ARIC Manuscript Proposal # 819

PC Reviewed: 08/23/01   Status: _A_   Priority: _2_
SC Reviewed: 09/06/01   Status: _A_   Priority: _2_

1.a. **Full Title:** Weight change patterns in adults with type two diabetes

b. **Abbreviated Title (Length 26 characters):** Weight change in diabetes

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

   **Lead:** Esa Davis Washington, MD  
   **Address:** Johns Hopkins University  
   **600 N Wolfe St, Carnegie 291**  
   **Baltimore, MD 21287**
   
   Phone: 410-614-0076   Fax: 410-614-9068  
   E-mail: ewashing@jhmi.edu

   **Writing group members:** Hsin-chieh Yeh, PhD, Peggy Miller-Davis MD,  
   June Stevens, PhD, Jim Pankow, PhD, David Williamson, PhD,  
   MS, Bruce Duncan, PhD, Maria Ines-Schmidt, PhD, Fred Brancati,  
   MD, MHS

3. **Timeline:**
   - Data analysis- begin immediately upon approval
   - Manuscript first draft – Dec 2001

4. **Rationale:** Prospective studies investigating weight change and type two diabetes in adults have provided two types of evidence: First, that weight gain during adulthood is associated with increase incidence of type two diabetes. Second, that weight-loss is associated with a decrease in the risk of developing diabetes and improving health outcomes in obese adults. The few observational studies done using individuals with diabetes suggest an association between weight-loss and a reduction in cardiovascular, diabetes, and overall mortality. From such observational studies, weight-loss recommendations are being made for individuals with type two diabetes. Descriptions of the weight change patterns in “healthy” adults from observational studies were valuable in designing subsequent randomized control trials to demonstrate effectiveness of weight-loss interventions. Likewise, understanding the weight change patterns in individuals with diabetes will provide guidance in designing randomized control trials to investigate the effectiveness of weight-loss interventions in this population. For example, in planning the look AHEAD trial, a randomized control trial investigating the long-term effects of weight-loss in overweight individuals with type two diabetes, knowing the weight change patterns would have been valuable in subject selection and setting expected weight-loss goals.
To our knowledge, no prospective studies have described the patterns of weight change in adults with type two diabetes. It is conceivable that medications (insulin, sulfonylureas), poor glycemic control, co-morbid diseases, dietary changes and physical activity will influence the weight patterns in individuals with type two diabetes and potentially impact the success of weight-loss interventions. We are proposing a study to prospectively investigate patterns and predictors of weight change in middle age adults with diabetes. Description of weight change in type two diabetes and the identification of predictive factors would be invaluable for the planning of intervention trials.

5. Main Hypothesis/Study Questions:
We hypothesize that medications, glycemic control, and co-morbid conditions strongly influence weight change in type two diabetes and therefore weight-loss in these individuals will be accompanied by fewer benefits compared to those without diabetes. In testing this hypothesis, we will first provide answers to the following research questions:

What are the patterns of weight change in adults with type two diabetes?
How do these patterns change by age, sex and ethnicity?
What are the predictors of weight gain in diabetes?
What are the predictors of weight-loss in diabetes?
What are the effects of long-term weight change on co-morbid parameters such as blood pressure, lipids?
How does weight change in the interval before and after the diagnosis of diabetes?

6. Data (variables, time window, source, inclusions/exclusions):
Variables: Main outcome variables: weight change, change in BMI, change in waist circumference

Exposure variables: age, baseline BMI, baseline weight, waist-hip ratio
duration diabetes, severity diabetes (indicated by creatinine, ABI, retinal photographs), medications (insulin, sulfonylureas, diuretics, SSRI’s) poor glycemic control, fasting blood glucose, fibrinogen, wbc, f8c, vwf

Co-variables: gender, education, ethnicity, smoking status, alcohol consumption, physical activity, dietary intake, parity, HRT, abdominal circumference, Co-morbid illness (HTN, CVD, CA), and events (CHD/others which might lead to intensified interventions) lipid profile, serum creatinine, blood pressure, family history DM,

Time window: first, second, third, and fourth visits (to equal 9 years follow-up)

Inclusion: individuals with data at baseline with greater than 3 yrs follow-up data
Exclusion: missing data

7.a. Will the data be used for non-CVD analysis in this manuscript? ___X___ Yes  ____ No
b. If Yes, is the author aware that the file ICTDER0two must be used to exclude persons with a value RES_OTH = “CVD Research” for non-DNA analysis, and for DNA analysis RES_DNA = “CVD Research” would be used?       ____ Yes       ____ No
(This file ICTDER01 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript?       ____ Yes       X ____ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER01 must be used to exclude those with value RES_DNA = “No use/storage DNA”?       ____ Yes       ____ No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at:  http://bios.unc.edu/units/cscA/ARIC/stdy/studymem.html

______  Yes  _______ No