1.a. Full Title:
Predicting 2-hour glucose from fasting plasma glucose values

b. Abbreviated Title (Length 26):
Predicting 2-hour glucose values

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

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3. Timeline:

Preliminary analyses will begin immediately with Atherosclerosis Risk in Communities (ARIC) and Cardiovascular Health Study (CHS) data. Final analyses will await compilation of visit four ARIC data. The target date for manuscript completion is August, 1999.

4. Rationale:
The 1997 American Diabetic Association (ADA) and 1985 World Health Organization (WHO) diagnostic criteria of diabetes differ. The ADA criteria reflect the 1997 ADA expert committee recommendations (1). Significantly, they lower the diagnostic fasting plasma glucose (FPG) value from 140 mg/dL to 126 mg/dL. Additionally, they emphasize FPG values while the WHO criteria include an oral glucose tolerance test (OGTT) and both FPG and 2-hour plasma glucose (2HPG) values.

A 2% decrease in the prevalence of undiagnosed diabetes was initially observed in comparison of ADA (4.4%) and WHO (6.4%) criteria when applied to National Health and Nutrition
Examination Survey (NHANES) III data from individuals 40-74 years of age (2). This degree of difference was deemed acceptable in light of the anticipated increased screening with the ADA criteria (2,3). However, further variation in the agreement between the two criteria has been observed. Several subsequent analyses comparing the ADA and WHO criteria have demonstrated greater discrepancies in rates of diabetes diagnoses (3,4,5,6,7).

Development of a model predicting 2HPG values based upon FPG values and relevant demographic variables (age, body mass index, and gender, race, and waist circumference) has both epidemiological and clinical application. The epidemiological utility of the model arises not only from the predictive nature but also from the description of demographic variables influencing the FPG-2HPG relationship. Studies suggest age and body mass index may impact differences observed in diabetes diagnoses (3,4). However, detailed description of the relationship between FPG, demographic variables, and 2HPG is lacking. It is of greatest importance to know factors that influence the FPG-2HPG relationship in order to know when the FPG value is most appropriately used.

While the model is most useful in population research, clinical application exists as well. The clinical utility lies in the model's ability to aid the clinician in predicting a 2HPG value. An example of anticipated application is the scenario where an elderly or obese subject has a FPG not suggestive of diabetes (≤ 126 mg/dL), but the clinician is suspicious of diabetes. Use of the model with computer assistance to predict a 2HPG value may aid the clinician in deciding to repeat the FPG and/or order an OGTT. Future application of the model may extend to predicting diabetic-associated morbidity and mortality once prospective data is available.

Both the ARIC and CHS epidemiological studies contain variables conducive to this analysis. Combining the data sets offers two advantages. First, it provides an age range for model development spanning five decades of life (54-100 years of age). Second, age-specific analysis may examine how age alters the relationship between the FPG, the covariates, and the 2HPG value.

4. Main Hypothesis:

Primary Objectives: Development of a simple model for predicting a 2HPG value based upon a FPG value and demographic variables is the primary objective. Additionally, description of the relationship between the independent variables (including confounding and interactions) and the dependent variable will be completed.

Secondary Objectives: Demonstration of the model's internal validity and description of the accuracy when applied to the ARIC and CHS cohorts are the secondary objectives.

5. Data (variables, time window, source, inclusions/exclusions):

Independent variable: FPG value.
Dependent variable: 2HPG value.
Covariates: Age, Body Mass Index, Gender, Race, and Waist Circumference.
Source: Combined ARIC and CHS data. 5201 observations are available from CHS. Currently, approximately 11,000 observations are available from ARIC Visit 4 (anticipated total = 11,800).

Multivariable regression analysis will explore the relationship between FPG and 2HPG and serve as a basis in developing the prediction equation. Adjustment for the covariates will be made. Higher order variables including polynomials and one-way interaction terms will be analyzed. Reliability evaluation will proceed by a split-sample approach with cross validation (8).

Inclusions: Participants with fasting plasma glucose and 2-hour plasma glucose values.
Exclusions: Subjects with a history of diabetes or taking diabetic medications.

References:
7. S Gimeno, S Ferreira, L Franco, M Iunes and the Japanese-Brazilian Diabetes Study