies is very difficult. Dr. Lytle said that such linkages require social, physical, and often policy level changes in not one but two or more community agencies. A great deal of time is needed to forge these community partnerships. While she believes such linkages will enable the interventions to be more powerful, effective, and sustainable than single-agency interventions, the investigators and the partners have to be committed to the time, even years, it takes to be successful.

Dr. Lytle listed several challenges for researchers. Highly defined research goals often conflict with the community-based research concept of starting where the community is. Individual-level assessments are often the researchers' primary goal while the intervention's goal is really environmental change. Dr. Lytle stressed that these issues require assessment of both sets of factors since our intervention goals include both change in individuals and change in the environment. Assessment tools for both individual and environmental factors need to be developed and tested for their reliability and validity. Researchers also worry about effect size, which may not be appropriate when operating with large community interventions that move slowly.

In conclusion, Dr. Lytle recommended that innovative ways be sought to increase institutionalization of trans-community interventions. The TAAG sustainability component that involves proactively identifying and working with program champions during the active intervention phase may be one way to enhance sustainability. She added that communities are aware of and concerned about the childhood obesity epidemic and very willing to be part of the solution.

GO-GIRLS I and II

Ken Resnicow, PhD, *Professor, Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, MI*

Dr. Resnicow stated that he would be describing two programs that were really quite different—GO GIRLS I and GO GIRLS II. GO-GIRLS I was a pilot feasibility study conducted at the Rollins School of Public Health of Emory University in four Atlanta public housing developments 7 years ago. GO-GIRLS II was an efficacy trial that was just completed.

GO GIRLS I. The initial study was funded by the PAN (Physician Activity and Nutrition) program of ILSI (International Life Sciences Institute), National Foundation for the Centers for Disease Control (NFCDC). The goal was to see what could be done about obesity in a low-income population, predominantly African American. The girls were 11- to 17-years-old with BMIs above the 85th percentile. There was not a control group for this phase. The main comparison was between girls with high and low attendance. There also were a variety of feasibility outcomes.

Information Gained From Formative Research. Dr. Resnicow stressed that the extensive formative research, essential to such a study, was very informative. The term "thick" emerged in the focus groups. Thick is desirable. Thick is sexy and occurs before big, which comes before nasty fat, which precedes obesity. The girls defined thick as being before your thighs rub together and your arms wobble. The formative research also showed very low intake of fruits and vegetables, less than one serving a day. There were also large knowledge gaps about nutrition. Most of the girls thought their average total daily caloric intake should be between 50 and 200 total calories a day.

Session Components. A 6-month intervention group met twice a week for 4 months and then once a week for 2 months. An exercise physiologist conducted the 2-hour sessions that were held in donated community space in public housing. Most of the sessions had four components: nutrition education, behavior modification, physical activity, and food preparation (a recipe of the day). Some session material was from *Know Your Body*. The nutrition education/behavioral modification components included information on how to read food labels and activities such as scooping out a teaspoon of fat for every four grams on a food label. Novel elements included satiety training in which the girls rated their hunger after approximately every 100 calories over 21 to see if their satiety sensitivity could be retrained. In another session, the girls were blindfolded and asked to taste foods and guess what they were. These were mostly healthy foods, and they enjoyed trying new things. A lot of work also was done on emotional eating and communication. The girls received individual counseling sessions in which they reviewed their eating and activity patterns and set individual goals for themselves. At later sessions, they weighed in and reviewed their progress. The physical activity sessions, aimed at decreasing sedentariness, were a mixture of familiar and new activities, such as ice skating.

Dr. Resnicow explained that there were incentives to encourage attendance and participation. For example, the girls received $15 at baseline for being screened and $30 at their posttest assessment. For participat-

ing in sessions, they earned points that could be redeemed at the GO GIRLS store. Items in the store were donated or purchased at low cost.

Measures. Measures included DXA, abdominal diameter, skinfolds, height and weight/BMI, aerobic capacity (treadmill test), and total cholesterol, triglycerides, and HDL. The nutrition/exercise component included 24-hour dietary recalls, dietary patterns, a 7-day exercise recall, and a 24-hour exercise recall. Behavioral/ psychosocial measures addressed outcome expectations, barriers to exercise, knowledge, self-efficacy, and preferences. Dr. Resnicow noted that one purpose of this pilot study was to test some measures as well as intervention feasibility. Process analysis included session observation and participant ratings. Both methodological and outcome papers have been published.

Results. Dr. Resnicow reported that 41 percent of the girls whose BMI was between 30 and 53 said, "I'm just a little overweight." Three percent of this group even thought they were a little underweight. He added that this misperception of what overweight is has been shown repeatedly.

At baseline, the overall group of girls, whose average age was 13, had a BMI around 34 and approximately 45 percent body fat measured by DXA. On the average, 59 percent of the girls attended each session, so the "control group" of low attenders was made up of 41 percent of the girls. At 8 weeks, there was only an 18 percent dropout but by 6 months, this increased to 45 percent.

At 6 months, there was slight effect on nutrition knowledge and a borderline effect on high-fat preferences in a positive direction for the high-attendance group. Most of the behavioral, physiological, psychosocial, and dietary intake outcomes were also in a positive direction. Girls in the high-attendance group reported a decrease in calories in the recalls and food frequency measure, which was specifically created for the study using laminated pictures (that are sorted by category) rather than a paper and pencil questionnaire. Those in the low-attendance group, however, reported either a lower change in calories or an increase.

Lessons Learned from GO GIRLS I. Dr. Resnicow explained that the results of these many measures provided the study group with valuable information on what works and what does not, information that was used to design GO GIRLS II. The girls liked learning cooking skills using healthy recipes and also enjoyed the African American guest gourmet session. They also had liked the field trips, the HipHop/Funk aerobics, and using the Caltrac. Use of the experiential versus didactic, scare tactics, and emphasis on emotional overeating were also promising techniques.

Not so promising were compliance with homework (e.g., food diaries), parental involvement, getting girls to delay gratification, attendance, and reporting of dietary data. There was also considerable staff burnout, and there were some barriers in use of the public housing setting during a period of welfare reform.

GO-GIRLS II. Presenting reference data based on National Health and Nutrition Examination Survey I (NHANES I), Dr. Resnicow showed that, as most people in the field know, the increase in obesity is more accelerated in African-American males and females (Troiano RP and Flegal KM. 1998. Pediatrics 101:497-504). Not so well publicized is the fact that, according to NHANES III data (Troiano RP and Flegal KM.

1998. Pediatrics 101:497-504) and a paper representing a different sample (Gordon-Larsen P et al. 2003. Obesity Research 11:121-129), there is a strong inverse association of overweight (> 85th percentile) to family SES (socio-economic status) in Caucasian girls that is quite different than it is for African-Americans, where the correlation of SES with weight is basically flat.

Based on findings, the study group decided to work with middle- and upper-income African-Americans for the GO GIRLS II efficacy trial. They selected African American churches in Atlanta as their setting. These large churches have gyms and schools on their campuses and are central to life in the African-American community. More than 80 percent of African American adults regularly attend church services. Pastors, in addition to being leaders concerned about the mind-body-spiritual health of their parishioners, also serve in the role of opinion leader and communicator in the community.

Formative Research. In focus groups conducted with parents, it was learned that along with believing that the girls' weight was not a problem ("just big boned," "will grow out of it," 'big, not obese," "she's just thick"), parents gave inconsistent messages. Mom would set a rule and dad would break it. There was frequent eating in restaurants, including fast food outlets, which studies have shown contribute to weight gain. Dr. Resnicow said that an unexpected message was that weight had become such a tense topic, particularly around shopping for schoolclothes, that mothers and daughters just did not talk about it anymore. Girls reported in the focus groups the same perceptions about "thick" and obese that had been heard in the GO GIRLS I focus groups. They said they received positive attention for being big. They did express a dislike of their stomachs, thighs, arms, and legs being more than "thick." They reported low rates of exercise and attributed these to exercise being unfeminine and tomboyish, a dislike of sweating, and the fact that they spent a lot of time talking on the phone. They also ate a lot of salty snacks and fried foods and sodas.

Study Overview. Funded by NHLBI, the GO GIRLS II trial was held in 10 middle-upper income African-American churches, with 10 to 20 families per church. The churches were randomized into moderate- (6 sessions) and high-intensity (20-25 sessions) programs over a 6-month period, with a 1-year follow-up. Criteria for the girls was the 90th percentile or higher. We did not use a no-treatment control group because the churches would not agree to participate unless everyone received an intervention. Dr. Resnicow stressed that the moderate-intensity group received six high-quality sessions involving the parents and youth and also received incentives. In addition to their sessions and incentives, the high-intensity group also had an overnight retreat where they did physical activity and bonded. They also took field trips to a fruit and vegetable farmer's market, received pedometers and two-way pagers, and participated in six motivational interviewing calls.

The intensive group had weekly sessions for 6 months, with the parents attending every other session and meeting first separately and then coming together for the cooking part of the session. During each session, the girls had to identify target foods from the food frequency cards and list three or four individual target behaviors to focus on, which were later discussed in their motivational interviews. There was a behavioral component, physical activity, and food preparation and tasting. Process goals included improved communication with parents, which was an

important topic for discussion in both the girls' and the parents' groups; improved nutritional habits regarding nutrient content, portion size, and second helpings; increased nutrition knowledge about portion size, macronutrients, fast foods, and beverages; increased activity; and decreased sedentary time.

Components. Similar to GO GIRLS I, the sessions included a number of activities liking taking scoops of fat or sugar, making posters about body image and what is beauty, and food preparation and a visit from an African-American chef. There was a gym in most of the churches, and the girls did at least 20 minutes of MVPA. Dr. Resnicow said they were fortunate to have a superb African-American staff of exercise physiologists and dieticians and masters in public health students from Emory. The parents came as requested and, in one session, they enjoyed a retreat to a National Park where they walked.

Motivational Interviewing. The motivational interviewing was conducted by counselors who had at least a Masters degree. Each girl received four to six calls, half about their diet goals and half about their physical activity goals. Each girl had identified nutrient and food groups and food patterns. The interviewers gave them feedback about their target behaviors. One mechanism used involved two-way pagers and messages that the girls wrote each week about help they needed with their target behaviors. For example, a girl who was trying to break a habit of stopping at Wendy's at 3 p.m. would get a beep on her pager at 2:50 and hear, "Watch out for Wendy's." The girl could then push a button on her pager that responded "yes" or "no." Other girls might hear "Did you take your walk today?" or "Don't forget to take your fruit to school."

Outcome Measures. The primary outcome goal was reduced BMI. Secondary outcome measures included waist/hip circumference, blood pressure, lipids, insulin, glucose, cardiovascular fitness, dietary intake, physical activity, sedentary time, and cognitive measures such as efficacy, norms, body image, and family communication. There were also several psychosocial outcomes regarding self-efficacy, self-esteem, emotional eating, outcome expectations, body image, exercise barriers, family communication, social support, neophobia, and meat preference.

Dr. Resnicow explained that the GO GIRLS II dietary change model was based on identifying target foods and applying a framework of substitution, moderation, and abstinence as the three rules. A "traffic light" diet was not used. The girls were taught to take responsibility for their food choices. Each week, they were allowed to use three "once in a while" cards that allowed them one portion of a non-target food, such as chocolate cake. The cards were a technique to teach them to take responsibility for occasionally indulging, rather than trying to conform to an all-or-nothing syndrome or doing binging.

Results. There were 124 girls in the cohort, with a mean age of 14. Recruitment had not been a problem, although the churches had overestimated the number of girls who were overweight. The dropout rate was less than in the GO GIRLS I study. The study group had picked the 90th percentile as the cutoff for eligibility because of concern over the dropout rate in GO GIRLS I. Dr. Resnicow said, in retrospect, they probably should have used the 95th percentile.

Basically, there was no effect on BMI in the primary analyses. The moderate-intensity group, which served

as the control group, had a 32.4 BMI at baseline and, 6 months later, it was 34, for a 1.6 increase. In the high-intensity group, BMI went from 31.6 to 32, a 0.4 increase, which, in a sense, was in the right direction for girls who were growing and maturing.

In the moderate-intensity group, four out of six sessions was the average attendance. Those in the high-intensity group attended 13 of 23 sessions. Dr. Resnicow reported that there were some dose-response effects based on attendance. For those who attended 75 percent or more of the high-intensity sessions, which was about one-third of the group, BMI and weight decreased. He added that for growing girls, just staying the same weight might have been a positive outcome.

Lessons Learned. Dr. Resnicow concluded that the lack of effect might have been due to insufficient dose. Longer duration than 6 months and more frequency than weekly sessions might be required. A structured diet for change of dietary intake might have been more successful than the free-form approach of discussing nutrition and problem behaviors. Perhaps structure is required for behavior change. The substitution, moderation, and abstinence model, which appealed to them as consumers, may also have allowed them to follow the path of least resistance and was liked because it did not push them to change. Lastly, Dr. Resnicow suggested that, paradoxically, perhaps the program was so much fun that it failed. Attendance was very good. The girls and their parents came and had a good time. The program became a popular after-school social club for the girls and their moms. However, there are still analyses to be performed and much was learned that can be built on for future interventions.

Obesity Prevention Among Inner-City Preschool Minority Children

Marian L. Fitzgibbon, PhD, *Professor, Psychiatry and Preventive Medicine, Feinberg School of Medicine, Northwestern University, Chicago, IL*

Dr. Fitzgibbon presented Hip-Hop to Health, Jr., an obesity-prevention trial funded through NHLBI. The rationale for the study was the high prevalence of obesity among minority children as they grow older. Rates of overweight are comparable among 2- to 5-year-old children across ethnic groups, but the rates shift as the children age. Part of the rationale also was the probability of childhood overweight persisting into adulthood. This probability increases to approximately 80 percent by late adolescence.

The primary aim of this study was to alter the trajectory toward overweight among preschool minority children by reducing increases in weight after experiencing a weight control intervention. Dr. Fitzgibbon stressed that the goal was long-term; changes were not expected immediately following the intervention. The primary outcome was changes in BMI at year one and year two post-intervention in children from schools randomized to a weight control intervention or a general health intervention. Overall increases in height and weight due to normal growth and development were expected. Secondary outcomes addressed dietary intake, physical activity, and television viewing. Dr. Fitzgibbon said the sample was powered for changes in BMI, but not necessarily powered for these secondary outcomes. Secondary outcomes were based on parents' reports, since this study was for 3- to 5-year-old children. Dietary intake included a single dietary recall of total dietary fat and saturated fat, each as a percent of total caloric intake,

and grams of dietary fiber per 1000 k/cal. Physical activity was based on times per week, and intensity was based on the Borg scale. Television viewing was in hours per day.

Study Design. Twelve Head Start sites were recruited. The schools were paired based on class size and then randomized, one to the weight control intervention (WCI) and one to the general health intervention (GHI). Dr. Fitzgibbon pointed out that the Head Start sites were adjacent to public housing complexes or WIC (Women, Infants, and Children) clinics sponsoring a Special Supplemental Nutrition Program. The study was designed as a 14-week intervention, with assessments (with anthropometric data) at baseline, post-intervention, and at 1- and 2-year follow-ups.

Weight Control Intervention. The weight control intervention held three classes per week, 40 minutes in length, of which 20 minutes was ongoing physical activity and 20 minutes was interactive healthy eating activity. There were also newsletters mirroring what the children were doing in class and twice-a-week aerobics classes for parents. The first class introduced the concepts of go-and-grow foods versus slow-foods, using hand-held puppets to represent foods in the food pyramid. Then the children followed the adventures of these characters as they learned about healthy eating and exercise. There was Mr. Vegetable, Miss Fruit, Miss Dairy, Miss Sugar, and Mr. Fat. Dr. Fitzgibbon remarked that the children loved these characters. Weekly concepts included portion sizes, grains, fruits, vegetables from A to Z, milk (including switching to 1% milk), and protein. Other weekly lessons were about heart healthy exercise, things to do instead of watching TV, groovy moving, healthy snacks, and "healthy me." The curriculum and newsletters were available in both English and Spanish. Dr. Fitzgibbon stated that the study group worked with people in the community and with health educators to make the program developmentally and culturally appropriate.

General Health Curriculum. The GHC was one class per week, 20 minutes in length, in which such topics as immunization, brushing teeth, calling 911, seat belt safety, and so forth were discussed. This intervention also included a weekly parent newsletter mirroring the class curriculum.

Cultural Specificity. Elements that made the program culturally specific were that there was easy and safe access to the program; the program fostered identification among the data collectors, interventionists, and participants; and the program addressed cognitive and environmental barriers to exercise and adoption of a low-fat, high-fiber diet that includes more fruits and vegetables.

Measures. Measures included demographics, anthropometrics, dietary intake, and physical activity. Demographics based on parental reports were for age, gender, and ethnicity. Anthropometrics included weight measured using the Seca digital scale, height measured by portable stadiometer, and BMI. Parents reported their child's dietary intake over a 24-hour period, allowing for periods when the child was in school and not observed by the parent. The dietary intake recalls were documented by hand and then entered into the latest available version of the Nutrition Data System for Research. Parents were also responsible for reporting the number of times in the past week the child engaged in physical activity, the intensity of the activity on a scale from 0 (completely relaxed) to 10 (maximum effort, totally breathless and sweating). Parents also reported the number of hours per day of TV viewing.

Baseline comparability of the WCI and GHI schools were assessed using two-sample t-tests for continuous variables and chi-square tests for categorical variables. To test the primary and secondary hypotheses, SAS Proc Mixed was used with the individual school as the unit of randomization, yielding a test statistic with 10 degrees of freedom for the 12 schools. For tests of the primary hypotheses, year 1 and year 2 post-intervention change in BMI was the dependent variable. SAS Proc Mixed analyses were conducted with and without adjustment for baseline age quartile and baseline BMI. For dietary and physical activity measures, the SAS Proc Mixed and the absolute values at follow-up were used, adjusted for the baseline value, rather than the change scores.

Children's Characteristics at Baseline. At baseline, the children, half of whom were boys and half girls, were approximately 4 years old. There were more African Americans than Latinos. Anthropometrics for the intervention and control groups were comparable for BMI, but not for weight and height, because the control children were slightly older. Both groups were at least in the 85th percentile. Dietary intake of total fat, saturated fat, and fiber were about the same in both groups at baseline. The control group parents reported a greater frequency of exercise.

Parents' Characteristics at Baseline. Parent characteristics at baseline were fairly evenly distributed between the intervention and control groups. The mean BMI of the parents was a little over 30, which is considered obese.

Results. Dr. Fitzgibbon presented data unadjusted for site, age, or BMI. At 1-year, there was very little change in BMI in the intervention group (from a mean of 16.5 to 16.6), whereas there was a change in the control group (from a mean of 16.8 to 17.4). At 2 years, the intervention group had moved up to a mean BMI of 17.1 and the control group was at 17.9. However, when the data was adjusted for site, age, and baseline BMI, differences at 1 year in BMI are 0.02 for the intervention group and 0.64 for the control group and at 2 years, they were less than 0.5 for the intervention group and were 1.14 for the control group. These differences were also true for data on the African-American children only.

Analyzing the data by gender, the boys in the intervention group did better than the girls did, and both the boys and girls in the intervention group did much better than their counterparts in the control group at the year 1 and year 2 follow-ups. This was also true when making comparisons by age and BMI percentile at baseline. Dr. Fitzgibbon reported that, while there were changes in BMI, there were no differences in dietary intake or physical activity.

Limitations of the Study. Since the study was designed for inner-city, low-income, minority children whose foods incorporated the WIC Special Supplemental Nutrition Program, Dr. Fitzgibbon stated that the generalizability of the intervention to other populations is unknown. There were no significant differences between the WCI and GHI groups on any of the dietary or physical activity measures, except for saturated fats at year 1 for the GHI group. Dr. Fitzgibbon added that this lack of differences may be real or it might be due to a lack of sensitivity in the measures used. Another limitation of the intervention is that it was conducted by specially trained early childhood educators, rather than classroom teachers, which would make a difference, obviously, because these teachers received a lot of training and were invested in having a very successful program. There was also a strong emphasis on uniformity of the intervention.

Lessons Learned. Hip-Hop to Health, Jr. did demonstrate success in reducing BMI in children at the year 1 and year 2 follow-ups. Dr. Fitzgibbon stressed that these results indicate that early childhood interventions present a compelling strategy for long-term obesity prevention.

Future Directions. Supported by some foundation money, the Feinberg School of Medicine researchers at Northwestern University are planning to develop an effectiveness trial in which they will train classroom teachers to implement the program. They are also working with a company to mass-produce the popular puppets that were used in Hip-Hop to Health, Jr. All the original puppets were handmade, which would not be feasible for an intervention on a more widely disseminated basis.

Prevention of Childhood Overweight: The Role of Child Care Settings

Barbara A. Dennison, MD, *Associate Professor of Clinical Pediatrics, Columbia University; Clinical Professor of Epidemiology, SUNY-Albany School of Public Health; and Director, Bureau of Health Risk Reduction, Division of Chronic Disease Prevention and Adult Health, New York State Department of Health, Albany, NY*

Dr. Dennison stated that part of the rationale for focusing on childcare centers is because that is where preschool children are The percentage of children attending organized childcare centers has grown dramatically over the past 30-40 years and currently approximately 85 percent of children attend some kind of organized childcare setting before they start kindergarten. Dr. Dennison explained that by the time of kindergarten entrance, many dietary, physical activity, and TV viewing habits are already established. Moreover, the prevalence of overweight has increased among this population, and childhood overweight becomes more engrained over the preschool years, with tracking being higher among 5-year-old children than among 3-year-old children.

There have been a number of studies of eating behaviors and overweight in preschool children. Extensive research by Dr. Leann Birch, Pennsylvania State University, has shown that preferences for foods are increased by increasing exposure; by modeling behaviors of parents, other adults, and peers; and by positive psychosocial associations. Preferences for foods are decreased, however, when used as a contingency or a reward. Dr. Birch's work also showed that maternal control of children's eating is associated with overweight, at least in girls, and with increases in adiposity. Many other studies have shown that nutrition education does not result in behavioral changes. Programs such as Dr. Christine Williams' "Healthy Start," which was designed to decrease blood cholesterol levels and did so, did not affect children's weight or body mass index.

Brocodile the Crocodile. Dr. Dennison pointed out that as the obesity epidemic has spread worldwide, there has been a call for a paradigm shift from the individual to the community environment and from treatment to prevention. Brocodile the Crocodile was a 39-week randomized controlled trial in 17 childcare centers, designed in response to this changing paradigm. Staff from the Brocodile the Crocodile program visited the intervention centers weekly to provide three components: 30 minutes of musical movement, based on the *Kindermusik* program, healthy eating through provision of healthy snacks and 30 interactive educational sessions, and a program of 7 interactive sessions to reduce TV and video viewing. There also was a take-home component for parents. The TV

reduction program, modeled in part after Dr. Tom Robinson's school-based curriculum, "Student Media Awareness to Reduce Television (SMART) (Wilde ML, Lauritsen K, Saphir MN, Robinson TN: Stanford Prevention Research Center, Stanford University School of Medicine, Stanford, CA)" and Dr. Marie Winn's community efforts to reduce television viewing (The Plug-In Drug), was the most successful. It promoted positive behaviors, such as reading instead of watching TV and eating meals as a family with the TV turned off. The Berenstein Bears book, *Too Much TV*, was used as a catalyst for children and parents. After the intervention, there was a 4.7 hour per week difference in TV and video viewing between the intervention and control centers, and a 50 percent reduction in the percentage of children who were watching 2 or more hours per week of TV and video (Dennison BA, Russo TJ, Burdick PA, Jenkins PL. Arch Pediatr Adoles Med 2004; 158:170-176). The intervention included 4 weeks to inform, motivate, and challenge children and families to spend a week with no TV viewing followed by a party to celebrate surviving the week. This was followed by a plan for budgeting TV viewing. Dr. Dennison noted that this study and others have shown that children who attend organized childcare centers watch significantly fewer hours per week of TV and videos than stay-at-home preschool children.

Dr. Dennison explained that as they moved forward, it was felt that other individuals, groups, and population segments needed to be involved, as suggested by ecological theory. There was a need to increase buy-in support and investment by the childcare staff and community members to sustain the efforts with the preschool children; therefore, they turned to community participatory research approaches.

Rural Community Partnership to Promote Fitness by Age 5. This program involved two small rural communities, each with populations of approximately 10,000 people. There was an intervention community and an assessment-only control community. The intervention program was built on the Brocodile the Crocodile program and targeted preschool children and parents directly. It also targeted the medical community, restaurants and fast food establishments, and various forms of childcare centers such as preschools, daycares, and Head Start centers. It also targeted the larger community. Repeated cross-sectional assessments were made at the time of kindergarten registration.

Medical Community. Focus groups were held with all the pediatric providers in the community and their nursing staff. In the focus groups, it was learned that physicians and nurses were not calculating or using BMI and that they often did not recognize children who were overweight or at-risk of overweight. They said they were afraid they would alienate parents if they mentioned that their children were overweight. Also, they doubted anything they said would be helpful, and they were not clear about what to say or how to help. The study group worked collaboratively with the medical community to change the nature of well-child visits and of their routine anticipatory guidance. There was an effort to increase BMI screening and to diagnose children who were overweight or at-risk of overweight and to make routine assessments of diet, TV viewing, and physical activity part of the well-child visit. The changes in routine anticipatory guidance involved what providers and the nurses routinely say at visits and the materials handed out to parents.

The first step in making the changes to the well-child visits was to increase measurement of height and weight, calculation of BMI, and the plotting of all three on growth charts. The study group first conducted baseline chart reviews of children who presented for well-child visits. Interestingly, they found that measurements varied with the nurse and not with the medical provider. Between baseline and the first follow-up assessment, training sessions were provided for both nursing staff and medical providers, and at the assessment, there was a significant increase in the percent of children who had BMI plotted. Nurses have also been provided with individualized feedback and additional training, and Dr. Dennison said she expects to see even more improvement in the use of body mass index, diagnosis of overweight children, and assessment of diet, TV, and physical activity at the second follow-up assessment scheduled for the end of the summer 2004.

Restaurants and Fast Food Outlets. Students in a 2-year Associates Degree culinary arts program at the local college, SUNY-Cobleskill, went to all the local restaurants and fast food establishments and collected menus and the recipes for "kids' meals." Working with Dr. Anne Rogan and the school's faculty, they analyzed the nutrient composition of the "kids' meals," and then using only the given menu items, developed Fit 5 meals that met the following criteria:

- Calories: 400 to 500 k/cal.
- Total fat less than 30 percent of calories.
- Saturated fat less than 10 percent of calories.
- 1 vegetable serving.
- 2nd vegetable or 1 fruit serving.
- 1 dairy serving (4 ounces).

The students then went back to the eating establishments and presented their menus to the restaurateurs. A follow-up will evaluate whether these meals were added. Dr. Dennison said the students are optimistic because the owner of the local McDonald's, who also owns eight other McDonald's, was very enthusiastic; he has already added 1% fat chocolate milk as an option with "Happy Meals" and said he would be willing to add and sell any new food items that people would buy.

Childcare Centers. The staff and directors of the centers did a self-assessment of the childcare environment, policies, and behaviors related to nutrition and physical activity. At focus groups, the staff at each of the childcare centers identified ways to improve in four domains—nutrition and healthy eating, physical activity, TV and video viewing, and psychosocial behaviors that affect activity and television viewing. Dr. Dennison's staff provided ongoing support, feedback, and training.

Nutrition and Healthy Eating. To improve nutrition at the childcare centers, staff were encouraged to first write down and then to work on improving their nutrition policies, focusing on improving the healthy foods available by increasing the variety and number of fruits and vegetables and by substituting low-fat milk for juice and juice drinks. They also developed policies about what foods parents could bring to celebrate birthdays or holidays. Staff were also encouraged to change their use of foods in relation to psychosocial behaviors. Dr. Dennison explained that study staff found that although many centers had a policy of not using food as a reward, staff often had difficulties in translating this policy into what they were doing. For example, at one center where staff said they had such a policy, there was a large poster of a pizza pie on the wall. Staff explained that when

the children were especially good, a slice was added to the pie. When the pie was full, the children were rewarded with a pizza party.

Physical Activity. Again staff at the centers were asked to write down their policies for physical activity and then to work on improving those policies to put more activity into physical education, group activities, and play time. Two training sessions, based on the early childhood SPARK program, developed by Dr. James Sallis and his colleagues at San Diego State University, was provided to the staff at the childcare centers along with some equipment. One focus of this component was defining what was meant by inclement weather to comply with a policy requiring outdoor activity in the winter as long as the temperature was not inclement. Originally, inclement had been defined as not below 32 degrees Fahrenheit, but other conditions obviously are applicable. Staff also wrote down policies for TV and video viewing, and training sessions and materials for a TV reduction program were provided to help support changing policies for use of TV and videos.

Dr. Dennison explained that it was around the TV viewing component, that they were able to get the community involved in reaching out to the parents. Using asset-based community development theory to drive brainstorming sessions with the childcare providers, a plan was developed in the 6-week period before the national TV Turn-Off Week campaign. Because of their relationship to the childcare centers, and since they also had other community connections, such as being a boy scout leader, people became very enthusiastic about developing ideas and volunteering to provide for alternative activities to compete with TV viewing time for preschoolers and their families.

Faith-based groups were heavily involved in providing volunteers. The Head Start center located in a former school opened up its gym for evening indoor activities such as karate, playing with clowns, moving through an obstacle course, and doing arts and crafts, all led by volunteers. The library offered storytelling one evening a week. SUNY at Cobleskill had an open house at their agricultural farm and since it was spring, there were lots of newborn animals. SUNY also provided for indoor swimming and outdoor activities such as fishing and soccer. A local pond was stocked and Boy Scouts provided equipment and helped parents teach their children to fish. A Maple Festival Parade was scheduled at the fairgrounds for the last Saturday of National No TV Week. The High School Student Environmental Action Coalition, a group of local high school students, built a No TV float and provided a band that lured the children like the pied piper. They biked, skated, and walked with their parents to the fairgrounds, where a singer-songwriter, Skip West, performed children's action-packed songs that got the children up and dancing. Afterwards, children listed on a large wall-sized poster their favorite activities other than watching TV.

Results. Dr. Dennison presented some data from the project, which is ongoing. At baseline, the assessments showed that there was a higher prevalence of overweight children in the two communities (intervention and control) than was reported in NHANES III for Caucasians, which the population mostly was, or for 4-year-olds in the New York State WIC program. Structured physical activity was assessed at baseline and then after the training. During SPARK activities, activity counts measured by Mini-mitter Actiwatches went up a little. In fact, the children were considerably less active when doing regular group physical activities than when they were doing SPARK activities, both before and after a second training.

During the first two cross-sectional surveys, there was no significant change in mean BMI. There was a non-significant decrease in the prevalence of children who were overweight in the intervention community and a significant, 2.9 millimeter, difference in triceps skinfold thickness between the intervention and control communities.

Lessons Learned and Successes. Both the implementation of the Reduction in TV Viewing Curriculum and the application of the asset-based community development mode that generated so much excitement, enthusiasm, awareness, and involvement of the community were keys to the success of the TV reduction component. There was an increase in physical activity, particularly during SPARK-related activities. There was also improvement in nutrition because of the newly written nutrition policies. There were changes in snacks and in birthday and outside food policies. In addition, there was an increase in use of low-fat milk at the childcare centers and in the children's homes. Dr. Dennison added that there is possibly some preliminary evidence suggesting a reduction in adiposity.

Challenges. Dr. Dennison stressed that in doing interventions in childcare settings, it is important to include other individuals and spheres of influence affecting the lives of children, including parents, other family members, and the community. It has been said that it takes a village to raise a child, and indeed it does. Other outside influences included the media and marketing.

A primary challenge in conducting interventions in these settings is the high rate of staff turnover. These are, after all, mostly low-paying jobs. Another challenge is the politics involved and the competing demands for time and resources. For example, Head Start now is required to look at academic achievement and nationwide they are doing testing in Head Start in October and May of all children for the "no child left behind" initiative. Post-intervention follow-up is important and will probably need to occur in non-childcare settings such as the schools.

It is difficult to assess impact of individual components in a community intervention. With community participatory research, certainly focus groups and formative analysis is time-consuming and the evaluation is qualitative. Developing relationships and establishing trust with communities takes time, and because the interventions are less prescriptive, the analysis is more difficult.

Future Directions. In spite of the challenges, Dr. Dennison emphasized that childcare centers are very promising targets as venues to prevent childhood overweight. It may be that younger children are more malleable. Furthermore, because regulatory policy changes may infringe on individual rights, it may be easier and more acceptable to implement regulatory or policy changes to protect younger children. Society is more amenable to protecting its younger children. For example, laws requiring car seats for children less than 3 years of age were in place long before laws requiring seatbelts. As policy, regulatory, or legislative changes affecting childcare centers and schools occur, which is happening across the country, opportunities will be created for natural experiments to evaluate the impact of such changes on children's activity, nutrition, and/or prevalence of overweight. Dr. Dennison stressed that this will, however, require prompt funding mechanisms and quick start-up capability.

In conclusion, Dr. Dennison stated that multi-dimensional, multi-component community-based changes probably offer the greatest hope for stemming the obesity epidemic, but they need to be further evaluated. Community participatory research is an idea whose time has come. However, along with the additional time required to conduct these studies, it must be remembered that because they are less prescriptive, they are more difficult to implement and more difficult to analyze. On the other hand, Dr. Dennison suggested that these interventions are probably more sustainable, although this too needs to be evaluated. As successful innovations are discovered, both translational research and funding are needed to diffuse these ideas.

Applying Theory and Methods of Community-Based Drug Abuse Prevention to Pediatric Obesity Prevention

Mary Ann Pentz, PhD, *Director, Center for Prevention Policy Research, Keck School of Medicine, Department of Preventive Medicine, University of Southern California, Alhambra, CA*

Dr. Pentz proposed to discuss aspects of her work in community-based prevention research in the drug abuse prevention field that could translate potentially to obesity prevention, such as potential risk factors, mediators, and strategies. She stressed that she was not suggesting that prevention effects obtainable in drug abuse prevention can generalize readily to obesity, but rather that translational theory can potentially be used in either field.

For example, adolescence is a particularly vulnerable risk period for both obesity and drug use development. Dr. Pentz said that an interesting event occurs in the early adolescent period, which, for most youth, is about the same time as the transition to middle school in 6th grade. As part of neural development, this age group, reaching puberty, is undergoing maturational changes that are extremely rapid. It is the second time after the age of 0 to 2 that such rapid changes are seen in frontal and subcortical systems functioning. These systems affect two areas related to obesity as well as drug use. They affect motivation to change, impulsivity, addiction, and satiation (Chambers et al. 2003. American Journal of Psychiatry 160(6):1041-1052; Committee on Nutrition. 2003. Pediatrics 112(2):424-430). In fact, Sanofi, a drug company, is about to enter a Phase III clinical trial to test a drug, Rimonabant, which is meant to equally address obesity prevention and prevention of tobacco addiction as a physiological therapy.

Dr. Pentz stated that the field of drug abuse prevention has demonstrated that there are multiple community influences that impact on youth. Typically, drug abuse prevention begins with a school program and moves outward to work with family, the media, the community, and policymakers. The literature suggests that a school program is key to achieving behavioral change in youth. Community programs or media programs and most family programs that do not incorporate a school program, either based on environmental change or a curriculum, achieve very little effect, according to the literature.

Integrative Transactional Theory. Dr. Pentz explained that one of the more comprehensive theories that drives the field is integrative transactional theory, which basically bundles together personal, social/situational, and environmental level influences that operate as risk factors. Some also act as protective factors.

Personal Level. On the personal level, shared risk factors include engaging in high-risk behaviors that show a cluster pattern (Irwin et al. 1997. Annals of the New York Academy of Science 817:1-35) meaning that obese children who are not monitored well might also be engaging in risky sexual behaviors and other health compromising behaviors. Other risk factors common to the drug abuse field and obesity are poor executive cognitive functioning (i.e., poor decision-making), low impulse control, and excessive time spent watching TV (Davis et al. 2004. Obesity Research 12:929-935; Committee on Nutrition. 2003. op. cit.; Tarter et al. 2004. Drug Alcohol Depend 73(2):121-132).

Social/Situational Level. Risk factors at this level include negative peer modeling (Committee on Nutrition. 2003. op. cit.); negative parental monitoring, both of obesity and a lack of alternative healthy behaviors (Strauss, R.S., Rodzilsky, D., Burack, G., Colin, M. 2001. Archives of Pediatrics & Adolescent Medicine 155(8):897-902); and close parental monitoring (Klesges et al. 1991. American Journal of Clinical Nutrition 53:859-864). Close parental modeling is the only risk factor Dr. Pentz has found that works in the opposite direction in obesity. In the field of drug abuse prevention, the more closely a young adolescent or child is monitored, the more protective this is. In obesity, and it is not clear why this is true, close parental monitoring tends to lead to overweight, possibly because the parent wants to keep the child close to home and offers them a snack or candy or whatever to stay inside. Other risk factors that occur in obesity but not in drug abuse are self-image or self-concept. In obesity, there is no perceived personal risk or negative social consequence in engaging in a particular behavior reported in the literature, whereas these are strong risk factors in drug abuse. The two most powerful mediators of change in the field of drug abuse prevention, whether in a school or community program, involve social/situational risk factors. One is changing the perceived approval by peers and others of whether or not you use drugs. The second is the whole idea of counteracting or changing perceived social norms, which is a major operator, both as a risk factor and a mediator. Dr. Pentz said this last factor may potentially have a role in obesity prevention.

Environmental Level. Lack of access to healthy alternatives is common to both fields, as is lack of or inconsistent policies and product marketing (Committee on Nutrition. 2003. op. cit.).

Dr. Pentz stated that these influences and the way they interact indicate the need for a multi-component, community-based prevention strategy. Such a strategy can counteract these multiple social influences with programs that are aimed at each of the sets of influence (school, parent/home, community, policy, and mass media). They can be used together to reinforce social norms for either non-drug use or alternatives to current eating practices and lack of exercise. Together they can provide more sustained program exposure than one channel alone can do.

Relevant Theories. Dr. Pentz noted that Social Learning Theory, Social Cognitive Theory, Problem Behavior Theory, Social Support Theory, and Persuasion Marketing Theory all play a role in drug abuse and obesity prevention. What is important in the obesity field, and missing in drug abuse prevention, is the health belief model and planned behavior.

Potential Shared Mediators. Mediators have been shown to change as a result of prevention/ intervention. Self-efficacy and decision-making skills operate at the personal level (Strauss et al. 2001. Archives of

Pediatrics & Adolescent Medicine 155(8):897-902; Davis et al. 2004. Obesity Research 12:929-935). At the social/situational level, prosocial bonding to peers who engage in the desired kinds of behavior (Strauss et al. 2001. op. cit.); parent modeling skills through changes in parental behavior and, in the drug abuse field, changes in parent/child communication (Wrotniak et al. 2004. Archives of Pediatrics & Adolescent Medicine 155(4):342-347); and involvement in prosocial activities (Sothern SM. 2001, Pediatric Clinics of North America 48(4):995-1015) are all alternatives to either drug use or lack of exercise. A potential mediator at the environmental level is restricted access policies such as restricting access to tobacco, alcohol, and other drugs or restricting access in schools to fatty foods and sweetened beverages (Committee on Nutrition. 2004. Pediatrics 112(2):424-430.). Another mediator is providing opportunities for alternative activities (Committee on Nutrition 2003 op. cit). More active in the drug and tobacco field is teaching young adolescents media literacy skills to counteract marketing and advertising, which has potential for obesity prevention, also (Committee on Nutrition 2003. op. cit.).

Midwestern Prevention Project (MPP). The Midwestern Prevention Project, also called Project Star, was a very early multi-component, community-based trial for which follow-up is ongoing 20 years later. It was funded by the National Institute on Drug Abuse (NIDA), Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Prevention (SAMHSA/CSAP), and the Kauffman and Eli Lilly Foundations and was based on the Integrative Transactional Theory model of behavior change that drives the personal, social/situational, and environmental risk factors. The trial took place in Kansas City and Indianapolis in 107 middle schools. Most of the design was randomized but in some cases, where schools already had prevention programming for the year, the schools had to be matched demographically. Project Star had a Media Program (31 per year), School Program (18 sessions), Parent Program (2 sessions), and a Community Organization Program and Policy Program, that are ongoing. Initiation and implementation of program components were staggered over the 5-year period of the trial. Dr. Pentz emphasized that her group uses a separate mass media model to motivate the community to support the idea of prevention, which also may be necessary to make communities aware of the need for obesity prevention.

Organizational Elements. Dr. Pentz explained that since 1985, her group has followed the 10-step community organizational model that basically creates community organizations with leaders. The model provides for organizational and evaluation steps from needs assessment through reinforcement of the implementers and target population participants. An example of results from such a program was an intervention for reduction of daily cigarette use at an Indianapolis school site that ended in 1990.

MPP Effects on Mediators. At the personal level, the Midwestern Prevention Project programs built on the models mentioned by Dr. Pentz have achieved changes in self-efficacy, in personal beliefs about consequences, and in intentions to use drugs. At the social level, they have brought about decreased and changed peer-perceived norms for use and peer approval for use, increased refusal skills, and increased prevention communication and support by parents. Environmentally, the interventions have decreased community norms for use, increased awareness of media influence on use, and increased youth and parent awareness and support of policy, which is key to increasing an impact in the school environment.

Lessons Learned. Currently, Dr. Pentz is working with the STEP trial, which involves training community leaders, teachers, parents, and youth to implement 6 evidence-based prevention programs in 24 cities in 5 States. ABC Television is a partner. STEP is a randomized trial with three conditions. One lesson learned in working with community leaders is that the largest risk factor for not moving forward at the community level is lack of community readiness. Second to that is community leaders' perceived empowerment. Another important lesson is that prevention programs and messages must be linked among the program components. For example, the implementers of a family-based program, school-based program, and Head Start program must know about each other. An example of the importance of this linkage is that the control groups in the Kansas City area could have watched the 31 major media pieces aired in the year or availed themselves of community-level or policy inputs, but less than 4 percent of them did because they did not have school or parent programs to cue them in. Dr. Pentz stressed that another important factor for obesity prevention will be positive and repeated media support.

For obesity prevention, Dr. Pentz suggested that program emphasis on environmental-level mediators and interventions would be more powerful in affecting changes than they are in the drug prevention field. Other areas for emphasis will be product availability and access and working to change the school environment, not just individuals. Finally, development of weight standards for goal-setting will be key, not standards having to do with measures, but standards based on what adolescents believe the social consequences of being heavy are. These will help drive the intervention.

The Built Environment and Obesity in Children

Ross C. Brownson, PhD, *Professor of Epidemiology, Department of Community Health, Saint Louis University School of Public Health, St. Louis, MO*

Dr. Brownson pointed out that research studies examining the effects of the built environment are very different from research studies that involve randomized trials. The objectives for his presentation were to describe the potential role of the built environment in influencing childhood obesity, to understand the current state of the science, and to explore potential innovative approaches and opportunities for future research.

Potential Role of the Built Environment.
Dr. Brownson explained that he would be addressing the physical environment in community settings such as schools, the home, and childcare facilities. While there are other aspects of the built environment that also are important for obesity, his focus would be on the role of that environment on the expenditure side of the energy balance equation (i.e., influences on physical activity). Obviously, obesity is an energy imbalance between intake and expenditure. Dr. Brownson said that he would be talking about how children move, and how they should be able to move, within the broad community environment to get from home to school, to shopping, to the playground, and other places.

Ecological data for 1974 to 1995 from the Surface Transportation Policy Project, based on data from the Nationwide Personal Transportation Survey and CDC, indicate children are walking less and more are overweight, trends that, even though not highly correlated, are moving in the wrong direction. From 1950 to

2000, the increase in miles per person per day traveled by car follows linearly the increase in childhood overweight. Such travel is not just commuting to work, for which vehicle miles have not increased very much, but driving children to school, to soccer games, and to do errands and such. Data on per person utilitarian trips by mode show that approximately 90 percent of these trips are by automobile, 3 percent by public transit, 9 percent by walking, and another 1.7 percent by other means such as biking. Dr. Brownson stressed that such trends nationally are a major issue. Also, this dependence on the automobile is an important factor when discussing the physical infrastructure of communities and promotion of physical activity.

Dr. Brownson illustrated the goal of building activity into daily routines through non-structured techniques with a clever cartoon showing one employee saying to another employee in the office, "I'm trying to fit 30 minutes of exercise into my busy schedule. Today I took 120 15-second walks." Although this would not comply with the CDC ACSM recommendation, the idea behind changing the built environment is to create ways to increase physical activity in people's lifestyles other than the structured activity of going to a health club, for instance.

State of the Science. Cross-sectional correlational studies have provided more information than have traditional kinds of intervention studies, according to Dr. Brownson. Cross-sectional studies have shown that, for adults, access to recreational facilities such as bike paths, walking trails, sidewalks, and parks, consistently correlates with physical activity levels. Although effect sizes are only in the range of 1.8 to 2.5, they are fairly consistent across different settings (urban, rural, United States, Australia, different countries). There are fewer studies with children, but most of the studies have had positive associations with access to facilities, programs, and opportunities to exercise.

From transportation, urban planning, and other literature about elements of the built environment, it is known that there are factors, mostly in the urban environment, that seem to correlate well with people being physically active or inactive. Some of these factors are population density, connectivity (getting from point a to point b), and land-use mix. An example of poor connectivity is the subdivision with a lot of cul-de-sacs, where a lot of people live and traffic speeds are low, but it is difficult to get from one place to another because the neighborhoods do not connect. The alternative to that is more of a grid design. Land use mix affects the ability to go shopping, to go to school, to do errands, and so forth without having to get in the car every time someone wants to go someplace. Dr. Brownson noted that an area where there has not been a lot of research is in how specific design attributes affect various types of lifestyle activities, such as recreational physical activity compared to transport activity where enabling factors are likely to differ.

Safety, both "stranger danger" and "traffic danger," is also a major concern that comes up in designing interventions about the built environment. When parents are surveyed about barriers to their children being more physically active, these two safety concerns are usually the top two items listed. Dr. Brownson noted that statistically traffic danger and the ability to get from one place to another without encountering high speed traffic is the greater threat, but media reports of child abductions strongly affect parents' willingness to let their children participate in after-school programs.

There have not been many intervention studies to affect the built environment, and these have not produced much data. Such interventions are not the typical kind of studies in which a group is selected, the intervention is implemented, and then assessments of the intervention's effects are made. In studying the built environment, investigators are generally examining what is taking place in the environment at the "community scale" or "street scale" and how that affects people (so called "natural experiments"). For example, studies of the street-scale environment look at changes in neighborhoods and how those changes might affect various endpoints. Often physical activity is not the only or even the primary endpoint, because a lot of these studies are done by people who are not public health researchers.

Dr. Brownson listed a few intervention studies, several of which are from Europe. For example, a study from London looked at the positive effect of lighting on footpath use (Painter. 1996). Another study found a 23-percent increase in bike use when bike lanes were added to streets (Macbeth. 1999). It was demonstrated in another study that when streets were redesigned for shared use, there was a significant increase in street play among children (Eubanks-Ahrens. 1967). Dr. Brownson pointed out that outcome measures are also different in the built environment studies. For example, the children did not wear motion sensors, and yet measures of street play can be an objective way of looking at physical activity. He added that there is still a great deal to learn about what is taking place in the built environment with respect to overweight and obesity.

Interaction of Built Environment Factors. Epidemiologists speak about necessary and sufficient causes. A necessary cause must always precede some effect; a sufficient cause inevitably initiates or produces an effect. Dr. Brownson stated that the built environment is probably a necessary but not always sufficient cause. Aspects of the built environment need to be present for children and adults to be physically active in healthy ways that increase energy expenditure and decrease childhood obesity. Parents, peers, and teachers and social norms are all interacting factors within the built environment that have not been widely studied. The food environment, especially access to healthy foods, is another aspect of the physical built environment that needs to be researched further.

Future Directions. Dr. Brownson recommended that research be funded in natural experiments because researchers have little control over what is happening in the built environment, so these studies generally cannot be randomized designs. An example of an effective type of study in this area is Dr. James Sallis' Active Living Research being funded by RWJF and, to some extent, by NIH. Active Living by Design, another RWJF program, is really a demonstration project, but there is an evaluation component being built into it to help determine its effectiveness, although not only for the built environment. There is also interesting work being done through promotional campaigns, social marketing, policy change, and examination of interaction of factors. California, for example, is funding a study on making routes to school safer, including making changes in the built environment.

Another suggestion of Dr. Brownson's was to work with partners outside of the usual public health arena such as urban planners, travel researchers, street engineers, architects, and persons in charge of metropolitan planning organizations. He stressed that linking up with such multidisciplinary partners is critical to gain understanding of the built environment and to be able to affect that environment.

Dr. Brownson noted that endpoints vary widely, depending on who is doing the study. He recommended looking at some of the intermediate indicators such as physical activity and diet, as well as measures of obesity such as skinfolds. As the literature develops, there will be opportunities to do systematic reviews as was done for the *Guide to Clinical Preventive Services* (Harris RP, Helfand M, Woolf SH, et al. Current methods of the U.S. Preventive Services Task Force. A review of the process. *Am J Prev Med.* 2001;20(3 Suppl):21-35) and the *Guide to Community Preventive Services* (Briss PA, Zaza S, Pappaioanou M, et al. Developing an evidence-based Guide to Community Preventive Services—methods. The Task Force on Community Preventive Services. *American Journal of Preventive Medicine*. 2000;18 (1 Suppl):35-43).

One challenge in conducting such systematic reviews is determining what defines an intervention or group of interventions. Dr. Brownson noted this will be particularly difficult with built environment interventions because they are so diverse.

Another important area is policy research, such as safe routes to schools, changes in zoning regulations, sites for schools, and school sizes (e.g., a mega school accessible only by car or bus versus a neighborhood school). Grandparents and possibly parents walked to school because they *could* walk to school, which more often than not is impossible today. Another opportunity is the amount of money being spent in Federal highway dollars, part of which might be better spent, for several reasons, in promoting non-motorized activity.

Lessons Learned. In conclusion, Dr. Brownson paraphrased Voltaire who said something like "Don't let the perfect be the enemy of the good." He also pointed out that, while many people have used them to jump out of planes, parachutes have never been subjected to a randomized trial. Dr. Brownson read the following quote from a *British Medical Journal* article:

> The effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. We think that everyone might benefit if the most radical protagonists of evidence-based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute. (Smith GC, Pell JP. 2004. BMJ. 2003 Dec 20;327(7429):1459-61)

Dr. Brownson suggested the authors intended the protagonists to be the placebo arm. Putting humor aside, he reminded the group that staying with the traditional biomedical study designs preferred by most researchers is not going to advance the field. Researchers need to be open to innovative approaches and different ways of looking at the world when studying aspects of the built environment. There are ideas and opportunities for smaller studies, for looking at natural experiments, and for using quasi-experimental designs or time-series designs.

Group Discussion With Panel of Speakers From Session 3

Facilitator: Diane R. Beth, MS, RD, LDN, NC
Department of Health and Human Services

Prior to opening the floor for questions and discussion, Dr. Beth announced an agenda change. The final three presentations for Session 3 would be heard the next day.

Community Awareness and Media Literacy.
In response to a question from Dr. John Elder, San Diego State University, about how to increase community awareness and community enthusiasm about the obesity issues of fast foods, TV and video watching, and inactivity and how to teach children advertising literacy, Dr. Pentz first cautioned about focusing on negative situations as a motivator for community action, particularly since it is important to not alienate people but instead convince them to help. For example, in a tobacco policy intervention at the University of Minnesota, Dr. Jean Forster used youth activism but did not alienate the vendors in doing so. Dr. Pentz suggested that something that might be capitalized on that has a positive force in marketing in the food industry is the concept of a loss leader, which is seen in grocery stores and fast food outlets all the time. For example, when a 99-cent hamburger is advertised for the month of July, it draws in a lot of families with children. Perhaps a corporation could be convinced to cooperate by sponsoring a healthy loss leader, such as a salad for 99 cents in July, even at a local level; they would still make money. The other concept is to do this episodically, which is what people in the media do. This creates novelty, so each wave or each 2 months, something different is highlighted.

Regarding teaching media literacy focused on influences, Dr. Pentz continued by saying that the current STEP trial has been having some amazingly unexpected effects. STEP is a small study within a study, a sub-design of a larger trial. One of the components is called the media buzz curriculum. It is only four sessions long and received 100 percent implementation by the teachers who will teach it again next year with no prompts, probably because it is novel, received high interest from the children, and was seen by the teachers as relevant to health education. It is one of the first prevention media literacy programs specific to drug abuse, so it is not an open-ended media literacy program. Dr. Pentz suggested that a similar curriculum could be developed for an obesity intervention.

Dr. Resnicow contributed that in a course he taught last year on health communications, the final exam required the students to create a truth-type campaign for obesity, diet, and physical activity based on the work they had done in the previous weeks in deconstructing a truth campaign about tobacco use. He noted that people are very reluctant to alienate any of the industries, but data have shown in Florida and elsewhere that truth campaigns are effective. He suggested that the idea be considered for particular age groups, particularly since market forces are a very strong influence on children's behavior. Use of taxation as a deterrent was another issue that Dr. Resnicow thought should be discussed.

Building Community Linkages. Dr. James Sallis, San Diego State University, commented that an important research area that both Dr. Pentz and Dr. Lytle had spoken about is that of how to facilitate links between community groups and the schools. Dr. Sallis asked if anyone had ideas about approaches to doing this.

Dr. Lytle replied that participatory research will not supply all the answers, but she agreed that funding research that builds into the design substantial time to bring communities together is essential, along with including flexibility for reasonable outcomes. For example, is commitment to BMI as an outcome at the individual level the only allowable one or can other outcomes at the environmental or community level be considered? She suggested that these issues—longer time to do the partnership-work in studies and recognition of community- or environmental-level outcomes—merit discussion as future research directions.

Dr. Pentz stated that there are strategies that have been found helpful in increasing linkages. From Project STAR and the Midwestern Prevention Project, it was learned that if a champion who is very credible in the community can be identified, this will draw not only reluctant community leaders together but also open doors to schools. This happened in both Kansas City and Indianapolis. In the STEP trial, where the cities were smaller by design, approximately 20,000 to 104,000 people, it was found that if the organizations within coalitions already have a strong school presence, that helps the coalition to open doors and begin a dialogue with the schools. A third strong factor is if the community organization or coalition approaches schools and says, "We have the resources and we would like to design activities or programs at the community level. However, we want these activities to complement what you do in the school. What do you do for prevention? What would you like to see happen? What can we do to complement your efforts?" This is a very well-received message by schools.

Also in MPP, the study group worked with the schools and mass media first and then developed the community coalitions. On the average, this second part took another year and a half. This phasing was done because they felt that, in the United States, people mobilize around youth first, not themselves. Besides, adults do not want to change their own behavior. It was thought that if they could provide feedback to the community organizations based on results of the school program, the groups were more likely to come on board to create a coalition. In the STEP trial, the reverse was tried by starting first with community leaders and organizations, and this has proven to be more difficult because the groups do not have anything concrete to latch onto. Dr. Pentz said both of these situations might pose a researchable question—under what conditions should one start the organizational process first with communities versus the school intervention?

Dr. Resnicow suggested that a lot might be learned about working across sites in communities from the three cardiovascular community trials, Pawtucket, Minnesota, and Stanford, and from the New York State Heart Health initiatives.

Future Directions for After-School Programs. Dr. Bernard Gutin, Medical College of Georgia, commented that one of the goals of the meeting was to identify future directions for research. He asked if NIH had considered funding a trans-NIH initiative that took the non-disease-specific approach of doing multiple prevention interventions focused at a particular site, such as doing an after-school program with outcomes for obesity prevention (fitness and nutrition), drug abuse prevention, pregnancy prevention, violence prevention, and so forth. Dr. Gutin stated that conducting and evaluating such a trial could have many implications. Producing outcomes in multiple areas of concern would interest legislators and school officials.

Dr. Lytle answered that she thought the University of Texas had adapted CATCH for an after-school program, which would be one example of an intervention looking at several behaviors at the same time, including physical activity, nutrition, and smoking, and producing multiple outcomes. Results have not yet been published.

Dr. Gutin asked if there was any information about data supporting a State-wide initiative in California to have after-school programs in every school, although this did not happen due to budget constraints. Dr. Pentz had not read any background reports on this initiative, but thought such information, if it existed, would have come from the research on latchkey status, which showed that providing after-school programs where there is positive adult supervision of children deters children from engaging in drug use, violence, and other activities.

Dr. Resnicow agreed that there is a very large opportunity and need for after school programs. Working parents want their children to be in positive environments until they are picked up at 6 p.m. The University of Michigan has a couple of research grants for programs in the after-school setting, although not across disciplines as Dr. Gutin had suggested. Most of them are focused on the endpoint of overweight and are dietary/physical activity interventions focused on energy imbalance. Dr. Resnicow remarked that the novelty of crossing disciplines sounded like an interesting opportunity for research in an unexplored area if viable connections could be made. Because some of the literature suggests that cognitive functioning might be improved by physical activity, his group recently submitted an application to look at cognitive functioning as a result of their after-school obesity intervention that is comparing 20 minutes and 40 minutes of physical activity. This suggests that there might be other connections that exist. For example, there was a study that showed that some children who tend to be sedentary are also children who tend to use drugs and participate in other antisocial behavior, whereas children who are active in sports tend to have fewer high-risk behaviors. There are at least some epidemiological studies showing that certain behaviors cluster and so this is an interesting direction to consider.

Potential Future Directions for GO GIRLS.

In response to a concern of Dr. Stevens about the implications of doing an analysis such as the one he had done on those who attended 75 percent or more of the high-intensity sessions versus those who completed fewer sessions, Dr. Resnicow replied that the group was very clear in stating that, based on its power, the study's overall intervention outcomes were null. The value in the dose-response analysis was the possibility of looking at baseline and other characteristics of those who were willing to participate to this extent to see if there were any factors that might predict outcomes. It was an interesting process to find that girls who came to 16 or more sessions actually lost weight or reduced their BMI. Dr. Resnicow stressed that this type of analysis would not be used to conclude the study itself was effective; however the data might suggest that the dose was insufficient, that certain baseline characteristics were common to the high-attender group, or provide other valuable information that could help design a future trial, perhaps with a higher dose. Dr. Stevens agreed with using the analysis to characterize the type of people who do or no not complete an intervention or to guide future research, but cautioned against using the term "effect" in connection with the data.

Dr. Eva Obarzanek, NHLBI Project Officer for GO GIRLS, noted that 10 churches was not a large sam-

ple size and the difference between the intervention and control groups was 1.2 BMI units, which is not a bad effect size. Dr. Obarzanek complimented Dr. Resnicow on a very well-developed intervention that hopefully can be packaged for other churches to pick up as part of a long-term goal for translation. Dr. Resnicow had suggested that perhaps what was needed was a stronger dose of the intervention. She asked him if he felt that church-based interventions were still desirable community sites for interventions.

Dr. Resnicow answered that the group is pursuing improvements in the intervention design as they consider churches excellent sites, especially for recruiting African Americans. He is currently working with the National Cancer Institute on a very large national church-based program called Body and Soul, and he is still enthusiastic about churches as intervention sites. His group has just finished filming and editing an interactive, motivational interviewing and training kit for black churches. He agreed with Dr. Obarzanek that the effect in the GO GIRLS intervention was okay and that it could be argued that one unit has some public health impact, although it is smaller than they had projected it would be. The study group had power calculations and goals that they were disappointed in not meeting. He added that he felt investigators often overstated their reactions in reporting results and he preferred to be less sanguine. If a study does not meet its power projections or if something is borderline, Dr. Resnicow said that it should be reported as not significant. If the study had included another 4 churches, then the results probably would have been significant, although the study was powered for 10 to 12.

Dr. Fitzgibbon asked Dr. Resnicow if the group, in their efforts to be culturally sensitive in the GO GIRLS project, had been less structured in their dietary and physical activity recommendations than they would have been with a different population. Dr. Resnicow replied that, for a variety of reasons, they were committed to the approach they took and would have used this same approach, rather than a traffic light-type dietary intervention, with a Caucasian cohort. He did not see the lack of structure as a black/white issue. For their next attempt, they might consider a more structured approach.

Built Environment Issues. Dr. June Stevens, University of North Carolina at Chapel Hill asked Dr. Brownson if any of the cross-sectional studies indicate levels of activity for children who live in a grid versus those who live in a cul-de-sac. She noted that speakers invariably advocate grid neighborhoods, but parents tend to move to cul-de-sac neighborhoods because they want to let their children play in the street.

Dr. Brownson said he really did not know of any such data. The current studies do not really allow researchers to finely differentiate one neighborhood from another, especially when it comes to children's physical activity. Adult studies clearly indicate that connectivity, mixed land-use, and higher density contribute to a higher rate of physical activity. It is possible to have mixed land use in a cul-de-sac neighborhood, where there are connections between neighborhoods and traffic is still slow. For example, a new subdivision being developed outside St. Louis will appear to have traditional cul-de-sac neighborhoods, but there will be a walking trail through the neighborhoods and retail establishments. The subdivision will incorporate mixed land use and have a town square quality, which will enable people to enjoy a fair amount of physical activity in their daily routines.

Faced with some major trends in development today, Dr. Brownson suggested that it was going to be important to work with developers.

Dr. Kathleen Sellers, Bassett Healthcare Research Institute, commented that she had read in literature received from her son, who is an undergraduate student in urban planning, that there is a correlation between the enhancement of suburbia and sprawl since the 1950s and an increase in adiposity. The hypothesis is that since people can no longer regularly walk to areas such as the grocery store, the child-care setting, and the school, they have to get into a car and drive to get anywhere. Dr. Sellers agreed that more collaboration with urban planners is needed.

Dr. Sallis reported that his group recently completed a small study with adolescents that basically agrees with the built environment studies with adults regarding walkable neighborhoods and physical activity. Dr. Sallis added that, however, that this is one of very few studies with children about urban design issues. It is also true that families move to cul-de-sac neighborhoods because they say, "This is going to be a good place for my kids to play." This is a research question that will hopefully be part of the Active Living Research Project.

Dr. Robert Kuczmarski, NIDDK, commented that his concern in talking about changing the built environment is that it is based on the assumption that if you build something, people will use it. He lives in a planned, relatively affluent, racially diverse community that is a cul-de-sac type neighborhood but the cul-de-sacs are all connected by paved blacktop bike/walking paths. The community has 28 outdoor pools, parks, playgrounds, and basically an ideal environment to encourage physical activity. However, when he looks around there, he does not see less obesity than he sees anywhere else he travels in the United States. Dr. Kuczmarski suggested that before pursuing other research on the built environment, it might be a good plan to take advantage of existing planned communities such as those in Columbia, Maryland; Reston, Virginia; Portland, Oregon; and Boulder, Colorado, to conduct evaluation research and find out if sidewalks and so forth do make a difference and, if not, why not. For example, one reason he and his neighbors do not let their children walk or bike to school on the paths, even though the paths were intended to connect homes to schools, is that they go through a wooded area, and the parents are concerned about their children's safety. There have been problems with children being beaten up and with having their bikes stolen. There also have been more serious crimes, against adults, on the paths. Evaluation studies of planned communities, some of which have existed for 30 years and will be around for another 30 years, could contribute valuable data if researchers can be found who see this as a unique opportunity and are willing to pull together urban planners and other multi-disciplines and submit an application for such a study.

Dr. Brownson agreed. An urban planner had told him that 80 percent of urban environment for the next 20 years is already built, so there is not going to be any major re-building for some time. On the other hand, there are smaller scale projects that can be done such as the Active Living by Design idea that Dr. Sallis is working on that can improve the built environment and make it more activity friendly. One problem is most funding mechanisms, such as the peer review process, do not support the quick action often required when opportunities arise to do some innovative projects. Dr. Brownson suggested NIH consider a

means to speed up the process for such projects that need funding within 6 months or a year in order to continue with a natural experiment that shows promise.

Dr. Brownson added that one of the big issues in cross-sectional studies has been selection bias. For instance, do people move to activity-friendly communities because they themselves are active people and would be active wherever they lived? With a cross-sectional design, it is difficult to determine this. However, researchers are seeing a 160 percent net effect in activity-friendly communities compared to the non-activity-friendly communities, which is a large effect that is unlikely to be due to self-selection. Dr. Brownson suggested that one way to study this would be to study behaviors among people who moved from one neighborhood to another.

Dr. Pentz spoke about a couple of architects who have won awards for designing small communities, where cars are left at the edge of the community, there are walking paths, and the community is more or less self-contained with its own post office and so forth. They originated this in Seaside, Florida, and started a trend that has progressed to other places, including a community outside Washington, D.C. They have also spawned spin-offs by other architects, in Oregon, for instance. Dr. Pentz suggested these communities offer an interesting study opportunity, even with self-selection bias, because the people who wanted to move there did so by lottery. This provides a control group of people who had the same bias but who did not make the lottery cut.

Dr. Resnicow raised the question of how to motivate for-profit builders to construct environments that facilitate increased physical activity and how to increase consumer interest in purchasing homes in such environments.

Dr. Sallis answered that there is a fair amount of interest in the building and architectural field, and certainly in community planning, about these issues. People know about Seaside and Kentlands (in Gaithersburg, Maryland), and other new urbanist communities. One of the problems is that, in most places, building a walkable community is illegal. So even if developers are dedicated to doing it, they either cannot or must go through so much paperwork, hearings, delays, and expense to obtain variations and waivers that they often give up. There are legal roadblocks in their way based on zoning, building codes, and road design. Dr. Sallis said that if it were not so difficult, there probably would be a lot of interest among the developers because consumers do like such neighborhoods. A study of people who live in suburban Atlanta showed that, given a choice, 30 percent of them would rather live in a more walkable neighborhood; whereas the estimate for new neighborhood construction is that only about 2 percent of it is what would be termed walkable. There obviously is a market failure, but it is not necessarily the fault of the developers. They have to work within a system that has been created over decades to support auto-oriented developments.

Dr. Sallis stated that an influencing factor that has not been discussed much is public opinion and public preferences. Rather than holding developers accountable, Dr. Sallis recommended conducting research on how to motivate the public, not just to be more active and to eat healthier, but to be advocates for environmental changes that will make their personal behavior changes easier as was done with the anti-tobacco and anti-drug campaigns. He added that is

not only a legitimate but probably a necessary kind of research question. Dr. Sallis said his group would be open to funding such a study and hoped NIH also would be interested.

In his response to Dr. Resnicow's question, Dr. Brownson said he thought lessons will need to be learned from success stories, mostly with qualitative methods, because not much is known currently about what it takes to get a zoning variance or what will interest builders. The builders that Dr. Brownson has worked with are willing to listen but, as Dr. Sallis said, they must deal with many roadblocks to building more walkable communities. However, if they begin to see a 30 percent, or even 15 percent, consumer market, Dr. Brownson thinks they will be willing to move forward.

Dr. Sallis added that trying to change laws, building practices, and transportation funding are enormous issues and present a multi-dimensional problem that must be taken seriously, but this will not happen simply because public health-related persons say this would be a good thing. Better data are needed. Given that a number of studies, not all of which have been published yet, show a link between walkability of neighborhoods and BMI, he and Dr. Brownson have been discussing with NIH the possibility of going beyond cross-sectional studies to do some prospective or migrations studies.

Recommendations for Intervening at Earlier Ages. Dr. Treviño, Social and Health Research Center, San Antonio, commented that the solution might be a lot simpler than building a whole new city or changing whole neighborhoods. He pointed out that some of the school-based interventions with older children that were discussed during the meeting were very large interventions with minor results, whereas the interventions that Drs. Pentz and Dennison had described with younger children were small, such as puppet shows, but had encouraging results in BMI and skinfold changes. Dr. Treviño suggested the key may be to work with preschools and earlier age interventions.

Dr. Lytle agreed about the importance of intervening with younger children to prevent adiposity at earlier ages; however, she felt it was also important to continue efforts to change the school, social, and community environments to ensure that these do not negatively impact the children as they grow up and go through stressful developmental stages, particularly at puberty and the middle-school age. She emphasized that good programs are needed across the lifespan to inoculate people against the many risks that they encounter.

While agreeing with Dr. Lytle, Dr. Fitzgibbon also suggested that additional work be done in the preschool years. This age group has not been the focus of many studies because developmentally this is a difficult age to work with, particularly with measurement issues of diet and physical activity. One cannot rely on parents' reports of their children's dietary intake and physical activity because they are not observing them all day long. However, it is definitely an opportune age at which to intervene.

Dr. Resnicow added that it will continue to be important to see how well changes track. BMI change seems to track well, but analyses of behavior change in physical activity and diet are mixed and tend to be short-lived.

Dr. Dennison agreed that no age group should be ignored. She suggested that children younger than the preschool age of 3 to 5 years also need to be

studied. Dr. Nicolas Stettler (at Children's Hospital of Philadelphia) has shown that rapid infant weight gain is associated with increased risk of overweight. A study by Dr. Robert Whitaker found that newborns whose mothers are overweight early in pregnancy are at increased risk of being overweight when they are preschoolers.

Dr. Matthew Gilman, Harvard Medical School, introduced the subject of the Life Course Model of Chronic Disease, an etiological model, not a behavior change model, that takes into account not only accumulation of risk and tracking risk factors over time but the possibility of critical or sensitive time periods in which a change at a physiologically sensitive developmental period can have long-lasting effects, even if these are not evident right at that point. In other words, in intervening at very young ages to prevent obesity, there could be a latency period. Dr. Gilman suggested that intervention really needs to include all developmental stages of organs and systems, from conception to adulthood. For example, intervening to prevent gestational diabetes might be very important in interrupting an intergenerational cycle of obesity. Dr. Dennison was correct that there are now several studies that suggest that accelerated infant weight gain, even in the first 4 to 6 months of life, can translate to obesity at age 7 or even at age 20. Infant feeding style may have a significant effect on accelerated infant weight gain and on obesity through other mechanisms, as well, both behavioral and metabolic. Infants cannot generally be randomized to breastfeeding or formula, but units can be randomized to promote breastfeeding. A large-scale study of breastfeeding promotion is going on now in the Republic of Belarus. There is not an equivalent study in the United States or anywhere else. In thinking about innovative approaches to prevent obesity, Dr. Gilman recommended that there be studies that begin in infancy.

Interventions in Family Daycare. Dr. Gilman asked those working in the preschool interventions if they had done any studies in family childcare settings, since many children, Caucasian, Latino, and African American, are taken care of by family providers of daycare and receive much of their nutrition and physical activity information from these family members.

Dr. Dennison responded that in the rural community intervention in New York, they had attempted to work with everyone providing licensed childcare and so they did work with some family providers, although not those who were unlicensed. There are barriers to interventions in these family daycare settings. For example, the amount of video viewing that goes on is unbelievable. These providers do not have the manpower that other childcare settings have, so when they are preparing meals or it is quiet time or they are providing before-school and after-school care to other children, they rely on the TV or videos. On the other hand, these childcare providers were incredibly enthusiastic and were interested in trying the ideas presented, in spite of the limitations they had regarding time and the resources to do physical activity. Home settings also do not have gyms.

Dr. Fitzgibbon said that Northwestern had not worked with family providers but had talked with agencies in the Chicago area who do work with them. Currently, her group is working with WIC, public housing, and the Chicago public schools.

The Gap Between Policy and Practice. Dr. Karin Pfeiffer, University of South Carolina, commented that her colleagues had noted a serious gap between policy and practice, as Dr. Dennison had mentioned. Dr. Pfeiffer asked if others had observed this, particularly in the preschool setting, and what impact this might have on interventions.

Dr. Fitzgibbon replied that Northwestern had not intervened yet in the school food service in the Chicago public schools, although there have been programs that have done so successfully in other school systems. She agreed that there often is a lot of talk about healthy eating and physical activity that is not put into practice. There are challenges in working with vendors, and it is true that complying with USDA standards does not ensure that food will be healthful. Role modeling by teachers is another issue.

Dr. Dennison noted that if one asks directors of childcare centers what their policies are, their answer is likely to differ from what the staff say the policy is. How the question is framed also makes a difference. This issue indicates the need for validation of assessment instruments for policies and environments, which Dr. Alice Ammerman is working on. Dr. Beth added that she would be presenting the next day information about NAP SACC, an environmental rating tool that was developed for childcare settings.

The first day's meeting was adjourned at 6:05 pm.

Day 2

Dr. Kuczmarski opened the Day 2 session by explaining that the initial speakers for the day would be Session 4's Drs. Resnicow, Robinson, and Story, per the original agenda, followed by the three speakers carried over from the previous day's Session 3, Drs. Ammerman, Moore, and Beth. Following the presentations, there would be another change in the agenda in order to accomplish the feedback goal of the meeting and still conclude by noon. Breakout groups would be formed to discuss five or six questions and report their findings back to the overall group for a general discussion. Dr. Kuczmarski then introduced Dr. Allen Spiegel, NIDDK Director and co-director of the NIH Obesity Research Task Force.

Dr. Spiegel expressed his appreciation to all those who were participating in this meeting. By coming together to offer their advice, those present have indicated they realize the public health importance of focusing on pediatric obesity as a primary target of the overall obesity problem. Dr. Spiegel noted that prevention of obesity is not only a key target of Dr. Elias Zerhouni, Director of NIH, but also a priority of DHHS Secretary Tommy G. Thompson, with whom he and Dr. Zerhouni would be meeting that afternoon to review and defend the FY 2006 budget for NIH. Dr. Spiegel also expressed his appreciation to Dr. Kuczmarski and other NIDDK and NIH colleagues for their work in organizing this meeting and for their cooperative efforts on the NIH Obesity Task Force. He recommended that the participants visit the obesity research website (http://www.obesityresearch.nih.gov). The website was designed to provide a single NIH resource for researchers interested in conducting obesity prevention and treatment studies.

SESSION 4

SESSION 4

Overview of Previous Day

Ken Resnicow, PhD, *Professor, Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, MI*

Dr. Resnicow first acknowledged the incredibly high quality of research that the speakers had presented during the previous day's meeting. He noted there is tremendous capital and considerable history already in pediatric obesity research. On the other hand, distribution of the studies is uneven across sites. There is a large portfolio of research in schools, some of which is already in a dissemination phase. Dr. Resnicow was particularly pleased to hear that CATCH, SPARK, M-SPAN, Planet Health, and Take 10 are being widely adopted. Environmental research, however, is still in its infancy. Researchers are working to establish basic epidemiological data. These studies are not yet ready for dissemination. The research across sites thus spans an entire gamut.

Dr. Resnicow said the dissemination phase raises the question, "What is required to consider something effective?" particularly with regard to appropriate outcomes. He stressed that the interventions, regardless of the study results, are better than the usual practices. Whether this is enough to justify moving forward with dissemination is a question for the group to consider along with identifying different institutional or professional issues, outcomes versus goals, biological outcomes versus behavioral outcomes, and so forth.

Other questions involve how to replicate the studies, how they should be diffused and franchised. Physicians tend to be the gatekeepers for weight management, obesity, and diabetes. However, most successful behaviorally based weight control programs have been developed and implemented by behavioral specialists. There is a technology transfer issue and gap about to what extent the intervention effects achieved by these highly skilled specialists (under efficacy conditions) are generalizable to standard medical practice. The majority of physicians lack the confidence, motivation, time, skills, support services, and economic incentive to treat their overweight patients. Dr. Resnicow proposed solutions both within and outside the current paradigm (see slide presentation at http://www.niddk.nih.gov/fund/other/Diabetes-Translation/KenResnicow.pdf). Both solutions require collaboration between the medical, behavioral, and social science communities.

Continuing with his overview of the previous day's presentations, Dr. Resnicow said there is still much to be learned from the vast literature on prevention of smoking and drug use among children and youth. In smoking prevention, change in smoking behavior is considered a viable outcome of media campaigns, indicating the need for discussion about what is the realistic outcome for various prevention channels, including media. Must it always be BMI? The previous day's discussions also showed that other disciplines need to be included, such as urban planners and those conducting research on technology and health behavior change.

Dr. Resnicow pointed out that a frequent comment from the previous day was "We need a champion. We need a hero." He noted that often when researchers are asked to talk about their success stories, they reply "Oh, there was this principal who was a champion." Unfortunately, acquiring this individual is very difficult to predict or to create. There is not much research on how to create "tipping point" people. Dr. Resnicow suggested that it is important to discuss what this means in terms of ability to proactively create positive, contagious effects.

Reducing Children's Screen Time to Prevent Obesity
Thomas N. Robinson, MD, MPH, *Associate Professor of Pediatrics and Associate Professor of Medicine, Division of General Pediatrics and Stanford Prevention Research Center, Stanford University, CA*

Dr. Robinson calculated from Kaiser Family Foundation 1990 data that children between the ages of 2 and 17 spend between a quarter to a third of their entire waking life in front of a screen, most of which is television viewing. Evidence has linked this television viewing to obesity. Primarily, there have been three main mechanisms. One is displacement of physical activity, for which evidence has come from natural experiments where television was introduced into communities where it previously did not exist in the 1960s and 1970s. There is also mixed data from epidemiological studies about whether television is related to physical activity. More often than not, this tends to be a null or a weak positive association.

Increased calorie intake while watching TV is the second mechanism. This appears to be related to effects on satiety and actual eating behavior or in response to advertising. Epidemiology studies show the predominance of high-fat, high-calorie foods and limited fruits and vegetables being shown on television. There have also been good experimental studies done over time that show that children's intake is affected when they are exposed to ads promoting foods.

Finally, a third mechanism has been whether watching TV decreases metabolic rate and thus energy expenditure. One study suggested this but up to this point no one has been able to replicate it, and in the replication studies no difference has been shown between TV viewing and other sedentary behaviors.

CDC data from two national epidemiologic studies have shown a dose-response relationship between prevalence of obesity and hours of television.

Although television has been issue for a long time among parenting and child advocates, Dr. Robinson stated there have been very few attempts, until recently, to try to reduce children's television viewing or to see what happens if children watch less TV. Most of the emphasis has been on media awareness or critical viewing skills, primarily from people interested in media itself and who feel that media is a positive thing and want to maintain media use in some way.

Stanford School-Based Study. Dr. Robinson explained that at Stanford their first attempt to study television viewing was with 200 third and fourth grade children in San Jose schools during one school year (.Robinson TN. 1999. JAMA 282:1561-1567). This was a small, quasi-experimental, randomized trial, in which one school was randomized to receive an intervention to decrease television, video game, and video tape use without specifically promoting other activities as replacements. The purpose of this approach was to isolate the role of reducing television viewing alone, as opposed to whatever other activities might be used to replace it, such as after-school programs and such. The other school received assessments only.

The intervention was based on behavioral theory and incorporated 18 classroom lessons, starting with self-monitoring, then awareness, and then going through a 10-day TV turnoff to increase mastery experiences and efficacy. Next, TV was budgeted to 7 hours per week for the next 20 weeks of the school year. This phase of the intervention included the use of a monitor that helped people budget, but only about 40 percent of parents said they ever hooked this up. The

intervention also addressed intelligent viewing (something media proponents have been talking about), which involved using the TV guide and other things to plan ahead and to give children a responsibility to budget their time prospectively. Dr. Robinson said that, although parents were included in the intervention via newsletters, the researchers found that, at least in school-age children, the most effective approach to change children's behavior is to work directly with the children and to change parents' behaviors, also work directly with the children. This is true, because, at least in Stanford's experience, parents have many other items on their agendas, and they will do what their children are excited about. (For additional details, see the following website: http://noTV.Stanford.edu.)

Outcomes are being measured and school performance is being examined also in the Stanford study. Decreases in television viewing are being reported and along with that, significant changes, even in this small study, in body mass index, with about half as much increase in the treatment school as the control school, an average of about a 2 pound difference for normal weight children of average height over one school year (Robinson TN. 1999. ibid). Similar changes are seen in triceps skinfold and waist circumference, with this difference approaching nearly an inch in waist circumference over 7 months. Planet Health also included reducing television viewing as part of their 2-year intervention and is another example where decrease in television viewing was associated with changes in the prevalence of obesity, defined by both triceps skinfolds and BMI. There are also effects on other family members, which might be expected. Even though this was a school-based curriculum, fathers, mothers, and other children in the household also decreased their television viewing substantially. Dr. Robinson noted that this is an example of one site, intervening in the school, influencing another site, the home environment. The program is being disseminated to schools, at a fee, through Stanford's Health Promotion Research Center. Interestingly, much of the interest has come from concern over youth violence and from an anti-consumerism movement.

GEMS Pilot Study at Stanford. Stanford has also been one of the intervention arms of the GEMS pilot study. In results from 61 African-American girls, randomized to either the after-school dance and home-based TV reduction program or the standard health education control, there also were decreases in household TV viewing. An interesting result that occurred across at least three of the four GEMS sites was that there was a significant decrease in weight concerns in the treatment group compared to the control group, which is interesting with regard to the concern about interventions possibly increasing eating disorders. In response to some of these interventions, there also may be improvement in school grades based on TV reduction only.

Childcare Setting. In a study in childcare centers for preschoolers reported by Dr. Barbara Dennison, seven lessons of the curriculum were focused on television viewing and resulted in significant reductions in TV viewing by these younger children (Dennison, BA. 2004. Arch Pediatr Adolesc Med 158:170-176).

Primary Care Settings. Dr. Robinson said Stanford has done one pilot study in a primary care setting, in which 7- to 12-year-old children were randomized to either a 5-minute behavioral intervention where they were helped to set goals and given a TV allowance to take home or to a 5-minute counseling intervention where they were just told about reducing TV viewing and its importance and given the American Academy

of Pediatrics pamphlets on television and children (Ford, BS et al. 2002. Am J Prev Med 22:106-109). The study was conducted with African-American children, boys and girls, in a family medicine clinic in a low-income area. Both groups self-reported large decreases in screen time over just a 1-month period of time, with no differences between groups; however, Dr. Robinson cautioned that the data are from self-reports, not objective measures. The group in the behavioral program reported significantly more time playing outside and more organized physical activity than the group that received just the counseling intervention. Dr. Robinson said this would suggest that the intervention was a little more effective than the counseling, and at least it is one example where a 5-minute intervention in a primary care setting may have had some effect on children's behavior.

Another study by Dr. Leonard Epstein examined what children do when they are not watching TV and what they do while watching TV that might relate to obesity (Epstein, LH et al. 2002. J Pediatr 140:334-339). This study with 13 non-obese 8- to 12-year-old children indicated that increasing sedentary behavior by 50 percent results in an increase in calorie intake and a slight decrease in physical activity. Decreasing sedentary behavior by 50 percent, on the other hand, did not produce much of a change. None of the results were significant, but this study was done with only 13 children. Dr. Epstein has reported that in other studies with overweight or older children significant changes have occurred from decreasing sedentary behavior. Dr. Robinson suggested this may indicate that the type of child, or where the child is in age and weight at baseline, may influence their response to an intervention and/or their exposure to media. It is not clear from these television viewing studies whether changes are the result of diet or activity level, although it appears that changes occur in both areas. More experimental data will be needed to clarify what is actually happening.

Relationship of Eating and TV. Dr. Donna Matheson from Stanford recently published data on two different samples related to eating while watching TV (Matheson DM et al. 2004. AJCN 79:1088-1094). One sample was a group of third graders in a multiethnic school district. The other sample was a group of low-income fifth graders, mostly Mexican Americans. Each group did three 24-hour recalls on non-consecutive days, weekdays and weekends. They were asked, "During these 24-hour recalls, with each food, what were you doing while you were eating that food? Were you in the car? Were you watching TV? Or what?" The study found that in relation to media, less than 4 percent of calories were consumed while at the movies, watching movies on a VCR or DVD, playing video games, working on the computer, and all the other media. Most of the food consumption related to media use was in watching TV. On weekdays, on average, from 16 to 18 percent of the children's total daily energy intake was consumed while watching television, and this is during the school year, so presumably some of their intake occurred during school. On weekends, it was higher (26 to 30 percent of the total daily energy intake). Dr. Robinson stated that what was remarkable to the study group was that the results were consistent among such different populations. He added that data to be published from the low-income GEMS sites shows very similar estimates for low-income African-American girls in four different cities around the Nation.

Dr. Robinson stated there was an inconsistency in correlation with BMI that makes it difficult to determine if TV viewing is one of the mechanisms related to causing obesity. In the third grade sample from the

multi-ethnic school, there were some correlations related to BMI that were moderate in terms of percent of energy from fat consumed while watching TV or the average energy density of the food eaten while watching TV. In the other sample of the low-income fifth graders, the correlations were essentially null.

It has been suggested that children tend to snack on higher fat, higher calorie foods because of the advertising or the types of foods that are eaten on TV. The study did not find that the patterns of foods or the types of foods consumed differed when the children were watching TV compared to when they were not watching TV. In fact, they tended to drink fewer soft drinks and eat less fast food while watching TV, and did not eat more of the foods classified as advertised foods, such as sugary cereals, while watching TV versus when not watching TV.

Future Research Directions. Based on the progress to date, Dr. Robinson listed the following research priorities, although not necessarily in this order, with regard to screen time:

- Understanding the mechanisms of what is happening when children watch TV.
- Delivering interventions in other settings such as primary care or childcare sites.
- Studying both younger and older children.
- Discovering more powerful interventions.
- Moving to effectiveness trials.
- Promoting diffusion research.

Dr. Robinson said it is important to understand what is happening when children watch TV that might increase their risk for obesity. Is it diet or activity or a combination of both that is affected and just how is diet affected? Another Stanford study is exposing children to eating either with the TV on or with it off to see if they actually do consume more calories in front of the TV from a distraction effect or whatever. He added that teenagers spend a tremendous amount of time with media, beyond TV viewing, and there has been very little research done with teenagers and the effect of instant messaging and email and what is called partial or minimal attention or partial/simultaneous attention, where youth are using many media all at the same time.

In looking for more powerful interventions, Dr. Robinson mentioned what he called stealth interventions, where the focus is on activities or ideologies that people are very excited about anyway and will do or react to, and that, as a side effect, may have an effect on their viewing behavior or their health-related behaviors. An example is participation in an after-school program, where children obviously are not in front of the TV or the refrigerator for that part of the afternoon. It can be potentially more appealing to join an after-school program than to cut down on TV, even though both may have the same outcome. In the GEMS study in Oakland, the girls talk about social justice issues and media as a racist issue in terms of the ownership of media and the messages and stereotypes that are seen in media. Such discussions can be very compelling and may make for more powerful interventions. Activities that interest a group, such as dancing, or ideologies that already exist within the community can be built upon them to promote healthier behaviors.

Another area of intervention might be in the home environment. Studies indicate that about 70 percent of children of elementary school age have a TV in their bedroom and the percentage is higher for teens. No one has actually studied if it is possible to take TVs out of children's bedrooms, whereas that may be

the most potent intervention for reducing the media environment in a household.

Finally, Dr. Robinson stated there needs to be more research on the processes necessary to take interventions to the next step. In the substance abuse area, particularly in smoking, there has been a lot written over the last several decades about how to diffuse effective curricula; however, there has not been much done about studying that process, even though there are conceptual models available.

School-Based Studies in Perspective

Mary Story, PhD, RD, *Professor, Division of Epidemiology and Associate Dean for Academic and Student Affairs, , School of Public Health, University of Minnesota, Minneapolis, MN*

Dr. Story opened with a summary slide of a Cochrane database of systematic reviews of the 1985 to 2001 literature on obesity prevention in childhood performed by Dr. Karen Campbell and others at the - Deakin University in Australia (Campbell K., Waters E., O'Meara S., Kelly S., Summerbell C. 2004. The Cochrane Library, Issue 4, Chichester, UK). Dr. Campbell's group selected only randomized controlled studies and non-randomized studies with a control group that had at least 3 months of exposure. Two reviewers independently extracted data and found that in the whole literature worldwide there were only 10 studies on obesity prevention in children, 8 of which were school-based interventions.

Cochrane Systematic Review. The results of the school-based interventions in the Cochrane review were basically disappointing. More than half of the studies found no difference in excessive weight gain between the intervention and control groups. Dr. Story then reviewed post-2002 studies and found mixed results in the literature on obesity prevention. She added that what is striking is that there have been so few studies on obesity prevention. There have also been some school-based studies from 1966 to 1996 for obesity treatment, but none since 1996 in which overweight children were treated in a school system, even though 11 of the 12 prior studies resulted in a significant reduction of weight in these overweight students. Most of these were conducted in the 1970s and the 1980s. They had small sample sizes, and there were a lot of methodological problems. Although there currently are many concerns because of the issues of stigma, labeling, and teasing, and schools may not be the best site for treatment, Dr. Story recommended that the role of schools in treatment—not just prevention—be examined again based on these intervention results.

Advantages and Disadvantages of School Sites. Looking at the prevention literature raises the question, "Why haven't school interventions shown more results?" Dr. Story suggested the answer is that we are still in the first generation of studies. School-based interventions are difficult and complex to implement. Multiple-risk studies like CATCH have not been designed for obesity prevention, and not many studies have been done; therefore, school-level interventions should not be abandoned simply because there has not been much success so far. After all, schools have the advantage of being the site where children are many hours every day. Ninety-five percent (95%) of children ages 5 to 17 are enrolled in school. No other institution has such continuous and intensive contact with children. Children eat one to two meals 5 days of the week at school, which is about 30 percent of their total daily energy intake. Schools have resources such as gyms, equipment, playgrounds and playing fields, and PE programs.

As a site, schools can leverage peer influence and change social norms as well as providing contact with parents. Dr. Story suggested that further improvements, many of which were discussed in this meeting, are needed in such studies. These improvements include the following:

- More articulation of the theories being applied.
- Design of interventions based on better identified modifiable determinants of overweight such as risk and protective factors that mediate diet and physical activity.
- More family involvement.
- School-based environmental and policy change interventions.
- Improved and different methods and designs.
- Increased sensitivity of self-report diet and physical activity measures and probably more objective measures.
- More smaller scale, innovative studies.

In addition to their advantages as sites for intervention, Dr. Story noted that schools do have disadvantages that must be taken into consideration. Most of the school-based studies on obesity prevention have used a one-size-fits-all intervention, and Planet Health and other studies have demonstrated that interventions may function differently by gender. It may be difficult to do gender-specific interventions in schools or tailor interventions to specific cultural/ethnic groups. Another school issue is that universal prevention programs or primary prevention may not be of sufficient dosage or targeted enough to have an impact on children who are already overweight. It is difficult now to get sufficient classroom health time, because of the curriculum issues about academic achievement and standardized testing. There are structural issues such as space or time for PE. Although school can be a great place to reach families, engaging them can be difficult. Dr. Story said that the major limitations—and an issue to be dealt with—of school-based prevention studies to date have been that efforts have been "school-centric" in the sense that they focused exclusively on in-school programs.

Appropriate Outcomes. Dr. Story next addressed the critical issue of "What is the main outcome?" If it is BMI change, or reduction of obesity, or reduction of excessive weight gain, then it will be necessary to go beyond in-school programs. It has been shown that in-school programs can change diet, can modify the school food environment, and can increase physical activity. However, to impact weight and body fatness, Dr. Story emphasized that studies must move beyond the school-based, in-school program. To illustrate her point, she presented data on calorie distribution by eating location from the National Continuing Survey of Food Intake of Individuals by USDA (Lin, Guthrie, and Frazao. 2001. Food Review 24:8-17). These data showed that only one-third of all calories consumed by 6- to 11-year-olds and 12- to19-year-olds are eaten away from home, which includes school. Two-thirds of all calories are still consumed in the home environment. Thus obesity prevention requires family involvement.

Lessons From Other Youth Health Promotion Areas. Youth health promotion and prevention literature in other fields confirm the need for family involvement. The entire July 2003 issue of *American Psychologist* was a special supplement on prevention science for youth health promotion. Obesity and diet and physical activity were not addressed but Dr. Story recommended that other areas such as substance abuse, risky sexual behavior, school failure, juvenile delinquency, and violence can provide information valuable to obesity interventions (Weissberg et al.

2003. Am Psych 58:425-432). In these areas, it was found that, in total, family-focused prevention efforts have a greater impact than strategies that focus only on parents or on children. Dr. Epstein clearly showed this in his presentation. Across these five content areas, it also was shown that combined school and family programs deliver more benefits than those conduced independently of each other, and that community programs that include policy changes and media campaigns are much more effective when they combine family, peer, and school components.

Importance of Parental Involvement. Dr. Story stated that the basic challenges of having more parental involvement are that the most effective ways to involve parents through school-based approaches are not known, parental involvement decreases markedly during middle school and high school, and rates of involvement by low-income and poorly educated, single, minority parents are relatively low and better ways are particularly needed to involve them. Overall, more research on how to engage parents is needed, including recruitment and retention strategies, prior relationship building, and removing of barriers to attendance (e.g., childcare, incentives, transportation). Research is also needed to understand the types of family involvement that best lead to program implementation and outcomes. Such techniques include behavioral parent training, family workshops, telephone counseling, take-home activities, and events at school. Information also is required on the optimal intensity and dose of the intervention.

Principles of effective family-focused interventions presented by Drs. Kumpfer and Alvardo in *American Psychologist*, although they were in areas such as conduct disorder, school failure, juvenile delinquency, and substance abuse, also had relevancy for obesity prevention (Kumpfer and Alvardo. 2003. Am Psych 58:457-465). The authors found the most effective programs were multi-component interventions that addressed strategies for improving parental monitoring, focused on improving family communications and family relations, and produced behavioral, cognitive, and affective changes in the family's overall environment and within the family dynamics. They also found, across these different content areas, that increased dosage or intensity of the intervention of about 25 to 50 hours was needed with higher risk families versus only about 5 to 24 hours with lower risk families.

Importance of Being Age and Developmentally Appropriate. Drs. Kumpfer and Alvardo also found in youth health literature that the programs had to be age and developmentally appropriate and that tailoring the intervention to cultural traditions improved outcome effectiveness. Several studies have shown that high rates of family recruitment and retention (80 to 85%) are possible with incentives such as providing food, childcare, and transportation. As discussed earlier in this meeting, the effectiveness of a program was highly tied to the trainers' personal efficacy and confidence, personal characteristics, and ability to structure sessions and be directive. Dr. Story stressed that the competency and characteristics of trainers is a critical issue and an area about which more knowledge is needed, especially in training classroom teachers to deliver interventions. In working with parents, interactive skills building rather than lectures increased program effectiveness, especially with low SES parents, and helped empower them to identify their own solutions.

Need for Environmental and Policy Changes. Dr. Story added that environmental strategies and policy change at the school level are also important. Researchers like Drs. Mary Ann Pentz, Jim Sallis,

Simone French, and Leslie Lytle have done a great deal in this area. They have shown that, although it is difficult, food service in elementary and high schools can be changed. Limiting access to sweetened beverages and other high calorie foods in vending machines and modifying food prices is effective in increasing consumption of healthy foods. Peer promotion through use of student advisory boards also is effective. More physical education classes and more active recess time helps, although these have not been packaged into an overall obesity prevention program. The school walking clubs being implemented in some schools around the country have been effective. Dr. Don Bishop at the Minnesota Department of Health has a study with American-Indian children where they do a daily walk for 30 minutes and this is being tried in some other Indian schools. This is an example of an innovative program that can be tried elsewhere.

Use of School Health Centers. Although they do not appear in the literature on obesity prevention or treatment, Dr. Story called attention to the approximately 1,500 school-based health centers (about half in high schools and half in elementary and middle schools) around the country that provide onsite medical, mental health, and preventive services. They are typically open about 30 hours a week during the school year. Approximately 39 percent are open during the summer; two-thirds are in urban communities and one-quarter in rural areas; and over half serve students who are African-American or Hispanic. Dr. Story suggested these school-based health centers might be a venue for obesity prevention and treatment. They have been effective in reducing adolescent pregnancy. Dr. Story further recommended that school-based intervention studies develop close connections to other after-school and youth-serving programs in the community, as TAAG is doing.

Study Design and Evaluation. Another possibility involves the study design and evaluation issue such as the need for alternatives to randomized controlled trials and group randomized trials. Group randomized trials require that a large number of schools be involved, they are expensive, and it is difficult to obtain fidelity to the intervention implementation and outcome evaluation. New designs that use fewer schools and still provide for statistical power are needed.

In the *American Psychologist* issue referred to earlier, Dr. Nation provided a systematic analysis of youth risk behaviors and the prevention literature (Am Psych 2003; 58:449-456). Three program areas were found to be effective in prevention of risk behaviors. One was program characteristics such as comprehensiveness, including intervening on multiple levels as well as in multiple settings; varied teaching methods, especially behavioral change and skill-building activities; sufficient dosage; being theory driven; and developing positive relationships between children and parents, between providers of the intervention and children, and between the providers and the parents. Matching the program to the target group was the second principle. Dr. Nation's group found that appropriately timed and developmentally relevant programs were most effective, which ties in with what was said in yesterday's meeting about identifying critically sensitive times to intervene for maximum impact, as TAAG is doing by intervening before the decline of physical activities. Socioculturally relevant programs are also a part of this second area. The third principle was that program implementation and evaluations must focus on the outcome evaluation and on well-trained staff.

Future Research Directions. In summary, Dr. Story provided the following list of recommendations for future research:

- Smaller scale, more intensive interventions.
- More school- and family-focused connections, especially ones that involve parents.
- School environmental strategies implemented in tandem with individual-level classroom strategies.
- More intervention studies on school policy changes.
- New design and evaluation methods.
- More attention to process measures of program quality and fidelity to better understand the mediating and moderating variables that influence program effects.

As an example of a comprehensive approach, Dr. Story referred the audience to the example of Dr.Geoffrey Canada, whose work in Harlem was recently highlighted in the *New York Times Magazine*. (June 20, 2004). Based on the concept in youth development literature that there are always resilient high-risk youth who "beat the odds," Mr. Canada, a former youth worker, created the Harlem Children's Zone to change the odds. He took 24 blocks in Harlem and set out to change the schools, the families, and the neighborhoods to promote healthy youth development. His premise is that each child will do better if all the children around them are doing better. In the area of youth development, his program is considered very radical thinking, but in Dr. Story's opinion thinking differently about the issue of obesity prevention and learning from other fields is exactly what is needed. For example, there is interesting work being done in Europe that is worth investigating to help inform interventions here.

Group Discussion With Panel of Speakers From Session 4

Facilitator: Ken Resnicow, PhD, *University of Michigan School of Public Health, Ann Arbor, MI*

Dr. Benjamin Caballero, The Johns Hopkins University, asked Dr. Robinson how the sedentary screen time at home compares to other sedentary time for children such as doing homework or in-school time watching TV or doing classwork at desks.

Dr. Robinson replied that it is difficult to measure total sedentary time for children because it is based on self-reports and these are known to be inaccurate. In the study sample, self-reports and parental reports suggest that screen time is unrelated to other activities such as doing homework. This may be because some children do their homework and read while in front of the TV and so their activities are mixed within a timeframe. The study is also finding that screen time has less to do with the amount of time that children spend in different activities than it does with their home environment, such as having a TV in their bedroom or having one or more computers at home. These latter two factors seem to be much more highly related to standardized test scores than anything else that is measured in terms of the amount of time spent in different activities. Even in schools where the intervention included implementing a curriculum to reduce TV viewing, it was not unusual to find teachers using a videotape at the end of the school day to calm children down or to fill in the time before dismissal, which was inconsistent with the messages the teachers were giving to the children. Basically, there is no clear picture of how much time children spend doing various activities. Dr. Robinson suggested that possibly better measures are needed such as direct observation of sedentary behaviors to determine just which ones are contributing most to the obesity problem.

In response to a question from Dr. Howell Wechsler, CDC, about the recent findings from a European study on video game use and weight among children, Dr. Robinson said that he would include all screen time as one factor. There are such wide differences in what children prefer and in parents' evaluations of different behaviors, that it is not practical to separate the activities. For example, some parents approve of video gaming because they believe it increases coordination and will turn their youngsters into great fighter pilots. Therefore, he would let the family decide which media type they want to decrease.

Dr. Karen Peterson, Harvard School of Public Health, said that in Planet Health the study group had considered adding a parental component to link the family to the school but the results from CATCH seemed to indicate that their parental link had not been as effective as desired. She asked Dr. Larry Webber, Tulane University School of Public Health, what had and had not worked with this element.

Dr. Webber verified that the CATCH researchers had not been able to show differential effects between the school-based and school-based plus family component. This may have been due to the small number of schools in each component, but it was more likely due to the type of intervention used, which was basically a homework approach and a once-a-year health fair at the school. This was not intense enough and did not directly involve parents on a daily basis. The homework intervention was very dependent on the enthusiasm of the classroom teacher in promoting the children's doing these activities at home, coming back to school, and then reporting it on a poster using some mechanism. Dr. Webber said the lack of results also had a lot to do with the short duration of the intervention and perhaps a lack of intensity on the part of individual teachers.

Dr. Story said that sending home newsletters, having a family fun night once or twice a year, or having homework was an effective type of family involvement. She added that there needs to also be much more on parenting, such as the parental monitoring described by Dr. Epstein. These techniques need to be developed. Another factor in CATCH, Pathways, and other school-based studies is that parental participation rates have been relatively low.

Dr. Resnicow commented that when parents receive a note that their child has problem behaviors or is at risk of failure, this gets their attention, whereas it is difficult to get them excited about nutrition or physical activity. Perhaps the lesson to be learned is that parents need to be alerted that their child is at risk of syndrome X or something.

Dr. Robinson added that the clinical setting, such as in Dr. Epstein's work or the clinical work at Stanford, does make a difference because the parents are coming in because they are aware of a problem. The subjects are self-selecting; the study is not reaching out to the whole general population. Even in schools considered relatively good, involving parents in a population-based study generally means going to them rather than asking them to come to an intervention site. That is one reason for the family interventions for GEMS taking place in people's homes versus attempting to get parents to come to back-to-school nights. All the parent intervention is in the home, one-on-one. Another technique that has been found effective is having the children perform. When children from the low-income areas of Oakland do dance performances, four family members for each child show up to see them. The whole community comes

out. Even the older brothers come. The schools cannot get over the type of attendance these performances have because they cannot get parents to show up for anything.

Dr. Story seconded this comment by saying the same was true of Pathways. Parents came when the children were performing or receiving certificates. They would also come to eat with their children in the school lunchroom, which is another way to get families involved.

Dr. James Sallis, San Diego State University, commented that although the school-based interventions have not shown positive effects on BMI or overweight, they have shown environmental, policy, and behavioral changes in diet and physical activity. The interventions have thus been successful in helping the intervention schools to become part of the solution instead of continuing to contribute to the problem. The results also show that the school-based contribution alone is just not enough to affect the total energy balance of the child, the child's total dietary intake and amount of physical activity. The current frontier for research then is to expand by adding home interventions, after-school programs, and community programs.

Dr. Resnicow and Dr. Story agreed with this statement and urged that the breakout groups discuss the possibilities for combining intervention components and sites. Dr. Resnicow noted that one complication is that sometimes there are BMI effects that do not appear related to the behaviors. Dr. Robinson added that the school-based studies are the ones that have the fewest successes to date.

Dr. Roberto Treviño, Bienstar Health Program, San Antonio, introduced the issue of cultural differences to the discussion. He noted that cultural attitudes have an impact: For example, his father tells him that his son is too thin. He can disagree with his father, but for someone outside the culture to do so would not work. Dr. Treviño stressed that many times the problems must be solved from within the culture. Outsiders coming into the culture, making statements, and taking strong stands will not be effective. He urged that leadership be developed from within the ethnic cultures to start making changes in order to see improvements within the minority populations.

Dr. Story and Dr. Resnicow definitely agreed that efforts need to be couched in other terms, such as the social justice suggested by Dr. Robinson, rather than just as adiposity.

With regard to developing champions, Dr. Leslie Lytle, University of Minnesota, suggested that longer intervention periods might allow for more coaching of likely candidates and help such persons to evolve as champions. A longer trial would enable them to think about what they will do when the study group is gone. This is being tried in TAAG. One of the current problems is that potential champions are identified halfway through a trial, which does not leave enough time to proactively work with them and empower them to carry on. Dr. Lytle added that there is a lot more that can be done in this area.

In regard to developing champions, Dr, Mary Ann Pentz, University of Southern California, commented that several investigators have found that after the first year of starting an intervention, there is a group of people who show intense interest and tend to be potential implementers. These people are matched with a trainer and observed during the second year as they are implementing the intervention and by the third year they are trained as master trainers who can

go out and train others. This has been successful in training persons in school and parent programs, but has not been tried yet in training community leaders.

Dr. Lytle also expressed some concern about considering the efficacy of school-based interventions accomplished and moving on into effectiveness, dissemination, and institutionalization. She said there are many aspects of school-based trials that still need to move towards efficacy. For example, training teachers to implement behavior change has not been adequately tested. Her experience is this may be unrealistic. Granting funds to schools for effectiveness trials may be premature. Dr. Story agreed that there needed to be further decisions on what the intervention targets should be, particularly determinants related to diet and physical activity.

Dr. Resnicow suggested that determining which interventions were ready for dissemination and which concepts warranted further work, perhaps even basic research, was another area for discussion in the breakout sessions. For example, if reducing TV time is now evidence-based and using a traffic light diet is evidence-based, then these components could be used at different sites in different types of research studies.

Dr. Martina Vogel-Taylor, NIH Office of Disease Prevention, remarked that she frequently interacts with persons in non-governmental organizations, including administrators, school legislators, and others, who are interested in school health programs. A question she hears from these people who are looking for tools and ways to tie school health to obesity in particular is how can teachers be motivated to teach health in the classroom and how can administrators and community leaders be motivated to involve their schools and organizations in partnerships with research institutions and researchers. They are especially interested in being able to show a connection between school health programs and academic achievement.

Dr. Resnicow responded that there is some data being accumulated showing this relationship. The STOPP-T2D study mentioned earlier is expected to provide a good measure of academic change in the intervention group. Dr. Resnicow said that this is the sound bite that many are looking for but it does not exist yet in the data. The data are a little mixed. Some of the larger trials, such as TAAG, may provide information on reduction of problem behaviors in the classroom, increased attendance, better grades, parent satisfaction, and so forth, in 2 or 3 years from now.

Dr. Bill Kohl, CDC, added that this is another area for NIH and CDC collaboration. CDC is funding a 3-year PRC to look at school-based physical activity and measures of not only academic achievement but discipline, classroom behavior, antecedents, and so forth.

Dr. Resnicow brought the discussion to a close. Following a break, Dr. Diane Beth, North Carolina Department of Health and Human Services, moderator of Session 3 on community and trans-community sites, introduced the first of the three speakers who were carried over from the previous day's agenda.

The Role of CBPR in Childhood Obesity Prevention and Treatment

Alice Ammerman, DrPH, RD, *Director, Center for Health Promotion and Disease Prevention and Associate Professor, Department of Nutrition, University of North Carolina at Chapel Hill, NC*

Dr. Ammerman explained that CBPR stands for community-based participatory research, a research methodology. She added that she would also be describing a small pilot study in CBPR. Dr. Ammerman offered the following provocative anecdote to set the stage for thinking about CBPR. At the conclusion of one of her group's studies, a pastor was asked, "What comes to mind when you think about a researcher?" His answer was, "I think that some people feel like researchers come and suck things out of the community and go back and don't leave anything behind that is positive so you are thinking both about damage in terms of lack of feeling and lost trust…of feeling like they have been mistreated in some way but also feeling that the researchers got a lot more out of it than they did."

Advantages of CBPR Vs. Traditional Research. A slide presented by Dr. Ammerman contrasting CBPR methodology with the traditional research mode showed that CBPR has the potential to bring a lot of benefit to researchers as well as to the community. The traditional intervention process begins with identification of a health issue and proceeds through study design, recruitment, measurement, intervention, and data analysis steps. The CBPR methodology incorporates community participation at each of these steps and provides a benefit from the community's involvement at each of the steps.

At the health issue identification step, the community members are asked what health issues they are concerned about, which provides the benefit of their being motivated to participate in the intervention. The traditional approach applies for funding and then tries to find a community to participate.

Dr. Ammerman stated that the National Institute of Environmental Health Sciences (NIEHS) has been one of the early pioneers of CBPR research. For example, in a recent study focus groups were first conducted with pastors, and one of the issues the pastors came up with was a concern about toxic wastes associated with the hog farm lagoons in their community. North Carolina is the hog farm capital of the world. The pastors were linked with an epidemiologist at the University of North Carolina (UNC) who was conducting this kind of research. Since the community through their pastors identified the issue, there will likely be very good participation in the epidemiologists' research.

At other steps, the community often can help with issues related to enhanced recruitment and retention. Community participation can increase reliability and validity of measures. Pilot testing can enable understanding of the cultural norms in that community. Community "buy in" can also mean that the interventions are more likely to be relevant to the community and thus more likely to be successful.

Evidence Review of CBPR Studies. The Research Triangle Institute International-UNC Evidence-Based Practice Center (EPC) recently completed a systematic evidence review of CBPR funded by the Agency for Healthcare Research and Quality (AHRQ). Dr. Ammerman said the review has not been published yet but will soon be on the AHRQ website. Although such a literature review is difficult with CBPR, the usual methods were used to conduct the review.

An important factor in evidence reviews is the quality of the research. Separating CBPR into the CBP and the R part, the research issues were similar to what anybody would look for in terms of a clearly specified question, appropriate study population and sample size, a control or comparison group, retention and follow-up, external and internal reliability, quality of measures, and analysis. In terms of the CBP part, the EPC looked at a "laundry list" of potential ways for a community to be involved, ranging from selection of the research question to actual application of the findings to an identified health concern, which is a hallmark of CBPR—the hope that there will actually be an application of what is found from the study. Other elements that were included were shared decision-making structures and capacity building.

Studies were defined as CBPR if there was co-learning and reciprocal transfer of expertise—not just researchers teaching community members how to do community research. Other qualifying elements were shared decision-making, mutual ownership of the research process and products, and a commitment to the application and dissemination of findings. Dr. Ammerman noted that researchers are often skeptical about CBPR. One researcher heard a description of CBPR and said, "That sounds like the inmates running the asylum." At the time Dr. Ammerman heard about this comment, her son was reading *One Flew Over the Cuckoo's Nest*, a model where the inmates actually were better than the professionals at figuring out their own problems and addressing them, which has some parallels to CBPR.

UNC's overview included 123 articles pertaining to 60 CBPR studies, 30 of which were interventions and only 12 that were completed, evaluated, and met inclusion criteria. There were modest positive health effects across a variety of topics, although Dr. Ammerman did not recall that obesity was specifically included. There were a limited number of observational studies, primarily in the environmental justice area. A large number of papers reported on CBP methods, but provided very little in terms of research outcomes. Several studies are still in process, and Dr. Ammerman expects these to add to the literature because they are being done well in terms of both the research and the CBP elements. Many studies appeared to use some of the elements of CBPR, but even though five different search terms were used, Dr. Ammerman thought that not all studies were uncovered.

Characteristics of those identified included an average of two publications per study. Only 2 percent of these were prior to 1980 and 40 percent were published between 2001 and 2003. Dr. Ammerman explained that earlier work occurred in CBPR but in areas other than health such as worksite issues, occupational safety, and so forth. Recently, there have been a couple of special issues on CBPR. The American Public Health Association (APHA) and the *Journal of General Internal Medicine* both published special issues. Types of community involvement that were most often addressed in the studies included recruitment and retention and measurement instruments and data collection, both areas that occurred in more than 75 percent of the studies. There was very little involvement with proposal development or financial responsibility for the grants.

Review Findings. Dr. Ammerman stressed that the main finding from the review was that significant research quality is not unrelated to strong community involvement. It is not an either/or situation, but it certainly appeared that high quality research and intense community involvement are not contrary to each other. The reviewers found examples of very

outstanding research combined with collaborative community participation throughout the research process. Another implication from the review was that authors and journal editors need to be aware of the need for and commitment to improved standards for reporting research processes and results.

Girls Rule! Pilot Study. Dr. Ammerman next briefly reviewed a pilot study conducted by UNC and funded by NHLBI and NIDDK. The study called Girls Rule! focused on trying to develop and understand whether an obesity intervention was feasible as a church- and home-based intervention. The pilot included pre-adolescent African-American girls ages 6 through 9 and their primary female caregivers. In addition to acceptability and feasibility, the study included measures of BMI and body fat, primarily to determine if these could be measured in a larger study. The study design allowed testing of the intensive intervention twice, essentially, because the initial control group later served as an intensive intervention group when the initial intensive intervention group became a maintenance and environmental intervention group. This design allowed all the churches to participate in some form of intervention.

Outcome measures that were tested for use in a future randomized trial included BMI, body fat, CSA monitors for physical activity, and sexual maturity as primary outcomes and 24-hour diet recalls and psychosocial factors as secondary outcomes. There were three forms of sexual maturity. A pediatrician examined the daughter, then the girl assessed herself, and then the mother assessed her daughter.

Dr. Ammerman listed the following key formative findings from the pilot study:

- Heavier girls and their caregivers both wanted to be thinner but did not always see the child's current weight as a health concern.
- Family life was hectic and thus there was limited time for meals resulting in frequent eating out, especially at fast food outlets.
- The girls viewed their caregivers as role models, particularly regarding physical activity.
- There was a wide variation in the home environments regarding access to healthy and unhealthy foods and physical activity opportunities.
- In most households, there were limited controls on
- TV viewing and a lot of TVs in bedrooms.
- Caregivers did perceive that their daughters would benefit from a healthier diet and better physical activity habits.

In the 8-month intensive intervention, there were 23 weekly sessions at the church for the girls interspersed with combined child and caregiver sessions and separate caregiver sessions. Dr. Ammerman reported that, although the study group was concerned about whether people would let them into their homes, the four home visits went very well with people actually opening up their cabinets and refrigerators and asking, "What can I do to make this better?" The researchers also looked at the physical environment in relation to physical activity such as a place to jump rope, use a hula hoop, or go for a bike ride. In addition to home visits there was a phone call and excursions to introduce the girls and their caregivers to different activities and some role modeling, like women's basketball games, an African dance, roller-skating, a jump rope team exhibition, and a river hike. There were also events for the church members such as a kick-off event, a jubilee, and a popular "informance," which was an event where the girls performed and also provided information.

At the sessions there was a lot of hula hooping and food tasting. There was a Girls Rule! dance. The study group learned that a traditional Hip-Hop dance would not be very acceptable in southern rural churches, so they did a step dance instead. A UNC master's student came up with a song that went with the dance and had a strong self-esteem theme. The girls acted out commercials. There were weekly challenges such as art work or poetry writing to be done at home that reflected what they were learning about healthy eating. Some of the caregiver and combined sessions included hikes. An activity called photovoice was tried that Dr. Ammerman felt held potential for social justice type issues. Photovoice was intended to use photos to speak about what is healthy and what makes it hard to be healthy. For example, a photo of the playground at church might communicate "This playground doesn't have much we can do" which can carry a message to the pastor and parishioners.

Initially, the study group proposed to do a very structured telephone intervention during the maintenance period, but then realized that they needed to look at environmental issues, so they tried a number of things, which did not work out very well since this had not been planned from the beginning. Because of time limitations, Dr. Ammerman did not discuss this phase of the pilot study or the results of the study. Basically, the Girls Rule! intervention was rated highly by the girls, their caregivers, and the church leaders. Changes in some lifestyle and attitudinal measures showed trends in a positive direction. The use of an African American church and individual homes as the setting for an intervention was found feasible and was welcomed by the participants. Involving the primary female caregivers was very important. There needed to be more work done on promoting physical activity and reducing TV watching, and there were many challenges related to sustainability.

Lessons Learned. Considering Girls Rule! as a possible model of a CBPR-based intervention, the study group has included guides and checklists for proposal writers in their articles that have been submitted to journals. Dr. Ammerman emphasized that good CBP cannot substitute for the R. On the other hand, there is no reason why there cannot be good quality in both areas. Bringing community partners to the table very early is critical. It is important to describe the potential research benefits, not just the community benefits, in a proposal. Dr. Ammerman recommended trusting community partners to understand more of the research basics than researchers normally give them credit for comprehending such as why studies use randomization. She added that everything should be "put on the table." Good intervention ideas often come from the community. Sustainability needs to be planned for from the beginning. Dr. Ammerman particularly stressed the guideline to think long, hard, and creatively about the optimal balance between scientific rigor, implementation constraints, and ethical treatment of community partners, which is a challenge for reviewers as well. There is a great deal of pressure on review panels to only approve the most rigorous study designs. Dr. Ammerman recommended that researchers start challenging themselves to think more seriously about other options that could be used.

Study authors have also drawn up a list of tips for funders and reviewers. The list includes providing adequate guidance; recognizing that it takes time to develop partnerships by building in a planning phase and start-up time; balancing the science, burden, and ethics; and considering that RCTs (randomized con-

trolled trials) are not the only option or that they can be modified to accommodate community concerns. The budget needs to compensate for community burden. Another important element is evidence that a true partnership has been developed. Finally, it is important to include experienced CBPR researchers and community members on review panels for these types of studies.

Changing Physical Activity, Body Image, and Food Choice Behaviors Throughout a Community

Sylvia Moore, PhD, RD, *Professor and Director, Medical Education and Public Health, University of Wyoming, Laramie, WY*

Dr. Moore explained that her project, Wellness IN the Rockies (WIN the Rockies), is an integrated and innovative approach to change physical activity, body image, and food choice behaviors throughout a community. The project was funded via a competitive grant under USDA's Initiative for Future Agriculture and Food Systems (IFAFS), which no longer exists.

Selection Criteria. IFAFS funding was intended for integrated projects that cut across State lines and across multiple sites. Dr. Moore's co-investigator was a Cooperative Extension Service specialist in foods and nutrition at the University of Wyoming, so they combined medical education and the cooperative extension to create this innovative approach that spanned three States (Idaho, Montana, and Wyoming) and involved three land grant universities (University of Idaho at Moscow, Montana State University at Bozeman, and the University of Wyoming at Laramie) and 6 communities, all with populations under 10,000 (American Falls and Preston, Idaho; Lewistown and Miles City, Montana; and Powell and Torrington, Wyoming). The communities were participatory and all shared a connection with the University of Washington School of Medicine.

Other selection criteria for the six communities included that there already be body image and body size acceptance activities taking place in the State and the communities had to have a low income presence, which was determined by examining the nutrition education and food stamps programs in the communities. Communities also had to include members of the States' largest minority group, which is Latino, but this is only 2 to 3 percent of the population, not a large number of persons. American Falls, Idaho, was an exception with approximately 50 percent of the population being Latino. Preston, Idaho, Lewistown, Montana, and Powell, Wyoming, were the intervention communities, and the other three were comparator communities. Dr. Moore stressed that she did not use the word "controlled" because nothing was done to control what otherwise was happening in the environments of these rural communities.

Messages. The WIN the Rockies messages focused on health, not weight. They emphasized that health comes in many sizes and many shapes, which was particularly important because the population in these communities was relatively heavy and there was no wish to attack anyone. The goal was for them to adopt healthier behaviors whether or not they lost a lot of weight. Healthy behavior meant being more active through daily lifestyle activities and planned activities. It meant eating to be healthy and to enjoy food. As a dietitian, Dr. Moore stated that people do not eat food if it does not taste good, therefore eating was hailed as one of life's pleasures and fruits and vegetables were labeled as original fast foods—pre-McDonalds and Burger King.

Study Design. Because this was an IFAFS grant, it was intended to be integrative not only in terms of being across States and sites, but also in terms of research driving the intervention, which in turn would modify and fine-tune the research. Also, the Cooperative Extension program required there be products, outreach, and education.

Dr. Moore briefly outlined the timeline for WIN the Rockies from its grant award in the fall of 2000 to the start of data collection through a cross-sectional survey in October 2001, which had a 51 percent response rate. A second cross-sectional survey in 2003 required very little follow-up and returned a 56 percent response rate. A school cohort included fifth grade classrooms followed through the fifth and sixth grades. A randomly selected adult cohort was drawn from people who participated in the cross-sectional survey. Through a narrative research qualitative component, the group conducted individual interviews and focus groups. Community portraits were developed, and a number of education interventions took place.

Preliminary Findings. Although data analysis is in process currently, Dr. Moore presented some preliminary findings from self-reports of adults. The participants who had a higher body mass index drank more sweetened beverages, ordered super-sized portions, and ate while doing other activities such as watching TV. They reported a lower frequency of participation in physical activity and perceived themselves as not getting enough exercise. Dr. Moore pointed out that these people are not unintelligent; they know what they are not doing. Women reported higher intakes of fruits and vegetables, except for potatoes, and higher intakes of high-fiber cereal. They did not order super-sized portions as often as men did and ate their dinner from foods prepared at home more frequently than men did. Compared to men, they had lower intakes of sweetened beverages, and unfortunately, lower intakes of milk.

In terms of body dissatisfaction, a component that frequently is not considered, more women than men had low body satisfaction scores. Women basically do not like the way they look. They do not look like the supermodels. In men, body dissatisfaction was associated with a lower frequency of physical activity. Both genders were likely to be self-conscious about activity if they felt dissatisfied with their bodies.

The children designed their own water bottles and put messages on them such as "It's fun and cool to live an active life"; "Win by eating healthy'; and Every BODY is different" illustrated by two different sizes of fish. Dr. Moore cautioned that water bottles for use in schools must be clear in most jurisdictions.

Student assessments showed that the children were heavy and not fit, which is not really surprising given the national data. The mean BMI was between the 75th and 85th percentiles. Boys averaged 10.3 minutes to run 1 mile (< 50th percentile), and girls averaged 11.5 minutes (< 50th percentile). One community, American Falls, Idaho, as mentioned before was approximately 50 percent Latino. The Latino children were a lot heavier than the other children and this did skew the data.

Only 17 percent of the children reported eating two or more vegetables each day and only 22 percent reported eating two or more fruits daily. They did drink milk, and 61 percent drank 2% milk. Some of the communities were in dairy production areas. Seventy-eight percent (78%) reported doing something else while eating. Fourteen percent (14%) had PE every day, while 44 percent reported they

watched TV or played video games for 3 or more hours each day outside of school. Dr. Moore evoked laughter with a cartoon showing a young boy in front of a TV, remote in hand, while his father says, "When I was your age, I had to walk to the TV."

Fifty-three percent (53%) of adults reported feeling guilty about eating, and 71 percent said they did not get as much activity as they needed. Of the adults, 74 percent reported watching 2 or more hours of TV each day, and 62 percent watched it while they ate dinner. Dr. Moore noted that with a lot of the adults who lived alone, this was their social outlet. TV was company.

Qualitative findings listed by Dr. Moore are just being reviewed. Many people were frustrated that they might look healthy but they did not feel healthy or they felt healthy but did not look healthy. Weight was seen as a shield, not just in terms of the sexual assault things that the literature has referred to, but also in terms of social acceptance. Thin women were perceived as threatening to a lot of their female peers. There had been changes in self-image over time. Older men were more comfortable with belly-over-the-belt than they were when they were younger. There was extreme peer power, both positive and negative, regarding protection and pressures to be different. A lot of people were food pushers, those who say "your child is too thin," or "grandma cooked it, you should eat it." In the values scale, Dr. Moore noted that one of the really interesting things was that physical activity needed to have a purpose for many, many people. Another important value was the "clean your plate" idea, "people are starving in China."

Because of the community participation concept, it was left up to the communities to decide who their champions were. Dr. Moore said that in the intervention towns, community walking programs worked incredibly well. The Cooper Clinic taught the community walking programs, and the group leaders went to lovely Jackson, Wyoming, for this training. Although the meetings were very busy, fitness breaks were built in so the participants could go out and look at the mountains. Each community developed its own program. Some were hospital-based programs, some were school-based programs, and one was a Bureau of Land Management (BLM) program. All communities began walking programs, and all communities had people from all ages walking. Dr. Moore pointed out that these are small towns and so the community impact can be easier in such places.

Dr. Moore referred the participants to the WIN the Rockies website to download the free-of-charge WIN Kids lessons (http://www.uwyo.edu/wintherockies). She added that an advantage of Government funding is being able to offer intervention items for free. Items that are difficult to download may be purchased from the University of Wyoming. A student advisory group in Laramie, Wyoming, helped put the lessons together and pre-tested them in fifth grade classes before dissemination. Graduate students tested their effectiveness following the intervention.

The study group learned that students are receiving the message that milk is important, but they are still decreasing milk consumption, so cognition does not translate into behavior. They also know that sweetened beverages contain sugar, but they still like them. They do not know much about the 5-a-day message and are not familiar with appropriate portion sizes. They tend to think what is served is a serving, which to them is logical. Dr. Moore presented a couple of Peanuts cartoons to illustrate student perceptions.

Strategies. Community portraits were developed at the beginning and end of the project. Dr. Moore presented an example from Preston, Idaho, whose single grocery store provided 197 linear feet for soft drinks, 107 for water, and 38.5 for all types of milk. There were nine fast food restaurants and seven other places to eat. Two of the four clothing stores offered options above size extra large but did not offer anything in sizes 2 or 4. Lunch break in the grade schools lasted 45 minutes, and so the study group encouraged the recess-before-lunch concept.

Strategies for these rural communities included community advisory boards, which were considered imperative. The boards started up early in the project, met often, and actively guided activities in each of the communities. Another critical strategy was partnering with local newspapers and radio. There were national media outlets coming in, in terms of TV. Originally, it had been planned to spend some scheduled funds on television but this turned out to be pointless because there were no unique markets in these communities. In addition to the local media, billboards were used instead. Dr. Moore stated that these billboards replaced beer commercials in two of the three towns, which was interesting. The study group found that there was a need to fill health promotion gaps, so after school programs, health fairs, summer fairs, and other local traditions like 4H fairs, county fairs, and so forth were used. The small business community was very enthusiastic about getting involved with the program.

Community partners were diverse. Parks and Recreation was an obvious natural. The Bureau of Land Management was another important partner. Hospitals, banks, certainly the Cooperative Extension Service, and, of course, schools were also valuable partners.

Lessons Learned. Dr. Moore stated that the walking programs were the easiest component to implement. They were fun and did not intimidate or challenge anybody. One challenge was finding safe and convenient places to walk. For example, in Lewistown, Montana, a major U.S. highway goes through the center of the town. There were no crosswalks or crosswalk guards and no traffic light. Children were not walking to school. The community, working with the study group, managed to correct this environmental problem. Indoor space is also a challenge in these rural areas. Many do not have recreation centers. The groups have been working on getting school gyms opened up and acquiring access to military facilities and armories, which has been more difficult since 9/11.

Dr. Moore said the fruit and vegetable coupons worked beautifully in the nutrition component. The local grocery stores and the participants were enthusiastic about these, and it was a way to increase eating these healthier foods. Dr. Moore added that they will be watching to see if this increase is sustainable. The healthy beverage campaigns were also effective, particularly the 1% milk campaign. Portion awareness campaigns are ongoing. These are a little harder to convey to people, particularly low-income audiences. A program called Cook Once, Eat All Week was very popular and was helpful in teaching portion size and in providing food preparation and purchasing advice.

Eat Smart, Move More North Carolina

Diane R. Beth, MS, RD, LDN, *Nutrition Coordinator and Coordinator, North Carolina 5-A-Day Program, Physical Activity and Nutrition Branch, Chronic Disease and Injury Section, Division of Public Health, North Carolina Department of Health and Human Services, Raleigh, NC*

Ms. Beth explained that she would be presenting quasi-experimental best practices from the North Carolina Eat Smart, Move More obesity prevention program initially funded by a CDC grant in 2000. The initial CDC grant of approximately $400,000 per year has now become approximately $800,000 a year for basic implementation funding. Ms. Beth stressed that State and local organizations believe they cannot wait until the best research studies are designed, implemented, and disseminated before they tackle the issue of obesity. They attempt to find the best available research and move ahead with this. Carmen Hooker Odom, Secretary of the North Carolina Department of Health and Human Services (NCDHHS), summed up the State's philosophy and mission in addressing obesity as follows:

> Obesity is preventable, but it requires an approach that begins with our children and is consistent throughout our society…we must involve individuals and families, businesses and industry, government and NGOs, [non-government organizations] and policy makers at all levels.

Of the $400,000 received for the initial program, approximately 40 percent ($180,000) went directly to local community grants. Approximately $60,000 went to the University of North Carolina, which is partnering with NCDHHS, to help with evaluating the program and to conduct the Nutrition and Physical Activity Self Assessment for Child Care (NAP SACC) project, and the remaining $160,000 covered all other costs. Ms. Beth added that other partners contribute resources.

The model for the NC program is based on the Dietz IV (coined by Dr. William Dietz in the Division of Nutrition and Physical Activity at the Centers for Disease Control and Prevention). The Dietz IV are considered to be (based on the research literature) the four major contributing factors to prevent/control obesity including: breastfeeding, reducing TV time, increasing physical activity, and healthy eating/5 fruits and vegetables a day. The model is used to reach adolescents, infants, and children via their communities, organizations, and families through activities that promote increased opportunities for healthy eating such as the 5-a-Day program, reduction of TV viewing, physical activity, and breastfeeding. (See http://www.EatSmartMoveMoreNC.com).

Guiding Documents. Ms. Beth stated that three documents form the basis of the program. Two are blueprints: the *North Carolina Blueprint for Changing Policies and Environment in Support of Healthy Eating and the North Carolina Blueprint for Changing Policies and Environment in Support of Physical Activity*. The blueprint documents provide a variety of suggested outcomes and strategies and steps communities can take to work on policy and environmental change. The third document is *Moving Our Children Toward a Healthy Weight*, which specifically targets children. In keeping with NCDHHS' philosophy that it takes many partners working together to ensure a coordinated and integrated infrastructure, a 100-member task force helped develop the recommendations for the Healthy Weight Plan. There is a continuous effort to focus on policy and environmental change and provide consistent communication

strategies across programs. The three documents were launched on September 25, 2002, in a Statewide event attended by more than 400 people.

Healthy Weight Plan for Children. The Healthy Weight Plan for Children has 12 key recommendations—5 at the individual/interpersonal level, 6 at the policy and environmental level, and 1 for surveillance and research. The recommendations take place in six settings that are consistent with the settings set forth in the blueprints for physical activity and healthy eating. These settings are families, schools/childcare, communities, healthcare, media/communications, and surveillance and research.

In listing the following key recommendations for policy and environmental change, Ms. Beth noted that considerable progress already has been made on the first three:

- Setting State standards for all foods available in schools, in after-school programs, and in child care.
- Establishing State policies to ensure adequate time for physical activity in schools and in after-school programs.
- Providing more community-based opportunities for leisure time and recreational physical activity.
- Creating an environment that make healthy eating and active lifestyles the norm.
- Obtaining third-party coverage for overweight prevention and treatment services.
- Providing equitable access to prevention and treatment.

Key recommendations for tailoring programs for individual and personal change were developed by the task force based on research and include the following:

- 60 minutes of physical activity daily.
- Consumption of fewer sweetened beverages.
- No more than 1-2 hours of TV/video time a day.
- Serving smaller portion sizes.
- Preparing and eating more meals at home.

Recommendations for surveillance and research include monitoring BMI, chronic diseases related to weight, and nutrition and physical activity behaviors. Ms. Beth said that North Carolina, like other States, is working to find the best surveillance mechanisms.

The initial CDC obesity grant was primarily targeted at children and had a few policy interventions, with settings both in the Women, Infants, and Children (WIC) program and the Child and Adult Care Feeding Program (CACFP). Formative research has been completed. Ms. Beth said that there has been some success in WIC, although there is still not a policy change to support alternative food packages such as making 1% or less milk the norm on food vouchers. Education was expanded in the WIC program to include physical activity. In CACFP, the goal of rules changes to support healthful foods has been temporarily set aside, but efforts were completed to expand education to include physical activity. The **N**utrition **A**nd **P**hysical **A**ctivity **S**elf **A**ssessment for **C**hild **C**are (NAP SACC) project also is moving forward in the childcare setting.

NAP SACC Project. The lead partner for NAP SACC is the University of North Carolina (UNC) School of Public Health, with Dr. Alice Ammerman serving as the lead Principal Investigator. The project's goal is to improve nutrition and physical activity policies and practices through a self-assessment and targeted technical assistance provided to childcare and preschool centers. This includes improving the quality of the food served, the amount and the quality of

physical activity, the staff-child interactions, and the center's nutrition and physical activity policies. Ms. Beth said that again a development team was put into place for this effort and included staff from the Division of Public Health, UNC, and North Carolina Prevention Partners, which is a 501C3 organization. The primary funding has come from the CDC obesity grant provided to the NC Division of Public Health. Ms. Beth suggested that Sara Benjamin, MPH, be contacted to learn more about NAP SACC (919-966-3927 or ssbenja@email.unc.edu) or Dr. Alice Ammerman (919-966-6082 or alice_ammerman@unc.edu).

Ms. Beth briefly reviewed the NAP SACC development and assessment processes. Key informant interviews with child care staff and focus groups with parents were conducted. Literature, regulations, and best practice guidelines were reviewed and experts were consulted. An advisory committee was created. The assessment tool was drafted based on national recommendations, standards, and best practices, sent out for review, and revised to ensure it was a valid tool. Finally, a NAP SACC Tool Kit was developed based on the assessment tool. It included nine nutrition and six physical activity areas of assessment.

NAP SACC was piloted in eight counties in North Carolina from May through December 2003. There were six intervention and two control counties, with two to five centers chosen per county. The centers worked with an assigned childcare health consultant. According to the baseline data, there was not a significant difference between the intervention and control counties. The pilot results did show that 13 of the 14 intervention centers significantly improved their overall NAP SACC score for nutrition and physical activity (average increase of 13 points out of a possible 132). The control centers also increased their scores but not significantly.

Ms. Beth explained that NAP SACC is currently going through an in-depth evaluation. UNC is conducting a follow-up assessment with the childcare centers and childcare health consultants, doing phone interviews with all the childcare center directors and focus groups with the consultants. Site visits are also being made at six of the intervention centers to observe and document changes. The research has shown that, along with cost, the most important issue for whether the center made changes was how easy or how difficult it was to make that change.

Next steps for the NAP SACC project include an expert review of the NAP-SACC instrument, follow-up with the advisory group, revision of the tool kit materials and the assessment instrument, development of a statewide dissemination plan, and evaluation of the feasibility of web-based dissemination of the project. Dr. Dianne Ward, from UNC, will be the Principal Investigator for the next phase of the project, which will undergo a larger, 2- to 3-year evaluation. UNC is hoping to get some additional funding from other sources to pay for this, because the $60,000 from the NCDHHS will not be adequate. Ms. Beth stated that eventually, there will be national dissemination of NAP-SAAC, with materials available in Spanish, and then development of a Baby NAP.

Healthy Weight Initiative. Moving on to discussion of the Healthy Weight initiative, Ms. Beth explained that a major goal was to develop State standards for all foods available at school (Eat Smart: North Carolina's Recommended Standards For All Foods Available In Schools). These standards were issued in May 2004. A number of partners participated in development of the standards, including the Department of Public Instruction, the NC Division of Public Health and the North Carolina Cooperative Extension Service. The standards are intended to promote policy and environmental changes at the State and local levels to

increase opportunities for healthy eating at school and reduce the risk of costly chronic health conditions associated with poor diets and obesity. The standards are voluntary with different recommendations for elementary, middle, and high schools. Standards are reflected in different areas, such as vending, after-school and school events, school meals, and ala carte. NCDHHS has applied for a $200,000 USDA TEAM Nutrition Grant, which will help provide training tools over a 2-year period to assist schools implement the standards. Ms. Beth stressed that one of the reasons that NCDHHS has been able to successfully work with young children and schools to implement changes related to physical activity and healthy eating is that the State has had an amazing infra-structure in place for so many years.

Winner's Circle Healthy Dining Program. One of the programs that has been in place for about 4 years and supports the standards is the Winner's Circle Healthy Dining Program, a statewide and now a national healthy dining initiative. It was developed by North Carolina's Prevention Partners, including local partners, with CDC money from NCDHHS, through the Heart Disease and Stroke Prevention Branch. (See http://www.ncwinnerscircle.com and http://www.winnerscircle.org.) Ms. Beth said Winner's Circle empowers local partners to offer various dining venues technical assistance to identify and promote healthy menu items. This aim leads to a second aim, which is to create consistent, credible, and easily recognizable nutritional guidance for consumers in participating dining out venues through menus, menu inserts, brochures, table tents, and so forth. Ultimately, through these efforts along with marketing tools and local promotions, the program aims to see an increase in consumer demand for healthy items when eating away from home.

The Winner's Circle program is supported by a large group of partners. The North Carolina Winner's Circle Healthy Dining Program is coordinated through the NC Division of Public Health, Physical Activity and Nutrition Branch with funding support from the CDC. All statewide and local Winner's Circle activities are coordinated through the NCWC Program, which includes providing training and technical assistance to the local Winner's Circle communities who really do the work. NC Prevention Partners manages the national program, Following their training, Winner's Circle leaders either build a team or are networked with a variety of coalitions in North Carolina and build their program by working with restaurant (or other dining venue) owners or vending machine companies, whatever fits the need in their specific community. They market the program, promote it, and also participate in evaluating the effectiveness of the program.

Counties have both community- and school-based Winner's Circle teams. The school portion of Winner's Circle was added in the last 2 years and has been highly effective, partly because schools can promote healthy items in their meals. Ms. Beth noted that the Winner's Circle is really supportive of the recently issued Eat Smart: North Carolina's Recommended Standards for All Foods Available In Schools. She listed several Winner's Circle successes, including increased signage, labeling, and marketing of healthy foods and beverages in food venues throughout North Carolina. More healthy food and beverage choices are being made available on menus. The nutrition guidelines themselves have been a success. There is increased awareness of the Winner's Circle logo. The program also has been adopted and expanded into many venues.

Active Community Environments (ACEs) Program. Another program under the Eat Smart Move More initiative is the Active Community Environments Program. This program includes training, an ACEs guide (*Winning With ACEs*) that is available on the website, and a community assessment tool. The guide is a practical "how to" for public health practitioners and partners to make environmental changes that will facilitate physical activity such as a walking and bicycling suitability assessment. There is a walk-to-school module that approximately 10 counties have implemented. Ms. Beth noted again that this program also depends on a variety of partners such as the Department of Transportation, Active Living by Design, the Department of Public Instruction, the UNC School of Public Health, and the North Carolina Smart Growth Alliance.

North Carolina Statewide Health Promotion Program. Ms. Beth explained that in 1999, North Carolina, because of the work in its cardiovascular health program, made the conscious decision to focus on policy and environmental change. The State has a funding structure called the North Carolina Statewide Health Promotion Program that administers $3.7 million dollars of CDC Preventive Health Block Grant money, and State dollars that go to all 100 health departments in North Carolina. On the average, the local departments receive between $20,000 and $30,000 annually. The State expects to collect some excellent data from the local, community-driven programs. The health departments are required to engage community partners and to mobilize and promote positive environmental changes for nutrition, physical activity, and also tobacco use. They must address health disparities. They also complete an annual Community Action Plan with objectives and a budget and participate in the Progress Check evaluation reporting system. Ms. Beth said the community action plans indicate they many of the counties are implementing programs in schools, ACEs, the Winner's Circle program, walking to school, and the School Health Index.

NC Progress Check Evaluation System. Progress Check is an Access-based system derived from a national model and developed by the North Carolina Heart Disease and Stroke Prevention Program. The system, which has been in use for a couple of years, captures policy and environmental change outcomes and the processes required to achieve the changes. Ms. Beth presented examples of several programs. A worksite in Alamance County in Burlington, North Carolina, increased physical activity by establishing an on-site walking track and exercise room. They also made low-fat snack foods available and fresh fruits and vegetables from local farmers and started a community worksite garden. The company became a smoke-free workplace, offering smoking cessation programs for the nearly two-thirds of their employees who smoked. Other examples included climbing walls installed in elementary schools, new policies to increase physical activity during the school day, changing foods in vending machines, replacing soft drinks with water and milk, implementing the Winner's Circle program, replacing fryers with ovens in school kitchens, implementing Color Me Healthy (a curriculum developed to help preschoolers eat smart and move more) in daycare centers, a physical activity prescription pad for physicians, media campaigns, and a local ordinance to require sidewalks in new developments and to retrofit existing neighborhoods. Ms. Beth stated that programs and resources are available to health professionals and consumers on the Eat Smart Move More website (www.EatSmartMoveMoreNC.com).

Lessons Learned. Ms. Beth stressed that there is an evaluation program in place to monitor and assess the programs to improve healthy eating and physical activity in overweight children and adults; however, it is still too early to determine which of the many programs being implemented at the State and local levels are the most effective or make the most difference. Programs are being evaluated to not only identify and implement best practices but also to determine the most effective use of program funds and to document the process and resources needed to bring about environmental and policy changes. Ms. Beth added that North Carolina would welcome the opportunity to collaborate with other States, local communities, and researchers to help answer the "what is working best" question.

Group Discussion With Panel of Speakers From Second Part of Session 3

Facilitator: Diane R. Beth, MD, RD, LCN, *NC Department of Health and Human Services*

Dr. Resnicow mentioned that he had recently moved to a school that has a strong philosophy of community-based participatory research. He said that he thinks CBPR can be done in State schools where researchers are provided with a lot of hard money, but that it is difficult to do in soft money environments. The other criticism he has heard is, "If we had waited for Africa to tell us that they wanted help for HIV, a couple million people would have died." On the other hand, strict adherents to participatory research will not suggest an intervention unless the community asks for it. Given these two viewpoints, Dr. Resnicow asked Dr. Ammerman how to approach the fact that sometimes it is necessary to market to change perceptions about risk and to place ideas on a community's agenda. For example, to counteract the fact that people greatly overestimate the risk of abduction of their children and this fear can be a minor barrier to encouraging children's outdoor physical activity. Perhaps it is ethical and appropriate to do social marketing or other strategies to correct that risk perception. In other words, when is it correct to be proactive and change people's perceptions and thus the community's priorities?

Dr. Ammerman agreed there are definitely extremes in both positions. There are many elements of the CBPR model, and funding groups rarely just wait for the community to tell them what they want. This is not an all-or-nothing concept, but partnering early with the community and empowering them to take the lead in resolving a health problem can enhance research outcomes.

Dr. Bernard Gutin, Medical College of Georgia, remarked that there are very powerful and effective adversaries in the advertising and food companies, the fast food industry, the environment, and so forth. He suggested that intensity of efforts to prevent childhood obesity have to be increased and particularly the intensity of physical activity needs to be higher than typically recommended. SPARK showed some years ago that physical education specialists were more successful than trained classroom teachers in accomplishing this. Dr. Gutin also pointed out that dieticians understand the importance of physical activity in the energy balance but do not build it into interventions at a high intensity level, probably because this is not their area of specialty. He added that since children only eat 25 to 33 percent of their calories at school, the potential impact of the school-based intervention on eating is relatively small. On the other hand, they may get a very large percentage of their vigorous physical activity in school, so that

may be a target that should receive more attention in future research.

Dr. Moore agreed. In Lewistown, Montana, kinesiology graduate students implemented some programs in combination with some medical students. The kinesiology students stressed the need for greater intensity and were more skilled at implementing such activities. Physical activity specialists are needed as partners.

Dr. Gutin continued by saying that in interventions there initially is a very high intensity of supervision, particularly for efficacy trials. In the Fit Kid program, where it is now regular teachers in the school who are providing the intervention, when the study group pays one of its regular visits, the teachers increase the intensity of their intervention, which suggests that more supervision is needed beyond the efficacy trial. The project does try to have a PE teacher be at least one of the teachers implementing the intervention in the school, because a specialist is more committed to a particular specialty.

Dr. Mary Ann Pentz, University of Southern California, commented that the community organizational model she presented the previous day was published in JAMA in 1989, and was participatory action research. She noted that agreement needs to be achieved between internal and external planners, the community people. Currently, those in the drug abuse prevention field are facing a dilemma related to the feedback from research data that is prepared and sent back to the community. A full-time person spends several months preparing reports to interpret the data and relate it to the questions of interest to the community. The reports are delivered to site facilitators with clear instructions about how to share it with their community coalitions, and approximately 60 percent of the time, the report sits on somebody's desk. The budget for the current feasibility STEP trial does not provide the funds to fly a researcher to 24 cities each year to personally provide them with feedback. Dr. Pentz asked how to get communities to use the data that is translated for them.

Dr. Ammerman recommended that it be pointed out to the community facilitators that this is a problem and they are not upholding their end of the bargain if they do not use the report data to reach those who need to take action. Dr. Pentz responded that this was exactly what they would be doing when they trained their next group of facilitators. It was just a shock when this happened to them and they learned it was a common experience in the field.

Dr. Ammerman suggested there also might be a better way of disseminating the data such as a totally different mechanism or media for providing the information. This is a challenge.

BREAKOUT GROUPS

Moderator: Ken Resnicow, PhD, *Professor, Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, MI*

Dr. Resnicow suggested the participants organize into four groups of approximately 10 persons and spend 45 minutes on the following questions, selecting at least three of those they felt were most important:

1. **Research Priorities:** List five (or more) pediatric obesity research priorities for site-based research.
2. **Levels and Types of Research:** In considering various levels and types of research (i.e., pilot studies/basic research, efficacy, effectiveness, dissemination), which level of research is needed for various sites and/or intervention approaches for pediatric obesity?
3. **Advantages and Disadvantages of Site Perspective:** What are the advantages and disadvantages of approaching pediatric obesity from a site perspective?
4. **Outcomes:** What are the appropriate outcomes for various sites and/or types of pediatric obesity interventions?
5. **Trans-Site Studies:** Propose a few trans-site pediatric obesity prevention research studies.

Group 1

Chair, June Stevens, MS, PhD, *University of North Carolina at Chapel Hill, NC*

Research Priorities. The group listed:

- Better measures of assessment, particularly dietary behavior.
- Better ways to reach and communicate with families.
- Assessment of potential economic effects of obesity prevention.
- Effects and uses of the media, both its effect on the obesity epidemic and how it can be used to influence healthy behavior.
- Determining what the diet message should be. Is it low-fat? low-carb? low sugar drinks? don't drink fruit juice?

Levels and Types of Research. The group's answer was new and innovative ideas need to be tested at all levels. It is important to think "outside the box" and do some high-risk research. Pilot studies are needed, but it is not possible to wait to disseminate some interventions until all the problems are solved and there are clear, definitive studies available. There is knowledge now on how to change school lunch programs and PE classes, so these are ready to move forward to effectiveness and dissemination research. It was strongly stated that more needs to be learned about how to do effectiveness and dissemination research and how dissemination works. For example, it may be possible to disseminate an intervention given a particular set of circumstances, but it also needs to be applicable to other circumstances such as many different levels, different places, different cultures, and different financial resources.

Advantages and Disadvantages of Site Perspective. One of the advantages of selecting a particular site is that it reaches a large target group. For example, children gather at schools. Parents are at worksites. Both adults and children are at churches. For a problem like obesity that is incredibly highly prevalent and for which the risk is ubiquitous, a particular site

is a natural gathering place for people and thus potentially can lower costs and facilitate dissemination. A disadvantage of focusing an intervention on a particular site is that it may be difficult to reach those who are not naturally at the site, such as the challenge of reaching parents for a school-based intervention, children through their parents' worksite, or non-church-goers at a church site. Because of these disadvantages, the group encouraged the use of trans-site research.

Outcomes. Self-reports of behaviors, social norms, and so forth are very useful for assessing knowledge and indicating what is currently happening. Dr. Stevens' perspective is that when a self-report is used to measure a behavior, then the result should state this is "self-reported behavior." In other words, do not report that physical activity behavior was changed when what changed was self-reported physical activity, because it is known that bias is induced by interventions. Although self-report information is useful and helpful, not being clear when a measure is self-reported and when it is objectively measured is a disservice to the field.

The group felt that objective measures are preferred. Objective measures of behavior or environmental changes, such as observing physical activity behaviors and measuring environmental changes (e.g., what kind of milk is being served), are good focuses. For physiological measures, fortunately, body weight is easy to measure. The group agreed that the outcome should fit the intervention. For example, effects on plasma cholesterol and blood pressure would not be likely for a low potency intervention and so these measures would not be needed.

Trans-Site Studies. Innovative, trans-site studies were strongly recommended.

Group 2

Chair, Thomas Robinson, MD, MPH, *Stanford University, CA*

Research Priorities. The group listed the following future research directions, but not by priority:

- Increase the duration of the interventions themselves, include a longer-term follow-up, and increase the intensity of the interventions.
- Conduct studies examining school and community linkages and school and family linkages.
- Conduct studies of community participation and participatory research to learn ways of identifying the community being targeted and different ways to effectively achieve community "buy in" and participation.
- In environmental research, develop pilot and natural experiments that include nutrition as well as physical activity in everything from the individual home environments to the larger, more structured environment in order to change specific behaviors or specific environmental factors.
- Develop studies about motivators of diet and activity behaviors that are applicable regardless of the site to learn how to influence family and community agendas about improving health and preventing/decreasing obesity and to develop messages that are consistent with those agendas.

Levels and Types of Research. The group focused on pilot studies and on efficacy studies that are needed to develop an arsenal of interventions that can inform policy and practice. It was considered important to link intermediate measures of physical activity and

diet to body composition. One of the current barriers to being satisfied with having measures of these activities as the outcome is that it has not been shown that they necessarily mediate changes in body composition. This connects back to the previous point about the need for longer-term interventions and greater intensity.

Advantages and Disadvantages of Site Perspective. This question was not addressed specifically, but one of the concepts that arose during the discussion was that of the community as a learning laboratory with multiple sites where multiple events could take place.

Outcomes. One theme was that the outcome needs to match the timeframe and goals for the intervention. For example, in some types of studies, it might be unrealistic to think about body composition changes because of the timeframe or specific intensity of the intervention, whereas for other studies, body composition change would be the appropriate outcome. There really cannot be a single outcome.

Group 3

Chair, Sylvia Moore, PhD, RD, *University of Wyoming, Laramie, WY*

Advantages and Disadvantages of Site Perspective. The group felt that an advantage of site-based research is that, especially for efficacy research, it makes control easier, impacts can be measured more easily, and it probably makes it easier to understand small approaches to the larger problem of obesity. Approaches can be more easily targeted and theory-based for a particular site. In addition, such studies tend to be less costly and easier to manage logistically. They enable a more intense effort and increase the researcher's self-efficacy in addition to the population's self-efficacy. The disadvantage of using the site-based approach is that it might restrict innovation, miss generalizability, and violate the ecological view or nature of the problem.

Outcomes. To be appropriate, outcomes should be linked to the population served, although unfortunately all the modifiable determinants are not known. There were concerns about not having appropriate assessment tools and about which perspective would determine the appropriate assessment tool, the research perspective or the community's perspective. The group was reminded that formative research should always come with community participation before efficacy research, and that the application research may actually be able to assist development of standards in terms of types of outcomes, particularly if, in the intense efficacy studies, there is some objective validation of self-report tools and other techniques that are simpler to use for studies in a large population.

The heart rate monitor was seen as a very useful and usable tool as a measure of physical activity. Accelerometers were considered less useful, particularly for very overweight children, because they do not measure the intensity of the physical activity. Diet measures are the most difficult at this point in time. There was a strong plea for some real-time measures, including such ideas as use of a camera and direct observation. These can be useful at a site, but do not include what happens off-site or at other times when there is no direct observation. The overall consensus was that the ultimate goal of the intervention is improved health, and thus the health needs of the targeted group should be primary. It was suggested that in targeting a whole population, there should be more intense outcomes for high-risk sub-segments of the population such as improving insulin sensitivity.

Group 4

Chair, Matthew Gillman, MD, SM, *Harvard Medical School, Boston, MA*

Research Priorities and Levels and Types of Research. Considerable time was spent on the need for more efficacy studies. Theory and practice suggest that interventions that are developmentally appropriate to the age of the person, culturally based, and have some individual tailoring also have the most potential for benefit. The group recommended that future studies should incorporate these concepts, whether the intervention is in a childcare setting, in a family, in a school, or wherever. They also considered it important to combine new techniques, such as web-based technique and other interactive techniques, with the theory-based interventions.

The group discussed one-size-fits-all interventions versus tailored interventions. They thought that giving people skills to change their behavior in an environment that does not allow such behavior change may not be as effective as trying to change the environment first and then giving the individual skills to change behavior. More epidemiological data are needed about the determinants of diet and physical activity and about which dietary components are related to excess weight gain in childhood.

Environmental studies were considered to be more in their infancy than other studies. Natural experiments and quasi-experimental designs are needed to study environmental change, including before-and-after studies and studies that can lend themselves to time series analyses and so forth.

The group also recommended that, in addition to doing "kitchen sink" interventions, there should be research in the formative stages to distinguish which interventions might be most valuable in larger scale interventions. Finally, they agreed that strategies must be age-appropriate, particularly in studies examining younger ages, since current experience is largely with elementary school children and teenagers.

Outcomes. Initially, the discussion took the position that the appropriate outcome depends on the site of the intervention, the target of the intervention, and the targeted population. Then the group agreed that an RFA for obesity must include an obesity outcome such as BMI and thus height and weight are basic measures for any obesity initiative. In some studies, especially studies of efficacy or studies that are smaller scale, body composition should be an outcome beyond BMI, whether that means waist circumference or other measures of body composition that are more invasive. Then for ultimate health outcomes, or at least intermediate health outcomes, measures such as glucose, insulin, and blood pressure are required. The final concept was to tailor the outcome to the study size, with smaller studies requiring more intense outcomes.

Trans-Site Studies. The group agreed these types of interventions are potentially of great interest. The consensus among the group was that, since little is known about these versus single-site interventions, it would be valuable to have an initiative that would allow for pilot studies with quick turnaround mechanisms to study the ability to do trans-site interventions.

BREAKOUT SUMMARY

In summary, Dr. Resnicow stated there is a need for research across the whole gamut, from basic research, to epidemiological research, through dissemination. It was suggested that for components that have shown efficacy, such as increasing moderate and vigorous activity in PE classes, changing food service offerings, and reducing TV time, it is possible to move forward to dissemination and/or combinations of interventions. On the other hand, some basic research questions remain and need to be addressed. There is an interest in trans-site interventions such as school plus home or school plus church, much like testing two behaviors or two theories. Age appropriateness, developmental appropriateness, and matching outcome to the intensity and duration of the intervention were also emphasized.

General Discussion

Facilitator: Thomas Robinson, MD, MPH, *Stanford University, CA*

Dr. James Sallis, San Diego State University, presented three issues based on points made by the breakout groups. First, research in the family or home holds promise as a site in preventing obesity. He recommended focusing on proven mediators as targets such as parent's monitoring reduction of TV watching, consumption of more fruits and vegetables in the home environment, and transporting children to places where they can be physically active. Second, Dr. Sallis would encourage more focus on after-school activity in specific community settings because these offer networks or systems such as Boys and Girls Clubs, YMCAs, youth sports programs, and community recreation centers that can promote physical activity, in particular, and have not been tapped very well. Dr. Sallis suggested asking such questions about these agencies as "What are they doing now to promote physical activity?" What could they do better? How can we help them do that better?" As public systems, these are sites that remain understudied and are sites where interventions could be institutionalized. Dr. Sallis added that the current youth sports system sometimes is effective at turning children off of physical activity, but the system could be changed. Third, another outcome for interventions might be advocacy for environmental and policy change. Dr. Sallis recommended that stimulating people at specific sites to become advocates holds promise. For example, this could be parents or youth activists in school. He noted that funding interventions with this outcome may not fit into the current NIH grant processes.

In response to a question from Dr. Robinson about what type of advocacy should be measured as an outcome, Dr. Sallis replied that this is a frontier about which little is known at present. The best way to learn what can be accomplished would be through experimenting. At a meeting of the Society of Behavioral Medicine, Dr. Mel Hovell presented an interesting study in which researchers visited local businesses and said, "If there were more sidewalks and street trees, people would want to come to your businesses more" and the business owners then advocated for those changes to their local government.

Dr. Tim Lohman, University of Arizona, strongly called for NIH to provide for long-term follow-up of studies in order to be able to measure the long-term effects of interventions. The short-term efficacy trials need to be improved; however, reliable results from studies might be found if they could be followed for 3, 5, or 10 years. If such follow-up was mandated, then it might be possible to say the interventions affect nutrition and physical activity over the long-term and

thus affect the energy balance, long-term, and therefore affect obesity. Dr. Lohman stressed that in addition to efficacy short-term, the long-term impact is needed.

Dr. Robinson pointed out that Dr. Ammerman also had mentioned that longer time is needed to see how a community responds to an intervention and if the intervention changes behaviors.

Dr. Matthew Gillman, Harvard Medical School, expressed the hope that some of the initiatives resulting from this meeting would focus on preschoolers. He suggested that clinical sites be included when proposing trans-site research studies in this age group because this is an age when children visit the doctor frequently. For example, an effort to remove TVs from these children's bedrooms might be more effective if the intervention were done both in a childcare setting and reinforced in a clinical setting.

Dr. Kuczmarski answered that there will be an RFA for a site-based initiative that could involve pediatric care providers. There will be a separate RFA specifically for the primary care setting (http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-04-020.html). He added that, in reference to pilot studies, there is a PAR 04-082 (a program announcement with referral) for small, clinical research grants that receive an NIDDK in-house review instead of being reviewed by a standing study section at the NIH Center for Scientific Review. These grants are basically R03s funded for up to $100,000 a year in direct costs over 2 years and are non-renewable. For translational research, there are R18s and R34s. R18s resemble R01s, and R34s are like R21s, except these are PARs and are reviewed in-house. These are PAR 02-153 (http://grants.nih.gov/grants/guide/pa-files/PA-02-153.html) and PAR 03-060 (http://grants.nih.gov/grants/guide/pa-files/PAR-03-060.html).

Dr. Beth, North Carolina Division of Public Health, recommended that NIH-funded trials be required to work with the CDC-funded States that are already doing many of these natural experiments and need partners to bring their helpful structure and expertise in evaluation and research to the table. An example is the partnership that North Carolina has with the University of North Carolina. She pointed out that unless a public health group already has an active partnership with a university, the group is unlikely to be aware of research announcements, which tend to be worded in language that relates to researchers not public health practitioners. Dr. Beth added that her staff has many ideas but could use assistance with working strategically with research partners.

Dr. Kuczmarski said that NIH could encourage such partnerships, but could not make it a requirement. He agreed that partnerships with State health departments, academia, WIC clinics, and so forth provide for a more effective trans-site approach. The university provides the research skills and the public health setting offers access to populations

Ms. Robin Hamre, National Center for Chronic Disease Prevention and Health Promotion, CDC, offered her agency's assistance in linking up with the 28 funded nutrition, physical activity, and obesity prevention States. Ms. Hamre can be reached at rhamre@cdc.gov and can provide contact names, phone numbers, and email addresses.

Dr. Stevens noted that a great deal of research can be accomplished under the current R01 funding limits. On the other hand, for prevention research in the public health arena a grant for $2.5 million in direct costs over 5 years is very often insufficient.

Dr. Denise Simons-Morton, NHLBI, explained that the $500,000 in annual direct costs is not an absolute cap, but the sponsoring institute has to agree to accept an application for a budget that exceeds this amount. Each institute has different internal procedures for doing that and it is an exception, but it is possible. There is also a process for approval of longer studies. Dr. Simons-Morton added an RFA is coming out on pediatric clinical sites. NHLBI has an advisory group on obesity that is evaluating the institute's portfolio and will recommend initiatives. For example, NHLBI is considering a community-oriented, primary care-focused RFA that would mandate a link between the clinical site and the community in testing an intervention. The RFA is for obesity at any age group.

With regard to linking primary care physicians with the community, Ms. Hamre explained that Drs. Bill Dietz and Ken Resnicow and others have been working with pediatric research in an office-based setting network that includes pediatricians and nurse practitioners who are willing and able to do research in their practices. Ms. Hamre again offered her assistance in providing contact information with this research network of healthcare providers.

Dr. Sallis, San Diego State University, noted that there is a fundamental hypothesis that changing individuals without changing their environment is difficult to impossible; whereas, when the environment is set up to make healthy choices easier, an individual intervention should be more effective. Dr. Sallis suggested this hypothesis leads to the researchable question of whether the interaction between changing the environment and changing the individual is much better, or whether doing an individual intervention in a favorable environment versus doing it in an unfavorable environment just gives you different results. He added this is one of the central questions in obesity prevention, and encouraged NIH staff to think about specifically funding studies on this question.

Dr. Larry Webber, Tulane University School of Public Health, stated that one of the issues in site-based research at pediatric ages related to the need for longer-term studies is that, in general, in a mobile population like that in the United States, children do not spend many years at any one site, whether it is schools, daycare centers, camps, or other sites. Dr. Webber recommended that the group think creatively about research designs that can overcome this problem when working with a population that will spend at most 6 years at a location and very often only 1, 2, or 3 years. The tendency to create cohorts to follow makes it very difficult to determine how much intervention they are receiving and also to locate these individuals for follow up. Dr. Webber said that it will be necessary to be innovative in thinking of the site as the unit of assignment randomization and in deciding how to be more effective in using it as the unit of analysis.

In closing, Dr. Robinson remarked that many good ideas have come up in the discussions. He encouraged potential applicants to develop their ideas into proposals and submit them to NIH.

Dr. Kuczmarski agreed and stressed that researchers should send in their ideas, not just rely on PAs or RFAs. He pointed out that it is important to remember that approximately 85 percent of the extramural funds from NIH are investigator-initiated grant applications. Another 10 percent are in response to program announcements, and only about 5 percent of all extramural grants come as a result of RFAs.

Dr. Kuczmarski again thanked the organizers, session moderators, and discussion facilitators and all those present for their active participation in the meeting. He emphasized that their comments would help guide future research directions.

The meeting adjourned at 12:25 pm.

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