Section B

Introduction

B.1. Respondent Universe and Sampling Methods

Three hundred sixth grade students and parents will be recruited in 3 Baltimore City middle schools in the fall of 2006. Two hundred and seventy-seven seventh graders for whom burden hours are requested are currently study participants. The sex and race composition of the sample of youth already enrolled in the study closely resembles the composition of the respondent universe, with 93% African American, and 3% White and 4 % other groups in response to the race item, and 10% Hispanic in response to the ethnicity item. Parents report similar ethnicity as their youth. All incoming 6th grade youth and their parents will be eligible to participate in the study. Estimates of the sex and race compositions of the respondent universe for the middle school are provided below. These estimates are based on 6th – 8th grade enrollment in the 2005-2006 school-year.

Response Universe of Participating Schools (all grades, 2005-2006)

	School 1	School 2	School 3
Sex	N =499 (%)	N =849 (%)	N=952 (%)
Males	247 (49.5)	444 (52.3)	500 (52.5)
Females	252 (50.5)	405 (47.7)	452 (47.5)
Race/Ethnicity			
American Indian or Native Alaskan	0 (0.0)	10 (1.2)	0 (0.0)
Asian	0 (0.0)	1 (0.1)	1 (0.3)
Native Hawaiian or Pacifica Islander	0 (0.0)	0 (0.0)	0 (0.0)
Black or African American	498 (99.8)	754 (88.8)	251 (65.0)
White	0 (0.0)	43 (5.1)	131 (33.9)
Hispanic or Latino	1 (0.2)	41 (4.8)	3 (0.8)
Enrollment by Grade			
Grade 6	168 (34)	235 (28)	294 (31)
Grade 7	171 (34)	285 (33)	318 (33)
Grade 8	142 (28)	329 (39)	340 (36)

Source: Baltimore city schools, school profiles.

http://www.bcps.k12.md.us/Student_Performance/test.asp?schoolnum=DAS.

Accessed June 22, 2006.

B.2. Information Collection Procedures/Limitations of the Study

Design

A randomized trial will be conducted to determine the efficacy of an intervention designed to increase academic engagement, reduce/prevent aggression, and improve interpersonal relationships among high-risk early adolescents. The small scope of the study is justified because the intervention has not been previously rigorously tested.

Procedures

Incoming sixth graders and their parents will be recruited in 3 Baltimore, Maryland middle schools (see **Attachment 8** for letters of concurrence**)**. Presentations promoting the study will be made during school orientations in the Spring of 5th grade and Fall of 6th grade.. Research assistants will explain the study to the parents and youth and answer any questions that they have at 6th grade orientation. Research staff will also visit 6th grade classrooms to encourage student participation and answer student questions. Staff will also attend school events (e.g. back-to-school night, parent report card pick up) to which parents have been invited, in order to increase familiarity with the study, encourage participation, and give opportunities to provide consent. Interested families will provide written parent consent, early-adolescent assent, contact information, and demographic information (see **Attachment 4**).

Johns Hopkins University School of Medicine (JHU) is responsible for data collection. All youth surveys will be administered by research staff in the schools on personal computers (see **Attachment 3**). All interviews with parents will be conducted over the telephone by a CATI service. Parents and youth will be randomly assigned to the special intervention or comparison groups and complete baseline assessments in the Fall of 6th grade. Youth will be surveyed subsequently in the springs of 6th and 7th grades. Variables of interest include youth behavior related to academic engagement and aggressive and deviant behavior, youth attitudes and expectations, social skills, intent/motivation, and social competence related to school and aggressive and deviant behavior, as well as parent attitudes, expectations, and involvement related to youth academic involvement and aggressive and deviant behaviors (see **Attachment 2**). We will examine school disciplinary records from the participating middle schools for adolescents involved in the study at the end of each academic year.

Sample Size/Power

We currently have 660 students in the sample. Our retention rate from the baseline to first follow-up, based on the first two years of data collection, has been 82%. We are recruiting an additional 300 youth, adding an estimated 198 to the sample, using the 66% average response rate from previous years. This will bring the total estimated sample to 858, with a program evaluation sample of 703, given an 82% retention rate. We currently have 253 parents in the sample, and would expect to add 144 parents, given the 48% average response rate for an estimated total of 397parents in the final sample.

Two primary outcomes of interest are overt aggression (OA) and relational aggression (RA) (Little et al. 2001). Using means (OA=1.30, RA=1.35) and standard deviations (OA=. 39, RA=. 39) from a similar population (Little, personal communication, 1/28/03), an estimated sample of 224 would be required to detect a 10% reduction in aggression, or an effect size of about .33, assuming power = .80 and alpha = .05. Academic engagement is also an outcome of interest. The measure to be used for this study is adapted from the Personal Achievement Goal Orientation (PAGO) subscale of the Patterns of Adaptive Learning Scales (Midgley et al. 2000), with a reported mean of 3.35 and standard deviation of 1.02. An estimated sample of 238 would be required to detect a 10% increase in the PAGO, or an effect size of about .33, assuming power = .80 and alpha = .05. Thus, the study appears to have adequate power to detect relatively moderate differences between the two groups.

Analyses

Bivariate and multi-variate analyses will be employed. To assess predictors of academic engagement and aggressive behavior, linear regression controlling for sex and school will be the primary statistical method. Analysis of the longitudinal data for the comparison group will be assessed using longitudinal growth and structural equation modeling. To test for treatment group differences, repeated measures analysis of variance (ANOVA) will be conducted, with time-by-treatment interactions being of primary interest.

Quality Control

Youth survey data is collected on personal computers, and parent interview data is obtained through the CATI system, eliminating data transcription errors. Telephone interviewers are trained by JHU staff. Conduct of the parent interview in the home or other select locations using laptop computers will be offered as an option to parents. With the permission of the interviewee, the JHU staff will listen to a small number of interviews during each interview period to assure fidelity to the protocol. In addition, weekly reports are sent to JHU and PRB listing number of parents to be interviewed, how many have been interviewed and the time period left for interviews to assure that interviews are completed in a timely manner.

In our experience, most parents and early-adolescents are interested in the subjects of aggression and school engagement and participate in the survey as long as participation is convenient. To assure that survey participation is maximally convenient, we have developed relatively brief questionnaires. Students are assessed during the regular school day. Students are not pulled from Math classes to ensure no disruption in that instruction as per teacher request. Students are also not pulled during their gym classes, as we have found this resulted in resistance on the part of youth. Study staff has been instructed to be as accommodating to teacher and student schedules and requests as possible (e.g. not pulling students during pretest reviews, or during group projects).

B.2.1. Statistical Methodology for Stratification and Sample Selection

B.2.2. Estimation Procedure

B.2.3. Degree of Accuracy Needed for the Purpose Described in the Justification

B.2.4. Unusual Problems Requiring Specialized Sampling Procedures

No specialized sampling procedures are necessary.

B.2.5. Use of Periodic (Less Frequent Than Annual) Data Collection Cycles

Periodic data collection cycles are not used.

B.3. Methods for Maximizing the Response Rate and Addressing Issues of Nonresponse

Methods to Maximizing Response Rates

In our experience, most parents and early-adolescents are interested in the subjects of aggression and school engagement and participate in the survey as long as participation is convenient. To assure that survey participation is maximally convenient, we have developed relatively brief questionnaires. Information on the study and consent form are sent home at the beginning of the school year as part of the packets sent by schools with other information and forms parents are required to sign and return. Youth are assessed during the regular school day. We work closely with schools and youth to assure that the time spent on the assessments is not too intrusive. For example, students are not pulled from math classes, classes taking or reviewing for tests, or preparing for the state-wide standardized tests. Further, as per student requests, students are not pulled during gym class. We have the flexibility in our scheduling to assess students at those

times most convenient for students and teachers. Study staff is in the schools for over a 2-3 week period, with 3-4 scheduled make up assessments days scheduled. Students who are present in the building are almost always assessed. School staff have been helpful in identifying students who tend to be absent and assisting us to assess them when they are present. Students are also quite willing to help study staff identify and find students. We have found students are quite willing to complete the survey when these procedures are in place.

Each parent receives a small incentive ($20) each time s/he completes a survey. Contact information, including most convenient times to conduct the phone surveys, will be collected as part of recruitment and survey procedures to reduce loss to follow-up. Parents will be contacted as many as 15 times to schedule and complete interviews.

Current Response Rates

Response rate are calculated by dividing the number of youth and parents that complete each interview (numerator) by the number of eligible students (denominator). Number of eligible 6^{th} grade students include all incoming 6^{th} graders, that is eliminating those repeating the 6^{th} grade from the total number of students. We expect a completion rate of 66% for the continuation of the study based on previous years rates. Response rates by school for the study ranged from 38-77 %, with an overall rate of 66%. Almost all (94-98%) of students with consent were assessed at baseline. Follow-up data was obtained for 74% of students measured at baseline. Reasons for not retaining students in the sample include transfers to schools not in the study, suspensions/expulsions, and high chronic absenteeism. These schools are characterized by high mobility with in and out

transfers ranging from 18-28% of the student population in 2004-05. In two schools, students are frequently absent, with 45% and 69% of students absent greater than 20 days during the 2004-05 school year.

Although these rates are lower than the 80% expected, it is not unusual for a study of this type, particularly in low-income high-risk populations, to have lower response rates (Cook, Herman, Phillips, & Settersten, 2002; Goodman, McEwen, Dolan, Schafer-Kalkhoff, Adler, 2005; Miller-Johnson, Sullivan, & Simon, 2004; see **Attachment 7** for references). Active parental consent and student assent procedures were used. In a high school based study that compared active and passive consent procedures, Frissel and colleagues (Frissel, D'Amico, Ellingstad, McCarthy, Metrik and Brown, 2004) report a response rate of 45% response rate among those in the traditional-active consent sample compared to over 90% in the two passive consent samples. In a school-based violence intervention study similar to the current one but with only student participants, schools also varied in their reported participation rates, 55 – 81% with an overall average of 71% (Miller-Johnson, Sullivan, & Simon, 2004). In another study asking for parent and youth participation, 57% of eligible students participated, with data available on both youth and parent on 46% of those eligible to participate (Goodman, McEwen, Dolan, Schafer-Kalkhoff, Adler, 2005). Perhaps the addition of requesting parent participation lowered participation rates for youth in the current study.

Parent assessments were competed at a much lower rate, 44-63 %. Parents proved fairly difficult to reach, and resulted in a disappointing percentage of those who agreed actually participating in the telephone interview. To address this for the continuation of the study, we ran a small pilot, doing home interviews with 20 current participants to

assess what methods would improve our responses. It was found that greater persistence in calling (increasing the call back number from 10 to 15 calls) and offering the option to conduct the interviews in the home were more successful strategies to obtain information than the current system. These strategies will be implemented in the coming school year.

B.4. Tests of Procedures or Methods

As this is a renewal, most procedures and tests will remain the same as in previous study years. One procedural innovation is the addition of a home option for parent interviews. The interview instrument will not change. This change is a result of in-depth home interviews with parents of current study participants to explore ways to increase our parent participation in the study.

B.5. Names and Telephone Numbers of Individuals Consulted

Actual data collection is the responsibility of the contractor, Tina Cheng, MD, MPH, at Johns Hopkins University School of Medicine, (410-614-3862). Data analysis is the responsibility of the Project Officer, Bruce Simons-Morton, EdD, MPH, (301-496-5674), in collaboration with other study investigators within the Division of Epidemiology, Statistics, and Prevention Research. These study investigators include Mark Klebanoff, MD, (301-496-5267), Director of the Division of Epidemiology, Statistics, and Prevention Research, who is an epidemiologist with expertise in the analysis of clinical trials; and Kai Yu, PhD, (301-496-6813), Chief of the Statistic Branch, within the Division of Epidemiology, Statistics, and Prevention Research.