

Feasibility of obtaining hemoglobin A1c measurement by mail to assess glycemic status for diabetic women in the Women's Health Initiative (WHI)

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ABSTRACT

Background: Hemoglobin A1c (HbA1c) is currently recommended by the American Diabetes Association (ADA) as the standardized measure for glycemic control, typically measured by a venous blood draw. However, the WHI does not regularly scheduled measures of HbA1c and to obtain study-wide HbA1c measures by blood draw in the WHI at this phase is neither feasible nor cost-efficient. Having measures of HbA1c would enable unique research opportunities in an aging cohort that build on established WHI interest areas: (1) the assessment of new anti-diabetic medications and their impact on glycemia and co-morbidities, such as CVD, and (2) age-related sequelae of glycemic status and/or diabetes in relation to risk of CVD and cancer. A potential more feasible alternative to sample collection using phlebotomy is self-collected dried blood spot samples by finger stick. This approach is cost-effective and imposes relatively low participant burden for HbA1c measurement in the WHI. Published findings show a strong correlation between HbA1c measured in dried blood spot and fresh blood ($r = 0.92$).

Objective: The WHI provided funds for feasibility study (AS 444*) to explore mail-based collection of dried blood spot samples to assess glycemic status for WHI participants with diabetes.

Methods: A pilot study recruited 480 women [mean age 77.6 years old (SD=6.2)] randomly selected from WHI women in the Northeast region who self-reported diabetes diagnosis after enrolling in the WHI. Among consenting participants, we collected dried blood spot samples by mail at two time points for assessing HbA1c and a questionnaire to determine the acceptance and comfort level with this method.

Results: Of 480 women contacted with history of post-baseline diabetes diagnosis, a total of 403 (84%) responded and 188 (47%) consented to participate in this pilot study. Because 110 (27%) women of the 403 women initially contacted informed the study team that they did not have diabetes, we contacted the subset of 291 women in the recruitment pool who had listed diabetes medication use on at least 1 medication inventory. Of these, 240 (82%) responded, 154 (64%) consented to participate with 138 (90%) returning the completed dried blood spot card and the questionnaire. Completed questionnaires showed that 82 % of these participants were familiar with the finger stick method and were willing to provide dried blood spots using this same technique for future studies. In addition, 78% of the women completed the second (repeat) blood spot collection.

Interpretation: Collection of HbA1c by mail is feasible among women with diabetes based on medication use in the WHI. We acknowledge the limitations of a small sample size, being conducted within only one WHI region. However, we believe a study utilizing a pragmatic cost-effective method for assessing HbA1c in older women is novel and pertinent in older women where management of diabetes medications and comorbidities is of increasing concern. These feasibility results provide preliminary data in support of using this method of assessing HbA1c in future studies wanting to assess glycemic control in older WHI women. The WHI ASC has approved a revised research plan and resubmission to NIH is being planned for February 2016.

* AS444: Feasibility of hemoglobin A1c measurement by mail for diabetic women in the WHI; PI Yunsheng Ma: NERC Feasibility 2013.

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