

BUDGET JUSTIFICATION

OVERVIEW

We propose a 4-year study. There will be a 3-month Developmental Phase that will be followed by a 36-month enrollment period (18 months at four clinics and then 18 months at a different four clinics). When children and their caregivers are enrolled into the study, their medical visits will be audio-taped recorded. All of the audio-tapes will be transcribed into text and coded. The children will be interviewed immediately after their audio-taped medical visits and the caregivers will fill out surveys. The research assistants will conduct home visits one month after the audio-taped medical visits to re-interview children and administer a survey to caregivers. During the final six months of the project, we will complete all analyses, manuscripts, and reports.

PERSONNEL

Betsy Sleath, PhD, RPh, Principal investigator, 25% effort years 1-4, will be responsible for coordinating the project. She will: (1) train and supervise all of the employees working on the project, (2) oversee the transcribing and coding of the audio-tapes, (3) be responsible for data analysis, and (4) be responsible for preparation of the final report.

Guadalupe X. (Suchi) Ayala, Ph.D. M.PH. Co-principal investigator, 20% effort years 1-4. Dr. Ayala, a clinical psychologist will be responsible for helping Dr. Sleath coordinate the project. She will: (1) help supervise the employees working on the project, (2) help Dr. Sleath train and oversee the coding of the audio-tapes, and (3) assist with preparation of the final report.

Dennis Williams, PharmD. Co-investigator, 10% effort years 1-4. Dr. Williams, a clinical pharmacist will train the research assistants on how to assess appropriate inhaler technique. He and Dr. Davis will regularly monitor (monthly) and check the research assistants' performance by observing the research assistants' assessment of inhaler technique for 10% of the patients. Also, Drs. Williams and Davis will review the interview data and abstracted chart data to classify each child as having mild, moderate, or severe persistent asthma.

Gail Tudor, Ph.D., Co-investigator, 10% effort years 1-3; 20% effort year 4. Dr. Tudor, Assistant Director of the UNC Biostatistics Consulting Laboratory, will provide statistical and design expertise for the project. She will analyze the data and assist Dr. Sleath in writing the final report.

Stephanie Davis, M.D. 20% effort years 1-4

Dr. Davis, a certified pediatric pulmonologist at the UNC School of Medicine, will take responsibility for training the research assistants on how to do spirometry. She will meet with them regularly and will routinely check their performance. She will train the research assistants to review each child's medical record to abstract information to determine whether they have mild, moderate, or severe persistent asthma according to the NHLBI guidelines. Dr. Davis will regularly monitor and check their performance by also reviewing 10% of all of the medical records. Drs. Davis and Williams will each separately review the interview data and abstracted chart data to determine whether each child has mild, moderate, or severe persistent asthma.

Karin Yeatts, Ph.D. 5% effort years 1-4

Dr. Yeatts, an epidemiologist in the UNC Department of Public Health, who specializes in studying asthma among children, will provide expertise on the epidemiology of asthma in North Carolina and environmental and trigger control.

William Campbell, Ph.D., Co-investigator, 5% effort years 1-4. Dr. Campbell will provide expert advice on the use of medications in children since he is principal investigator of the UNC Center of Research and Therapeutics of medications in children. Dr. Campbell will assist with preparation of the final report.

Brenda Kutcher, Project manager, 100% effort years 1-4, will assist Drs. Sleath and Ayala in managing the other employees on the project. She will: (a) make sure the research assistants have adequate supplies at each site for data collection, (b) coordinate data collection across the research sites, (c) track data as it is collected and returned from the data collection sites, (d) coordinate correspondence between Dr. Sleath and the other investigators, (e) be responsible for data entry and data cleaning, (f) code audio-tapes, and (g) coordinate the home visits with the research assistants. She also will provide coverage for data collection at the sites if needed.

Medical transcriptionist, to be appointed, 25% effort months 5-12 of year 1; 30% effort years 2 and 3; 30% effort months 1-6 of year 4 will be responsible for transcribing the audiotapes that are collected.

4 research assistants 40% effort each for months 4-12 of year 1, all of year 2 and 3, and months 1-4 of year 4). The research assistants will be responsible for recruiting patients, audio-taping the encounters, conducting the office and home visit child interviews, administering the caregiver questionnaires. Each research assistant will be responsible for data collection at a different clinic.

CONSULTANTS

Patricia Bush, Ph.D. (\$1000/year, years 1-4)

As the nation's leading expert on medication use in children, Patricia Bush, Ph.D. will provide expertise on measurement and medication use in children. She will provide advice throughout the coding and analysis of the audio-tape data.

Robert Annett, Ph.D. (\$1000/year, years 1-4)

Dr. Annett, a clinical psychologist, will provide expert advice on measurement and analysis.

Michael Schechter, M.D., M.PH. (\$4000/year, years 1-4)

Dr. Schechter, a pediatrician and asthma health services researcher, who has practiced in North Carolina and worked with these practices prior to relocating to Brown University last year. He greatly contributed to the conceptualization of this grant prior to moving. He will provide expertise and back-up support to Drs. Davis and Williams on reviewing spirometry results and medical record data to determine asthma severity. He will assist Dr. Sleath in maintaining good working relationships with the clinics.

NON-PERSONNEL

Supplies

We will purchase 30 chronologs to assess adherence that can be used by different subjects throughout the study. (30 times \$300=\$9,000 year 1).

In addition, we need to purchase a chronology docking station and software so the information from the chronologs can be downloaded=\$1100 year 1

Eight digital audio-tape recorders and eight noise reduction microphones =\$1600 year 1

Spirometry equipment will be purchased to assess lung functioning during the office and home visits. Each research assistant will be assigned a spirometry device. Four spirometry machines at \$1500 a spirometry machine =\$6000 year 1.

One laptop computer will be purchased for each of the four research assistants working at the clinics. Four laptop computers at \$2000 a laptop=\$8000 year 1. The laptop computers will be used with the spirometry equipment and for patient tracking.

Computer software (\$1000 per year)

Project supplies: batteries for tape recorders, albuterol, other project supplies (\$2000/year)

Photocopying=\$600 years 1-4

Travel

In-state travel to clinics

Year 1 is comprised of a 9-month enrollment period= 9 months times 16 trips per month (4 trips per clinic times 4 clinics) times an average of 160 miles round trip times \$0.36=\$8294.40

Year 2 consists of a 12-month enrollment period=12 months times 16 trips per month (4 trips per clinic times 4 clinics) times an average of 160 miles round trip times \$0.36=\$11,059.20

Year 3 is also a 12-month enrollment period=12 months times 16 trips per month (4 trips per clinic times 4 clinics) times an average of 160 miles round trip times \$0.36=\$11,059.20

Year 4 is a 3-month enrollment period=3 months times 16 trips per month (4 trips per clinic times 4 clinics) times an average of 160 miles round trip times \$0.36=\$2764.80

Out-of-state travel

Present results at professional meetings (\$1500 times 2 meetings=\$3000 year 3; \$1500 times 3 meetings=\$4500 year 4).

Travel for Dr. Schechter to visit yearly with UNC project staff. \$1200/year, years 1-4.

OTHER EXPENSES

Phone

Support is requested for phone calls between members of the research team at UNC and Wake Forest as well as communication between research assistants at the clinics and the UNC/Wake Forest research team. Support is also requested to remind families of the home visits.

\$1200 a year for years 1-4

Postage

Support is requested for mailings between UNC and Wake Forest as well as mailings between the clinic research assistants at the clinics and the research team.

\$500 a year for years 1-4

Child and caregiver incentives

Child incentives \$15 times 2 interviews times 360=\$10,800 (\$3,000 year 1; \$3000 year 2; \$3000 year 3; \$1800 year 4)

Caregiver incentives \$15 times 2 interviews times 360=\$10,800 (\$3,000 year 1; \$3000 year 2; \$3000 year 3; \$1800 year 4)

Clinic reimbursement (\$16,000 year 1; \$24,000 year 2; \$24,000 year 3; \$8,000 year 4)

Each clinic will be reimbursed \$500/month (\$9000 over an 18-month period) to offset the costs of a clinic staff member who will serve as liaison to the project. The clinic liaison will identify eligible patients and call the caregivers of potentially eligible patients to briefly about the study and to ask them to bring in their child's asthma medications if they are interested in learning more about it before their visit. The clinic liaison will also maintain weekly contact with the research staff.

Biostatistics Computer Services

The biostatistics consulting laboratory charges a \$3991/FTE/year for computer services. Therefore, since Gail Tudor, Ph.D. is 10% effort years 1-3 and 20% effort year 4, we are requesting \$400 for years 1-3 and \$800 for year 4.

PRINTING COSTS

Consent and HIPPA forms: 4 forms times 4 pages per form times 360 times \$0.10=\$576

After visit child and caregiver surveys: 2 times 8 pages per form times 360 times \$0.10=\$576

Home visit child and caregiver surveys: 2 times 8 pages per form times 360 times \$0.10=\$576

Medical record abstraction forms: 2 pages times 360 times \$0.10=\$72

Total=\$1800 year 1

SAMPLE