# WOMEN'S INTERAGENCY HIV STUDY
# PREGNANCY PROTOCOL
# QUESTION BY QUESTION SPECIFICATIONS
# POSTPARTUM FORM (PR02)

**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.).

If, however, a participant is scheduled to return during her third trimester for an extra visit within the same core visit window, the forms completed at this visit (PR01, F22, F08, F08a, F31, C60, C65, F10, F29, L01, L03 and L04), will be labeled by adding a ".1" to the current visit number (i.e., visit 11.1, visit 12.1, etc.). This will allow data collected during the extra third trimester visit to be distinguished from data collected during the regular core visit during analyses.

In either case, a copy of this form should be forwarded to WDMAC for data entry. Forms can be faxed to Johanna Goderre at 410-614-7125 or mailed to:

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## SECTION A

**OB DESIGNEE PROMPT: REVIEW THE MEDICAL RECORD AND COMPLETE FORM PR02 AFTER PARTICIPANT HAS BEEN SEEN FOR A CORE WIHS VISIT AND AT LEAST ONE MONTH HAS ELAPSED SINCE HER DELIVERY OR PREGNANCY TERMINATION.**

A1. Circle code 1 if the Clinician is completing the form based on interview/discussion with the participant. Circle code 2 if the OB Designee is completing the form based upon abstraction of the participant's medical records. OB Designees proceed to question A2; Clinicians skip to question A4.

A2. **OB DESIGNEE**: Record whether the medical record was obtained. If no, code 2 (NO) and specify the REASON records were unobtainable. After specifying REASON, **END**.

A3. **OB DESIGNEE**: Record the date of the chart review in MM/DD/YY format. Skip to A5.

A4. **CLINICIAN**: Record the date of interview with the participant in MM/DD/YY format.

**Questions A5–A8.**

It may be best to ask question A8 first. First ask, "**Was there only one fetus [or baby] in this pregnancy, or were there more? If there were more, how many more were there?"** Then ask, "**Did you give birth to a live baby?"** If the patient had a multiple gestation, remember to ask about each fetus.

If the patient indicates she gave birth, but to a dead fetus, she had a stillbirth. Stillbirth indicates a fetus born dead; intrapartum stillbirth means the fetus died during labor. Antepartum stillbirth also is known as intrauterine fetal demise, or IUFD; e.g., the patient usually complains of decreased or no fetal movement; no fetal heartbeat is detected via Doppler or ultrasound when the patient is seen.

If the patient states she did not give birth at all, ask if she had a miscarriage or an abortion, or an ectopic (usually a tubal pregnancy, but may also include ovarian, cervical and very rarely abdominal pregnancies). All "spontaneous" abortions (e.g., missed, incomplete, inevitable, etc.) are included in the term "spontaneous abortion" and "other" abortions would include voluntary terminations.

After one has determined the outcome for each fetus, one can then backtrack and ask questions A5 and A6.

A5. Record the date the pregnancy ended. The pregnancy may have ended due to a live birth, stillbirth, miscarriage, abortion or tubal/ectopic pregnancy. Clinicians should have a calendar available to aid the participant in determining the date her pregnancy ended.

A6. Record the approximate gestation in weeks at time of termination/delivery.

A7. Record the total number of fetuses terminated and/or delivered.

A8. Record the outcome of the participant's pregnancy for each fetus. The column completed should correspond to that particular fetus number out of the total number of fetuses indicated in question A6. For example, if the woman delivered one stillbirth only, then the clinician would record the outcome for that fetus in column a ("fetus #1"). If the participant was carrying two fetuses and one was a live birth and the other a stillbirth, antepartum, then the clinician would complete both column a ("fetus #1") and column b ("fetus #2"). The code corresponding to each outcome should be circled.

If code 1 or 2 ("live birth" or "stillbirth, intrapartum") has been circled, proceed to Section B.

If code 3 ("stillbirth, antepartum") has been circled, skip to Section F.

If code 4, 5, 6 or 7 ("spontaneous abortion," "other abortion," "tubal/ectopic" or "other") has been circled, **END** the form.

## SECTION B. INTRAPARTUM COMPLICATIONS

**PROMPT: INTRAPARTUM IS DEFINED AS THE TIME FROM ONSET OF LABOR TO DELIVERY.**

**PROMPT: ALTHOUGH APPLICABLE TO BOTH CLINICIAN AND OB DESIGNEE, THE FOLLOWING QXQ SPECIFICATIONS ADDRESS THE CLINICIAN. SOME SKIP INSTRUCTIONS MAY DIFFER BETWEEN CLINICIAN AND OB DESIGNEE. CLINICIANS SHOULD CIRCLE <-8> IF THE PARTICIPANT DOES NOT KNOW THE ANSWER TO A QUESTION. OB DESIGNEES SHOULD CIRCLE <-8> IF THE REQUESTED INFORMATION IS NOT CONTAINED ON THE PARTICIPANT'S CHART.**

B1. **Preterm, premature rupture of membranes**

Ask the patient, "**Did your water break before you went into labor and before 37 weeks (or three weeks before your due date)? How long beforehand?"**

Preterm, premature rupture of membranes (PROM) indicates rupture of membranes any time before 37 weeks and before the onset of labor and is associated with a high risk of chorioamnionitis (question B3). Some authorities define PROM as occurring 24 hours before delivery.

Code YES if spontaneous rupture of membranes occurred more than three weeks prior to participant due date. Diagnosis of PROM must be documented by one of the following:

- Visualizing a pool of amniotic fluid in the vagina or gross leakage of amniotic fluid from the vagina.
- Positive nitrazine paper reaction produced from the vaginal fluid that does not appear to be contaminated by blood and a fern pattern seen on microscopic examination of air-dried vaginal fluid.
- Positive peri-pad test after installation of indigo carmine dye.

B2. **Maternal fever** – Code YES if the participant had an oral temperature $\geq$ 100.4°F or 38.0°C, or a rectal temperature $\geq$ 101.4°F or 38.5°C.

B3. **Clinical diagnosis of chorioamnionitis**

One may ask, "**Did you get special antibiotics in labor to fight an infection [other than HIV or prophylactic antibiotics for patients at increased risk of group B strep colonization]?"**

Chorioamnionitis is a clinical diagnosis indicated by the presence of fever in labor with maternal and/or fetal tachycardia, ineffective contractions, history of PROM, and possibly purulent amniotic fluid. It can also be diagnosed via culture or pathological examination of the placenta and the umbilical cord. The patient may well not know whether she had chorioamnionitis or not, but it is unlikely that she had it if there was no maternal fever. Ultimately, this question will be answered definitively by chart review.

Code YES if diagnosis AND the absence of any other cause AND any two of the following:

- Oral temp $\geq$ 100°F or 37.8°C, or rectal temperature $\geq$ 101°F or 38.3°C.
- Fetal heart rate persistently greater than 160 BPM.
- Maternal heart rate greater than 120 BPM in the absence of tocolytics or known maternal heart tachyrhythmia.
- Uterine tenderness not associated with contractions.
- Purulent cervical discharge or amniotic fluid.
- Premature labor unresponsive to tocolytic therapy and an amniotic fluid Gram stain positive for a single type of organism.

B4. **Pre-eclampsia**

Ask, "**Were you ever told while you were in labor that you had something called pre-eclampsia, which is sometimes called toxemia? Were you told your blood pressure was high?"**

Pre-eclampsia has been described in the Form PR01 QxQs with regard to pregnancy-induced hypertension (PIH). In the case of pre-eclampsia, the patient will have elevated blood pressures as described below, as well as proteinuria and edema, generally of the face and hands as well as

the legs. (Most pregnant women will have some dependent edema that is not pathological.) The patient may also complain of headache, scotomata and, rarely, mid-epigastric pain. Such patients may have been induced because of pre-eclampsia, as the treatment for pre-eclampsia is delivery of the fetus. It may also present in the postpartum period; however, this question addresses intrapartum events only. Again, this question may be answered best through chart review.

Code YES if diagnosis AND/OR blood pressure criteria AND uterine protein criteria are met. Blood pressure criteria include: intrapartum blood pressure persistently ≥ 140/90 OR rise in systolic pressure of ≥ 30 mm Hg and diastolic pressure ≥ 15 mm Hg over first trimester blood pressure. Uterine protein criteria include: intrapartum proteinuria of ≥ 1+ by dipstick OR 300 mg protein in 24 hour collection.

B5. **Eclampsia**

Ask, "**While in labor, did you have a seizure or go into a coma or become unconscious? Do you have epilepsy, or were you in an accident that put you in a coma? Were you ever told you had eclampsia, which is not the same as pre-eclampsia?"**

Seizure or coma in a pregnant woman without other explanation (e.g., history of epilepsy, or trauma) is considered to be diagnostic of eclampsia until proved otherwise. It carries with it a significant risk of mortality for both mother and fetus.

Code YES if diagnosis AND/OR participant fulfills criteria for pre-eclampsia from B4 AND participant has seizures intrapartum without any other known reason for seizures (e.g., history of seizure disorder).

**Questions B6–B8.**

Ask, "**Were you told you were bleeding very heavily, heavily enough that you were told your blood pressure was low or your pulse was too fast because of the bleeding? Did you receive a blood transfusion for the bleeding or some type of emergency surgery for those reasons?"**

It is likely that questions B6–B8 will be difficult for many patients. Some patients may require a surgical procedure, such as the repair of a fourth degree laceration or the removal of a retained placenta, without being hemodynamically unstable. Some patients may receive a blood transfusion during cesarean section before hemodynamic instability has occurred. These questions will probably need to be answered from chart review. Surgical procedures that may be related to obstetric hemodynamic instability include: manual removal of placenta, curettage, repair of lacerations (vaginal, cervical, vulvar), exploratory laparotomy, hypogastric artery ligation, and emergency hysterectomy (following delivery or at the time of cesarean section).

B6. **Hemorrhage with hemodynamic instability** – Code YES if diagnosis AND/OR bleeding AND a BP less than 90/60 OR maternal heart rate greater than 120 BPM. Include only those episodes treated with fluid/volume expanders.

B7. **Hemorrhage requiring surgical procedure** – Code YES if diagnosis AND/OR bleeding that necessitates surgical intervention, such as dilation and curettage, hysterectomy or uterine artery ligation.

B8. **Hemorrhage requiring transfusion** – Code YES if diagnosis AND/OR bleeding that necessitates transfusion intrapartum to maintain hemodynamic stability as defined by one of the following:

- To correct BP < 90/60 or maternal HR > 120 BPM.

- To maintain hematocrit > 20.

B9. **Genital herpes**

Ask, "**Did you have an outbreak of genital herpes while you were in labor?"**

Code YES if diagnosis AND/OR written clinical skin findings intrapartum, consistent with diagnosis when there is a history of genital herpes OR positive herpes culture from vesicular lesions.

B10. **Genital condyloma (warts)**

Ask, "**Did you have genital warts at the time you were in labor?"**

Code YES if diagnosis intrapartum AND/OR written clinical skin findings consistent with diagnosis.

B11. **Placenta praevia**

Ask, "**Did you have a condition called placenta praevia?"**

Placenta praevia is a condition in which the placenta covers the internal os of the cervix, and can cause significant hemorrhage for the mother and, to a lesser extent, the fetus. It presents with painless vaginal bleeding in third trimester, and is usually bright red. It may be diagnosed during the antepartum course by ultrasound.

Code YES if diagnosis intrapartum AND/OR bleeding after 28 weeks of pregnancy AND documentation that the placenta overlies the cervical os by one of the following:

- By ultrasound.
- At double set up.
- At time of cesarean section of the placenta covering the cervical os.

B12. **Abruptio placenta**

Ask, "**Were you ever told you had an abruption of the placenta while in labor?"**

Abruptio placentae occurs when the placenta separates from the uterine wall before delivery. It usually causes bleeding of dark red blood with pain. It presents in the third trimester. The diagnosis of placental abruption is clinical although there are ultrasound findings which may be suggestive of abruption.

Code YES if diagnosis intrapartum AND/OR examination of the placenta at delivery reveals retroplacental clot OR clinical diagnosis in patient with two of the following:

- Vaginal bleeding.
- Uterine tenderness.
- Increased uterine tone between contractions.

B13. **Cord prolapse**

Ask, "**Were you ever aware that the umbilical cord had come out of the vagina before the baby was born? You would have been rushed to the operating room for a c-section, and**

**someone would have had to hold the cord up with his or her hand in your vagina until the baby was born."**

A cord prolapse is a true obstetrical emergency; the umbilical cord prolapses into the vaginal canal, causing cord compression and resultant fetal hypoxia. This may occur in cases of abnormal presentation (footling breech, etc.) in the presence of ruptured membranes. The cord must be elevated as high in the vagina as is possible with an assistant's hand to try to relieve the cord compression until the fetus is delivered by emergent cesarean section. Because of the emergent nature of the situation, and the fact that an assistant's hand will be in the patient's vagina from the time the prolapse is noticed until the baby is delivered, most patients will remember this event.

Code YES if diagnosis intrapartum AND/OR documentation of protrusion of the umbilical cord through the cervical os.

B14. **Other clinically-significant intrapartum problems** – Indicate if there were any other intrapartum problems that occurred during labor and delivery. Examples include polyhydramnios, oligihydramnios, uterine dystocia, retained placenta, and acute blood pressure problems. If YES, circle code 1 and SPECIFY the type of problem on the line provided. If NO, skip to Section C. Do not list complications affecting only the baby here.

## SECTION C. LABOR AND DELIVERY SUMMARY

C1. Ask, "**Did your water break on its own, or did the doctor, midwife, PA, etc. have to break it for you?"**

Record whether the participant's membranes spontaneously ruptured or were artificially ruptured. Many patients may not remember the time or even date the water broke. This information may have to be obtained from chart review.

a. Record the month, day, and year that the membranes ruptured. If the date is unknown, record <-8>. Clinicians should have a calendar available to aid the participant in determining the date her membranes ruptured.

b. Record the time that the membranes ruptured. Specify AM or PM. If the time is unknown, record <-8> and skip to C2.

C2. Ask, "**Was the color of the water clear, greenish or thick like pea soup, the color of red wine, or the color of pus? Did anyone tell you the baby had moved its bowels inside (meconium) by looking at the color of the water?"**

Indicate the character of the amniotic fluid. If no amniotic fluid information is available in the labor and delivery record, circle code <-8>.

- Clear – Normal amniotic fluid, pale yellow straw colored.
- Meconium – Greenish-brown in color.
- Port-wine – Deep reddish fluid.
- Purulent – Thick pus-like consistency sometimes associated with an unpleasant odor.

C3. Indicate whether there was an onset of spontaneous or induced labor which resulted in delivery. If YES, code 1 and proceed to C3a. If NO, code 2 and skip to C4. Do not use the hospital

admission as onset of labor time. If participant had a planned cesarean section and experienced no labor, code 2.

a. Enter the date when regular, painful uterine contractions began which ended in delivery, regardless of whether they began spontaneously or by induction. If unknown, enter <-8>. Clinicians should have a calendar available to aid the participant in determining the date when uterine contractions began which ended in delivery.

b. Enter the time when regular, painful uterine contractions began which ended in delivery, regardless of whether they began spontaneously or by induction. Specify AM or PM. If unknown, enter <-8>.

C4. **Labor Induced –** Record whether labor was induced. If YES, code 1 and proceed to C5a–h. If NO, code 2 and skip to C6.

C5. Ask, "**Was your labor induced because you had gone past your due date?"**

Labor may be induced for a variety of reasons. All of the possibilities from question **C5a–d** and question **C5f** have been discussed above. Some practitioners will induce labor at 41 or 42 weeks because of concern about placental insufficiency. Many women will be in specialized care after 41 weeks so that fetal testing may be performed semiweekly (an nonstress test, or NST, of the fetal heart rate, and possibly a detailed sonogram known as a biophysical profile, or BPP, consisting of the fetal movement, breathing movement, amount of amniotic fluid, and fetal tone). If there is evidence of fetal compromise, induction may be considered or undertaken.

Specify all indications that are applicable and circle "NO" or "DON'T KNOW / NOT RECORDED" for those that are not applicable.

a. Premature rupture of membranes – Spontaneous rupture of the membranes occurring more than one hour prior to the onset of regular uterine contractions.

b. Chorioamnionitis – See QxQs for question B3.

c. Hypertension complications – As defined in **pre-eclampsia (**Diagnosis AND/OR blood pressure criteria: intrapartum blood pressure persistently ≥ 140/90 OR rise in systolic pressure of ≥ 30 mm Hg and diastolic pressure ≥ 15 mm Hg greater than first trimester blood pressure AND uterine protein criteria: intrapartum proteinuria of ≥ 1+ by dipstick OR 300 mg protein in 24 hour collection.), **pregnancy induced hypertension** (Diagnosis AND/OR blood pressure persistently ≥ 140/90 mm Hg OR rise in systolic pressure of ≥ 30 mm Hg and diastolic pressure ≥ 15 mm Hg greater than first trimester blood pressure, AND without proteinuria, AND no known hypertension prior to pregnancy.), and c**hronic hypertension requiring treatment** (Diagnosis AND/OR 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.)

d. Maternal diabetes – As defined in p**re-gestational diabetes** (hyperglycemia before pregnancy), g**estational diabetes** (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) or i**nsulin therapy during pregnancy** (diagnosis of gestational diabetes AND hyperglycemia is controlled by the administration of insulin and diabetic diet).

e. Other maternal indication – Specify the maternal indication leading to the induction of labor. Examples include prolonged rupture of membranes, Rh incompatibility.

f. Fetal indication, IUGR – Diagnosis AND/OR estimated fetal weight less than the 10th percentile.

g. Fetal indication, postdate – Diagnosis AND/OR gestational age greater than 42 weeks or 294 days.

h. Other fetal indication – Specify the fetal indication leading to the induction of labor. Examples include severe isoimmunization, fetal anomalies.

C6. **Fetal distress**

Ask, "**Were you told that the baby was having trouble during your labor?"**

Fetal distress, or uncertain fetal status, is often diagnosed in labor based on fetal heart rate patterns in and of themselves and/or relative to the uterine contraction pattern; or on results of fetal scalp electrode sampling.

Code YES if diagnosis AND/OR description to include either of the following:

- Prolonged fetal bradycardia – defined as fetal heart rate < 100 BPM for at least five minutes.
- Fetal scalp sample less than 7.2.
- Persistent late decelerations.

C7. **Fetal scalp electrode used**

Ask, "**Was a small wire attached to your baby's head during your labor?"**

A fetal scalp electrode allows for fetal monitoring (when there is a lot of loss of contact via external monitoring because of fetal movement) by attaching an electrode directly into the fetal scalp. A sample of fetal blood may also be extracted in this way. Its application requires the presence of ruptured membranes. It is relatively contraindicated in the HIV+ patient because of concerns about viral transmission. The date and time of first application may need to be abstracted from the chart.

Specify whether a fetal scalp electrode was used. If YES, code 1 and proceed to C7a. If use of fetal electrodes is not indicated in the charts, code NO and skip to C8.

a. Record the date of the first application in MM/DD/YY format. If unknown, record <-8>.

b. Record the time of the first application. Specify AM or PM. If unknown, record <-8>.

C8. **Intrauterine pressure catheter (IUPC) internal monitoring**

Ask, "**Was a special tube inserted inside your uterus to put fluid inside, or to see how strong the contractions were?"**

Intrauterine pressure catheterization (IUPC) serves three purposes: it is the only way of direct measurement of the strength of uterine contractions; it may be used in women at high risk of uterine rupture (previous cesarean sections) receiving oxytocin (Pitocin) to determine the strength of contractions; and it may be used to instill sterile saline into the uterus, also known as

amnioinfusion. It requires the presence of ruptured membranes. Note this is not the same device as a fetal scalp electrode.

Specify whether there was intrauterine pressure catheter (IUPC) internal monitoring. If YES, code 1 and proceed to C8a. If NO, code 2 and skip to C9.

a. Record the date of the first application in MM/DD/YY format. If unknown, record <-8>.

b. Record the time of the first application. Specify AM or PM. If unknown, record <-8>.

C9. **Fetal scalp blood sampling**

Ask, "**Was a sample of your baby's blood taken from his/her scalp before he was born, while you were in labor?"**

Specify whether there was fetal scalp blood sampling. If YES, code 1 and proceed to C9a. If NO, code 2 and skip to C10.

a. Specify the number of separate times that scalp blood sampling was done. If unknown, record <-8>.

C10. **Delivery information –** Specify whether delivery information is available. If YES, code 1 and proceed to C10a. If no, code 2 and skip to Section D.

a. Date of delivery – Enter the month, day and year of delivery. If unknown, record <-8>. Clinicians should have a calendar available to aid the participant in determining the delivery date.

b. Time of delivery – Enter the time of delivery. Specify AM or PM. If unknown, record <-8>.

C11. **Type of delivery** – Specify whether the delivery was vaginal or cesarean. If the delivery was vaginal, proceed to question C12. If the delivery was cesarean, skip to question C17.

C12. **Type of vaginal delivery** (CIRCLE ONLY ONE CODE)

- Vaginal cephalic spontaneous – Only include cephalic presentations that did not require assistance with forceps or vacuum.
- Vaginal cephalic assisted with forceps – Only include cephalic presentations which were assisted with forceps.
- Vaginal cephalic assisted with vacuum – Only include cephalic presentations which were assisted with vacuum.
- Vaginal cephalic assisted with both forceps and vacuum – Delivery assisted by use of both forceps and vacuum at some point in time, but not necessarily concurrently.
- Vaginal breech – Include all breech deliveries that were vaginal births regardless of forceps use.

If delivery type is unknown or not recorded, circle code <-8>.

C13. **Episiotomy** – Indicate if an episiotomy was done.

C14. **Perineal laceration or extension of episiotomy**

Ask, "**Did your episiotomy (the cut that was made to enlarge the vaginal opening) tear, or did your vulva or vagina tear during delivery?"**

Indicate if there was a perineal laceration or extension of episiotomy.

**PROMPT: CLINICIANS SKIP TO QUESTION C15 AFTER COMPLETING C14. OB DESIGNEES SKIP TO QUESTION C15 IF RESPONSE TO C14 IS NO OR NOT RECORDED. OTHERWISE, PROCEED TO QUESTION C14A.**

a. **OB DESIGNEE**: Specify the degree as recorded. If degree is not recorded, circle code <-8>.

- 1st Degree – Laceration which does not extend into the fascia and muscle of the perineal body.
- 2nd Degree – Laceration extending into the fascia and muscle of perineal body, but not into the rectal sphincter.
- 3rd Degree – Laceration extending into the rectal sphincter.
- 4th Degree – Laceration extending into the rectal mucosa.

C15. **Lacerations (other) –** Indicate if there was another laceration. If YES, code 1 and proceed to C15a. If NO, code 2 and skip to C16.

a. **Vaginal laceration** – Laceration of the vagina separate from the episiotomy which required suturing.

b. **Other Vulvar** – Laceration of the vulva separate from the episiotomy which required suturing.

C16. **Vaginal or vulvar hematoma**

Ask, "**Did you develop a bruise with swelling of the vagina or vulva?"**

Code YES if diagnosis AND documentation of a suprafacial collection of blood in either the vaginal or vulvar submucosa most often treated with incision and evacuation. This question is probably best answered by chart abstraction.

C17. **Placental delivery**

Ask, "**Did the placenta come out on its own, or did you need an operation to take it out?"** This question applies to vaginal deliveries only.

Indicate if there is information about the placental delivery. If YES, code 1 and proceed to C17a. If NO, code 2 and skip to C23.

- **Spontaneous/Manual Extraction –** A spontaneous delivery of the placenta is a delivery during which the clinician's hand is not inserted into the uterus to effect a delivery, whereas in a manual delivery it is. Spontaneous delivery of the placenta occurs when uterine contractions expel the entire placenta. If uterine contractions are insufficient to expel the placenta, the provider may perform a manual extraction to ensure that the entire placenta is delivered.
- **Curettage** – When fragments of the placenta retained inside the uterus require curettage for removal.

**PROMPT: IF C11=1 (TO INDICATE VAGINAL DELIVERY), SKIP TO QUESTION C23 AFTER ANSWERING QUESTION C17.**

C18. **Type of cesarean delivery** (CIRCLE ONLY ONE CODE)

- Cesarean, primary planned – Those cesareans that were planned (prior to labor) on patients who have not had a previous cesarean. Examples of indications are for congenital anomalies, fetal macrosomia.
- Cesarean, primary unplanned – All primary cesareans for maternal or fetal indications that arise in labor and therefore are not planned. Examples are cord prolapse, fetal distress.
- Cesarean, repeat planned – All repeat cesareans which are planned without an attempt at vaginal delivery.
- Cesarean, repeat unplanned – All trials of labor and attempts for vaginal birth after cesarean (for previous pregnancy) which fail.

If cesarean delivery type is unknown or not recorded, circle code <-8>.

C19. **Indications for cesarean**

Cephalopelvic disproportion, considered by some obstetric experts to be a diagnosis of exclusion, is present when the fetal head is too large to exit through the maternal pelvis. Failure to progress is present when the cervix fails to dilate despite oxytocin augmentation (when not contraindicated), rupture of membranes, etc. (the normal cervical dilation is one centimeter per hour in a multipara, and one centimeter per two hours in a nullipara). The other indications have been discussed above, except for breech presentation, which is self-explanatory.

Circle appropriate response code for each indication a–j.

a & b. Cephalopelvic disproportion/failure to progress – Diagnosis AND/OR arrest of labor in the active phase at >5 cm of cervical dilation or arrest of descent in spite of adequate uterine contractions.

c. Fetal distress – Diagnosis AND/OR description to include any of the following:

- Prolonged fetal bradycardia – fetal heart rate 100 BPM for five minutes.
- Fetal scalp sample < 7.2.
- Persistent late decelerations.

d. Breech or other abnormal presentation/lie – Diagnosis AND/OR description to include any of the following:

- Any breech.
- Shoulder presentation.
- Transverse lie.
- Other abnormal presentation.

**NOTE:** DO NOT INCLUDE CORD PROLAPSE HERE.

e. Active maternal herpes – Diagnosis AND description consistent with primary or recurrent active genital herpes.

f. Placenta previa – Diagnosis AND/OR documentation that the placenta overlies the cervical os by one of the following:

- By ultrasound.
- At double set up.
- At time of cesarean section of the placenta covering the cervical os.

g. Multiple gestation – Diagnosis of twins or more than two fetuses.

h. Prevention of HIV transmission – Diagnosis of maternal HIV infection.

i. Maternal indication – Diagnosis AND specify the indication. Examples include medical conditions like pre-eclampsia, diabetes, pelvic tumors.

j. Fetal indication – Diagnosis AND specify the indication. Examples are macrosomia, prematurity, or specific congenital anomalies like hydrocephalus or spina bifida.

k. Other indication – Specify any other condition not easily categorized above. Include patients that refuse trial of labor and cesareans done for cord prolapse.

C20. **Type of cesarean section** (CIRCLE ONLY ONE CODE)

Ask, "**Did the cut on your *uterus* go vertically (up and down), or horizontally (across)?"** Be sure the patient understands that this question does not refer to the scar on her skin.

The type of Cesarean section refers to the **uterine,** not skin, incision. A patient may have a Pfannenstiel incision (transverse or bikini cut) with a low vertical uterine incision. Most patients will not know the type of uterine scar. As vaginal deliveries are contraindicated after a low vertical, inverted T, or classical incision (because of a greater incidence of uterine rupture or dehiscence of the uterine scar), some patients will have been made aware of the risks after such a uterine incision.

- Low vertical (Kroenig) – A midline vertical incision in the lower uterine segment.
- Low transverse (Kerr) – A transverse incision in the lower uterine segment.
- Classical – A midline vertical incision in the upper uterine segment often extending to the uterine fundus.
- Other – Circle code 4 if type of cesarean section differs from any of those listed here (e.g., extraperitoneal). Please specify on the line provided.

Circle code <-8> if the type of cesarean section was not recorded or the participant doesn't know.

**Questions C21–C22.**

The patient will almost certainly know the date of the cesarean section, but may well not know the skin-to-skin time. Rely on the anesthesia record for these data.

C21. a. Record date cesarean began in MM/DD/YY format. If unknown, record <-8>. Clinicians should have a calendar available to aid the participant in determining the date the cesarean section began. (**OB DESIGNEE**: Incision and closure times from O.R. record are preferable; if not available, use anesthesia start date.)

b. Record time cesarean began. Specify AM or PM. If unknown, record <-8>. (**OB DESIGNEE:** Incision and closure times from O.R. record are preferable; if not available, use anesthesia start and end times.)

C22. a. Record date cesarean ended (approximate time of closure) in MM/DD/YY format. If unknown, record <-8>. Clinicians should have a calendar available to aid the participant in determining the date the cesarean section ended.

b. Record time cesarean ended. Specify AM or PM. If unknown, record <-8>.

C23. **Delivery anesthesia –** Indicate if participant recalls whether delivery anesthesia was administered. If YES, code 1 and proceed to C23a. If NO, code 2 and skip to C24. Please indicate "YES" or "NO" for each anesthesia.

- General – Anesthesia which is administered either intravenously or by inhalation and is accompanied by loss of consciousness. Examples of anesthetic agents include thiopental sodium, nitrous oxide or halothane.
- Epidural – Dilute anesthetic solution injected by catheter in the peridural space.
- Pudendal – Anesthetic solution injected over the ischial spine to anesthetize the lower two thirds of the vagina and perineum.
- Spinal – Anesthetic solution injected through dura - also called saddle block.
- Local – Anesthetic solution infiltrated in the perineum.
- Other – Indicate whether any other type not listed above was used. If YES, specify.

C24. Record any other complications of labor and delivery not already listed (e.g., a precipitous delivery, non-sterile delivery, trauma to infant).

## SECTION D. INTRAPARTUM LABS

**PROMPT: CLINICIANS SKIP TO SECTION E.**

D1. **OB DESIGNEE**: Record whether participant's (mother's) admission hematocrit was done. If YES, code 1 and SPECIFY result in D1a.

## SECTION E. INTRAPARTUM MEDICATIONS

E1. **Intrapartum antibiotics** – Indicate whether participant took intrapartum antibiotics. Examples include penicillin, cefoxitin, cefazolin.

E2. **Intrapartum glucocorticoids** – Indicate whether intrapartum glucocorticoids were given to the participant. Examples include hydrocortisone, betamethasone, dexamethasone, prednisone.

E3. **Intrapartum antivirals** – Indicate whether intrapartum antivirals were given to the participant. Include FDA approved and/or any antivirals participant may have taken as part of a research study during labor and/or delivery. Examples include AZT (zidovudine, Retrovir), Dideoxycytosine (ddC), Dideoxyinosine (ddI), or recombinant CD4 (rCD4). If YES, code 1 and proceed to E3a. If NO, code 2 and skip to Section F.

E3a. **Intravenous zidovudine** – Record whether intravenous zidovudine was administered. If YES, code 1 and either proceed to E3e (CLINICIAN) or to E3b (OB DESIGNEE). If NO, code 2 and skip to Section F.

E3b. **OB DESIGNEE:** Record the number of hours intravenous zidovudine was given prior to delivery.

E3c. **OB DESIGNEE:** Record the total dosage of zidovudine (in milligrams) that was given prior to delivery.

E3d. **OB DESIGNEE:** Record cervical dilation in centimeters at initiation of zidovudine.

E3e. **Other antivirals, including oral zidovudine** – Record whether other antivirals, including oral zidovudine, were given. If YES, code 1 and specify on the lines provided. If NO, code 2 and skip to Section F.

## SECTION F. POSTPARTUM HISTORY/COMPLICATIONS

**PROMPT: POSTPARTUM IS DEFINED AS THE SIX-WEEK PERIOD FOLLOWING DELIVERY.**

**PROMPT: INFORMATION IN SECTIONS F AND G PERTAINS TO THE POSTPARTUM PERIOD THAT OCCURS DURING THE DELIVERY HOSPITALIZATION ONLY. IF THE DELIVERY HOSPITALIZATION LASTS LONGER THAN SIX WEEKS, OB DESIGNEE SHOULD ABSTRACT ONLY FOR THE SIX-WEEK POSTPARTUM PERIOD FOLLOWING DELIVERY.**

**Questions F1–F3.**

See QxQs section **B,** questions **B6-B8.**

F1. **Maternal hemorrhage requiring surgical procedure** – Code YES if diagnosis AND/OR bleeding which required additional surgery to control the bleeding. Examples include retained placenta requiring curettage, placenta accreta requiring hysterectomy, vaginal lacerations requiring repair in an operating room.

F2. **Maternal hemorrhage requiring transfusion** – Code YES if diagnosis AND/OR bleeding that necessitated transfusion to maintain hemodynamic stability as defined by one of the following:

- To correct BP < 90/60 or HR > 120 BPM.
- To maintain hematocrit > 20.

F3. **Maternal hemorrhage postpartum with hemodynamic instability** – Code YES if BP < 90/60 or HR > 120 BPM and the participant was treated with fluid/volume expanders.

F4. **Endometritis**

Ask, "**Did you have a uterine infection after you delivered that required IV antibiotics?"**

Endometritis, also known as endomyometritis and parametritis, occurs in 25-75% of all women s/p cesarean section and 5% of women s/p vaginal delivery, and presents with postpartum febrile morbidity (> 100.4$^{o}$ F), a boggy, tender uterus, slow uterine involution, and foul smelling lochia rubra. Diagnosis may also be made based on endometrial cultures or endometrial biopsy. It is treated with gentamicin and clindamycin.

Code YES if diagnosis AND/OR oral temperature > 101°F or 38.4°C AND one of the following:

- Tender uterus to palpation.
- Foul smelling, purulent lochia.

F5. **Mastitis requiring antibiotics**

Mastitis, usually caused by *s. aureus,* most commonly occurs in breastfeeding women, and so should be a rare event among HIV+ mothers. It is characterized by fever, usually low-grade, with breast tenderness, induration, and redness. Treatment consists of ampicillin, compresses, and pumping the breast milk to enhance drainage.

Code YES if diagnosis AND/OR oral temperature > 101°F or 38.3°C requiring treatment with antibiotics AND any two of the following:

- Unilateral breast (not nipple) pain.
- Erythema and induration in one area of the breast.
- Fluctuance of one area of the breast.

**Questions F6-F7.**

See QxQs for Form PRO1, section **B,** questions **B8-B9.**

F6. **Cystitis requiring treatment** – Code YES if diagnosis AND/OR 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.

F7. **Pyelonephritis** – Code YES if diagnosis AND/OR clean catch urine culture of >100,000 organisms/ml of a single type AND maternal fever greater than 101° F of 38.3° C and costovertebral angle (CVA) tenderness.

F8. **Febrile morbidity** – For postpartum patients, febrile morbidity is defined as a temperature > $100.4^{o}$ F. Code YES if oral temperature ≥ 100.4°F or ≥ 38.°C after the first 24 hours post delivery or on any two occasions four hours apart in the first ten days postpartum.

F9. **Infection of cesarean incision**

Ask, "**Was there an infection of the wound from the c-section?"**

Code YES if diagnosis of endometritis OR endomyometritis OR uterine wound infection.

If not applicable, circle code <-1>.

F10. **Episiotomy infection**

Ask, "**Was there an infection of the episiotomy?"**

Code YES if diagnosis AND/OR oral temperature ≥ 100.4°F or ≥ 38°C on any two occasions four hours apart AND any one of the following:

- Pus drained from episiotomy.
- Episiotomy separates, debridement necessary.

If not applicable, circle code <-1>.

F11. **Other infection** – Code YES if diagnosis of specific infection AND/OR laboratory or diagnostic imaging confirmation. If YES, code 1 and specify on the line provided. If NO, code 2 and skip to F12. Examples include:

- Pelvic abscess – Clinical findings PLUS diagnostic imaging confirmation.
- Septic pelvic thrombophlebitis – Clinical findings AND a positive response to heparin therapy.

F12. **Postpartum tubal ligation**

Ask, "**Did you have your tubes tied after the baby was born to prevent more pregnancies?"**

Code YES only if tubal ligation is documented by operative report. Examples include Pomeroy, modified Pomeroy, Irving, Uchida, fimbriectomy.

F13. **Postpartum hysterectomy**

Ask, "**Did you have a hysterectomy, an operation in which the uterus is removed, soon after you had the baby?"**

Code YES only if hysterectomy is documented by operative report.

F14. **Postpartum dilatation and curettage**

Ask, "**Did you need a D&C, or scraping of the uterus, soon after you had the baby?"**

Code YES only if D & C is documented by operative report.

F15. **Other postpartum surgical procedure** – Specify surgery that is documented by operative report on the line provided. If no other surgical procedure, code 2 and skip to F16.

F16. **Other postpartum maternal complications** – Specify any medical or other conditions which occurred after delivery on the line provided. Examples include renal failure, pulmonary embolus, postpartum psychosis, thyroiditis. If patient required transfusion for any reason other than for hemorrhage as in F2, record it here.

## SECTION G. MEDICATIONS ON DISCHARGE

G1. Indicate if any non-HIV-related medications were prescribed to the participant upon discharge. If "YES," specify the medications prescribed on the line provided. Record all non-HIV medications, including vitamins and analgesics.