

2008-R-04

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

Project Title: Type 2 diabetes prevention in women with a recent history of gestational diabetes mellitus

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 condition affecting approximately 2% to 10% of pregnancies. Complications from GDM include infant macrosomia and associated birth trauma, neonatal hypoglycemia, and increased risk of obesity and diabetes in the 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. The Diabetes Prevention Program (DPP) study 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%. 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 glucose at the 6 week post-delivery visit 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. Women found during postpartum screening to have diabetes are routinely referred for treatment. Those with impaired fasting glucose or impaired glucose tolerance are at particularly high risk for developing type

2 diabetes and so may be the group most likely to benefit from lifestyle interventions.

Translational research is needed to identify strategies to adapt DPP-like interventions for postpartum women who face unique challenges when attempting to make lifestyle changes.

The overall objective of this PEP is to conduct translation research using the DPP intervention for diabetes prevention. The intervention should be modified for postpartum women with a recent history of GDM.

Specifically, the objectives are:

1. To develop a modified version of the DPP diabetes prevention intervention tailored to meet the needs of postpartum women and incorporates specific needs of the community.
2. To implement the intervention through community organizations and/or health centers.
3. To conduct an evaluation of the intervention, identifying factors which facilitate or impede implementation of the intervention at the level of the community, medical facility, provider, or patient.
4. To assess efficacy of the intervention using adherence to dietary and physical activity recommendations as an outcome.
5. To develop recommendations for implementation of a diabetes prevention strategy for women with a recent history of GDM based on the findings.

Awardee Activities:

1. Develop a research and analytic plan to design, implement, and evaluate a DPP-like intervention to reduce the risk of type 2 diabetes in women with a recent history of GDM. The proposal plan should include: a description of the study design, the study setting and the target population (including the prevalence of GDM in the target population), inclusion and exclusion criteria, a description of the process for identifying women eligible to receive the intervention (based on history of GDM and postpartum screening results), a description of the intervention and how, where, and by whom it will be delivered, and measures of baseline and post-

intervention body mass index, diet, physical activity and other relevant outcomes.

2. An evaluation plan that includes process measures such as acceptability of intervention to medical staff, ease of implementation, cost, and acceptability of the intervention to women. Researchers should also assess patient knowledge and understanding of GDM and future risk of diabetes before and after the intervention and barriers to the intervention. Researchers should outline a plan to determine why women are lost to follow up, including their reasons for dropping out of the study.
3. Collect and analyze data to assess the efficacy of the intervention and for process evaluation.
4. Report findings to medical staff and community organizations.
5. Disseminate findings in the form of presentations and manuscripts.

CDC Activities: CDC scientists will:

1. Provide technical assistance in designing, 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 data analysis 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. 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 access.
2. Evidence of a well-defined partnership with the department or organization where the intervention will be delivered. Evidence must be provided in the form of a Letter of Support describing the partnership and the

role of the department or organization in implementing the intervention.

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.*