2nd



Investigators Workshop
on Innovative Approaches
to Prevention of Obesity







Workshop Report

August 12-13, 2002







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Preface

The 2nd Investigators Workshop on Innovative Approaches to the Prevention of Obesity was held on August 12-13, 2002, in Arlington, Virginia. The following workshop report captures the most salient issues that emerged from the presentations and discussions at this workshop, and highlights selected common themes expressed by investigators engaged in pilot studies on obesity prevention research.

The challenges of conducting prevention research, and human clinical trials in general, can be quite diverse. Life-events, policy changes, and other extraneous factors beyond the control of the investigator can impact on fundamental aspects of research such as recruitment, retention, and adherence. These concepts became evident in the workshop deliberations and are among the topics that have been summarized in this workshop report.

This report can serve as yet another increment in our knowledge, gained through empirical research supported by the National Institutes of Health, to help move ahead the field of obesity prevention research, which is vital to the health and well being of hundreds of millions of people in the United States and worldwide.

The NIH Institutes, Centers, and Offices sponsoring the research projects that formed the basis of this workshop are grateful to the principal investigators for their continued involvement, for their candid presentations, and for sharing their experiences in this important and evolving area of biomedical/behavioral research.

A special thanks is due to Dr. Stephen Fortmann, Stanford University School of Medicine, for sharing with the workshop participants his insights on the emerging area of obesity prevention research, based on his career involving many years of experience in general prevention research. His presentation provided the basis of subsequent discussions in this workshop and is summarized in some detail in the workshop report that follows.

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Investigators Workshop on Innovative Approaches to Prevention of Obesity

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Introduction

Introduction

The trans-NIH initiative on Innovative Approaches to the Prevention of Obesity (RFA-DK-99-010) provided financial support for 20 scientific investigations beginning in 1999. On August 20, 2001, NIH sponsored a workshop that brought together the principal investigators who initiated pilot obesity prevention projects. This first workshop was designed to encourage the exchange of information on lessons learned, problems encountered, and successes achieved relative to recruitment and retention, intervention development, and adherence to interventions.

At the time of the first workshop, a second workshop was conceived that would focus on results achieved and recommendations for future directions. This second workshop was designed to facilitate information sharing among the investigators regarding intervention approaches, study achievements, successes and challenges encountered in various settings and populations sampled, and remaining challenges in obesity prevention, based on results and experiences obtained from the pilot studies funded under the RFA.

At this second workshop, information sharing was designed to be achieved through the combination of written tabular summaries prepared in advance by the principal investigators and included in a workshop booklet, brief oral presentations, and open discussions among the investigators.

Workshop Objectives

Workshop Objectives

The discussions and recommendations focused on the following workshop objectives and are summarized in relationship to these objectives in the workshop report that follows below:

- Identify how the RFA program advances the science of obesity prevention and treatment.
- Share and discuss experiences and preliminary results from the research projects, with an emphasis on which intervention approaches were most successful.
- Share and discuss lessons learned regarding recruitment, retention, measurement, intervention approaches, and intervention adherence.
- Increase understanding of how obesity prevention research may be a component of general prevention research.
- Identify recommendations for future efforts for obesity prevention research initiatives, including justification and opportunities for full-scale clinical trials.

Recommendations for Future Efforts

Recommendations for Future Efforts

From the discussions held on the two days of the workshop, Dr. Kumanyika presented the following list of recommendations as a wrap-up to the meeting:

- Establish an Obesity Prevention Research Network to facilitate collaboration.
- Find other funding sources for some of the obesity prevention research that is
 outside the scope of what NIH funds such as changing policies in worksites or
 community-based legislative changes. Some of this research agenda needs to
 precede NIH-type studies and might be funded by other agencies (USDA, CDC)
 or private organizations, as appropriate.
- Investigate intermediate outcome measures, especially in physical activity, which
 can be used in place of BMI, especially if the objective is to shift the curve of BMI
 on a population-wide basis.
- Recognize that those who do obesity prevention research are taking some academic risks—the studies take a longer time to do, there is a high possibility of failure, and there may be little to show for a 5-year effort. This research risk does not encourage out-of-the-box thinking, and some form of support is needed for these investigators.
- Offer small grants to conduct data analyses and mine the qualitative information and data of current pilot studies; provide contingency funds in future pilot study grants to cover unanticipated field research problems.
- Foster cross-cultural studies related to the environment and obesity to learn from other highly developed industrialized countries that have lower obesity prevalence than the United States does.

Recommendations for Future Efforts

- Go beyond segmenting the population by weight levels for obesity prevention. Look at who participates in the studies, who will never participate in the studies, and who will be most disadvantaged if a curve shifting intervention is not conducted. This view is a critical aspect of the health promotion versus the individual treatment models for low-income groups, who are likely to get worse if intervention remains within the medical model. The low-income group will tend to become victims of the environment because of the choices available to them versus choices available to those who can and will go for treatment or pick up on individual-oriented interventions.
- Provide investigators training through workshops to empower them to do more
 prevention research, such as food science, land planning or community dynamics.
 This training was done in genetics to respond to the genome revolution and update
 researchers with advances made since they graduated from school.
- Include more focus on the socio-cultural aspects of the environment, not just the physical aspects.
- Develop partnerships with the food industry, especially restaurants. As important as food is to people, more needs to be done to manipulate the choices available to them. The research has concentrated on people's choices, not on what they have to choose from, which is equally important, and is an uncharted area.
- Fund core facilities or mechanisms such as instrumentation grants as part of a multi-agency research agenda in order to provide logistical support to investigators as has been done in bench research.
- Think about secular trends occurring in communities to forecast future changes, such as pre-kindergarten in schools or provide a period between design and implementation of a community-oriented grant to allow for readjustment of the intervention based on changes that have happened in the community setting.

Recommendations for Future Efforts

In presenting the need for an Obesity Prevention Research Network, Dr. Kumanyika included the following elements and advantages of the network:

- Generates interest in obesity *prevention* research.
- Brings experienced and new investigators on board to collaborate with each other.
- Supplies an advisory group of experienced peers to deal with design contingencies and problems, thus saving time and dollars.
- Provides a central coordinating center for economies of scale in collecting, standardizing, and assessing data and in supporting study designs and strategies.
- Assists with the learning curve for study startup and the ability to do fast-track research since many startup factors would already be in place.
- Creates active comparison conditions for off-the-shelf use.
- Provides for data sharing and pooling; sharing of methodologies; and sharing of knowledge of cultural/ethnic adaptations.
- Facilitates collaborations to replicate and extend promising interventions.
- Fosters out-of-the box thinking, high-risk research, and true innovation.

General Conclusions on Obesity Prevention Research

General Conclusions on Obesity Prevention Research

Following the workshop, Dr. Fortmann provided a list of his observations and conclusions to help provide general direction for future obesity prevention research:

- Obesity prevention is a component of general prevention and shares many of its challenges and opportunities
- As a public health problem, the obesity pandemic is strongly related to the physical, social, and cultural environment, although individual obesity level is also strongly affected by genetic factors.
- Obesity prevention research is best conceptualized in the context of a comprehensive response to the obesity pandemic, which will require a wide range of components.
- There is clearly a need for well-designed, controlled intervention trials to explore better ways to prevent and treat obesity. These studies can be strengthened in several ways through:

Formative and pilot phases

Clear theoretical bases and designs that compare the effectiveness of different theoretical approaches

Consideration of the practical potential for dissemination of the intervention, if effective

Recruitment from real-world community settings, minimizing selection factors

Careful assessment of mediators and moderators in order to advance our theoretical understanding of behavior change while seeking effective interventions

Appropriate multi-level analytic approaches when the intervention is at levels above the individual

General Conclusions on Obesity Prevention Research

- Interventions can be designed to help individuals deal with the "toxic" environment since large-scale changes in that environment will take time, and will be stimulated by wider public appreciation of it.
- Approaches to stimulate improvements in food technology, and the role of the food industry in preventing obesity should be explored.
- Collaboration with experts in other fields, from urban design to genetics, is likely to be fruitful.
- •Interventions that are directed at more than one level (e.g., individual and school) are needed, although the design challenges are significant (or the resources needed to overcome the design issues are significant).
- Obesity prevention in both adults and children should probably not be labeled as obesity prevention, but as healthy eating and exercise.
- Physical activity and nutrition change are appropriate outcomes for obesity prevention. There is a need to continue developing reliable measures of both, including activity monitors and biomarkers of diet.
- More pilot studies are needed to stimulate innovation.

Workshop Report

The 2nd Investigators Workshop on Innovative Approaches to Prevention of Obesity confirmed that the prevention of obesity is a complex issue requiring further study if the Nation is to effectively stem this public health epidemic affecting nearly one-third of the U.S. population. In his welcoming remarks to the meeting, Dr. Robert Kuczmarski, Director, Obesity Prevention and Treatment Program, National Institute of Diabetes and Digestive and Kidney Diseases (NI-DDK), stressed that obesity is a widespread and intractable problem with a complex etiology and a dynamic landscape of contributing factors. There are no signs that its incidence or prevalence is abating. Dr. Eva Obarzanek, Research Nutritionist, National Heart, Lung, and Blood Institute (NHLBI), added that the lessons learned from the investigators will foster new initiatives and, possibly, collaborations among the groups to advance the science of obesity prevention. As part of his introductory remarks, Dr. Kuczmarski announced that NIH has issued a new RFA on environmental approaches to the prevention of obesity. At the time of this workshop, grant applications had been received and were being evaluated.

As the 3-year pilot studies under the trans-NIH RFA (RFA-DK-99-010) neared completion, the investigators presented their preliminary results and the recruitment, retention, and adherence challenges they had faced. Primary among these was the strong tendency for obese persons and the parents of obese children to not see their

weight as a health concern. The presenters also discussed their experience and problems with obtaining measurements suitable for research. Such measurements are critical to obtaining science-based evidence and to justify conducting clinical trials based on these interventions. Other obstacles many had faced were unanticipated events that occurred during implementation of their interventions that heavily impacted the design or intervention approach. Major challenges in helping people achieve energy balance included weight maintenance after weight loss and prevention of inappropriate weight gain at various ages and critical life stages—childhood, adolescence, pregnancy, and menopause. Other overarching themes were the consideration of an Obesity Prevention Research Network and other logistical support to enable researchers to do pilot studies within the timeframes and funding provided and the need for grant flexibility in order to "think out of the box" in addressing this type of research.

Based on their experience and their discussions at the workshop, the investigators provided recommendations to the sponsoring agencies—the National Institute of Diabetes and Digestive and Kidney Diseases; National Heart, Lung, and Blood Institute; National Institute on Aging; National Institute of Child Health and Human Development; Office of Research on Women's Health; and Office of Disease Prevention. The discussions and recommendations at this second workshop provided important insights into defining obesity prevention research.

In addition to the presentations of the investigators, Dr. Stephen Fortmann, Stanford University School of Medicine, was invited as a featured speaker to deliver a special presentation, describing the community health perspective in obesity prevention research. Dr. Fortmann was the principal investigator (PI) for the Stanford Five-City Project (1978-1998, 1980-1986). His presentation offered a bridge between general prevention research and obesity prevention research. Dr. Fortmann's discussion of the part played by the population model versus the medical model of prevention in intervening at different points on the risk factor level curve, and shifting of the curve, provided a focus for much of the discussion on the future directions for obesity prevention efforts.

Approaches used for the pilot studies included interventions for avoiding the development of obesity in children and adolescents and in controlling weight gain in women at critical life stages (pregnancy, peri- and post-menopause, post-smoking cessation). Interventions were conducted in community settings such as pre-schools and day care centers, public schools, churches, WIC and primary care centers, and homes. The Internet was also used as an intervention approach.

The workshop program book included summary information provided by the investigators including descriptive narratives of their study objectives, designs, quantitative and qualitative results,

lessons learned, and recommendations. Much qualitative information was obtained from debriefings, narratives, and general experiences while the studies were being conducted. At the meeting, participants received handouts of the presenters' slides. This report will not repeat this information; instead it is intended to summarize the discussions that resulted from the presentations and the recommendations made by the attendees. In addition to the investigators, those attending included members of the investigators' organizations and National Institutes of Health program scientists. A participant list was included in the program book, with an amendment to include additional registrants provided as a handout.

Advancement of the Science of Obesity Prevention and Treatment

Given that the science of obesity prevention is still relatively undefined, the general consensus was that this RFA on Innovative Approaches has made a significant contribution by advancing knowledge of the challenges involved in this form of research and possibly the importance of its distinction from obesity treatment research. Although some of the quantitative data that the investigators had intended to gather often fell short of their expectations due to recruitment and adherence problems, the qualitative information was still being analyzed at the time of the workshop and will provide important insights

to aid the design of future studies. The group strongly emphasized the value of the qualitative process data in furthering obesity prevention research and recommended additional funding of extensions to the studies be considered as one option to ensure that this information is not lost.

Identification of Most Successful Interventions

The fact that the majority of the interventions did not produce science-based evidence that would justify a larger clinical trial was not discouraging to the investigators. Each study produced valuable lessons learned and raised important issues. During her summary of the first day's activities, Dr. Shiriki Kumanyika, University of Pennsylvania School of Medicine and PI of the Black Women's Wellness Study, identified the following top five issues in obesity prevention research: (1) promoting healthy weight; (2) intervening for weight maintenance; (3) intervening for appropriate weight gain; (4) extending and/or enhancing treatment; and (5) using appropriate study designs for obesity prevention and treatment. In addition to reviewing the pilot studies in relation to these issues, Dr. Kumanyika selected the following studies as examples where there was sufficient preliminary data to suggest that the study investigators might be positioned to explore the potential of these pilot studies for development to full-scale trials:

- Brocodile the Crocodile, a 39-week study of 307 children ages 3 to 5 (and their parents) in 18 day-care/pre-schools to compare changes in the body mass index (BMI) z-scores for appropriate weight gain in the control and intervention groups following an intervention to increase physical activity, improve healthy eating, and reduce TV/video viewing. Results: significant decrease in TV/video viewing; increase in knowledge of healthy foods; no change in BMI z-score in intervention group and slight increase in control group, suggesting that the intervention was beneficial. Both quantitative outcomes and qualitative information need further analysis. Longer duration, more intensive studies are needed. (PI: Barbara Dennison, MD, Columbia University and Bassett Healthcare)
- HIP Teens, a family-based, limited contact, Internet-facilitated weight management (treatment) study of at-risk overweight (>85th percentile) adolescent (ages 11-15 years) African-American females (with at least one parent who is obese) in 58 families. This study provided initial face-to-face counseling for all participants and then compared a passive health education Internet intervention with a family-oriented behavioral Internet intervention that included frequent contact with feedback. Weight loss and weight maintenance among adolescents and parents were the primary outcomes. Preliminary results: low attrition; high consumer satisfaction; study not completed at time of

presentation, so final results were not available. This high-risk group needs to be targeted. The Internet can be a component of a multi-faceted community-based approach to prevent weight gain in this high-risk group. (PI: Donald Williamson, PhD, Pennington Biomedical Research Center)

• Primary Care Office Management of Obesity, an 18-month primary care physician-based study targeting difficult-to-treat, obese, lowincome, primarily African-American female patients (\sim 160, ages 18-65, mean 42 years) at high risk for obesity based on gender, socioeconomic status, and race to compare standard patient care vs. a comprehensive patient-centered approach (tailored to individual food preferences and caloric needs) to prevent weight gain (BMI 25-29), achieve weight loss (BMI ≥30), maintain weight following weight loss, and improve dietary behavior. Results: Weight loss: 80.8% in intervention vs. 47.7% in control; weight gain: 19.2% in intervention vs. 52.3% in control. Preliminary results suggest continued weight loss and significant differences between intervention and control groups with minimal intervention in primary care office. A clinical trial with more clinics could further test this treatment approach. (PI: Pamela Davis Martin, PhD, Pennington Biomedical Research Center)

• Mentor-Based Approach to Long-Term Weight Loss, a two-phase study in a university medical center targeting overweight women (ages 21-55, mean ~38-39 years; BMI 27-35, mean ~29-30) who achieve a weight loss goal during an initial 3-month treatment phase and then serve as mentors to a second group of women to examine if a mentor-based approach to modifying eating and exercise behaviors enhances longterm weight loss in the mentor-recipient and the mentor vs. a group that does not have mentors or does not serve as mentors. Results: 116 participants were enrolled although the results are not statistically significant, mentors and mentor-recipients did reduce their body weight more than non-mentor recipients at 6, 12, and 18 months of treatment. Mentors also increased their fitness times over non-mentors. The study is ongoing and final analyses will provide more definitive information. This form of social support is a promising new approach for weight loss treatment. (PI: John Jakicic, PhD, University of Pittsburgh)

Lessons Learned

Not only were the investigators challenged to design innovative approaches to obesity prevention, almost all were also challenged to be innovative in responding to events that affected their study in the areas of recruitment, retention, adherence, measurement, and intervention approach. The many lessons learned contributed to

the group's recommendations for modification of their approaches and further research. Dr. Kumanyika stressed that lessons learned helped identify feasible and relevant approaches for new research that needs to be done. Defining what is possible helps guide new initiatives.

Recruitment. The fact that many individuals do not recognize overweight as a health concern prior to being diagnosed with a weight-related illness (diabetes, high blood pressure, CVD) was a major handicap to recruitment, as well as retention and adherence. Parents and children/ adolescents were concerned with the social stigma related to overweight. A challenge in obesity prevention research is to recognize and be responsive to this sensitivity about being labeled "obese" while at the same time increasing the target audiences' knowledge and awareness of the seriousness of this condition so they will be motivated to make and maintain behavioral changes. The investigators stressed their use of "friendly" terms such as healthful lifestyle, healthful activity and their avoidance of the term "obese" especially in working with children/ adolescents and their caregivers.

In approximately half of the studies, changes were made to initial eligibility criteria to increase the sample size. Other investigators mentioned that they also would broaden their criteria in the future. Besides lack of understanding of overweight as a health concern, the target populations

tended to think of weight control and weight loss as being equivalent. They were primarily interested in committing time to weight loss, but not to weight maintenance. Another problem for both recruitment and adherence/retention was the number of conflicting demands on adults' lives. Lower than anticipated recruitment and retention results frequently meant too small a sample size to evaluate the efficacy of the intervention. One notable exception to the recruitment difficulties was Dr. Scott Going's success in receiving 800 responses to a single advertisement for the University of Arizona study.

The following techniques were employed or recommended to improve recruitment:

- Using appropriate language in the recruitment message to consider the target audiences' attitudes and beliefs about weight.
- Involving persons or groups that the target audience already trusts in the recruitment process.
- Delivering the message through a variety of channels—health fairs, free screenings, ethnic media, worksite and other bulletin boards, paychecks, feature stories, etc.
- Providing an intervention for the control group.

Dr. Kumanyika raised the following questions regarding recruitment issues:

- Are the treatment and control groups that are recruited more similar to each other than to the people who chose not to enroll in the study? If so, does this mean they are more motivated and therefore the intervention matters less? Are enrollment and monitoring all that are needed to result in weight control?
- Is there enough information about the motivations of the different target populations to anticipate recruitment problems or is additional research necessary?

Retention and Adherence. Enrollment issues affected retention and could not be foreseen. Dr. Barbara Dennison pointed out that the preschool/daycare setting enrollment and attendance were very fluid and affected by changing family circumstances such as changes in employment or arrival of a new baby. In addition, when New York State required school districts to offer prekindergarten to all children, Dr. Dennison's Brocodile study lost about one-third of its recruited subjects midway through the program.

On the other hand, Dr. Antronette Yancey, University of California at Los Angeles (UCLA), encountered an enormous increase in her study population's enrollment from 600 to 900 sixth graders that affected the intervention and the interface with the school administrators. Besides the huge increase in enrollment and a budget cut in the intervention school, both the control and intervention schools were among the 10 worst performing schools in the Los Angeles area, with many children transferring out of the schools, thus affecting retention. In Dr. Debra Krummel's WIC studies at the University of West Virginia, contacts and follow-up were hindered by the frequent change of telephone numbers. A 100 percent staff turnover in the partnering women's organization between the planning and implementation stages of Dr. Kumanyika's study required a major shift and reorganization for the intervention and overall implementation. Dr. Donald Williamson's Internet-based intervention had to adjust to loss of the study's initial service provider, an event that occurred just as participants were learning to use the intervention and caused a 4-month interruption and delay. The use of volunteers or existing agency staff, rather than dedicated research staff members, also impacted some studies.

The investigators stressed that young, pre-school children are a crucial age group to study because of the critical influence of their environment on their diet and activity level and its lifelong implications on healthy weight maintenance. In addition, more and more children are attending preschool. However, they are a difficult population to study. A major difficulty in the studies was maintaining parent cooperation with the intervention

that was in competition with the other demands on their time and the frequently stressful nature of their lives (e.g., employment changes, financial and marital stresses, pregnancies and multiple young children to care for.). Similar conflicts affected attendance at sessions and assessments for the postpartum and menopausal women. Postpartum women also had a high incidence of depression and high stress levels that impacted their behavior. Low-income families in particular lacked safe play areas for children and parents to participate in physical activities.

Lack of motivation to control their weight was a strong factor in both children and adults. For those at life stages where they were at high risk for weight gain, it was important that they understood this tendency so that they did not drop out or relapse when they did gain weight temporarily. Techniques that helped with adherence and retention included:

- Incentives (gift certificates, increased stipends, food tastings, trips, family events, etc.) to increase participation in activities, recordkeeping, interviews, and assessments.
- One-on-one individualized contact (face-to-face or via telephone/mail/e-mail),

- Take home materials that were culturally appropriate and easy to use, sustained interest in adherence to intervention, and served as tools for adherence/record keeping.
- Involvement of the whole family in the intervention.
- Adjustment of approaches to be responsive to family dynamics.
- Active involvement of the social/community group in the intervention (peers, church members, day care/pre-school/school staff).
- Active involvement and commitment of health care providers (physicians, midwives, nurse practitioners, nutritionists).
- Commitment of the social/community group leadership to the intervention's goals.
- Inclusion of an intervention for control group to retain them.
- Frequent update of web sites in Internet interventions to maintain interest and compete with other web sites.
- Extensive training of inexperienced or uninterested computer users and prompt feedback in Internet interventions.

- Obtaining additional phone numbers at recruitment.
- Flexible schedule for group sessions and follow-up assessments.
- Provision of social support, especially to lowincome women, to encourage their adherence and attendance.
- Possibly providing social support through carefully selected and coached peers or mentors as a promising approach.

Dr. Kumanyika commented that, unlike clinical efficacy trials where there is usually an extensive labor and dollar effort to retain subjects in order to assure "dose", the results of pilot studies may more realistically reflect the intervention's actual effect for the general population. She also noted that the low retention in these studies, along with the high level of effort needed and the small differences seen between the control and intervention groups post-intervention, is a strong argument for use of a health promotion model rather than a treatment model.

Intervention Approach

The presentations and discussions raised many issues regarding the intervention designs and approaches. These involved ethnic/cultural issues; weight management and weight gain study design

issues; ethical, feasibility, and general design issues regarding control and comparison conditions; and the outcome measure issues discussed in the next section. Lack of resources and decisions made by administrators in the community and school settings also affected the approaches.

Ethnic/Cultural Issues. Generalization and transportability of interventions to different cultural/ethnic groups is unknown. Different interventions are needed for different groups. Those who conduct the intervention need to be steeped in the culture and preferably members of the culture. The design must consider, learn, and value the importance of cultural beliefs regarding obesity and overweight, play, and parent/teacher roles. Parents feel they do not have time to "play," but can be engaged in "healthy activities" and "family activities." Ethnic populations tend also to be among low-income groups whose neighborhoods do not provide safe places for children to play, with or without a parent.

Weight Gain and Weight Management Issues.

The existence of a practical and feasible treatment model for weight maintenance in adults will require further development. The most successful to date have required intense interventions of long duration and have been expensive. Health promotion models are believed to merit further investigation. For children, there may be a treatment model in which parents or other caregivers teach the skills to place the child on the right track.

The question is when or if this treatment model can be discontinued at some point. Finding a means of motivating people who do not have an active health problem remains a challenge. There is also a strong need to adjust any intervention approach to family and individual critical periods in life and to the day-to-day demands on their time.

Control and Comparison Group Issues. It has become clear that control groups require some form of intervention on ethical grounds and to ensure their cooperation and retention. Control conditions need to be ethically and scientifically sound. For example, an ethical issue is the need to provide an appropriate program for the control who are also in a high-risk group; however, this design creates a design issue of comparing an alternative intervention with an active treatment. The control groups often compete with the intervention group by engaging in self-selected interventions.

High-risk groups who need an active treatment for obesity (e.g., obese adolescents) also need to be defined. Additionally, asking essentially healthy persons to postpone major life events such as pregnancy to participate in the intervention is probably unethical and intrusive, whether they are randomized to the intervention or control group. There are also feasibility and design issues in retaining the comparison groups.

Alternative Designs and Intervention Approaches. In other areas of health research, there are many uses of quasi-experimental designs. Most obesity prevention investigators are familiar with the randomized controlled trial design. They need to feel more comfortable with alternative designs and take advantage of opportunities for creativity in rigorously designing their studies. Study sections need to understand the challenges and unique characteristics of obesity prevention research and be willing to evaluate well-developed quasi-experimental designs accordingly.

Diet studies in cooperation with the food industry may provide stronger interventions. Some foods may be more effective in producing satiety and in controlling appetite and hunger motivation; other foods may produce hyperphagia leading to positive energy balance and excess weight gain. Multi-disciplinary approaches are needed to address physiological and behavioral factors in appetite control and food intake.

Research is required to investigate and quantify the impact of environment on a child's dietary and physical activity behaviors—in the home, school, and other community settings. Intervention models that can handle sporadic attendance may be needed to be responsive to family dynamics and fluctuating demands on participants' time.

Other Design and Intervention Issues. Other design issues involve the intrusiveness of the research process and the artificiality of the intervention in community and "real world" settings. Sorting out what can actually be studied may be a problem given the recruitment, retention, and measurement burdens. There is a question about the ability to translate and generalize the intervention to other groups. In the use of the Internet as an intervention or as a component of an intervention, what are the incentives to do the physical activity or other intervention and then return just long enough to log the results?

Outcome Measures

Scientifically sound, quantitative, primary outcome measures were a subject of concern and discussion throughout the meeting. Insufficient sample size to evaluate the efficacy of the intervention was widespread among the pilot studies. Investigators also stressed that outcome measures such as dual energy x-ray absorptiometry (DXA), bioelectrical impedance (BIA), and BMI are difficult to evaluate for growing children and even adolescents. Measurements are needed that are relevant for different age groups. Body composition may be a better measure of improvement in young children. Even for adults, investigators questioned the validity of BMI as a measurement over the short-term. For example they found it difficult to show an effect on BMI in the shortterm. The suggestion was made to find a means

of showing energy balance without using BMI. It was felt that there is a strong need for better tools to measure weight maintenance, food intake, and physical activity.

In the treatment literature, there is a strong bias that anything important that is going to happen will happen in the first 6 months, and study sections tend to adhere to that premise when evaluating pilot study results for proposed clinical trials. Is it also true in obesity prevention that the effect of the intervention must be seen in the first 6 months? Because of the sample sizes and measurement problems in these pilot studies, the researchers felt a longer follow-up period was needed to fairly evaluate the efficacy of the interventions. Dr. Michael Lowe, Drexel University, pointed out that the studies had baseline and outcome measures for the study period, but no knowledge of patterns of weight gain in the period before the intervention; the intervention outcome may be greater than it currently appears if it could be compared to weight gain in the previous year(s). Dr. Susan Racette, Washington University School of Medicine, added that menopause is not a 1-year event, so a longer period is also needed for valid measurement of outcomes in interventions surrounding the menopause period.

The group felt that the qualitative secondary outcome measures, that are still being analyzed, may provide the greatest value to the furtherance of obesity prevention research by providing needed

background information. Obtaining small grants to ensure the mining of these data was considered a worthwhile effort. Assessment tools also need to be developed and tested for secondary outcomes, such as assessing family dynamics and structure and the impact on the environment of interventions in community settings.

Community Health Perspective on Obesity Prevention Research

As an introduction to the participants' discussion of obesity prevention research as a component of general prevention research, the workshop attendees were honored and fortunate to have Dr. Stephen Fortmann present an overview of the community health perspective on obesity prevention research. Dr. Fortmann is Director of the Stanford University Center for Research in Disease Prevention and a Principal Investigator of the Stanford Five-City Project, a well-known community intervention project to raise awareness of the risk factors for cardiovascular disease and reduce the prevalence of those risk factors in the intervention communities. As a physician and cardiovascular epidemiologist, Dr. Fortmann has devoted 25 years of his career to intervention and prevention research.

Dr. Fortmann spoke first of the interdisciplinary nature of prevention. The challenge in bringing these multiple fields together—the biomedical, behavioral, social, and epidemiological

scientists—is that they use multiple paradigms and models and different words for similar concepts. Epidemiology is the basic science behind public health, and both concern population level factors in disease causation. Epidemiology examines the determinants and distribution of disease in entire populations and informs public health about what needs to be done to reduce disease risk and how to do it. One of the fundamental principles in epidemiology is that geographic and temporal disease variation is informative in determining the population level of a disease. Dr. Fortmann demonstrated this with slides on worldwide trends in coronary disease events. These trends indicated environmental changes determine disease prevalence differences across time and space. Since the 1960s, in the U.S., most of the decline in the death rates and the improvement in longevity are due to changes in cardiovascular disease over time.

A complete understanding of population health requires consideration of both population level and individual level factors. The biomedical and behavioral sciences tend to focus on the individual perspective, particularly in the United States. Elsewhere, there is more research on social medicine. Major diseases such as many cancers, cardiovascular disease (CVD), obesity, and diabetes are due to complex interactions of genetic and environmental factors. At the population level, it is the environmental factors are most critical, whereas for the individual, personal genetic

makeup and other individual-level factors are equally important. For CVD and obesity, populations are at high risk due to environmental circumstances such as dietary intake of saturated fats, excess energy intake, and lack of opportunities to exercise.

Medical Model of Prevention. In this model, the perspective is on the individual who initially develops risk factors that proceed to early or pre-clinical disease and then eventually to disease and death. Primary prevention commonly intervenes at the risk factor stage; secondary prevention tries to prevent the progression of the disease. Tertiary prevention attempts to delay death from advanced disease. "Primordial" prevention tries to prevent the risk factors themselves, which begins to approach the arena of public health. Only in recent years have physicians begun to incorporate chronic disease prevention into practice, initially with the treatment of hypertension and more recently treating cholesterol disorders and smoking.

Dr. Fortmann illustrated and contrasted the population model and the medical model with a bell-shaped curve indicating the prevalence of a risk factor in two populations. One of the populations had a higher mean level of risk than the other. A vertical line toward the right end of the curve represented the medical model of prevention, which seeks to screen, identify, and intervene with people at the highest end of the risk level distribution who, for example, have high blood pressure or high cholesterol or excess weight. The public

health model looks to shift the curve to the left for the whole population, which has a large effect on the high-risk population as well. The two models actually work together in prevention. Dr. Fortmann presented an example of a successful population shift to the left on a curve showing changes that occurred every 5 years in cholesterol levels in Finnish women resulting in fewer persons at the high-risk level after the shift. A 20-year concerted national public health effort to change dietary behaviors resulted in this shift for both men and women. (This curve illustration was referred to frequently in the later public discussion.)

Population Model of Prevention. Dr. Fortmann's population model combines social learning theory and the medical model. As in the medical model, the person is developing risk factors and disease and progression to death, but the model recognizes that the person's environment and behavior are affecting the person's development of risk factors and disease. The Stanford model also incorporates the reciprocal determinism of social learning theory that states that the environmental, behavioral, and personal factors interrelate. A person's characteristics and life events affect disease risk factors, along with behaviors, and the physical, social, cultural, and biological environment. Just as environmental factors affect behavior (safety of streets, cultural beliefs), a person's behavior can affect the environment through selfselection, and this self- selection of behaviors and environments is affected by a person's knowledge and attitudes.

Dr. Fortmann also presented a population model by levels which can also be helpful in comprehensive prevention efforts. At the top and most broad level are the political, social, and cultural structures in which people live. Next was information through media, which he identified as being part of the environment. Other environmental levels are the community, neighborhood, school, and worksite that are important for affecting behavior and for community prevention. Family is also an important influence on level for intervention. The individual and his/her physiology are the next levels, and the final level is the disease.

Dr. Fortmann noted that changes in public policy and the use of land use planning are examples of possible changes of the physical environment that could affect cardiovascular health. Of course, before there can be a political mandate to change the environment via public policy, the population has to be aware of the problem, accept the necessity for the change, and be willing to tolerate the change in their environment, as in smoking ban policies. The social environment is affected by parenting, education, health care access, the worksite, and legal structures. Medical care comes in with primary and secondary prevention in particular. Information media affects both the environment and the person. Individual groups become target audiences as the focus of interventions. Behavioral interventions include modeling, skills, motivation, and education. The population model is organized around

universal interventions that affect everyone in the population, selected interventions for subgroups such as smokers or the overweight in a broad sense, and targeted interventions for specific groups such as pregnant women. This model is likely more helpful than the primary, secondary, tertiary organization of the medical model.

The Example of the Five-City Project. Dr. Fortmann used the Stanford Five-City-Project (FCP) on cardiovascular risk as an example of the population model of prevention. FCP was primarily an educational intervention in two adjacent communities that focused on use of mass media with limited but long-term community participation and interpersonal contact. The intervention focused on the risk factors of smoking, exercise, and nutrition and included information on the risks for CVD, motivation to change behavior, and skills for changing risk levels. When the FCP intervention began in 1980, there was little political mandate for changing public policy to promote CVD risk reduction. Three control communities were used for comparison.

The FCP intervention used perspectives from Bandura's social learning theory (discussed above), the communication-behavior change (CBC) model, and social marketing. The CBC model organizes behavior change into stages including awareness, knowledge, motivation, skills, and maintenance. The CBC was used to organize the intervention, even though it was

recognized that human behavior does not necessarily adhere to such an orderly process. For example, awareness of the benefits of exercise was found to be high, but there was a lack of skills for smoking cessation and lack of knowledge about nutrition. Thus, exercise interventions focused primarily on motivation whereas smoking cessation efforts were directed primarily at teaching quitting skills. Social marketing, i.e., the use of marketing principles for social outcomes, was the third basis of the intervention. Social marketing requires considering the product (program, pamphlet), the price (time and energy rather than money), the placement of the product (where the target audience can find it), and promotion. Dr. Fortmann explained that social marketing is useful in preventing problems such as too high a cost or not having the product in place when it is being promoted. It also brings in audience segmentation, i.e., tailoring of the intervention.

FCP used a variety of messages integrated across multiple channels—radio/television/print, physicians' offices, worksites, and community organizations—to maintain interest and reach the entire population. Dr. Fortmann stated that although physicians feel frustrated by their inability to get patients to change behaviors, they are the most potent behavior change agents we have and deserve to be assisted in their efforts. The information dissemination was tracked and indicated that the average adult was exposed to approximately 5 hours of educational material per year

through the intervention project. This duration was sufficient to achieve broad awareness of the program, its logo, and the information. At the same time, the average adult was exposed annually to 292 hours of television advertising alone.

Dr. Fortmann provided several examples of the educational intervention components. Group sessions favored by behaviorists were impractical to reach the 30,000 smokers in these populations, so Stanford developed and distributed some 55,000 four-page "quit kits" accompanied by a magnet. The kits achieved about an 11 percent smoking cessation rate, which is less than classes can achieve, but triple the spontaneous quit-smoking rate. Focus groups were then conducted with the Spanish-speaking population to tailor the kits. The result was a simpler, less behavioral, and more directive kit. Even though the color of the two kits was quite different, focus groups and survey questions established that non-Hispanics identified white as the best color for health information materials, whereas the Hispanic groups preferred primary colors. Thus, asking, "What color should the booklet be" was an important question and a good example of not-so-obvious elements of successful tailoring. FCP also held a quit-smoking contest ("Smoker's Challenge") that was initiated because a local radio personality wanted to quit smoking and do it on the air over a 2-week period. The contest included a "Cool Turkey" quitting guide, which matched this two-week timeframe and the original Quit Kit, both

available through local stores and the health departments. Successful quitters were entered in a drawing for prizes donated by local businesses. The contest, radio, and print materials were all used to build a coordinated and comprehensive campaign. Other risk factor campaigns attempted to do likewise, although not always with the same degree of coherence.

The FCP results were less than hoped but better than credited and somewhat different from what the investigators had expected. Smoking cessation and lowering of blood pressure did better than improved diet and exercise, in spite of the high motivation for exercise. In the 1970s the lowering of saturated fats through changing milk and margarine choices did improve cholesterol levels, but by the 1980s, essentially everyone had done that, and further improvement was harder to achieve. Dr. Fortmann pointed out that the "quit" message for smoking is simple; the message for nutrition is much more complicated.

The results were also affected by secular trends and design limitations. Favorable secular trends affected control communities. FCP was quasi-experimental with only five communities, three as control and two as interventioncommunities. The FCP was 6-years long, which is long from the usual research perspective, but short from a public health perspective. For example, it has taken some 40 years for the message about smoking risks to result in significant lowering of smoking

rates; changes in nutrition and exercise also require many years to develop. Dr. Fortmann also noted that it is often said that information alone is insufficient to change behavior, but this conclusion is based on short-term trials. The anti-smoking campaign has succeeded despite being almost exclusively an information campaign. Smoking rates declined most rapidly when it became socially unacceptable to smoke, and it became socially unacceptable when the public had become thoroughly informed about the dangers of smoking and second-hand smoke. Thus long-term information dissemination can be effective, but it can take decades.

Dr. Fortmann cautioned that it is an oversimplification to say that, since the FCP and two other major cardiovascular community interventions for risk reduction (Minnesota Heart Health Project, Pawtucket Heart Health Project) were less successful than anticipated, the focus should be entirely on changing the environment. As important as environmental change appears to be, there are no data to support the effectiveness of environmental change. The conundrum faced by all is the lack of continuity following the intervention. In FCP, there was a concerted effort, that was only minimally successful, to leave behind resources for the communities to continue the intervention. Major questions that remain are, who is going to implement the results of intervention research studies and how can there be an ongoing continuous population level intervention?

Population Perspective on Obesity. Dr. Fortmann listed a variety of factors contributing to the current epidemic in overweight and obesity. At the individual level, there are strong genetic factors in determining BMI. At the population level, the environment has the greater influence. It appears that the majority of persons are genetically susceptible to developing obesity in the face of physical inactivity and excess energy intake. Today there is a strong economic drive to sell us more food, and current urban and suburban land use planning discourages walking and other physical activities. Results from the Behavioral Risk Factor Survey conducted by the Centers for Disease Control and Prevention dramatically demonstrated the enormous growth in obesity in U.S. adults in the 10 years from 1991 to 2000. This trend is also true for children, adolescents, and young adults. "Supersizing" has increased portion sizes as we obtain ever more meals away from home, and exercise levels continue to decline as we watch more television and increase computer use.

Dr. Fortmann stated that there is a strong overlap between obesity prevention and CVD prevention. Nutrition and physical activity are fundamental to both, and diabetes and insulin resistance are also important CVD risk factors. Economic forces are daunting for both obesity and CVD prevention: the selling of more food, the weight loss industry's formidable economic stake, and the major financial incentive for developing a weight loss drug rather than to address the fundamental causes of

the obesity epidemic. Societies where obesity is less common are societies not of joggers, but of people who walk; therefore, city planning is a key factor in these prevention efforts. Dr. Fortmann pointed out that there is an excellent opportunity here for an alliance between public health and environmentalists to create cities where people walk.

The audiences for obesity prevention require a diversity and multiplicity of messages and channels. Another challenge is changing media technology, not just the Internet, but also television. Marketing experts are concerned that TV viewers are just not watching commercials anymore, which unfortunately will also be a problem for communicating prevention information. In the health care arena, the ability to prescribe a drug to treat hypertension or smoking addiction makes health care professionals more comfortable with actively intervening with their patients; it may take the presence of a drug they can prescribe to get them more involved with obesity. Hopefully, the Diabetes Prevention Program study will help change this attitude based on its results which showed that a modest weight loss and physical activity intervention prevented the development of diabetes more than the drug intervention in a high-risk population. Also, Medicare is finally covering dietary instruction for persons with diabetes which marks the beginnings for reimbursement for non-prescription intervention. Dr. Fortmann reminded the audience that the primary

care physician cannot be the whole answer, because average office visits last approximately 10 minutes. Technology needs to be developed that can introduce the intervention through the physician's office and through other health care providers, without adding to the visit time.

Prevention Research Challenges. Randomized clinical trials (RCT) and emphasis on evidencebased outcomes research are appropriate. However, the generalization of RCTs is limited by the selection process, which tends to focus on persons who are already high-risk and overweight, in order to obtain the necessary effect size and adequate power to conduct a trial at reasonable cost. The study is therefore focused on a subgroup of the population, not everyone who needs to prevent weight gain. A diet and physical activity intervention is especially important for children and for those who do not see their weight as a problem. In conducting intervention studies, investigators provide special attention for a few months; however, the audience then returns to the toxic environment that counters the changes initiated. Unless this population level factor of the environment can be addressed, it will be extremely difficult to address the overall problem. Dr. Fortmann pointed out that many of the studies presented by the investigators are looking at aspects of these environments such as the school and family. The question is who is going to implement and disseminate these interventions. More research is needed on better methods for dissemination. A

number of effective curricula for doing CVD prevention in children sit on a shelf somewhere because teachers do not use them. Along with designs that are easy to use, there should be public health support of dissemination.

Dr. Fortmann stated that it is difficult to design randomized controlled studies at the community level or in parts of the community such as schools or worksites. Sometimes the design becomes the enemy of the overall goal because, in order to standardize the intervention over a number of sites, the intervention tends to become diluted and less effective. Dr. Fortmann urged that it is important that the best is not the enemy of the good here; instead it may be important to use designs that are not quite so tightly controlled so that the research may address the larger issues that have been noted at the workshop.

Obesity Prevention Research as a Component of General Prevention Research

Following Dr. Fortmann's presentation, Dr. Shiriki Kumanyika, University of Pennsylvania, moderated a panel on the relationship of general prevention research to obesity prevention research. The panel included Dr. Antronette Yancey, University of California at Los Angeles (UCLA); Dr. Debra Krummel, University of West Virginia; Dr. Michael Lowe, Drexel University; and Dr. Alice Ammerman, University of North Carolina at Chapel Hill.

Dr. Kumanyika opened the discussion by commenting that the disillusionment with earlier community-based trials that did not show a large effect against the secular trend was partially responsible for the current tendency to cling closely to the tried-and-true model of RCTs primarily at the individual level. This focus does not promote thinking out of the box and possibly moving ahead more constructively.

Dr. Yancey brought out that doing intervention research in communities and dealing with real world issues is not as straightforward an approach as controlled randomized trials. One of the issues is trying to shift the curve of prevalence of overweight and obesity in a population two-thirds of which is overweight but not motivated. To do this within the health promotion model is going to require strategies that engage everyone. With smoking, NIH policy for funding included the requirement that the institution have a smoke-free workplace, even before States had smoke-free legislation. Perhaps for obesity research there needs to be a policy that says to qualify for a grant, the organization must promote work-time walking, make healthy snacks available, and so forth.

Although Dr. Yancey's and Dr. William McCarthy's intervention in the two Los Angeles schools was impacted by the tremendous growth in the 6th grade population and the budget cuts that strained their resources, she wished to point out that their project was not without success.

They retained 70 to 80 percent of their participants in spite of the active mobility of this type of population and with parents who did not have a lot of inherent trust of researchers from a large institution. A preliminary result indicates that BMI gain was less in the intervention than control group over a 12-month period. Also, they learned strategies for better measuring fitness, and such lessons learned are very valuable in helping to continue these types of intervention projects, especially in schools with less difficult circumstances.

Dr. Lowe noted that many of the issues raised by the participants tended to focus on the question of what should be targeted in obesity intervention research, especially how much should be focused on the environment versus the individual, which may be a false dichotomy. In the United States, we are ethnocentrically oriented with our natural focus on American society, and to a certain extent, the U.S. is an anomaly worldwide, even among industrially developed countries. In industrialized, urbanized Europe the obesity rate is increasing but at a lower level. In developing countries, such as in Asia, the rate is much, much lower than in the United States. Dr. Lowe asked what is different in the culture and environment in the European societies similar to ours to produce a lower rate of obesity. Is it the food availability or the walking? Dr. Lowe suggested that a focus on this question regarding Europe and some of the other countries might provide some interesting research directions.

In referring to the points in the models presented by Dr. Fortmann at which preventive intervention takes place—from risk factors, to early disease, to late disease—Dr. Lowe commented that as the focus moves from tertiary to secondary to primary, the size of the undertaking becomes overwhelming because it approaches addressing the entire population. The more that prevention can be focused, the more cost-effective it will be. Currently, we are talking about "only" 60 percent of the population who are overweight or obese. In looking at markers of the risk factors, in a prospective, predictive way to indicate where to focus prevention efforts, it is obvious that it makes sense to intervene early in life, in childhood, even in infancy. Dr. Lowe suggested that to effectively focus interventions it is important to identify early behavioral markers and measures that indicate a tendency to gain weight independent of genetic influences, such as the sucking on a sweet solution in a study by Stunkard and colleagues.

Dr. Lowe agreed that a low level, small grant funding mechanism to try out-of-the-box innovative ideas is needed. These would cost less, be riskier, and have a higher possibility of failure, but they would generate new ideas and provide pilot data. He also pointed out that advances in cognitive neuroscience and social psychology could contribute to designing interventions based on behavioral models other than those currently being used, which are variations on social learning theory, older learning theory, and cognitive

behavioral therapy. These older models focus heavily on volitional, explicit, self-control of behavior with goals and a purposeful plan of steps. Whether it is the model, the implementation, or the technology, something is not working. In addition to refining these models, Dr. Lowe said it is time to question the adequacy of the models themselves and to consider newer models. This is especially true because the problems being dealt with are two biologically pertinent behaviors food intake and physical activity. From these other perspectives, a view of human behavior is emerging that places emphasis on the automatic nature of behavior, that many cognitive processes are implicit and non-conscious rather than explicit and purposeful, that there are unconscious effects of environment on behavior, and that many cognitive process variables that previous research has referred to are in fact post hoc rationalizations or explanations for environmental effects that are occurring in an automatic, non-volitional way. The related issue of free will versus determinism is very controversial, but there is some very serious scientific, provocative research being done in the area. For Dr. Lowe, it raises the question of whether current models are sufficiently robust to take into account all the effects of the environment to effectively guide obesity treatment and prevention research.

Dr. Ammerman expressed her ever-present deep concern over the trend of increasing obesity prevalence observed in the Behavior Risk Factor Survey maps produced by the Centers for Disease Control and Prevention. She emphasized the importance of the goal of shifting the curve of the risk factor levels and expressed her hope that from their discussions, the workshop investigators will come up with fundable, doable projects that study sections can approve, that will have good, publishable results, and that will enable all to feel they are accomplishing something real to shift the curve. Dr. Ammerman suggested that the slogan for the Obesity Prevention Research Network might be "Shift the Curve." Shifting the curve would also assist in reaching those people at a lower risk level who do not think they have a problem, by showing them that they are approaching having a problem.

Dr. Krummel said that she did not see the physical and social environment causing adoption of the behavior in the postpartum women in her study. However, the environment was clearly a barrier because there was not place for these ladies to change their babies on the 25-mile walking trail, strollers weren't allowed in one of the exercise environments, and so forth. She said that there are no measures as to just who is using this trail since it has been improved, but the belief is that it is the same people who used the trail before, not new people. Dr. Krummel raised the question of how the community can motivate new people

to use the trail. In the case of the women in her study, there were barriers, but for other inactive persons, the social environment needs to change. For example, in the university community, students can walk to school but it is not socially desirable and acceptable to walk to school. Students who do so are ostracized.

Dr. Krummel stated that the whole concept of diet is complex. There are so many diets being promoted that people are confused about "what is the best diet for me." To speak of total diet and its many components is difficult when people are looking for a simple message. There is a need to help people focus on calorie control, portion control, and healthy eating. This public health message has not really been emphasized.

Dr. Krummel said we need to work with the environment that exists in the United States and try to make some positive changes. She told of a restaurant study funded by the West Virginia Bureau for Public Health with CDC money to see how many places are offering heart-healthy options such as more fruits and vegetables or half portions for less money or smaller portions regardless of age, not just for children or seniors. A very small percentage of restaurants offered such options. The Nutrition Coalition for West Virginia next wants to use the study data and partner with others to further study or intervene in the restaurant environment. Canada and North Carolina have intervention programs at point-of-purchase which

have been shown to increase customer satisfaction, but very little has been published on these types of programs. Dr. Krummel suggested one of the next steps in prevention research might be the funding of an intervention with restaurants to get their cooperation in offering the public these choices. Having the choices alone may not change eating habits. There will still need to be efforts to raise awareness and to motivate people to change behavior, but having the choices available will help.

Discussion. Following Dr. Krummel's comments, Dr. Kumanyika noted that many organizations other than the National Institutes of Health are providing research funding such as CDC and State health departments. In order to compete for NIH funding, it is necessary to design a complete scientific model; however, there are not a lot of survey data available as a foundation for these designs such as Internet use for information on nutrition and how children react to changes in the vending machines in school. Including the exploratory research in the design causes a lot of false starts. Ancillary funding is needed to do some of this data gathering without having to do a complete study with blood samples and so forth and then find out that some of the basic assumptions of the study were not true. Funding sources other than NIH are needed to ensure that some of the research we are doing is not premature and based on premises that lack necessary exploratory information. Dr. Krummel agreed and mentioned

previous efforts by McDonald's with their Mc-Lean burger that failed and Burger King's new veggie burger that may succeed now that the environment has changed somewhat. In West Virginia, the intention is to conduct a small-scale pilot to see if restaurants offering healthy choices are financially successful, and if so, then do a larger-scale study.

Dr. Yancey provided information that the U.S. Department of Agriculture (USDA) does provide funding to States for nutrition network grants. Most of these have been awarded to local public health departments, but some are being given to academic institutions and community-based organizations. One example is the healthy diet program in San Diego that works with restaurants to alter recipes to cut fat by a third without changing the taste or texture.

Dr. Krummel agreed that there are programs out there; unfortunately their design and results are not published in the literature. In the West Virginia study, menus were checked to see if a symbol identified the healthy choices. Ethnic restaurants tended to do this more than other groups. In traveling, one does see these symbols on restaurant menus but it is not well publicized. Dr. Yancey said the American Heart Association had been encouraging use of these menu symbols and they might be a source of funding for an Obesity Prevention Research Network.

Dr. Lowe stated that one area that needs further research is in food sciences. There is a large potential to modify foods and the preparation of foods without changing taste or changing it only minimally, and taste is the major driver of food choices and over-consumption. Apparently some of the modifications food companies have made to lower fat have not been successful with customers. Studies are needed to learn how complex foods can be successfully modified to improve the nutritional benefits while not affecting taste. Research studies, such as those in Barbara Rolls' lab, have made dramatic differences in calories while masking the use of different substances. This can be one way for people to be eating healthier without even knowing it.

Dr. Kumanyika referred to studies in New Zealand where men's waistlines were reduced by teaching vendors to prepare chips (french fries) differently. Consumption of chips remained level, but the fat consumption went down by a third, which was a successful intervention.

Dr. Dan Bessesen of the University of Colorado stated his opinion that the environment does not drive human behavior but instead human behavior drives the environment. Instead of the environment targeting humans, in a free market society, the environment reflects what people have decided is desirable, as in land use planning and choosing to eat at McDonalds. The studies under this workshop's RFA focused on the person and the

behavior. None of the studies focused on behavior and the environment in a bi-directional way. Dr. Bessesen said NIH's move to look at the environment through the new RFA on Environmental Approaches to the Prevention of Obesity is very appropriate. It is important to work with the environment, such as the food industry, and with individuals. It is also important to think on a larger scale and engage the big food industry, not as an enemy to be punished with taxes, but as a partner and as a group to be sensitized like the efforts to sensitize individuals. The food industry needs reliable science-based tools to market these healthy changes. Unfortunately, there are no data to support this approach. The nutrition research required is so complicated that it is difficult to be rigorous and conclude there are proven benefits. Dr. Bessesen said he believes the food industry is ready to make incremental changes in food if government agencies such as NIH, CDC, and USDA can create an environment in which nutritional scientists can work with the members of this highly competitive industry. He recommended that it is the right time to forsake the "us or them" attitude.

A problem in comparing interventions for smoking and obesity is that smoking became stigmatized, whereas persons who are obese are already dealing with stigmatization, so there is a reluctance to use the word "obesity." The tendency is to try to remove the stigma and downplay the problem by saying it is not the person's fault.

On the other hand, it is difficult to make the person who does not see his or her excess weight as a problem aware that a serious problem exists and motivate the individual to make lifestyle changes if the word "obesity" is not used. Finding ways to talk about this is important, perhaps by focusing on behavior, not on the weight. It is also important to define concretely just what food these persons should eat and what activities they should do.

Dr. William McCarthy of UCLA noted that in the food industry the more value added to the processing of a product, the less intrinsic value there is in the product generally. This may create a problem in working with the food industry. Dr. McCarthy spoke of a study in Europe in which undergraduate men performed various activities from reading to sitting in a sauna to bicycling. During these activities, the men's macronutrient preferences varied demonstrably. A Gatorade study found that prior to exercise the preference for high-sugar solutions was much higher than after exercise. A study by Dr. Paul Williamson showed that there is a dose response relationship between fruit consumption and mileage run by women runners. These studies indicate that physical activity may be one way to modulate people's taste preferences rather than "trick" the consumer into eating healthier foods. Dr. McCarthy later added that although the solution to prevent excess weight is simple, life is not simple. For researchers, obesity prevention is obviously not

a simple proposition. In addition to energy balance, control of the waistline involves energy density, water, dietary fiber, and other diet components. This requires boiling down the complexities revealed in the research literature to a simple public health message that can fit into the media's 30 second commercial spot.

Dr. Lowe agreed that taste is an interaction between the taste of the food and the biological state of the organism. Unfortunately, most Americans are energy replete—they are not exercising, they are not hungry, and in this state, taste is driving their behavior. Taste might be modified by activity, but meanwhile it is worthwhile to reduce the energy density of their food while maintaining taste as much as possible.

Dr. John Jakicic, University of Pittsburgh, commented that treatment and maintenance are two different things. In his study, he reminded people during maintenance to remember what they felt like before they lost their weight. He suggested that these feelings, like walking up steps pre- and post-weight loss, be emphasized as feedback to help them maintain their weight. These feelings are more pertinent and immediate for them than what the scale says.

In referencing the very expensive research funded by snack food manufacturers to investigate optimal placement of products in retail grocery aisles so they will be visible to consumers, Dr. Jakicic

pointed out that this is the impossible competition that investigators funded by an R01 must deal with in marketing their interventions. As pointed out by Dr. Fortmann, packaging of the message is critical. Another competitive disadvantage is the misinformation available through the media. Commercial messages are not tightly regulated so as long as there are data that three persons benefited from doing something, the message can make the claim, even though the people in the commercial are not the people who will be using the product. He also pointed out that even when the environment provides access to indoor and outdoor physical activity facilities, people are not taking advantage of it. They live in their own microenvironment of the home and workplace. There is a saying that genetics loads the gun and environment pulls the trigger. Perhaps genetics builds the gun, environment loads it, but the individual is responsible for pulling the trigger. Dr. Jakicic cautioned investigators to look carefully at all three components in developing their ideas. He also pointed out that it is easy to say "don't smoke" in the workplace because this does not cost the employer anything. Although an advocate of time at work for physical activity, he questioned who would pay for the time or facilities. On the other hand, people do have post-work time for relaxation.

Dr. Yancey added that there has been a real push to alter the physical environment or economic environment, but very little focus on changing the socio-cultural environment. Most of the people who are going to be active on their own are doing so. It is the other people who need the social support. Dr. Yancey said that in her experience where there is a captive audience, social support, and to some extent peer pressure, there are very few people who will not participate as the workshop group had done on the previous day when they enjoyed the 10-minute worksite exercise during a break. In working with the environment, whenever the choice is voluntary, then most of those who opt out are those who most need the intervention.

Dr. Lowe said that all agreed that it is a decadeslong proposition to change the food and physical activity environments. In following up on examples of intermediate solutions, he mentioned building trails closer to people's homes and having groceries and restaurants offer healthier choices without charging more for them. Specially prepared foods and meal replacements enable persons to easily control their food environment in spite of the existence of a toxic environment around them. Previously, Dr. Lowe would not have recommended this; however, data over the past 5 or 6 years had shown this once-a-day meal substitution to be an amazingly effective and simple manipulation to enable weight maintenance after weight loss compared to more complex lifestyle change interventions.

Later Dr. Lowe suggested that the country was at the point with weight control that the nation was in the 1950s vis-à-vis smoking. In the 50s smoking was considered "cool" or even advertised as healthy. Today, only weight loss has the public's interest. Working to not gain weight is as foreign as the idea of quitting smoking was in the early 50s. People born in the last 50 to 60 years have that mind set. Dr. Lowe said that, hopefully, this investigator group and other efforts will gradually promote over the next 50 years the idea that preventing weight gain is as valuable, or more valuable, than losing it. The other point he wished to make was that there is a fundamental distinction between people coming to the prevention researchers' and the researchers going to the people. Those who come are motivated and committed. although usually only about weight loss, not about weight maintenance. When the reverse happens, researchers expect people to want what is being offered and do not always realize how little they do. Dr. Lowe gave as a similar situation the example of people who come to a psychotherapist ready to deal with a problem versus people in a hospital awaiting surgery who are depressed who receive a visit from a therapist and insist they do not need one. These are two totally different audiences; there is a need to figure out how to approach those at risk or with a weight problem who are not asking for help.

Another interesting comment was that the nutritional information (calories, fat content) that the Food and Drug Administration now requires on processed food labels is not available to the diner who eats out.

In response to a question from Dr. Kumanyika about anyone else working with modification of food products, Dr. Barbara Dennison, Columbia University and Bassett Healthcare, found that when she approached a local McDonalds about snacks for pre-school children, they were very interested at both the local and national levels in working with providing healthier snacks for children. They were willing to reduce portion sizes and offer more fruits and vegetables and low-fat dairy products. The local owner said, "If people will buy it, we will sell it." Questions remain as to whether they will market this, but there obviously is a desire among some persons in the food industry not to be a villain and to cooperate in dealing with this overweight/obesity problem.

Dr. Charlotte (Barney) Sanborn, Texas Women's University had a nutrition education study to increase calcium intake in kindergarten through fifth grade school children. General Mills initially funded the study in relation to a calcium-fortified cereal. When General Mills dropped the funding, it was taken over by the University. Refrigerators were provided in each classroom and milk provided. The children drank the milk because it was cold in comparison to what they received at lunch

where the cartons of milk were not as cold. This temperature preference was an interesting finding, along with the amusing feature that the teachers referred to the investigators who delivered the milk as "dairy fairies." Dr. Sanborn said that the innovative research RFA had offered a wonderful opportunity to those doing research with young children. It is very difficult to have big changes in primary outcomes in body mass index in these school children, but she felt they had had an impact with their study. She urged that innovative approaches continue to be funded, because those who work in the school systems cannot always offer a clean design or cannot randomize because of administrative rules or decisions. However, these innovative studies offer secondary outcomes that just might be the most poignant findings.

Dr. Christine Olson, Cornell University, spoke of the limited availability of many nutritionally recommended foods to many audiences at the highest risk of becoming overweight and obese. An exciting program in New York State has been the WIC Farmer's Market Nutrition Education Program. This is a partnership of WIC and local farmers to make available fresh produce in isolated low-income areas, inner city and rural. The WIC program provides vouchers to the WIC mother and to senior citizens to buy the produce. Unfortunately, the vouchers are limited to \$18 per season (May to October). However, it is important as a beginning in making these foods available to these high-risk groups, which must be done if we expect them to eat these items.

Dr. Kumanyika described the Food Trust in Philadelphia (formerly the Farmer's Market Trust) for which Sandra Sherman (also adjunct faculty at Columbia University) is the lead nutrition educator. Using State nutrition education funds, Dr. Sherman has initiated pilot programs in the schools to remove or change vending machine offerings and to change what the food service orders. A student committee does taste tests before changes are made. Dr. Kumanyika's group did not apply for the NIH environmental RFA because of lack of confidence about attaining BMI changes. The CDC then offered a similar, but very flexible RFA that she does expect to participate in.

Dr. Yancey referred back to the need for a culturally tailored marketing approach and content for recruitment instead of accepting as a given that whatever is put out there should work. A study that Dr. Yancey and Dr. McCarthy conducted on African-American women fighting cancer with fitness was marketed as changing dietary and activity behaviors to prevent cancer, not as a weight loss study. Most of the women who participated were overweight (average BMI was a little over 29), most lost weight initially, and, hopefully, there will be a long-term effect. All the women were given a membership in a health club. In addition, the intervention group was given nutrition education and hands-on use of equipment, and so forth. The control group attended nutrition lecture/discussions. There was an intervention effect on decreased depression that was sustained at the 12-month point. Dr. Yancey felt this was

another indication of the importance of focusing individuals' attention on how they feel and other positive elements.

Dr. Susan Yanovski, NIDDK, asked for additional feedback on the issue of primary outcomes. She noted that the prevention research literature is rich in providing important information regarding changes in knowledge, attitudes, and self-reported behavior, while objective, measurable outcomes are hard to find and cause researchers to question just what they are doing. The new environmental RFA provides that in small studies outcome measures other than BMI are acceptable because there are studies about changing vending machines and so forth from which BMI measures cannot be obtained. On the other hand, evidence-based medicine does require measurable outcomes. Dr. Yanovski asked, what measures other than BMI might be used to satisfy this scientific need.

Dr. Lowe responded that this scientific need was a challenge. In a recent conversation with Dr. John DeCastro, who is noted for his work on environmental and social determinants of eating and overeating, they discussed the issue of food records, which have a long and very controversial history. Dr. DeCastro said that he has had tremendous problems with reviewers who criticize his use of food records because they are full of error, usually in the direction of underreporting. He has been able to partly overcome this criticism by explaining that, because he uses within-subject

designs, whatever error exists is relatively constant within individuals and, therefore, the comparisons he makes are not adversely affected. Another option is to use several measures to cross check food records, 24-hour recalls, food frequency questionnaires, and perhaps biomarkers to reflect fruit and vegetable intake.

Dr. Sachiko St. Jeor, University of Nevada, remarked that she takes the challenge seriously of assessing outcome measures. Investigators need outcomes to evaluate the study and when the results are confusing, it is a problem. All the workshop studies offered opportunities to contribute methodological information, such as the techniques in her study to help the children overcome their concern with the DXA test. In the food records, where it is difficult to ascertain children's intake of food consumed outside the home, the study concentrated on common meals at home. Working with groups in which weight fluctuates, makes weight a very difficult outcome. In her study, they have tried to look at shortcuts, commonalities, and practical ways to interpret outcomes. Dealing with these difficulties in the pilot studies can contribute to methodologies for use in larger studies.

Dr. Donald Williamson, Pennington Biomedical Research Center, said that his group has been testing the validity of alternative ways of measuring dietary intake. One procedure they have developed is the use of digital photography to take

photos before and after eating foods with a known nutrient composition, for example, in a school cafeteria. From this direct observational approach, which is only useful in an institutional setting, they have obtained correlations of 0.98 against plate waste.

Dr. Dennison added that her studies have tended to look at behavioral methods of assessing diet, because most people (especially children) tend to be fairly habitual in their eating choices. For example, they have compared questions, such as the frequency with which parents serve a food (such as vegetables) at a meal or snack (such as lunch), with servings per day or nutrients from that food obtained via dietary records or standard food frequency questionnaires. For secondary outcomes, they focused on TV viewing. Assessment of child viewing was assessed using questions asking how many hours per day a child usually watched TV on weekdays, Saturday, and Sunday. The validity of these questions was assessed by comparing to the amount of time recorded on TV diaries and logs. The two methods yielded comparable mean numbers of hours and the values obtained were significantly correlated, which supports the use of these questions. Questionnaire assessments of activity, however, did not appear to yield reliable data. When asked about his/her child's activity, most parents tended to report that his/her child is more active than the typical child. Therefore, Dr. Dennison used activity monitors to try to quantify children's activity. They found that

they had to calibrate the monitors, so that one could translate the activity counts per minute into sedentary, moderate, or vigorous activity equivalents. This was a whole education in itself and a matter of trial and error, but it did provide hard data. The question remains, however, as to how these activity data relate to changes in adiposity. To look at change in adiposity, Dr. Dennison obtained repeated measures of children's height, weight, and BMI. They computed the slope (change in adiposity--BMI z-score-over time) for each individual child, and then the mean slope for the intervention vs. control group, using the daycare/preschool center as the unit of randomization.

Dr. Krummel wondered if it were possible to develop something similar to instruments used in CVD that show correlations between weight and behaviors. Using data from the national weight registry, could an instrument be developed based on certain behaviors—12,000 steps a day, fiber and fat intake, portion control, fewer snacks—that are positively correlated with success in weight management and use these behavior-changes as an intermediate instrument leading to changes in BMI?

Dr. Jakicic has a paper in press on an eating behavior checklist developed by Dr. Pat O'Neil to measure long-term weight loss and maintenance. His group had looked at a variety of instruments and determined this was the best

predictor of successful weight control because it addressed behavioral issues that people could respond to accurately. Dr. Jakicic stated that before deciding what measures should be used, the research question has to be clearly defined to determine what the outcome measures would be used for. If the interest is in behavior, then the outcomes should be about behavior. If the interest is in quantity or volume, then the outcomes are different. A number of companies are on the verge of coming out with devices to measure activity very accurately and relatively inexpensively, which will help in determining half of the energy balance equation. Dr. Jakicic noted that in the 18 studies presented at the workshop, almost everyone was measuring the same outcome but measuring it differently. He suggested that NIH establish a standard measure to be used by everyone studying obesity to measure eating and physical activity behavior so that the same data are collected and results among studies can be compared.

Next Steps: The NIH Perspective

Dr. Robert Kuczmarski and Dr. Eva Obarzanek, co-chairs of the meeting, presented the next steps from the NIH perspective.

Dr. Kuczmarski assured the group that NIH is committed to supporting research in obesity prevention. He reiterated the conclusion of all present that population-based approaches, which are the most practical goal in the public health arena, are going to be very challenging. The environment itself is almost overwhelming, offering society aggressively marketed, abundant, inexpensive, readily available, and highly palatable foods and beverages and innumerable opportunities promoting sedentary behavior and inactivity. The solution to overweight and obesity is simple but complex—energy balance. What the majority of persons need to do to achieve energy balance is known and fairly straightforward. However, we are working within the context of human behavior and a challenging, complex environment. Treatment trials such as the Diabetes Prevention Program and Look Ahead have made some headway in affecting weight loss by using one-on-one intensive lifestyle therapy. Although their results are impressive and instructive, the road ahead is a long and challenging one as we strive to better achieve in the general population sustained weight loss or weight control and learn how to prevent inappropriate weight gain in a cost-effective way.

As an extension of the innovative approaches developed under this RFA, NIH anticipates that the studies submitted under the environmental RFA will be another important step along the road of obesity prevention research. Many of these applications are also innovative. NIH recognizes that it is important to continue to try new and different ways to get a grasp on the prevention of overweight and obesity. The Institutes will continue to support mechanisms to foster pilot

and feasibility studies as recommended by the workshop attendees. Although the state-of-the-art may not yet be ready for a definitive clinical trial, more exploratory research may be warranted and NIH will consider what has been said. NIH may again explore the utility of a trans-NIH RFA mechanism for competitive obesity prevention research applications, especially for review by peer review groups who understand the research challenges. This approach would allow continuation and expansion of the promising research and ideas discussed at the workshop.

Dr. Kuczmarski said that it is important to remain optimistic and recognize that incremental small steps can eventually lead to the goal of population-based prevention of obesity. The pilot data are valuable steps in leading to the next stage of research. NIH is interested in seeing the results of the studies published in peer-reviewed journals to share the data and ideas from this workshop with a broader scientific audience. Publication of results will facilitate funding of future studies as peer reviewers learn what steps are being made to advance the field. Dr. Kuczmarski encouraged the investigators to share ideas spawned by their individual research or by the discussions at the meeting. He also urged them to use other funding mechanisms such as unsolicited R01s and R03s and to contact him regarding information about the R03 mechanism used by NIDDK for small clinical trials.

In closing Dr. Kuczmarski expressed his apprecia-

tion for the insightful contributions of each of the investigators and their stimulating discussions that provided a valuable exchange of ideas at the workshop. He particularly thanked the moderators and discussants and Dr. Fortmann for his presentation.

Dr. Obarzanek reminded the group that it took decades for the smoking epidemic to get turned around and that obesity prevention as health promotion is also going to take decades. It will require the confluence of individual and population-based approaches. The health care system must buy into health promotion as well. In addition to interventions with individuals and the environment, translation of research is critical, and we need to learn more effective ways to disseminate messages through all walks of society.

If it is necessary to overcome publication bias because of the lack of clear-cut effect in their results, Dr. Obarzanek suggested the investigators band together and produce a journal supplement as a group with support from NIH.

Dr. Obarzanek cautioned the group that working in the research arena does require producing an effect and thus, the design issues must be addressed. She stated that body weight is much easier to measure than physical activity, which is far more variable and unstable; the problem is that in weight control and prevention, the effect size

is small. To offset this problem, she suggested that research designs should be worked into larger sample sizes and longer duration studies, especially with children with whom it takes a long time for incremental divergence in the trajectory. With health promotion in obesity prevention, more than 2 years is needed.

The control group in community-type settings for obesity prevention has presented a new challenge. More resources may be needed to develop the control intervention required to accommodate community expectations. Adherence and retention continue to be difficult. There is a real question about what can be concluded about an intervention if only 30 to 40 percent of the participants are retained in the study. Part of the struggle is that in an essentially healthy population, motivation is lacking. There is still a lot of work to be done to deal with these issues and build the small steps to incremental successes in the primary care system, schools, worksites, community organizations, and the environment. Development work is also required in predictors of behavior change.

Obesity prevention boils down to a healthy diet and a physically active lifestyle, which need to go hand in hand. This is a simple message but will take a long time to get across and coalesce into weight control and obesity prevention. A simple message often takes a wrong turn. Initially the food industry helped by producing low-fat and skim milk and other low-fat dairy products, but

then ended up with higher calorie, higher sodium processed low-fat fun foods, such as non-fat cookies and cakes. Dr. Obarzanek agreed that the pre-washed prepared lettuce and healthy, fun-to-eat finger foods such as fruits and vegetables are a step in the right direction as an environmental intervention.

Dr. Obarzanek commented that it has been said that the role of clinical trials is to accelerate the secular trend, and we are at the early stage of that process for obesity prevention. NHLBI offers R01s and will join NIDDK in the environmental RFA. She suggested that when investigators have a good intervention but need a larger sample size and a longer term that they collaborate to test the intervention on a larger scale and apply for a cooperative agreement under a U01. The U01 does require a plan to translate and disseminate the results.

After thanking everyone for attending, providing the information to produce the program book, and sharing ideas that may lead to other research projects and collaborations and possibly an Obesity Prevention Research Network, Dr. Obarzanek concluded the meeting by thanking Dr. Kumanyika for her summaries and for moderating discussions on the final day of the workshop.

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