

February 16, 2005

To:

Mr. Ezra Hitzeman
1404 Pumphouse Drive
Richmond, VA 23224

From:

Cheryl Bodamer RN, MPH
VCUHS, Dept OB/GYN
P.O. Box 980034
Richmond, VA 23298

Dear Mr. Hitzeman,

Enclosed please find my research proposal for the study of Sudden Infant Death Syndrome in Richmond and the central region of Virginia. I have also included information for the estimated cost of this study.

Background: SIDS accounts for 72 infant deaths annually in Virginia (five year low of 58, high of 84) equal to a rate of .72 deaths per one thousand live births (2002). The incidence of SIDS is highest in the central region at about 25 deaths per year second only to prematurity. African Americans infants have three times the risk of dying from SIDS than white infants. Over the past several years, it has come to our attention through limited reviews that the majority of these deaths are occurring to infants sleeping in adult beds and rarely to infants sleeping face down in a crib. Available data on SIDS deaths is currently limited to information on the death certificates, which only tells us about the cause of death. In order to identify risk factors that are amenable to intervention, information on sleep position, sleeping environment and other risk factors for SIDS must be extracted by hand through a detailed examination of medical records related to the infant's death.

Hypothesis: Unsafe sleep environment is a significant risk factor among infants who die of SIDS in Central Virginia.

Specific Aims: 1. To examine information on sleep position and sleep environment and identify other risk factors in infants who died of SIDS. 2. To develop targeted public health recommendations to reduce the risk of SIDS.

As a result of this study, specific risk factors for SIDS will be identified for this geographic region. This information will be utilized to make recommendations and to implement local intervention strategies to reduce the risk of SIDS. The Central Commonwealth Perinatal Council will assist with dissemination of the information and implementation of the interventions.

Partner agencies: Virginia Commonwealth University and the Office of the Chief Medical Examiner, Virginia Department of Health.

Methodology: This is a retrospective cohort study of infants one week to one year of age who died suddenly and unexpectedly in 2003 through 2004 in Central Virginia. Cases will be identified through the database in the Office of the Chief Medical Examiner, homicides and deaths from medical causes will be excluded. This study qualifies for exemption under federal rules for Research Subjects Protection. This is a record review only and no patients will be contacted for this study. The confidentiality of subjects will be preserved. All records will be reviewed in the Medical Examiner District offices and de-identified. The data will be reported in aggregate with no identifiers.

The case files on the deaths will be pulled from the archives at Chief Medical Examiners office in Richmond and reviewed by a trained nurse abstractor. Information will be collected on approximately 15 different variables comprised of the cause and circumstances of death. The data will be entered into a database that we have designed and tested in a previous study using SPSS Version 11.0 (Statistical Package for the Social Sciences). Data will be analyzed for frequency of occurrence of the known risk factors for SIDS and cross-tabulations of sleep surface, sleep position, and co-sleeping.

Past experience: Cheryl Bodamer RN, MPH currently serves as the Director and Principal Investigator for the Richmond Healthy Start Fetal Infant Mortality Review Program (FIMR) at Virginia Commonwealth University. For the past seven years, we have conducted mortality surveillance including in-depth reviews of individual cases of SIDS in the City of Richmond. We have developed a collaborative relationship with the Office of the Chief Medical Examiner to assist in our efforts. In addition to identifying gaps in the health care system issues for women and infants, recommending policy changes, providing outreach education to professionals and

bereavement support to grieving mothers, the FIMR team has developed materials for a Back to Sleep Campaign and a safe sleeping campaign.

In 2002, we conducted a retrospective review of seventy-four cases of Sudden Unexpected Infant Deaths that occurred in 1999 across the state. Data sources included death certificates and case files at the Office of the Chief Medical Examiner. SIDS alone accounted for 78 percent (58) of the deaths, followed by deaths due to an undetermined cause and asphyxia due to overlaying and wedging. One third of the infants who died of SIDS were co-sleeping with an adult. Forty seven percent were sleeping in a crib at the time of death, 31% on an adult bed and 10% on a sofa. Over half (52%) were found prone, 22% on their back, and less than 1% on their side. Information on sleep surface and position is unknown for about 10% of the deaths. The conclusion from this pilot study is that a number of these deaths were preventable. There is also a need to collect data for subsequent years to determine if this is a true reflection of the risk factors associated with SIDS.

Cost of the Study: In order to conduct this study, we are in need of additional financial support for nursing research personnel to collect, analyze, and compile a report of the study. The cost of a nurse researcher is approximately \$25 per hour. Review of 50 cases (2 years of data) takes about 50 hours. Total personnel cost is \$1250. Materials and equipment will be covered by the Perinatal Council funds. Financial support for our Central Commonwealth Perinatal Council from the Virginia Department of Health is currently \$120,000 per year. Additionally, the University provides administrative and housing support for us, and the Office of the Chief Medical Examiner provides physician support. The strength of our proposal lies in our collaborative partners, our past experience, and the availability of needed data. Thank you for your consideration of this request for funding future research on Sudden Infant Death Syndrome.