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Design, implementation, and quality control in the Pathways American-Indian multicenter trial

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Abstract

Background—Pathways was the first multicenter American-Indian school-based study to test the effectiveness of an obesity prevention program promoting healthy eating and physical activity.

Methods—Pathways employed a nested cohort design in which 41 schools were randomized to intervention or control conditions and students within these schools were followed as a cohort (1,704 third graders at baseline). The study's primary endpoint was percent body fat. Secondary endpoints were levels of fat in school lunches; time spent in physical activity; and knowledge, attitudes, and behaviors regarding diet and exercise. Quality control (QC) included design of data management systems which provided standardization and quality assurance of data collection and processing. Data QC procedures at study centers included manuals of operation, training and certification, and monitoring of performance. Process evaluation was conducted to monitor dose and fidelity of the interventions. Registration and tracking systems were used for students and schools.

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Results—No difference in mean percent body fat at fifth grade was found between the intervention and control schools. Percent of calories from fat and saturated fat in school lunches was significantly reduced in the intervention schools as was total energy intake from 24-hour recalls. Significant increases in self-reported physical activity levels and knowledge of healthy behaviors were found for the intervention school students.

Conclusions—The Pathways study results provide evidence demonstrating the role schools can play in public health promotion. Its study design and QC systems and procedures provide useful models for other similar school based multi- or single-site studies.

Keywords

Multicenter trial; Quality control; American-Indian students; Schools; Diet; Physical activity

Introduction

The key to health promotion and disease prevention in the 21st century is to establish policies and environments that support positive health behavior and healthy lifestyle [1,2]. The biomedical, behavioral, social, and political sciences are increasingly recognizing the interactions and interdependence among genetic, biological, behavioral, environmental, and sociocultural processes involved in health, disease, and public health practice [3–10].

Ten leading health indicators for improving our Nation's health are included in the recent release of Healthy People 2010: Understanding and Improving health [1]. Two of the 10 health indicators are (1) physical activity and (2) overweight and obesity. A companion document, Healthy People 2010: Objectives for Improving Health [11], contains 467 objectives to improve our nation's health. The objectives are organized into 28 focus areas including three important areas: (1) nutrition and overweight, (2) physical activity and fitness, and (3) educational and community-based programs. The objectives focus on the determinants of health which are envisioned as the combined efforts of individual and community physical and social environments as well as the policies and interventions used to promote health. Another closely linked national effort related to improving our Nation's health is the new Guide to Community Preventive Services [2,12] which provides evidenced-based practice for effective public health interventions and strategies including physical activity [13].

Our nation's schools provide an existing infrastructure for reaching culturally and economically diverse youth populations in urban, suburban, and rural settings for public health promotion [5,11]. It is therefore important to provide evidence from well-conducted research studies on the effectiveness of school-based intervention for diet, physical activity, and obesity prevention as well as provide mechanisms for dissemination of tested programs and materials [10,14–19]. The National Heart, Lung, and Blood Institute (NHLBI) has supported numerous school-based research studies over the past several decades that have provided evidence-based findings for public health practice [4,15,20]. More recently, NHLBI has supported three challenging multicenter collaborative school-based trials, each with a different population and study endpoints. The first was the Child and Adolescent Trial of Cardiovascular Health (CATCH), which started in 1986 with a feasibility phase followed

by the main trial (1991–1994). Trial results and a 3-year follow-up have been reported [21–26]. The second was the Pathways study which began in 1993 and involved American Indian students attending elementary schools [17,27–30]. The third and most recent of the multicenter studies, Trial of Activity for Adolescent Girls (TAAG), was launched in 2000 and will report results in 2006. It involves testing strategies to prevent the decline in physical activity in middle school girls from diverse ethnic/racial backgrounds at six study centers located in Arizona, California, Louisiana, Maryland, Minnesota, and South Carolina.

The purpose of this article is to provide a brief overview of the Pathways study design and results, with particular attention to its quality control (QC) procedures. Aspects of QC include design of the data management system, data QC procedures at the study centers and Coordinating Center (CC), and registration and tracking systems. Study center QC procedures include manuals of operation, training and certification, and monitoring of performance. The organizational structure for the trial and recommendations concerning contributions to the field are addressed.

A brief overview of the Pathways Study

The Pathways Study was launched in 1993 as a field trial to test the effectiveness of a multicomponent school-based program intended to reduce the prevalence of obesity in American-Indian students by focusing on healthy environments as well as diet and physical activity. In the first (feasibility) phase (1993–1996), formative assessments and pilot studies were conducted to enable development and testing of the various parts of the intervention program and to produce a reliable methodology for estimating percent body fat (PBF) in American-Indian children and other measurement instruments and protocols. The second phase comprised the full-scale trial (1996–2000).

The Pathways design and results have been reported elsewhere [17,18,27,31]; the following is a brief summary. The feasibility study was implemented in eight schools at four study centers located in Arizona, New Mexico, and South Dakota. During Phase 2, the main trial was conducted in 41 different schools at the same sites. The study centers were Gila River Indian Community/University of Arizona, who partnered with the Gila River Indian Community and the Tohono O’odham Nation; Johns Hopkins University, who partnered with San Carlos Apache and White Mountain Apache Tribes; the University of Minnesota, who partnered with Sicangu Lakota and the Oglala Lakota Tribes; and the University of New Mexico, who partnered with the Navajo Nation. The CC was located at the University of North Carolina.

Eligibility criteria were established for selection of schools in the study. They were (1) projected enrollment of at least 15 children in third grade; (2) at least 90% of third graders were American Indians; (3) retention rates from third to fifth over the past 3 years at least 70%; (4) school meals prepared and administered on site; (5) existence of facilities for physical activity programs; and (6) approval of the study by school, community, and tribal authorities [31]. The number of schools varied by study center and ranged from 14 to seven schools per center. The schools included public, parochial, Bureau of Indian Affairs (BIA), and contract including several residential programs.

There were 1,704 students in the baseline cohort. As shown in Table 1, the average age of the students was 7.5 years. The genders were nearly equally divided with 881 boys (52%) and 823 girls (48%). The number of students per study center ranged from 526 students to 240. Randomization of schools occurred after all the baseline measurements for body composition were completed at the end of second grade. At the fifth grade follow-up, 84.9% of the students at baseline (1447/1704) were measured. This included 76.1% of the students in the schools and 8.8% who were tracked and measured outside a Pathways school. The study design employed in Phase 2 was a group-randomized trial; more specifically, it was a nested cohort design in which schools were randomized to study conditions and students within those schools were followed as a cohort to assess the effects of the intervention [27,32,33]. Twenty-one schools were randomly assigned to the intervention arm and 20 schools to the control arm. All eligible students were measured (height, weight, subscapular skinfold thickness, and bioelectric impedance) at baseline and again in the spring of their fifth grade year to obtain estimates of initial and final PBF values. The schools in each site were ranked according to their median levels of baseline PBF and divided into two equal sized groups, one half above and one half below the community median, defining two strata. Schools were randomly assigned within strata to the control and intervention arms of the study.

The intervention programs were implemented at school during third through the fifth grades. The four components were food service, skills-based classroom curricula, family, and physical education (PE). The program was designed to change school environments, to increase knowledge and improve attitudes about healthy eating and exercise, and to modify behavior toward healthier food choices and an increased level of daily physical activity. The impact of these interventions was gauged as differences, at fifth grade follow-up, between means for intervention and control students in measurements of: (1) energy and fat content in school lunches from menu analyses; (2) energy and fat content in meals from a 24-hour recall questionnaire and from school lunch observations; (3) physical activity levels measured by motion sensors worn for a 24-hour period and by questionnaire; (4) knowledge of the health promoting contents of the intervention curriculum in each school year measured by test questionnaire; (5) attitudes measured by self-efficacy scores on physical activity and food choice questionnaire; and (6) reported behavior concerning food choice intentions. The efficacy of the intervention in decreasing PBF was gauged by comparing the mean PBF values at follow-up in the intervention and control schools adjusted for the respective baseline means. Analyses were based on mixed-model regression methods appropriate to data from a nested cohort design [27,29,32,34]. In addition, the family component assessment included attendance rates at each family event, survey data from parents and students who attended, and the number of completed home-based activities reported.

Although no mean PBF difference was found between the two study arms, the results on certain secondary end-points suggested other significant effects from the intervention. Total and saturated fat was reduced in school lunches. There was a significant increase in knowledge between intervention and control for the classroom curricular units. Students in the intervention schools reported consuming fewer calories from fat with 28.3 vs 32.4 for control ($P < 0.005$) as measured by both 24-hour recall and school lunch observation. Also,

intervention school students reported, by questionnaire, healthier food choice intentions ($P < 0.001$), a greater knowledge of the elements of a healthful diet, and more physical activity than those in the control schools. No significant difference was found between the study arms for physical activity and PE [31,35–43], except for self-report.

Trial organization

Governance and administration

The administrative and governance structure of the trial was designed to ensure effective collaboration and communication among the four study centers, the Coordinating Center (CC), and the NHLBI program office. Investigators from each of the participating centers were involved in the planning and development phase of the trial and contributed to the protocol which included the study design. All the study sites adhered to a common study protocol for training, implementation of the interventions, data collection, data management, and quality control procedures. The funding mechanism was a cooperative agreement.

The Steering Committee was chaired by one of the principal investigators for both the feasibility study and the main trial. It was comprised of the five principal investigators, two American-Indian staff who were elected annually by the Seven Nations Committee, and the NHLBI program scientist. Each of the study centers and the CC had a project coordinator. As shown in Fig. 1, the work of the Steering Committee was conducted through six formal committees including Seven Nations, Design and Analysis, Measurement, Intervention, Presentations, and Publications and Project Coordinators. Numerous working groups reported to either the Intervention or Measurement committees.

The administrative procedures for the content of a collaborative multisite trial specified that the NHLBI Director appoint a Data and Safety Monitoring Board (DSMB) that included expert scientists in relevant fields. The six members of the DSMB met semiannually or annually and were charged with reviewing the protocol, data on recruitment and retention, quality control, adherence, and adverse events and safety, as well as management systems and study results. They monitored children’s growth for safety of the dietary modifications and possible injuries from increased school physical activity.

Study center organizational structure

As shown in Fig. 2, the structure and function for each study center was designed to facilitate, schools, tribes, and study-wide communications. Career development including advanced degrees, continuing education, and other training for staff hired from the local areas were important aspects of the field trial [44]. The intervention and measurement staff was organized into two separate teams to remove potential observational biases from staff who implemented the multilevel intervention components. Liaisons with tribal councils, school administrators, school boards, and family members were conducted at each study center to meet site-specific needs and policies.

Data management and quality control

Systems for data management and quality control were a critical and fundamental part of all research protocols and helped assure accuracy, precision, and completeness of data collection. This section describes the specific strategies adopted to establish and maintain standard study center procedures, an efficient data management system, data quality control, and data auditing procedures as well as a registration and tracking system.

Data management system design

The distributed data management system (DMS) provided the capabilities required for data entry and management. Functions included entry and validation, inventory, transfer, security and confidentiality, and retrieval and archiving of all data, as well as database updating and closure. The DMS was developed and maintained by the CC. The majority of Pathways data was entered at each field center where local databases were maintained and archived. The complete study database maintained at the CC was updated by data transfers from the field centers with scheduling driven by the data collection periods.

The DMS was flexible enough to handle a variety of data sources, and robust enough to allow for management of data from various subject units or respondents including individuals (students, family members, school staff) and groups (classrooms and schools). Data on body composition, knowledge, attitudes, and behavior (KAB) questionnaire and process evaluation interviews were collected on paper forms. Electronic data files were downloaded from the Tri-Trac-R3d research accelerometers used to record 24-hour physical activity levels. The DMS also could transfer coded records from the Nutrition Coordinating Center (NCC) to the CC on school lunch observations, 24-h recalls, and menu and recipe information on school lunches and breakfasts.

The DMS was required to mesh with a variety of institutional facilities, operational procedures, and staff capabilities at the participating centers while providing the necessary standardization and quality assurance in data collection and processing. To accomplish this, the CC provided documentation, and user support and training for the Pathways data entry system included instruction, demonstration, and hands-on practice with data collection instruments. Staff participating in the CC training sessions were evaluated and certified in the use of the data entry system.

The DMS allowed field centers to locally generate a variety of summary reports on data completeness, outstanding questionable values, etc., enabling each center to monitor the quality of its performance. This facilitated timely identification and resolution of problems in data collection and processing. In addition, the CC routinely generated reports concerning data quality (missing or overdue forms, outstanding queries, etc.), which in turn facilitated timely review, correction, and resolution of data quality issues. Another important feature of the system was the use of identifier labels and lists with a variety of sort options. Prior to conducting specific measurements in a school, the DMS provided appropriate lists and labels by school, grade, and classroom, including the location of cohort students and their eligibility status.

Data entry quality control procedures

The DMS required that initial entry of data from each type of form be done using an inventory system with identification, form code and version, and grade/semester time edit checks. The data entry system displayed screens that closely resembled the paper data collection forms. The system was menu driven with context-sensitive help available at any time. All data entry fields featured automatic editing checks that monitored range, skips, and nonentries (where a valid response was mandatory). Data verification was done by independent rekeying by a second member of the field center staff. Each data value was validated (edited) during entry. The system was configured to allow users to update data values as appropriate. A journal file of transaction records of all updates to the field center database was maintained to provide an audit trail of data entry processes. This enabled monitoring of the data processing activities and restoration of the database in the event of an emergency. At designated times driven by the data collection schedule the staff at study centers used a data management system option to create a data transfer diskette containing copies of all records added, changed, or deleted since the last transfer. This diskette was mailed to the CC, where the study database was updated and maintained with daily backup procedures and appropriate storage. Before each major analysis, the database would go through a series of closure checks to insure the completeness and correctness of data processing. These checks were performed on a frozen version of the database at a specific point in time; this assured that all forms had been received and processed, and that all queries were resolved.

Data auditing

During the 3-year Pathways feasibility phase the CC requested copies of body composition data collection forms from a minimum of 5% random sample from each site. Data from these forms were entered at the CC. This comparison provided the CC with an audit of data entry procedures and confirmation that the DMS verification procedures provided the requisite level of data quality. Additional audits at the CC were conducted during routine data management and analysis procedures. These included inspection of missing data patterns and review of tabulations and data distributions to identify outliers across subjects and sites and within subjects over time.

Registration and tracking

Registration and tracking forms were designed to identify and track students, classrooms, teachers, and schools during the main trial. Student, classroom, and school tracking forms were completed at the beginning of each school year and updated throughout the year. The registration and tracking of students as they moved from grade to grade, into different classrooms within a school, and even into different schools over the years of data collection were key elements of the study’s data inventory, management, and reporting capabilities.

Table 2 presents the numbers of second graders registered at the 41 Pathways schools in spring 1997 and the resulting Pathways cohort of 1,704 students. The baseline cohort was defined as where students with parental consent and complete measures for body composition. Table 3 presents the retention and attrition rates of this cohort over the 3 years

of data collection. The follow-up retention rate for measurements in the spring of 2000 at the end of interventions was 76.1%.

The tracking of students provided current grade and classroom locations for measurement lists and labels, and a current record of parental consent for the different measurement units, and allowed monitoring of expected numbers of measurements. Additional student tracking procedures were implemented to follow cohort students who left a Pathways school during the study. During the final measurement, students who remained in the general location of the field center were controlled and measured whenever possible. This tracking permitted the measurement of additional cohort students who would otherwise have been lost to follow-up [31].

In addition to student level data, classroom level data including the physical education (PE) calendars and teacher interviews was collected throughout the study. Yearly registration and identification assignment forms for each classroom containing at least one Pathways cohort student was required. Similar to student tracking, classroom tracking included updating the information throughout the year. School level registration and tracking included changes in a school's administration (principal), food service staff, PE specialists, and classroom teachers. Each student's form contained a link to his or her classroom; this link provided identification of each cohort student's location and verification that all intervention teachers had been trained and certified to teach the Pathways' curricula.

Study center quality control procedures

To ensure accurate, standard, and consistent measurements throughout the multicenter study, a variety of standard procedures were used. These included the documentation of measurement protocols, preparation of detailed manuals of operations, establishment of training and certification procedures, and performance monitoring.

Manuals of operations

All measurements required a manual of operations outlining the procedures needed to implement the protocol. The documentation ensured standardized procedures across the sites throughout the duration of the study. Each measurement component had its own manual that was reviewed and updated annually as necessary to accommodate different grade levels. Manuals contained requirements for cohort identification, random selection procedures when necessary, equipment, and material. They also specified staffing requirements and responsibilities, detailed measurement procedures, training and certification requirements, forms describing procedures for data recording, and all quality control procedures associated with intervention and measurement.

Training and certification

Quality control for body composition assessments—Before baseline and final measurements were conducted, centralized trainings were held to provide instruction, practice, and feedback on two skinfolds, height, weight, and bioelectric impedance measurements. Each trainee was certified for all body composition measurements after 12 hours of training and completing measures on approximately six subjects not in the cohort.

For body weight certification, agreement was within 0.5 kg for each subject and within 0.3 kg for the mean of the group. For height, agreement between expert and trainee had to be within 1 cm for each subject and within 0.5 cm for the mean of the group. For skinfold certification, agreement was within 30% for each subject and 20% for the mean of the group. For bioelectric impedance, agreement was within 20 ohms for each subject and within 10 ohms for the mean of the group.

During the baseline and final measurements, a minimum of 5% of the children at each school were measured again by an independent measurer and the paired measurements were monitored by the CC and used to direct additional training for field center staff as needed. During both the baseline and final measurements, a trained member of the CC visited each study site to ensure that the protocol was followed during the testing period.

Dietary interviewer training and certification procedures for menu and recipe data collection—Staff from the University of Minnesota Nutrition Coordinating Center (NCC) conducted 2-day central training workshops annually. The training incorporated practice in completing the forms in the School Food Service Data Collection Notebooks and methods for collecting data from the school food service staff. On completion of the training workshop, dietary interviewers were required to complete certification activities.

Quality assurance of menu data at the Nutrition Coordinating Center—Upon receipt of the School Food Service Data Collection Notebooks, NCC Quality Control Nutritionists screened the incoming forms for completeness of information. Inquiries were sent to site lead nutritionists to complete missing information and to clarify ambiguous items. Information was then entered into the nutrition data system and the data entry for each menu was checked for accuracy. Food and nutrient outliers were generated and menus were corrected as needed.

Dietary interviewer training and certification procedures for 24-hour dietary recall data collection—Staff from the NCC conducted a 3-day central training. The workshop included exercises designed to help the interviewers become familiar with the Nutrition Data System for Research dietary data collection software. Exercises also promoted skill in data entry, checking food service data for completeness and accuracy, and data management. Following the training, interviewers were required to successfully complete a series of exercises including two recalls collected with NCC training staff.

Quality assurance at the Nutrition Coordinating Center—All dietary recall forms were checked for completeness and accuracy at the NCC. Notes and missing foods were resolved. Food and nutrient data outliers were tabulated and the 24-hour recall data were further examined for possible entry errors. Dietary inquiries were sent to both the site lead nutritionist and the interviewers for resolution of immediate problems. Corrections were made and final checks conducted before sending the dietary data to the Pathways CC.

Quality assurance for administration of questionnaires—The Knowledge, Attitudes, and Behaviors and 24-hour Physical Activity Questionnaire were administered in a classroom setting four times during the study. A team of at least two trained Pathways staff

members served as proctors and administered the questionnaires in two 30-minute time periods. A train-the-trainers model was used to train proctors and administrators at each site. At least one trainer from each site participated in a central training and these trainers conducted local on-site trainings. Primary to these trainings was the requirement that each administrator and proctor practice the entire questionnaire in the presence of the trainer. Certification was granted to those attending the training who were judged capable of fulfilling the required positions. Quality control requirements included the collection of questionnaires from at least 80% of the eligible cohort and 70% with no more than five missing responses.

Quality assurance for TriTrac data collection—At baseline, TriTrac accelerometers were used for assessing physical activity in 15 randomly selected students in each of the 41 schools. The end-of-study measurement consisted of all available students from the original baseline sample, supplemented by randomly selected additional students as needed, to obtain a total of 15 per school. The CC provided the central training for the TriTrac measurements. A minimum of three data collectors was required to be trained for each measurement team with two members required for the actual data collection in any school. Training consisted of review of the procedures manual and data collection forms as well as how to operate the laptop computers using TriTrac hardware and software required for initialization and subsequent file retrieval. Team member certification required the collection of TriTrac data on five subjects within 2 weeks of the initial training session. Certification data was sent to the CC for verification as specified in the study procedures. In addition, each trained technician collected data on two persons during each week prior to actual data collection to insure sufficient practice and experience with the equipment and procedures. A final booster training conference call prior to each site's data collection completed the certification procedure. Quality control for TriTrac data collection consisted primarily of the training and certification procedures and the site monitoring that occurred during data collection.

Performance monitoring

Site visits—Data collection took place primarily during an 8-week window in the spring of each year. CC staff made a site visit to each study center during the baseline and end-of-study data collection periods. During these site visits, measurement activities were observed in at least one school at each site. Additionally, observations were made on (1) adherence to measurement protocols; (2) student identification and labeling of forms; (3) recording, collation, processing, and filing of data; and (4) confidentiality of procedures to preserve data. In addition, the CC staff verified participant consent; trained and certified data collectors on the measurement teams, and ensured that all quality control procedures were appropriately followed. CC staff met with each measurement leader during their visit and discussed any significant deviations from protocol or other concerns to ensure immediate action and resolution. The CC then sent copies of the site visit report to the NIHLBI staff responsible for oversight of the conduct of the trial and to the Principal Investigator of the site visited.

Conference calls—During the data collection period, the Measurement Committee held weekly conference calls involving the CC and staff from each site. During these calls, a staff

member at each site reported on collection schedules and any past week activities. The Quality Control Working Group reviewed data and performance reports regularly and reported to the Measurement Committee.

Internal performance monitoring—Each field site had a measurement coordinator who oversaw the body composition measurements, administration of the questionnaires on knowledge, attitudes, and behavior and physical activity, and Tri Trac data collection, and a nutrition coordinator who oversaw the lunch observation, school menu, and 24-h dietary recall data collection. These supervisors were responsible for assuring that their site followed all appropriate procedures for specific data collections and QC procedures, and for conducting subsequent additional training when necessary.

Mean errors for body composition measurements—A minimum of 5% replicate samples was taken. In all, 132 replicate measurements were made at baseline and 196 during final data collection. The percent difference between each original and replicate measurement (as a fraction of the original measurement value) was used as the index of measurement error. Table 4 displays the mean values of the original and replicate measurements and the mean percent error at baseline and at end of study. For both baseline and follow-up the mean values of all original and replicate measurements were not significantly different ($P > .05$). A high level of reliability in the measurements of height, weight, and resistance at both times is evident from their very small values of mean percent error. Reactance and the two skinfold measures exhibited a greater degree of discrepancy between the original and replicate measurements, reflecting the greater variability inherent in making these measurements. The mean percent errors at end of study for all measures were smaller than those at baseline, suggesting that experience gained at baseline improved reliability at the end of study. There were no significant site differences in mean percent errors at baseline or follow-up for any of the measures (data not shown).

Process evaluation—Extensive process evaluation was conducted throughout each year of the trial to monitor participation, dose, fidelity, and compatibility of the programs to the intervention schools. The evaluation design and the data collection instruments and questionnaires used are reported in detail elsewhere [28,36,38,39–42]. Process data was a key component of reports used by the Quality Control Working Group to assess the delivery of Pathways interventions [42].

Conclusion

Pathways was a multicenter collaborative school-based research study conducted in American-Indian schools located primarily in rural settings. The design of the trial was theory-based across interventions and measurement. Schools were the unit of randomization, but measurements were made at multiple levels over several years which presented numerous challenges in designing and implementing the study [45,46]. The data management systems, quality assurance monitoring activities, standardized manuals of operating procedures and training, and study governance have been addressed in this paper. The following are 10 key aspects of the study that we believe make important contributions to other researchers and practitioners in the field: (1) Pathways was the first school-based

field trial conducted with a partnership of tribal governments, school administrators, parents, students, and academic research teams involving American-Indian researchers and study staff. (2) The basic design was a group randomized trial. This approach involved schools as the unit of randomization and analysis. (3) Reliable results were assured through an emphasis on quality control throughout all phases of staff training, field measurements and observations, and data entry. (4) The multiple levels of interventions were coupled with appropriate multiple levels of carefully planned measurements. (5) The interventions were primarily delivered by existing school staff who received standardized training. (6) A process evaluation system was developed and conducted to compliment the overall trial study design. Many of the process measures were part of quality control procedures for the trial. (7) The classroom curricular units were based on a needs assessment and pilot testing with elementary teachers and American-Indian students from the same areas where the main trial was conducted. The three classroom curricular units were based on theory and skills, developmentally appropriate, and designed to incorporate American-Indian culture and traditions. A unique companion to the classroom curricula was an *Exercise Break Box* that contained activity breaks to be used during class time and recess. In addition, take home *Family Packs and Family Events* were implemented despite the many challenges of transportation and distances. (8) The Pathways Food Service intervention was an excellent example of adapting and testing an approach for school food service change that had been shown to be effective in the previous school-based CATCH trial. (9) The PE intervention included a resource binder of *Modified American Indian Games* that was used with an existing commercial PE curriculum called SPARK. (10) Lastly, the intervention materials have been prepared for dissemination via the following website: (http://hsc.unm.edu/pathways).

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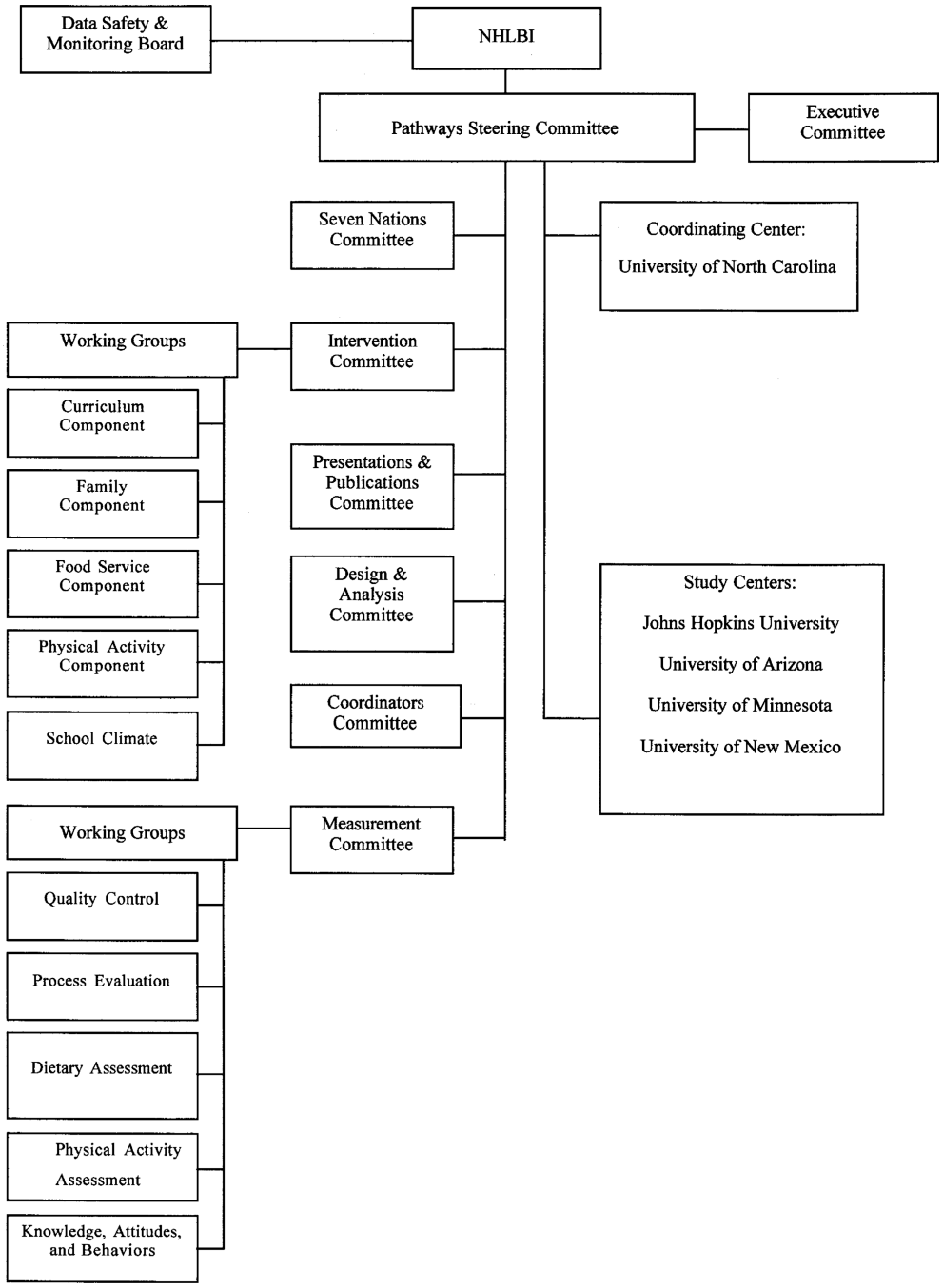

Fig. 1.
Organizational chart for Pathways study.

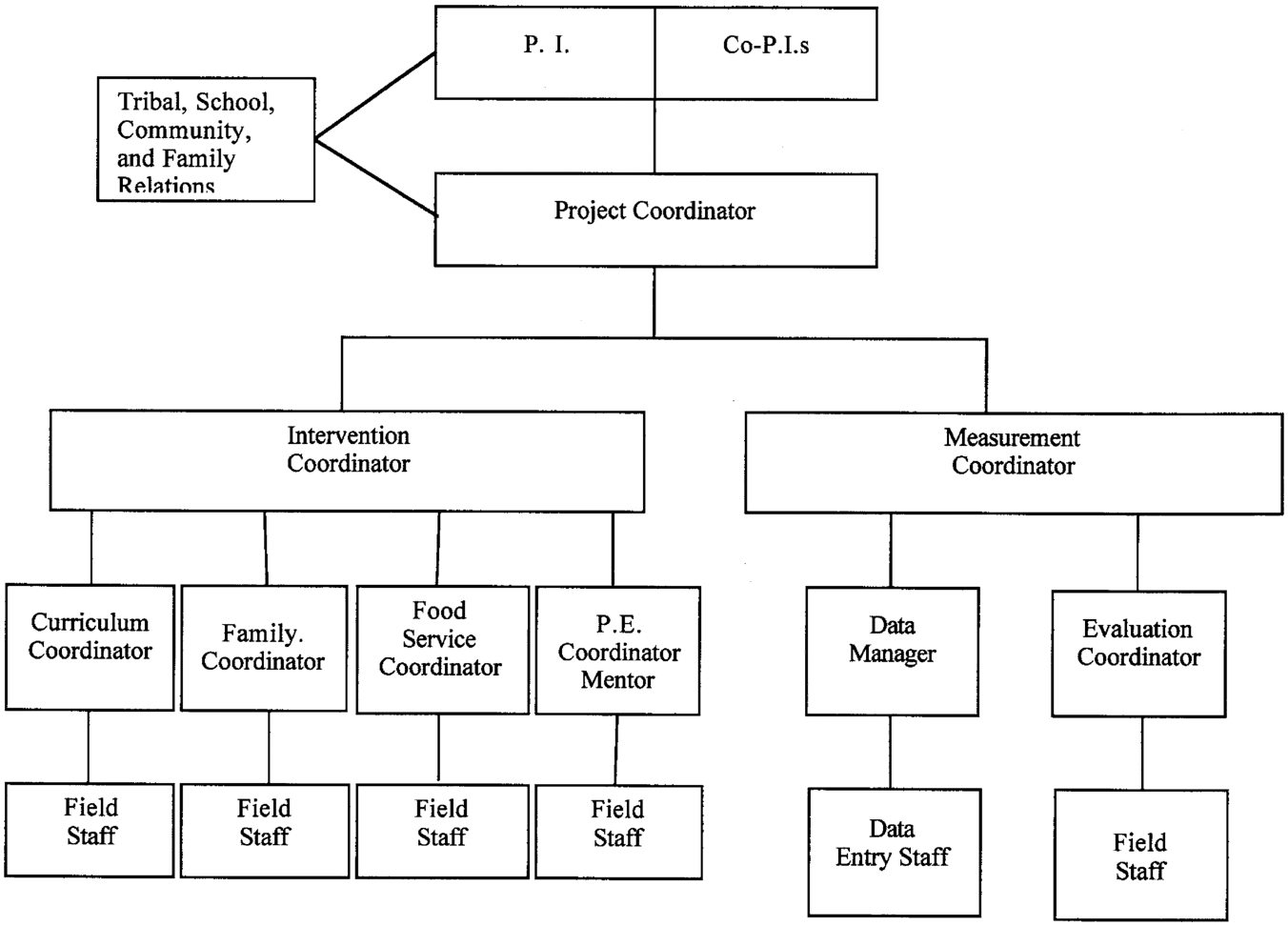

Fig. 2.
Organizational chart for Pathways study centers.

Table 1

Gender and age of cohort students at baseline by study centers

	JHU (White Mountain and San Carlos Apache Tribes)	GR/UA (Gila River and Tohono O'odham Nation)	UM (Oglala and Rosebud Sioux Tribes)	UNM (Navajo Nation)	Total
Male	263	125	230	263	881
Female	215	115	220	273	823
Total	478	240	450	536	1,704
Mean age	7.5	7.7	7.7	7.4	7.5
SD age	0.58	0.62	0.66	0.55	0.61

Note. JHU, Johns Hopkins University; GR/UA, Gila River Indian Community/University of Arizona; UM, University of Minnesota; UNM, University of New Mexico.

Table 2

Number of eligible students and Pathways cohort, by treatment

	Intervention		Control		Overall	
	N	%	*N*	%	*N*	%
Second grade students registered—spring 1997	1,044	100.0	1,015	100.0	2,059	100.0
Body composition consents	911	87.3	849	83.6	1,760	85.5
Body composition measurements	879	84.2	825	81.3	1,704	82.8

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Table 3

Retention/attrition of Pathways cohort students, by treatment and school year

	Intervention		Control		Overall	
	N	%	*N*	%	*N*	%
Spring 1997 baseline	879	100.0	825	100.0	1,704	100.0
Fall 1997–Spring 1998 (year 1)	742	84.4	728	88.2	1,470	86.3
Fall 1998–Spring 1999 (year 2)	691	78.6	696	84.4	1,387	81.4
Fall 1999–Spring 2000 (year 3)	644	73.3	653	79.2	1,297	76.1
Measured outside Pathways school (year 3)	96	10.9	54	6.5	150	8.8

Table 4

Quality control (QC) statistics by collection period for body composition

	N	Original mean	Replicate mean	Mean percent error
Height (cm)				
Baseline	131	129.6	129.5	0.30
End of study	196	146.8	146.8	0.20
Weight (kg)				
Baseline	132	31.9	31.8	0.34
End of study	196	46.1	46.1	0.18
BMI (kg/m^2)				
Baseline	130	18.6	18.6	0.74
End of study	196	21.1	21.1	0.46
Triceps skinfold (mm)				
Baseline	130	12.6	12.6	7.62
End of study	195	16.1	16.2	5.98
Subscapular skinfold (mm)				
Baseline	129	10.1	10.1	7.91
End of study	195	13.7	13.8	7.29
Reactance (ohms)				
Baseline	131	86.0	87.9	5.55
End of study	188	85.1	85.4	3.48
Resistance (ohms)				
Baseline	131	712.5	711.4	1.35
End of study	194	680.2	678.1	1.16

Note. Percent error = 100 × absolute value (original – replicate)/original.