Nicole Cyrille
IRB Proposal
February 16th 2012

To Investigate whether the Introduction of a Cardiovascular Disease Education Component into the Elementary School Physical Education Curriculum can improve the Cardiovascular Disease Awareness of Parents.

A. Study Purpose and Rationale

Cardiovascular disease (CVD) is a group of diseases that affect the heart and the circulatory system. It includes coronary heart disease (CHD), myocardial infarction (MI), stroke, and congestive heart failure (CHF). CVD is the leading cause of death in men and women in the United States. According to 2011 data from the American Heart Association, though CVD death rates have declined by 27.8% from 1997 to 2007, CVD still accounted for 33.6% (1 out of every 2.9) of all deaths in 2007. The burden of disease remains significant with death rates 405.9 per 100 000 in black males versus 294.0 per 100 000 in white males and 286.1 per 100 000 in black females versus 205.7 per 100 000 among white females in 2007. The total direct and indirect costs associated with CVD and stroke in 2007 was 286 billion dollars.[1] In New York State alone approximately 40 percent of deaths (>58 000) in 2008 were attributable to CVD with an estimated cost of approximately 32 billion dollars.[2]

Studies have shown that the prevalence of multiple risk factors for CVD is greatest among specific subgroups including Blacks and Hispanics, persons with lower education levels and those with low socioeconomic status. For example, data analyzed by the CDC from the 2003 Behavioral Risk Factor Surveillance System (BRFSS) survey which included 256,155 participants from 50 states showed that prevalence of having two or more risk factors was highest among blacks (48.7%) and American Indians/Alaska Natives (46.7%) and lowest among Asians (25.9%); The prevalence of multiple risk factors ranged from 25.9% among those who graduated from college to 52.5% among those with less than a high school diploma (or equivalent). Household income followed a similar pattern, with persons reporting $\geq$\$50,000 annual income having the lowest prevalence (28.8%) and those reporting <\$10,000 having the highest prevalence (52.5%) of two or more risk factors. [3,4] Persons in these groups however are more likely to be uninsured and not see a doctor because of the cost[3]. These at-risk groups are also less likely to have adequate CVD knowledge and know the signs and symptoms of a myocardial infarction or stroke[3,5]. Though CVD awareness among women has increased over the years, awareness among White women has remained significantly higher than among Black and Hispanic women. [6,7] Knowledge of CVD risk and symptoms has been associated with preventive actions encouraging individuals to seek help in emergent cardiovascular events which may lead to reduced morbidity and mortality .[8, 9]Future public health strategies must therefore target these groups and find innovative ways to influence them outside of the healthcare system.

The purpose of this study is to investigate how the introduction of a CVD education component into the physical education curriculum of elementary school children in a predominantly minority neighborhood can improve the CVD knowledge and awareness of their parents.

B. Study Design and Statistical Analysis

Study Design

This will be a multi-school randomized controlled study in which classes with children ranging from 9-11 years old, at three elementary schools will be randomly assigned to incorporate a CVD education component into their physical education curriculum for a period of twelve weeks. Children in the control group will continue with their regular physical education sessions while those in the intervention group will review a brief ten minute module at the beginning of their physical education sessions each week. Each module will include a take home activity which the children will be encouraged to complete with their parents. The parents of children in both the control group and the intervention group will complete a pre-intervention survey consisting of 20 questions related to CVD to assess the adequacy of their CVD knowledge and awareness. Parents with inadequate CVD awareness will complete the same questionnaire at the end of the study period.

Study Analysis

Baseline data including age, sex, race/ethnicity, level of education, socioeconomic status, and any diagnosed cardiovascular disease will be obtained. The primary outcome will be achievement of adequate CVD awareness on the post intervention questionnaire. It is anticipated that of the parents determined to have inadequate knowledge at the beginning of the study, 5 percent in the control group will have adequate CVD knowledge and awareness after the 12 week period versus 20 percent of those in the intervention arm. In order to achieve a power of 80 percent with a type one error rate of 0.05 this study will need 88 persons per arm as calculated by the chi-squared test.

Statistical analysis of results of the study will consist of $\chi 2$ analysis for dichotomous baseline variables, and continuous variables will be analyzed with t-tests.

C. Study Procedure.

This study will be conducted for a period of twelve weeks. Classes will be randomly assigned to participate in a CVD education component. Children in the control group will continue with their regular physical education sessions while those in the intervention group will review a brief ten minute module at the beginning of their physical education sessions. Each module will be developed and discussed with the physical education teachers prior to study enrollment and the teachers will be responsible for teaching the students. A different module will be completed per week for a total of twelve weeks. Each module will include a take home activity which children will be encouraged to complete with their parents.

D. Study Drugs*

N/A

E. Medical Device.*

N/A

F. Study Questionnaires

The study questionnaire will consist of 20 questions related to CVD risk factors and signs and symptoms of emergency CVD events such as a myocardial infarction or stroke. Questions will

be compiled from different survey questionnaires used in prior studies. These questions will be reviewed by CERE to assess validity.

G. Study Subjects
The parents of elementary school children ages 9-11 will be included in this study. This study will be conducted in schools located in predominantly minority neighborhoods.

H. Recruitment of Subjects
Parents will be recruited based on whether their child is a member of one of the classes assigned to participate in the study. They will be given information about the study at a scheduled Parent Teacher Association meeting. For parents who are unable to attend, their children will be given copies of the consent form with information about the study to take home for review. Written consent will be obtained by all parents prior to the study.

I. Confidentiality of Study Data
Responses will be assigned a code number and separated from names and other identifying information. The survey and code will be kept in a locked file cabinet and only the investigator and study staff will have access.

J. Potential Conflict of Interest
None

K. Location of the Study
The study will be conducted at the specified elementary schools pending approval by the school administrators.

L. Potential Risks
One risk is the inconvenience of giving one's time.

M. Potential Benefits
The CVD knowledge and awareness of both the parents and children may potentially be improved. This study may potentially demonstrate that the addition of a CVD component into the physical education curriculum of elementary school children is a useful public health strategy to help address the inadequate CVD awareness in target groups.

N. Alternative Therapies
None

0. Compensation to Subjects
Neither the parents nor the children will be compensated for participation in this study.

P. Costs to Subjects
There are no costs to the parents or children.

Q. Minors as Research Subjects

Approval from the Department of Pediatrics Committee on Human Investigation is required prior to IRB review.

R. Radiation or Radioactive Substances
N/A

Sources

1. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics—2011 update: a report from the American Heart Association. *Circulation. 2011;123:e18–e209.*

2. http://www.health.ny.gov/diseases/cardiovascular/heart_disease/docs/cvd_mortality.pdf

3. Liao Y, Bang D, Cosgrove S et al. Division of Adult and Community Health, National Center for Disease Control and Prevention (CDC) Surveillance of health status in minority communities - Racial and Ethnic Approaches to Community Health Across the U.S. (REACH U.S.) Risk Factor Survey, United States, 2009.

4. Centers for Disease Control and Prevention. Racial/ethnic and socio-economic disparities in multiple risk factors for heart disease and stroke: United States, 2003. *MMWR Morb Mortal Wkly Rep. 2005;54:113–117*

5. Giardina EG, Sciacca RR, Foody JM, et al. The DHHS Office on Women's Health Initiative to Improve Women's Heart Health: focus on knowledge and awareness among women with cardiometabolic risk factors. *J Womens Health (Larchmt). 2011;20: 893–900.*

6. Mosca L, Mochari-Greenberger H, Dolor RJ, et al. Twelve-year follow-up of American women's awareness of cardiovascular disease risk and barriers to heart health. *Circ Cardiovasc Qual Outcomes. 2010;3:120–127*

7. Mosca L, Ferris A, Fabunmi R, *et al.* Tracking women's awareness of heart disease: an American Heart Association national study. *Circulation. 2004;109:573–579.*

8. Goff DC Jr, Mitchell P, Finnegan J, *et al.* Knowledge of heart attack symptoms in 20 US communities. Results from the Rapid Early Action for Coronary Treatment Community Trial. *Prev Med. 2004; 38:85–93.*

9. Vaccarino V, Parsons L, Peterson ED, *et al.* Sex differences in mortality after acute myocardial infarction: changes from 1994 to 2006. *Arch Intern Med. 2009;169:1767–1774.*