WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
PREGNANCY PROTOCOL
PREGNANCY FORM (PR01)

Visit Number:

All forms completed during the participant's regular core visit (including PRNOTI, PR01 and PR02) will be labeled with the current visit number tag (i.e., visit 11, visit 12, etc.).

SECTION A: GENERAL INFORMATION

A4. Record whether the medical record was obtained. If no, code 2 (NO) and specify the REASON records were unobtainable. After specifying REASON, **END**.

A5. Record the date of the chart review in MM/DD/YY format.

A6. a. Record whether the gestation of pregnancy was determined by Last Menstrual Period (LMP). If YES, enter the date of the participant's LMP and the Estimated Date of Confinement (EDC) as determined by the LMP. If NO, skip to question A6b.

i. LMP = last menstrual period (first day of last period).

ii. Due date (EDC = estimated date of confinement) based on LMP. To calculate, add nine months (or subtract three months) from month of LMP and add seven days to day of LMP.

Example: LMP = 10/21/99; EDC = 7/28/00

b. Record whether the gestation of pregnancy was determined by exam within first 20 weeks. 20 weeks is roughly 4.5 months. If YES, enter the date of the exam and the number of completed weeks of gestation at the time of the exam. If NO, skip to question A6c.

i. Date of exam before 20 weeks.

ii. OB Designee can calculate with a pregnancy wheel by taking starting point at LMP and finding date of 1st exam on wheel.

c. Record whether the gestation of pregnancy was determined by ultrasound. If YES, enter the date of the ultrasound and the number of completed weeks of gestation at the time of the ultrasound. If NO, skip to question B1.

i. Date of ultrasound before 20 weeks.

ii. OB Designee can calculate with a pregnancy wheel by taking starting point at LMP and finding date of ultrasound on wheel.

SECTION B.

PROMPT: OB DESIGNEES SHOULD CIRCLE <-8> IF THE REQUESTED INFORMATION IS NOT CONTAINED ON THE PARTICIPANT'S CHART.

B1. **Incompetent cervix requiring placement of cerclage**

Incompetent cervix is suggested by a past obstetrical history significant for second trimester loss characterized by painless cervical dilatation. The patient will frequently be found to have membranes protruding through the cervix or will have significant cervical dilation on exam. An emergency cerclage may be performed in some circumstances at the time of dilatation, or may be performed electively around the end of the first trimester in a subsequent pregnancy. A cerclage involves the placement of a suture to hold the cervix shut. It is usually placed under spinal anesthesia at about 12–13 weeks if placed electively, and rarely placed beyond 26 weeks in an emergency. It is rarely placed through abdominal surgery.

B1a. Record whether the cerclage was removed at anytime after placement – antepartum, intrapartum, or postpartum.

B2. **Bleeding < 28 weeks** – Indicate whether any vaginal bleeding occurred during pregnancy prior to 28 weeks gestation and prior to the onset of labor. Twenty-eight weeks is six months, two weeks. If not applicable, circle <-1>.

B3. **Bleeding ≥ 28 weeks** – Indicate whether any vaginal bleeding occurred during pregnancy at or after 28 weeks gestation and prior to the onset of labor. Twenty-eight weeks is six months, two weeks. If not applicable, circle <-1>.

B4. **Pregnancy induced hypertension**

Pregnancy-induced hypertension is based on at least two measurements of blood pressure taken at least six hours apart in which:

- the blood pressure is > 140/90; or
- the systolic BP is > 30 mm Hg over the baseline BP; or
- the diastolic BP is >15 mm Hg over the baseline BP.

It differs from pre-eclampsia, or toxemia, in that there is no proteinuria or edema at this point, although patients with PIH may develop pre-eclampsia.

Indicate if during the pregnancy, the participant's blood pressure was persistently ≥ 140/90 mm Hg OR if the participant experienced a rise in systolic pressure of ≥ 30 mm Hg and diastolic pressure ≥ 15 mm Hg from her first trimester blood pressure. In addition, the participant must not have proteinuria, AND there must be no known hypertension prior to pregnancy.

B5. **Chronic hypertension requiring treatment** – Record if the participant experienced high blood pressure > 140/90 mm Hg that began prior to pregnancy or in the first twenty weeks of pregnancy which is controlled with anti-hypertensive medication.

B6. Most pregnant women will receive a one-hour glucose challenge test (GCT) between 24–28 weeks gestation; some at high risk of gestational diabetes mellitus (GDM) will also be screened early in pregnancy.

Record whether the participant was diagnosed with diabetes. If YES, proceed to B6a. If NO, skip to B7.

a. **Pre-gestational diabetes** – Indicate whether the participant's diabetes (hyperglycemia) occurred before pregnancy.

b. **Gestational diabetes** – Indicate whether the participant was diagnosed with diabetes during pregnancy by an abnormal three-hour glucose tolerance test. Criteria: two abnormal serum values from the following:

> Fasting - 105, 1 hour - 190, 2 hour - 165, 3 hour - 145 OR abnormal 1 hour post 50 gram glucose load of > 200 mg/dl.

AND control of hyperglycemia with diabetic diet alone AND no history of elevated blood sugar prior to pregnancy.

c. **Insulin therapy during pregnancy** – Indicate whether the diagnosis was made by the same criteria as B6b AND hyperglycemia is controlled by the administration of insulin and diabetic diet.

B7. **Intrauterine growth retardation (suspected)**

Intrauterine growth retardation (now termed intrauterine growth restriction) is diagnosed when the estimated fetal weight and other sonographic parameters determine that the fetus falls below the tenth percentile for its gestational age.

Indicate if intrauterine growth retardation is suspected. Diagnosis should be based on serial ultrasound and fundal height measurements.

B8. **Cystitis (requiring treatment)**

Indicate if the participant required treatment for cystitis. Diagnosis should be based on positive bacterial clean catch urine culture of > 100,000 organisms/ml of a single type OR positive bacterial urine culture of organism in any amount from urine from sterile site (e.g., cathed specimen) OR in a patient who has symptoms of a urinary tract infection, > 100 organisms/ml of a single type.

B9. **Pyelonephritis**

In pregnant women, fever, flank pain with costovertebral angle tenderness, and occasional nausea and vomiting suggest pyelonephritis.

Indicate if the participant experienced pyelonephritis. Diagnosis should be based on clean catch urine culture of > 100,000 organisms/ml of a single type AND maternal fever greater than 101° F or 38.3° C and costovertebral angle (CVA) tenderness.

B10. **Other clinically significant antepartum infection(s)**

Record if the participant has had any other antepartum infections other than those already listed. Infection(s) may be viral, bacterial, fungal or due to other agents such as mycoplasma, rickettsia. Diagnosis must be documented in a physician's note. If YES, circle code 1 and SPECIFY type of infection on the line provided. If NO, skip to question B11.

B11. **Other clinically significant obstetrical problems**

Record if the participant experienced any other obstetrical problems that occurred from conception to labor and delivery, such as placenta previa. Do not include obstetrical problems that led to or were coincident with labor that resulted in delivery. This information will be collected on PR02, Section B: Intrapartum Complications. If YES, circle code 1 and SPECIFY type of problem on line provided. If NO, skip to question B12.

B12. **Premature labor requiring parenteral tocolysis**

Record YES if the participant experienced regular uterine contractions after 20 weeks, and before 37 weeks, which were five to eight minutes apart or less PLUS one or more of the following:

- Progressive changes in the cervix.
- Cervical dilation of 2 cm or more.
- Cervical effacement of 80% or more.

If not applicable, circle code <-1>.

SECTION C. ANTEPARTUM MEDICATIONS

C1. **Antepartum antibiotics taken**

Indicate whether any antibiotics were taken during pregnancy before the onset of labor. Examples include penicillin, erythromycin, cefazolin. Specify which antibiotics were taken. Do not include antibiotics given during labor and delivery. This information will be collected on form PR02, Section B: Intrapartum Complications.

C2. **Antepartum glucocorticoids taken**

Glucocorticoids given may include prednisone, for asthma or other conditions, and betamethasone, to improve fetal lung maturity in women in preterm labor or, in some cases, in women at high risk for preterm labor. Betamethasone is given at 6 mg IM q12h x 4 doses weekly from the time of preterm labor, or early 3rd trimester, up to 34 weeks in such patients.

Indicate whether glucocorticoids were taken during pregnancy before the onset of labor. Examples include hydrocortisone, prednisone, dexamethasone, betamethasone. Specify which glucocorticoids were taken. Do not include glucocorticoids given during labor and delivery. This information will be collected on form PR02, Section E: Intrapartum Medications.

C3. **Antepartum zidovudine or Combivir taken** – Record whether zidovudine (AZT) or Combivir (ATC + 3TC) was taken during pregnancy before the onset of labor. If YES, circle code 1 and proceed to C3a. If NO, skip to question C4.

a. Record the average number of doses taken per week in the last month. Use leading zeros.

b. Record the date during the pregnancy when the participant began to take zidovudine or Combivir in MM/DD/YY format. If the participant was taking zidovudine or Combivir before finding out she was pregnant and has not discontinued that use, please report the date of her last menstrual period in field C3b.

C4. Record any comments in question C4.