

2008-R-27

**CIO Name:** National Center on Birth Defects and Developmental Disabilities

**Project Title:** The Effect of Prenatal Bleeding on Pregnancy Outcomes in Women with a Previously Undiagnosed Bleeding Disorder

**Project Description and Objectives:**

Von Willebrand disease (VWD) is the most common bleeding disorder in the United States affecting just over 1% of the general population. Symptoms of VWD include epistaxis, frequent bruising, menorrhagia, and post-operative bleeding. Although VWD occurs with equal frequency among men and women, women are more likely to experience symptoms of VWD because of the increased bleeding it may cause during their menstrual periods, during pregnancy, and after childbirth. Many women learn to live with the problems their bleeding causes, such as heavy periods, and do not realize that they may have an underlying bleeding disorder. Other women may have more serious bleeding problems such as hemorrhages after childbirth. Proper diagnosis and management of bleeding in these women could help avoid pregnancy and childbirth complications.

There are few reports which describe pregnancy and childbirth complications among women with VWD and other bleeding disorders; however, they suggest that these women are more likely to bleed during pregnancy and experience miscarriage and post-partum hemorrhage (PPH). Even among those reports, there have been no prospective studies to compare the prevalence of adverse pregnancy outcomes among women with bleeding disorders with their prevalence among controls. Previous studies have focused on women with a diagnosis of VWD or other hemostatic abnormality; however, these diagnosed women are often already receiving medical management for their disorder and are less likely to experience complications. There are many women who may have an undiagnosed bleeding disorder that need to be targeted for early intervention to prevent potential bleeding problems during this crucial period.

The goal of this project is to determine whether prenatal bleeding results in adverse outcomes for women with an underlying bleeding disorder compared to women without a bleeding disorder and controls. Study objectives of this program are:

1. To determine the prevalence of bleeding disorders among an obstetric population seeking prenatal care
2. To identify symptoms, risk factors, and co-morbidities associated with bleeding during pregnancy
3. To assess adverse pregnancy outcomes associated with early bleeding (e.g., miscarriage) and peri-/post-partum bleeding (e.g., post-partum hemorrhage, preterm birth)
4. To correlate presence of a bleeding disorder with adverse pregnancy and birth outcomes

**Awardee Activities:** A cohort of pregnant women will be followed from their first prenatal visit through the duration of their pregnancy. Applicants should address the following project activities:

1. Proposed recruitment plan and criteria for identifying study participants;
2. Strategies for enrolling and retaining the targeted participants in the study;
3. Collection and initial processing of venous blood samples to be sent to the CDC;
4. Proposed questionnaire that includes, at a minimum, medical history, bleeding history, and pregnancy outcomes and methodology for administration;
5. Abstraction of participant's medical record;
6. A description of how study findings will be analyzed and used to develop recommendations and guidelines;
7. Timeline with specific, measurable, time-framed objectives for the 2-year project period; and
8. Dissemination of study findings in the form of reports and manuscripts.

**CDC Activities:**

1. CDC staff will be substantially involved in the programmatic and scientific activities of the project beyond that routinely associated with grant monitoring.
2. CDC staff will collaborate on protocol development and study methods, logistics of data collection, questionnaire development, data management and analysis, analysis of venous blood samples, and manuscript development. All lab, questionnaire, and medical record abstraction data will be housed at CDC.

**Special Requirements:**

Direct access to an obstetric facility that has a minimum of 2,000 - 5,000 pregnancies per year. Evidence must be provided in the form of a Letter of Support from the clinic that includes

an estimate of the number of obstetric patients seen each year and a description of the partnership that includes access to the patients and data needed for the study and any limitations to access.

**Additional Review Criteria:** None

**Funding Preferences:** Preference will be given to a study site with a racial/ ethnically diverse study population.

**Other Information:** None

**Project Period Length:** 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.