

2008-R-02

CIO Name: National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health

Project Title: Improving postpartum follow up in women with a gestational diabetes-affected pregnancy

Project Description and Objectives: Gestational Diabetes Mellitus (GDM) is defined as carbohydrate intolerance leading to hyperglycemia with onset or first recognition during pregnancy. It is a common maternal complication affecting approximately 2% to 10% of pregnancies. Complications from GDM include infant macrosomia and associated birth trauma, as well as neonatal hypoglycemia and increased risk of obesity and diabetes in offspring. Up to one third of affected women have persistent disturbances in glucose metabolism after delivery, and it has been estimated that 15% to 50% will develop diabetes in the decades following the affected pregnancy. Evidence suggests that the incidence of GDM is increasing, concurrent with the rising prevalence of obesity and type 2 diabetes in the general population.

Intervention strategies to prevent or delay the development of type 2 diabetes in high risk individuals have now been identified and include lifestyle modification and pharmacotherapy. For example, the Diabetes Prevention Program (DPP) was a large randomized trial of over 3000 adults with impaired fasting glucose and glucose intolerance in which researchers found that a lifestyle intervention that included weight loss and increased physical activity reduced the incidence of diabetes by 58%. An intervention of metformin reduced the incidence by 31%. Studies of Hispanic women with previous GDM demonstrated that pharmacologic treatment of insulin resistance among women with impaired glucose tolerance persisting after delivery was associated with preservation of beta cell function and reduced risk for type 2 diabetes. Lifestyle interventions shown to be effective in randomized clinical trials such as the DPP study have not been tested in women with a recent history of GDM.

Postpartum screening with an oral glucose tolerance test (OGTT) or fasting plasma glucose test (FPG) at the six week post-delivery visit is recommended by several leading organizations (the American College of Obstetricians and

Gynecologists (ACOG), the American Diabetes Association (ADA), and the 5th International Workshop-Conference on Gestational Diabetes Mellitus Panel), both to identify women with preexisting diabetes and to assess risk of developing diabetes in the future. Women found during postpartum screening to have impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) would be good candidates for diabetes prevention interventions; however, studies suggest that the percentage of women receiving postpartum screening is low. While there are no population-based estimates of postpartum screening rates in the US, a number of studies have been conducted in various medical centers. In these non-population-based studies, the percentage of eligible women screened with any assessment of glycemic status ranged from 18% to 63%. The percentage of women receiving a recommended test (FPG or OGTT) was lower; as few as one in four eligible women were screened. Effective strategies for improving postpartum screening rates are needed.

Improving rates of postpartum screening is an important component of diabetes prevention in women with GDM. Postpartum screening allows providers to assess a woman's risk for developing type 2 diabetes and provides an opportunity to educate her about her personal risk and about the importance of lifestyle changes. If effective strategies can be identified that increase provider and/or patient compliance with postpartum testing recommendations, this information can also be disseminated to help medical centers improve their follow up rates. It is important to ensure that postpartum screening is followed by referral for appropriate services (specialty care for women with diabetes and diet/physical activity programs for women with IGT or IFG or who are obese).

This request for proposals is designed to identify strategies to increase postpartum screening rates and subsequent referral. Specific objectives are:

1. To identify strategies to improve postpartum screening in women with a recent history of GDM through office or health care delivery systems, raising provider awareness and compliance, and/or raising patient awareness and compliance.
2. To identify strategies to facilitate appropriate referrals after postpartum screening for diabetes treatment or prevention.

3. To assess provider and patient knowledge of GDM and type 2 diabetes risk.
4. To identify strategies to improve provider and patient knowledge of GDM and type 2 diabetes risk.
5. To identify factors that facilitates or obstructs postpartum screening and referral, at the level of the office or health care system, provider, and patient.

Awardee Activities:

1. Develop a research and analytic plan to implement and evaluate an intervention to improve postpartum screening and referral rates in women with a history of GDM. The plan should include: a description of the study design, the study setting and patient population (including gestational diabetes prevalence), a description of the process for identifying women with GDM and tracking their follow-up, inclusion and exclusion criteria, justification for sample size including power calculations when relevant, and measures of baseline and post-intervention postpartum screening and referral rates. If the study design is a randomized trial, a detailed description of the randomization process should be included. If an intervention is already in place, baseline data on screening rates should have been collected. A description of the intervention should include: an explanation of the intervention intended to increase postpartum screening rates, a discussion of actions taken by staff when women are found to have diabetes, IGT, IFG, or normal glucose tolerance, including provision of educational information and the referral process, and a description of the referral services.
2. Evaluation plan that includes process measures, such as acceptability of the intervention to office staff and patients, and ease and cost of implementation. Researchers should assess provider and patient knowledge and understanding of GDM and the future risk of type 2 diabetes before and after the intervention, barriers to postpartum screening, and barriers to referral follow up. Researchers should outline a plan to determine why women who did not receive postpartum screening or a referral were missed.

3. Collect and analyze data to assess changes in screening and referral rates and to evaluate the intervention.
4. Report findings to medical staff and any other participating organizations.
5. Disseminate findings through presentations and manuscripts.

CDC Activities: CDC staff will be substantially involved in the program and scientific activities of the project beyond that routinely associated with grant monitoring. CDC scientist will:

1. Provide technical assistance in developing and evaluating methodologies and data collection tools to be used in the project.
2. Assist in identifying resources that can be used for planning and executing the project.
3. Monitor scientific progress of the research activity.
4. Assist in analysis of data and interpretation of findings.
5. Collaborate in dissemination of findings (presentations, manuscripts, etc).

Special Requirements: The following criteria specific to this PEP will be used to determine the applicant's eligibility:

1. Evidence of a well-defined partnership with medical staff in an obstetrical clinic in which women with GDM are followed and with a sufficient patient population to allow for recruitment. Evidence must be provided in the form of a Letter of Support from the clinic that includes an estimate of the number of patients with GDM seen each year and a description of the partnership that includes access to the data needed for the study and any limitations to that access.
2. Evidence of a well-defined partnership with clinics or other facilities (such as community organizations) to which women will be referred. Evidence must be provided in the form of a Letter of Support describing the clinic or other facility's role in the study.

Additional Review Criteria: In addition to the standard five peer review criteria defined in the PGO RFA Template

for research (Significance, Approach, Innovation, Investigators, and Environment), the following additional review criteria specific to this PEP will be considered in the review process:

Previous experience, as documented by publications and grant funding, conducting similar research that includes successfully recruiting and enrolling study subjects.

Funding Preference: None

Other information:

<http://diabetes.niddk.nih.gov/dm/pubs/preventionprogram/>

http://www.bsc.gwu.edu/dpp/lifestyle/dpp_part.html

Projected Period Length: No more than 2 years

Approximate Total Project Period Funding: \$500,000. (This amount is an estimate, and is subject to availability of funds and **includes direct and indirect costs, excluding the additional academic partner administrative costs**).

Approximate Average Award: \$250,000 (This amount is for the first 12-month budget period, and **includes both direct and indirect costs, excluding the additional academic partner administrative costs**).

Approximate Number of Awards: 1

NOTE: *Applications must not exceed either the stated Project Period Length or the Approximate Total Budget Period funding per year. Applications in excess of these limits will be considered non-responsive and therefore will not be reviewed.*