ARIC MANUSCRIPT PROPOSAL FORM

Manuscript #623 REVISED

1. Full Title: Coronary Risk Stratification for Lipid-lowering Drug Therapy: Comparison of NCEP Guidelines and Estimates of Absolute Risk

Abbreviated Title (Length 26): Risk Estimation/Lipid Drug

2. Writing Group (list individual with lead responsibility first):

Lead: Jennifer G. Robinson, MD, MPH

Address: Iowa Heart Center 411 Laurel Street #2280 Des Moines, IA 50314

Phone: (515) 235-5090; Fax: (515) 284-0837

Email: jrobinson@iowaheart.com

Other members: Folsom

3. Timeline:

Data analysis Oct/Nov 1998; Manuscript preparation complete Jan/Feb 1999; Presentation American College of Cardiology Mar 1999.

4. Rationale:

Identifying primary prevention patients most likely to benefit from lipid-lowering drug therapy remains a challenging clinical issue. Current NCEP guidelines are intended to identify only the highest risk individuals with CHD as candidates for drug therapy. However analyses of a group of cardiology clinic patients showed NCEP (<13% 10-year CHD risk by Framingham equation) individuals with LDL-C greater than or equal to 160 mg/dl as candidates for drug therapy (see attached abstract). On the other hand, NCEP guidelines identified no cardiology clinic patients with LDL-C 130 to 159 mg/dl as candidates for drug therapy, despite many having 10-year CHD risk estimates by the Framingham equation exceeding 20-25%.

5. Main Hypotheses:

a. In a population-based sample, current NCEP guidelines will identify a significant proportion of individuals with LDL-C greater than or equal to 160mg/dl as

candidates for drug therapy despite low 10-year CHD risk as estimated by the Framingham equation.

b. A substantial number of older individuals with LDL-C 130-159 mg/dl are at high risk (>20%) of CHD event within the next 10 years as estimated by the

Framingham equation yet are not identified as candidates for drug therapy by NCEP guidelines. These patients may benefit from drug therapy based on the

results of the CARE study (Sacks et al. N Engl J Med 1996; 335: 1001-9).

c. Among individuals who go on to develop CHD, risk assessment before the event using the Framingham equation more often identifies persons for drug therapy

than NCEP guidelines.

6. Data:

Exam 3 (Exams 1 & 2 if CHD/PVD diagnosed by visit 2 or 3); exclude if coronary, peripheral or cerebrovascular disease present at Exam 1.

Variables: age, gender, CHD/PVD/CVD status, current smoking, diabetes, hypertension treatment or diagnosis, systolic blood pressure, diastolic blood pressure; total cholesterol, triglycerides, HDL-C, LDL-C, menopause

status, current postmenopausal HRT, race, premature family history of CHD, lipid-lowering medication

- 7. Analysis by gender:
- a. For individuals with LDL-C greater than or equal to 160 mg/dl: cross-tabulate 10-year Framingham CHD risk estimate [low (<13%), moderat (13-<20%),
 - and high (greater than or equal to 20%)] vs. NCEP treat? (yes or no).
- b. When a discrepancy exists between a recommendation to consider drug therapy based on NCEP guidelines and a recommendation based on Framingham risk
- estimate category [low (<13%), moderate (13-<20%), and high (greater than or equal to 20%)], determine the frequency of: LDL-C greater than or equal to
- 190 mg/dl, age greater than or equal to 65, borderline risk factors (SBP, DBP, HDL-C, LDL-C categories by gender), premature family history, treated
 - hypertension (blood pressure < 140/90 mm Hg), and diabetes in women.
- c. For individuals with LDL-C 130-159 mg/dl: determine proportion at low (<13%), moderate (13-<20%), and high (greater than or equal to 20%) 10-year
 - CHD risk by Framingham equation.
- d. CHD/PVD patients only: For visit preceding diagnosis of CHD/PVD, cross-tabulate NCEP treatment recommendation with 10-year Framingham CHD risk
 - estimate category