

Pathways: A school-based program for the primary prevention of obesity in American Indian children

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This report describes the proposed intervention and outcome measurement procedures for the Pathways study. Pathways is a multicenter school-based study aimed at reducing the alarming increase in the prevalence of obesity in American Indian children. It is designed as a randomized clinical trial, involving approximately 2,000 third grade children in 40 schools in seven different American Indian communities. During a 3-year feasibility phase, which was just completed, the major components of the intervention (school food service, classroom curriculum, physical education program, and family involvement) were developed and pilot-tested. The measurement instruments for body composition; physical activity; dietary intake; and knowledge, attitudes, and behavior were also developed and validated. Comprehensive process evaluation procedures also were defined. As of this writing, the full-scale intervention program is being initiated and is scheduled to be completed in the spring of 2000. The primary aim of the Pathways intervention is to reduce average percent body fat in intervention-school children by at least 3% compared with control-school children by the end of the 3-year intervention. This goal is to be achieved primarily by an increase in physical activity and a reduction in the percent of dietary fat intake. The program does not seek to reduce dietary energy intake. Rather, it is based on the assumption that a healthier, lower-fat diet, combined with an increase in energy expenditure by increased physical activity, will result in fewer excess calories deposited as body fat. (J. Nutr. Biochem. 9:535–543, 1998) © Elsevier Science Inc. 1998

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Introduction

Obesity is one of the major public health problems in the United States and in most developed countries. Recent surveys indicate that the number of U.S. children and

adolescents with body mass index (BMI) above the 85th percentile has increased from 15% in 1965 to 22% in 1991.¹ Although the tracking of childhood obesity into adulthood varies at different times, it is known that over 80% of severely obese adults were obese during late childhood and

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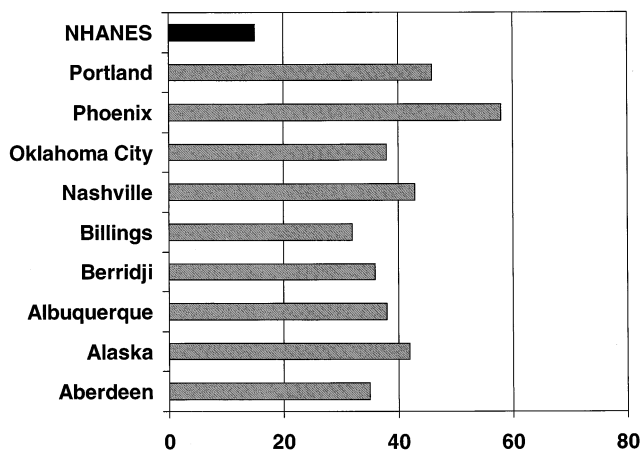


Figure 1 Prevalence of obesity (body mass index above the 85th NHANES percentile) in American Indian children ages 5 to 17-years-old, by Indian Health Service area. Data from the Indian Health Service, 1995.

adolescence.² Furthermore, several lines of evidence suggest that obesity during adolescence may have long-lasting adverse effects on health even when body weight returns to normal after adolescence.³

American Indian children and adults suffer obesity in much higher proportion than any other group in the United States. The prevalence of overweight (defined as a BMI >85th percentile of National Health and Nutrition Examination Survey [NHANES II] reference population) in American Indian adults is 34% for men and 40% for women, higher than the U.S. rates of 24% and 25%, respectively.⁴ The prevalence in 5- to 17-year-old American Indian children is shown in *Figure 1* (compiled and distributed by Indian Health Service areas). There is evidence of a secular increase in obesity among American Indians over the past 30 to 40 years.⁵ A dramatic increase in obesity among Pima Indians born after World War II was documented by Price *et al.*⁶ in 1993. A comparison of weight for height of Pima children also shows a major increase relative to earlier generations: a boy of 165 cm of stature today weighs 69 kg, compared with 58 kg for the same height in 1905.⁷ In another survey the increase in height and weight among Navajo boys between 1955 and 1989 was 6.1% and 28.8%, respectively.⁸

This epidemic of obesity among American Indians is a relatively new phenomenon. Early accounts of life among several tribes in the Southwest do not mention overweight as a characteristic of these populations.⁹ More specifically, a 1972 survey of White Mountain Apache children in Whiteriver, Arizona, reported that only 8% of children were above the 85th centile for BMI,¹⁰ whereas studies in the same community and age group in 1992 found that 35% of children were in that category.¹¹

There have been obvious changes in lifestyle in American Indian communities that can be linked to the epidemic of obesity: an increasingly sedentary lifestyle, increase in consumption of high-fat foods, and less opportunities for recreational activities for children and young adults.

Goals of the Pathways study

The Pathways study's aim is to develop, implement, and evaluate a school-based intervention for the primary prevention of obesity in American Indian children. That aim will be achieved by increasing moderate to vigorous physical activity, reducing fat content of school meals, and promoting healthier dietary practices at school and at home. The main outcome variable will be percent body fat (PBF) in intervention and control schools. Secondary aims will evaluate the impact of the intervention on physical activity level, dietary fat intake, and knowledge, attitudes, and behaviors related to food choices and physical activity. An extensive process evaluation plan will document the degree to which the intervention was implemented. Finally, data will be collected to monitor the safety of the intervention. These data will be reported regularly to an external monitoring board.

The Pathways project is divided in two phases: a 3-year feasibility phase, which is being completed as of this writing, and a 5-year, full-scale study, which began in the fall of 1997. The objectives of the feasibility phase were (1) to assess the acceptability and support from parents, students, and school and tribal authorities for a comprehensive, school-based program for the prevention of obesity in elementary schoolchildren; (2) to develop and pilot-test the different components of the intervention; and (3) to develop and test approaches and methods for measurement of primary and secondary endpoint variables. It was anticipated that the feasibility phase also would provide an opportunity for establishing strong links with schools and community leaders, and develop a field research team comprised of local American Indians with strong ties with the community.

The present report describes the development and validation activities carried out during the feasibility phase and the resulting components and procedures included in the final protocol for the full-scale intervention.

Pathways is based on a partnership between five universities and seven American Indian communities: Gila River Indian Community, Tohono O'odham (University of Arizona); White Mountain Apache, San Carlos Apache (Johns Hopkins University); Oglala Lakota, Sicangu Lakota (University of Minnesota); and Navajo (University of New Mexico). The University of North Carolina-Chapel Hill is the coordinating center for the study. The project is directed by a steering committee that is comprised of principal investigators from the grantee institutions, the National Institutes of Health (NIH) project office, and two American-Indian representatives from the tribes involved.

The study protocol underwent an extensive review and approval process, which included the approval from the institutional review boards of each participating institution, the tribal health authorities and councils, school boards, and an external Protocol Review Committee. In addition, written, informed consent and child assent was obtained for activities involving direct interaction with children, such as measurements and survey questionnaires.

Full-scale study design

The proposed full-scale study is a randomized clinical trial involving 40 schools serving American Indian children in

seven communities. For randomization, schools will be stratified within each field site based on median PBF, measured in children at the end of the second grade. Schools will be ranked at each field site based on their median PBF, and divided in two strata: higher and lower PBF, each containing half the schools of each field site. The study coordinating center will then randomly assign half of the schools within each stratum to intervention and half to control groups. The intervention will begin in children entering third grade in the fall of 1997 and will continue with this cohort until they complete the fifth grade in the spring of 2000. The unit of analysis is the school and the primary outcome variable will be the school's mean PBF, adjusted for baseline PBF.

Eligibility criteria for schools include: (1) third grade enrollment is at least 15 children; (2) 90% or more third grade children are American Indians; (3) the average retention from third to fifth grade over the past 3 years is at least 70%; (4) the school has its own cafeteria and provides lunch on site; (5) the school environment includes the minimum resources to implement the physical activity program; and (6) it is anticipated that the school will remain open and independent for the duration of the study.

Formative research

Formative research aims to understand the context of an intervention and the specific behaviors that may be of concern. In Pathways, extensive formative research was conducted in each of the participating communities, and constituted the basis to identify and prioritize risk factors for obesity and potential opportunities for enhancing program delivery.¹² Having to develop a common intervention across different American Indian communities posed an additional challenge and emphasized the importance of the formative research phase.

Data was collected with a combination of qualitative and quantitative techniques, which included in-depth interviews, semi-structured interviews, focus groups, and direct observation. Respondents included students, teachers, food service staff, administrators, parents, and community members. Interviewers encouraged people to openly express their views, concerns, and needs on a wide range of issues related to health and nutrition. Quantitative information permitted an objective comparison across sites in terms of school resources, dietary practices, and presence of factors that might constrain the implementation of the intervention. Both qualitative and quantitative data were integrated by means of a conceptual and procedural model. Risk behaviors were scored and prioritized, and common patterns across sites were identified and linked to the intervention development. A major contribution of the formative research data was to identify and prioritize those risk factors, permitting a more targeted development of the intervention (Table 1).

Development of the intervention

Although a number of studies have examined the relationship of obesity to chronic diseases,^{13,14} we are not aware of previous large-scale trials for the primary prevention of

Table 1 Selected risk factors for obesity in American Indian children: Data from the formative research of Pathways feasibility phase

High priority
Eat a lot of high-fat foods (S, H)
Encouraged to finish all their foods (S, H)
Have few opportunities to be physically active (S, H)
Watch a lot of TV, movies (S, H)
Eat seconds of high-fat foods (S)
Moderate priority
Eat a lot of fast foods outside school/home
Eat a lot of high-fat snacks (S, H)
Foods high in fat and sugar used as reward (S, H)
Eat lunch too quickly (S)
Not consuming enough fruits and vegetables (S, H)

S—school. H—home.

obesity in children. School-based interventions such as the Children and Adolescent Trial for Cardiovascular Health (CATCH) study have focused on cardiovascular health and have documented several effective approaches to reduce risk factors in school-age children.¹⁵ Building on previous studies, indigenous beliefs and values of participating American Indian nations were incorporated to create a program that supports healthier lifestyles and reflects those in the nations' traditional cultures.^{16,17}

The Pathways intervention combines elements of social learning theory (SLT) with the rich cultural heritage of American Indians in regard to physical activity and nutritious foods.¹⁹ By taking a holistic approach, the intervention aims to positively influence individual, behavioral, and environmental risk factors associated with obesity, particularly physical activity and eating behavior. Pathways seeks to enhance children's knowledge about physical activity and food choices, their values about health and nutrition, and their sense of personal control over their activity. By providing more opportunities for exercise and for healthier food choices, the intervention also promotes changes in the children's environment that support healthful dietary and activity practices. It attempts to influence families' food selections, tries to reduce the barriers to exercise and healthful eating, and creates peer support for exercising and selecting lower fat foods. Changes in children's behavioral attributes are promoted by adding to their repertoire of activities and food choices, and by developing skills for the practice of regular activities and for healthy food preparation. The intervention also aims to enhance children's ability for self-monitoring and goal setting.

The intervention design takes into account the specific learning patterns common to most native cultures.^{17,20} These learning modes are crucial elements for the success of the intervention. These indigenous learning modes include learning through observation and practice, learning from storytelling, learning metaphorically, holistic learning, learning by trial and error, learning through play, learning cooperatively, and learning through reflection. These modes were incorporated in the process of delivery of each component of the intervention.

To ensure that the content of the intervention was acceptable to all participating tribes, all working groups developing each component included American Indian rep-

Table 2 Summary of the Pathways intervention

Component	Objective	Content
Classroom curriculum	<ul style="list-style-type: none"> ● Targeted at 3rd, 4th and 5th grades ● Promote healthful eating behaviors and increased physical activity ● Integrate social learning constructs with American Indian traditions 	<ul style="list-style-type: none"> ● 12-week per year, twice weekly 45-minute classroom lesson ● Lessons linked by adventures of imaginary American Indian characters on their journey to healthy living
Food service	<ul style="list-style-type: none"> ● Reduce percent of calories from fat to no more than 30% ● Introduce dietary practices aimed at increasing the use of lower fat foods and fruits and vegetables 	<ul style="list-style-type: none"> ● Pathways guidelines for food service personnel ● Regular visit by Pathways nutritionist to support and monitor school lunch preparation
Physical activity	<ul style="list-style-type: none"> ● Increase energy expenditure ● Encourage moderate-to-high levels of physical activity in all children ● Promote practice of health-related fitness activities during and after school 	<ul style="list-style-type: none"> ● Three 30-minute physical education sessions per week during school time ● Exercise break during classroom time ● Guided play during recess
Family	<ul style="list-style-type: none"> ● Keep families informed and involved in the program ● Extend positive health behaviors learned at school to family members by promoting involvement of family and child in school-based program activities ● Create a supportive environment for children to adopt positive health practices 	<ul style="list-style-type: none"> ● Family Fun nights and workshops at school ● Family Packs linked to classroom curriculum ● Family Advisory Groups per school

representatives from each site. In addition, the study Steering Committee, which made the final decisions regarding the study, included two American Indian representatives, elected by all American Indians in Pathways. Furthermore, regular interaction with teachers, parents, and tribal authorities provided useful opportunities for feedback on the content of the intervention and on the other components of the study.

Components of the intervention

The Pathways intervention targets four areas: (1) classroom curriculum, (2) physical activity, (3) school food service, and (4) family involvement (*Table 2*).

Classroom curriculum

The Pathways curriculum targets children in the third, fourth, and fifth grades, and consists of culturally appropriate school-based lessons that promote healthful eating behaviors and increased physical activity. A culturally appropriate activity or lesson was defined as one acceptable to all the tribes participating in the study from the standpoint of cultural traditions and beliefs. The program is structured in two 45-minute classroom sessions per week for a total of 12 weeks. The sequence integrates several social learning constructs into a series of stories and activities linked through two fictional American Indian children, Amanda and Daryl White Horse, on their journey through the seven Pathways nations. By storytelling and associated activities, children are given the opportunity to identify with the main

characters and to model their healthy behaviors. During the course of the 12 weeks, students taste-test new foods and beverages and practice behaviors related to the goals for healthful eating and physical activity.

An important objective of the Pathways curriculum is to create an integrated school environment in which teachers, food service personnel, physical educators, and the students' families work together toward the common goal of practicing and sustaining the new behavioral skills introduced by the curriculum.

Physical activity

Although there are only limited data on level of physical activity in children,²¹ it is generally acknowledged that sedentary lifestyle is an important contributor to the development of obesity, both in children and adults.^{22,23} Conversely, it has been shown that reducing sedentary activities²⁴ or increasing moderate to intense physical activity leads to significant reductions in PBF in children, without affecting lean body mass.²⁵ School-based physical activity programs aimed at elementary schoolchildren have been successful in increasing level of activity during school time.²⁶

The Pathways physical activity component aims at increasing energy expenditure during school time by increasing the frequency and quality of physical education classes and by introducing classroom activity breaks and encouraging play during recess periods. Three main considerations guided the development of this component: (1) to develop moderate-to-high levels of physical activity for all children,

regardless of skill level; (2) to promote health-related fitness through aerobic activities and allow for sports skill development to enhance success and enjoyment of activities; and (3) to be as simple and as easy to implement as possible, not only by a physical education specialist but by classroom teachers as well. The Pathways physical education intervention is modeled after the SPARK program (Sports, Play and Active Recreation for Kids), which has been successfully implemented in earlier school-based health programs.²⁷ The Pathways physical education program aims at increasing physical activity for both motor skill development and fitness lessons. Although the SPARK program was not originally developed for American Indian children, our process evaluation data and pilot tests indicated that American Indian children enjoyed SPARK activities.

In addition to SPARK-based physical education, the Pathways physical activity intervention includes a unit of American Indian games derived from traditional games from each of the Pathways nations. The unit may be used in a variety of ways, by including it in physical education classes, or during recess or other active times.

The Pathways physical activity intervention is divided into 14 type I units (health-related fitness units) and 10 type II units (sport-related fitness units). Other modules include warm-up/cool-down activities, conditioning exercises, inclement weather activities, and American Indian games. The range of activities in units allows for the implementation of the program in a variety of school settings, even those with limited space or equipment. Type I units focus on the development of muscular strength and locomotor and nonlocomotor skills. Type II units emphasize development of sport-related skills, especially those with potential for future sports participation in the community. The goal of the intervention is to deliver a minimum of three 30-minute sessions per week. Training for physical education teachers will be offered at the beginning of the spring, fall, and winter periods.

The impact of increased physical activity at the school on total daily energy expenditure can be significant. We estimated that four to five 30-minute sessions per week would represent over 11,000 kcal over the school year, roughly equivalent to a reduction of 3 lb of body fat.

Food service intervention

The school cafeteria is a major source of daily energy intake for American Indian children attending elementary schools. The U.S. Department of Agriculture (USDA) School Lunch and Breakfast programs provides lunch and breakfast to approximately 25 million children every day, and is free for low-income families. Based on the calorie targets for breakfast and lunch set by the USDA and on attendance records from the school cafeterias, it can be estimated that children attending schools in American Indian communities consume as much as 60% of their daily caloric intake at the school. Thus, school food service provides a good opportunity to introduce healthful food choices.

The main goal of the Pathways food service intervention is to lower the amount of fat in breakfast and lunch meals. Although some studies question the efficacy of reducing dietary fat intake as a means of reducing obesity in adults,

other studies have shown a positive correlation between fat intake and measures of body fatness.²⁸ In children, diet energy density, which is largely determined by fat content, is an important determinant of total energy intake. The aim of the food service intervention is to reduce the percent of calories from fat to no more than 30% of the total, which is consistent with general guidelines for this age group. In addition to setting nutrition guidelines, the Pathways program introduces behavioral guidelines for the food service personnel that are aimed at changing and/or enhancing their skills in the planning, purchasing, preparation, and serving of meals. All food service staff will be trained in the implementation of these nutrient and behavioral guidelines, and the program will be supported by and monitored through periodic visits by a Pathways nutrition specialist.

To evaluate the potential impact of the Pathways food service intervention, a theoretical analysis of the nutrient content of 1 week of breakfast and lunch menus from three schools was conducted. The food service staff compiled the menus, which were analyzed using the Nutrition Data System (NDS) at the Nutrition Coordinating Center (NCC) of the University of Minnesota.²⁹ Two of the three schools averaged 34% and 40% calories from fat, and at lunch all three schools averaged 40% or 45% calories from fat. Applying all Pathways food service guidelines, fat content was reduced to 30% or less at breakfast in all three schools. Fat calories at lunch were reduced to 30% or less in one school and to 32 to 33% in the other two. The overall calories from fat at all three schools averaged 31%.

Family intervention

This component of the intervention has the objective of keeping families informed of and involved with the program's mission and activities, thus reinforcing the health behaviors introduced in the classroom and in the food service and physical activity components. Although our intervention is essentially school-based, we seek to extend positive health behaviors to children's family members as much as possible. Positive health practices in the household will lead to a supportive environment for the child, facilitating their own efforts to make those behavioral changes. The two activities for the family component of the third grade intervention include:

1. Family Packs, which consist of take-home materials linked to the classroom curriculum. Action Packs include printed material that promotes family activities related to physical activity and cooking healthy foods. Snack Packs include locally available, low-fat, low-sugar food items for the student to share with his or her family. These Family Packs are linked to the other components of the intervention and carry on the Pathways story line and health messages presented in the classroom curriculum.

To evaluate the rate of participation, each Family Pack includes a return card, which is to be completed by an adult family member. The return cards provide feedback on specific Family Packs and on the overall impression of the family intervention.

2. Family events, which are family gatherings at the school. The Family Fun Night is in the format of an educational

fair and involves families (parents, guardians and/or extended family), students, teachers, and school and tribal administrators. Events will be advertised in literature accompanying Family Packs and in the classroom. Examples of activities to be included in Family Fun Night are interactive booths for taste-testing of low-fat and high-fat foods items, fishing for fruit in a barrel of water, country line dancing, relay races, and distribution of educational materials. A low-fat meal that incorporates traditional American Indian foods also will be served. Attendance and level of participation will be monitored at the entrance and by a registration card given to each attendee to record activities in which they participate.

Another family event, the Family Celebration, consists of a demonstration of Pathways physical activity components by children to parents. Two activities are selected for presentation, giving children and parents an opportunity to share their knowledge and skills.

Development of measurement procedures

During the feasibility phase, instruments and procedures for endpoint and interim measurements were developed. As stated above, the endpoint measure for the study will be PBF, which will be determined by a combination of anthropometric and bioelectrical impedance measurements. Other measurements planned for the full-scale study include knowledge, attitudes and behavior, physical activity (by motion sensor and questionnaire), and dietary intake (by direct observation and 24-hour dietary recall).

Body composition

During the feasibility phase, an approach to assess body fatness in American Indian children was developed.³⁰ Using isotopic dilution as the reference standard, a specific equation to estimate body fat was developed, based on a combination of anthropometric measurements and bioelectrical impedance. Initial variables included six skinfolds, waist circumference, weight and height, and reactance and reactance. Using a stepwise logistic procedure, a regression model was developed to provide optimal predictability with the minimum number of measurement variables. The resulting equation, using bioelectrical impedance, weight, and tricipital and subscapular skinfold, predicts PBF with a root mean square error of 3.2%.³⁰

$$\begin{aligned} \% \text{ fat} = & -0.51 \text{ age} + 0.63 \text{ gender} + 0.46 \\ & \text{weight} + 1.61 \text{ triceps skinfolds} + 0.15 \\ & \text{subscapular skinfold} + 0.56 \text{ S}^2/\text{R} + 0.13 \\ & \text{reactance} - 0.04 \text{ triceps} \times \text{S}^2/\text{R} + 15.75 \\ & (\text{SEE} = 3.4\%) \end{aligned}$$

The following equation was also developed to allow for the estimation of PBF from available BMI data, for comparison purposes:

$$\begin{aligned} \% \text{ fat} = & 0.39 \text{ age} + 3.94 \\ & \text{gender} + 1.46 \text{ BMI} - (2.23 \text{ boys,} + 1.71 \text{ girls}) \end{aligned}$$

(SEE = 4.3%)

Project field workers from all sites were trained at one central location. Separate reliability studies were performed after training. Intraclass correlation coefficients were calculated from pooled data from all trainers using a random effects model. A full set of anthropometric measurements is planned at baseline and at the end of the study. Body weight and height will be collected annually during the study, with the purpose of monitoring the safety of the intervention.

Physical activity

The technical difficulty in measuring free-living physical activity in children has limited the available data on this important component of energy balance.³¹⁻³³ Obtaining quantitative and qualitative information on children's activity pattern and intensity is essential to evaluate the physical activity component of the Pathways intervention. A number of methods were considered, including heart rate monitoring,^{34,35} doubly labeled water,^{36,37} and direct observation. The two first methods were ruled out due to cost and parents' concern regarding attaching electrodes to children (heart rate monitoring) and ingestion of an isotope (although nonradioactive), respectively. Direct observation was considered too intrusive, particularly for after-school monitoring of activity. In the end, two methods for measurement of physical activity were evaluated and adopted: a specially designed 24-hour physical activity recall questionnaire (PAQ), which assesses frequency and type of activities, and a tri-axial accelerometer (TriTrac R3D Research Ergometer) to assess amount of activity.

The Pathways PAQ is adapted from other questionnaires used in studies of children and adolescents.^{38,39} It uses a checklist format to assess physical activity during the preceding 24 hours and is self-administered in groups. Information obtained by the PAQ includes the number of activities before, during, and after school, and the frequency of different types of activities. The intensity of activities can be estimated by using published metabolic equivalent units values for each activity. The PAQ was pilot-tested in 117 third grade children in six of the participating communities.

The second method adopted for physical activity measurement is the TriTrac R3D ergometer (Hemokinetics, Inc., Madison, WI USA). As a tri-axial accelerometer (as opposed to the earlier, two-axial model CalTrac), TriTrac is capable of measuring acceleration in three planes and thus is more sensitive to horizontal movement.^{40,41} Other advantages include small size (4.3" × 2.7" × 1.3"), light weight (6 oz), and solid-state circuitry with no external controls, making it more tamper-proof. The device can accumulate up to 14 days of minute-by-minute activity recordings. A proprietary software program permits downloading of data from the device into a desktop computer and standard spreadsheets for detailed analysis. The TriTrac device was tested in 80 of the 117 children who participated in the PAQ pilot study. Data were collected over two consecutive days following a standard protocol. A comparison between average vector magnitudes by TriTrac and PAQ activity indexes was performed using Spearman rank order correlations. Results showed low correlations for before school and

after school periods, averaging approximately $r = 0.15$, and somewhat higher correlations for the period of time during school ($r = 0.41$). These figures are consistent with previously reported data in older children, ranging from approximately $r = 0.3$ to $r = 0.4$.⁴⁰ It is known that questionnaires give useful information regarding frequency and type of activities, but are of limited value for identifying individual differences in activity. The most important information provided by Tritrac data will be intensity and patterns of activity throughout the day, including before and after school times.

Dietary assessment

The availability of appropriately validated instruments for the assessment of dietary intake in children is limited. Specifically, we are not aware of questionnaires developed for use in elementary school American Indian children. The reliability of adequate survey instruments as well as the accuracy of food composition databases are also limiting factors. Direct observation is a good and reliable alternative to dietary recall,⁴² but may be too intrusive to be used in the household. However, collecting data on food intake during school time is important in the context of Pathways because (1) a significant percent of total daily calories are consumed at school and (2) the dietary intervention aims primarily at changing intake of foods served at the school. Thus, we adopted direct observation as one of the means to assess dietary intake in children, but limited its use to school time. A random sample of 15 third grade children will be selected at each school for direct observation. Trained observers will record students' food consumption during lunch time at the school's cafeteria. At the end of the observation period, all food items left on the tray will be measured.

The amount and type of food consumed after school is obviously important as well. Although our program is school-based, it includes as one objective positively modifying eating patterns at home by providing opportunities for family members to try new foods and learn and use healthy culinary practices. The 24-hour dietary recall is considered the best approach for estimating total dietary intake in population groups.⁴³ During the Pathways feasibility phase, a food record-assisted 24-hour recall was validated relative to direct observation. Percent calories from fat in breakfast and lunch by the recall method had a good correlation ($r = 0.72$) with direct observation. The recall method also was shown to be acceptable to children. The procedures for data collection, training, and certification were also developed, following the guidelines and instruments of the NCC. Because of the cost, this method will be used only for follow-up measurement of dietary intake.

Dietary assessment also will include menu analysis. Data on menus, recipes, and food vendor information will be systematically collected from all schools participating in the full-scale study. This data will be collected at baseline, annually, and at the end of the study. Results will be used to assess the impact of the intervention on dietary energy intake, percent of calories from fat, and other diet-related variables.

Knowledge, attitudes, and behavior

Although the central outcome measure of the Pathways intervention will be body composition changes, determining the impact of the program on behavior and attitudes related to health and nutrition will be important to assess the effectiveness and cultural appropriateness of intervention components. Earlier studies focusing on grade-school children have relied on self-reported measures to assess changes in knowledge, attitudes, and behavior. In the CATCH study, knowledge and self-efficacy about healthful eating in third, fourth, and fifth grade children were measured using a classroom-administered questionnaire.^{44,45} Follow-up studies in that same cohort confirmed the validity of self-reported knowledge, attitudes, and behavior assessment.^{46,47} Based on those and other similar findings, our preliminary conclusion is that a self-reported, classroom-administered questionnaire would be a valid tool for use in the Pathways Study.

The Pathways questionnaire regarding knowledge, attitudes, and behavior is focused on healthy eating and physical activity. Several previously developed instruments were adapted for use, and a few previously tested questions were used intact. However, most of the components of the questionnaire had to be created. The Pathways questionnaire needed to be culturally and developmentally appropriate for third to fifth grade American Indian children and targeted to test the Pathways intervention. The diet-related component of the questionnaire explores what are considered to be determinants of risk behaviors underlying obesity. It also is based on those changes emphasized in the intervention, such as reducing dietary fat intake and consumption of sugary drinks. Target outcomes include knowledge of high-fat foods, self-efficacy to make healthy food choices, perceived social support for eating healthful foods, and intentions to choose healthful foods. The physical activity portion of the questionnaire covers four categories of factors: physical activity self-efficacy, social support for physical activity, perceived barriers to activity, and physical self-perception.

Starting from a set of 248 questions, the instrument used to measure knowledge, attitudes, and behavior was eventually reduced to 170 questions. Further reductions in this total are anticipated before its final form is defined for the full-scale study. Face validity was tested in a pilot study involving 32 children, and using 64 questions, in a semi-structured interview format. A larger subset of 130 questions was subsequently pre-tested in two classrooms at one of the field centers.

Process evaluation

The goals of process evaluation are to link impact and outcome data to intervention activities, to help interpret the mechanisms causing observed changes brought about by the intervention.^{48,49} This measurement activity will be an important component of the full-scale assessment. Process evaluation will provide the basis for determining the degree of implementation of the program and the type of constraints that individual activities face within the school

environment. Therefore, it is closely associated with quality control activities.

During the feasibility phase, the scope of process evaluation activities was defined, and the instruments for data collection were developed and tested.

The Pathways process evaluation is based on dissemination and diffusion theory, SLT, and the desire for triangulation of multiple modes of data collection. The process evaluation will systematically document (1) the training process and content; (2) the implementation of the intervention components, within and between sites; (3) the attitudes of school personnel to the intervention; (4) the exposure of staff, family, and students to the intervention components; and (5) the role of the field personnel and other conditions affecting the implementation of the intervention at each site.

Safety

During the feasibility phase there were no major concerns about the potential adverse effects of the intervention, because only limited components were implemented for short periods of time. However, for the 3-year full-scale intervention, the possibility of adverse effects should be considered. Although the Pathways program is not aimed at reducing total dietary energy intake, it is possible that reductions in the energy density of food items, due to their reduction in fat content, may lead to a decrease in the total daily energy intake. Combined with an increased energy expenditure caused by the physical education component of the program, this could theoretically lead to a negative energy balance and the consequent deceleration of growth velocity.

The Pathways food service intervention aims at providing a diet with no more than 30% of total calories derived from fat. The data from menu analysis in the feasibility phase indicate that a full implementation of the Pathways program may result in diets having fat-derived calories as low as 25 to 28%. Thus, one safety consideration is whether any adverse effect might be expected from this change. In the Dietary Intervention Study in Children (DISC) study,⁵⁰ dietary energy from fat was reduced from 33 to 34% at baseline to 28% at follow-up, although total caloric intake remained the same. Measurements at 1 year and at the end of the 3-year follow-up showed no differences in height, body weight, BMI, or sum of skinfolds between intervention and control groups. In the Bogalusa longitudinal study, there were no differences in weight or height between children consuming 30% or less calories from fat, compared with those consuming more than 30%.⁵² These results, along with the expert views of a number of committees and organizations, indicate that the reduction in percent of dietary fat-derived calories is not necessarily associated with adverse effects on growth. Of course, the Pathways food service intervention will comply with all dietary guidelines for healthy children regarding total calories and macronutrient and micronutrient levels.

Conclusions

During the feasibility phase, the four components of the intervention and the instruments for measurement were

developed. Pilot tests were performed to validate the use of these instruments in elementary school American Indian children. The feasibility phase also allowed for the development of stable field teams and for building a close working collaboration with school staff and educational and tribal authorities.

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