Question by Question (QXQ) Instructions for the HCHS/SOL
Pregnancy Complication Diagnosis Form (PCD)

A Pregnancy Complication Diagnosis Form (PCD) is filled out by the reviewer for all case packets that are sent to them for review by the CSCC. Initially, events will be classified independently by 2 reviewers with disagreements classified by an adjudicator. Case packets will include a set of medical records and an Event Summary Form (ESF). The ESF is a 1-2 page summary of pertinent information from the HCHS/SOL baseline study visit and of information abstracted from the medical records (i.e. a subset of information from the PRC abstraction form).

The first section of the form is called administrative information (0A-0D). When in electronic form, parts of this will be filled out by the CSCC. For training, please fill this out.

0a. Enter date that you (the reviewer) completed the form.

0b. Enter your staff or reviewer ID number. It is 3 digits.

0c. Event ID. This number is assigned by the CSCC. It will start with a letter representing the HCHS/SOL field center site. It is stamped on the top of the medical record.

0d. Event Date. Enter the date of arrival or the earliest date on the medical record.

Answer all questions by selecting one choice from the options provided.

1. This record requires a review for: Records are abstracted for both hypertensive disorders of pregnancy and gestational diabetes. Indicate here whether this record is being abstracted for preeclampsia/eclampsia, gestational diabetes, or both. Based on these selections, the reviewer will complete different portions of the form.

2. Hypertension prior to pregnancy: Review the medical record to determine whether the patient had evidence of hypertension prior to pregnancy. Record "Yes" if the patient meets AHA criteria for hypertension at a SOL visit or at a prenatal visit at less than 20 weeks - eg SBP ≥ 140 or DBP ≥ 90. Also answer "Yes" if the patient self-reports a diagnosis of Hypertension on a SOL Visit or AFU questionnaire, or if the medical record indicates "Hypertension" in the medical history section of the prenatal record or the admission H&P. Answer "No" if none of these criteria are met.

2a. Criteria for diagnosis of hypertension prior to pregnancy: Select the criteria used to make the diagnosis of pre-gestational hypertension.

3. Hypertension prior to 20 weeks: Record whether there is a documented SBP ≥ 140 or DBP ≥ 90 prior to 20 weeks' gestation, and whether there was documentation of treatment with an antihypertension medication prior to 20 weeks. If a medication which

can be used to treat hypertension was given with a documented indication other than treatment of hypertension - eg atenolol for cardiac arrhythmia - record "No" for question 3a.

4. Blood pressure criteria for diagnosis of gestational hypertension: Review the medical record for documentation of two blood pressures SBP ≥ 140 or DBP ≥ 90 more than 4 hours apart. If two blood pressures SBP ≥ 140 or DBP ≥ 90 are recorded, but no information regarding time is available, record "Unknown."

5. Was there evidence of proteinuria? Review the medical record for documentation of proteinuria. If there is no mention of proteinuria in the record, record "NR/unsure."

6. Were any of the following features of severe preeclampsia present? Review the medical record for diagnostic criteria for severe preeclampsia. If there are no data regarding a criteria - eg for platelets, no CBC is documented - then record "NR/unsure." Similarly, if there is no comment regarding headache, seizure, or visual symptoms, record NR; if there is documentation of absence of neuro symptoms - eg "Patient denies HA/visual changes" - then record "No."

7. Was intrapartum magnesium given for seizure prophylaxis: Review the record for evidence of Magnesium administration. If Magnesium was given for any indication, document "Yes." If there is documentation that magnesium was withheld - eg "Given elevated creatinine and pulmonary edema, risk of Mg outweighs benefit for seizure prophylaxis - record "No." If there is no comment regarding Magnesium, record "Unsure."

7a. Was seizure prophylaxis a documented indication? If the patient is <32 weeks or has concurrent contractions, Magnesium may be administered for neuroprotection or tocolysis, as well as seizure prophylaxis. Review the medical record to ascertain whether seizure prophylaxis was an indication for magnesium administration. If the record is not clear, document "unsure." If the record explicitly states that Mg is given for neuroprotection or tocolysis, with no mention of neuroprotection, document "No."

8. Was there a grand mal seizure during pregnancy? Review the medical record for evidence of a grand mal seizure. If there is no mention of seizure activity, record "4. No grand mal seizure noted."

9-12. Classify hypertensive complications of pregnancy using Table 7 of HCHS/SOL Manual 15 Endpoint Ascertainment Procedures, as detailed below.

Table 7. Diagnostic criteria for definite, probable, unlikely and unclassifiable pre-eclampsia and eclampsia		
	Pre-Eclampsia	Eclampsia
Definite	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 4 hours apart) AND 2) Proteinuria by one of the following criteria one of the following: a) ≥ 0.3g / 24h urine , or b) ≥1+ urine dipstick, or c) urine protein:creatinine ratio documented as "positive" by local lab criteria	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 4 hours apart) AND 2) a grand mal seizure during pregnancy in the absence of other known causes
Probable	1) a) Mention of pre-eclampsia, or other keywords for pre-eclampsia in the medical record AND b) Mention of protein or albumin in the urine in the medical record OR 2) Documentation of intrapartum magnesium for seizure prophylaxis	A grand mal seizure during pregnancy in the absence of other known causes for seizure
Unlikely	Normal documented blood pressure, AND urine protein not documented or <1+, AND no mention of preeclampsia for this pregnancy in obstetric records in a record with reasonable documentation	No mention of seizure or eclampsia during this pregnancy, in a medical record with reasonable documentation
Unclassifiable	Contradictory information or inadequate medical record such that unable to classify as pre-eclampsia or not	Contradictory information or inadequate medical record such that unable to classify as eclampsia or not

Table 7a. Diagnostic criteria for definite, probable, unlikely and unclassifiable gestational hypertension and pre-eclampsia with severe features		
	Gestational hypertension	Pre-eclampsia with severe features
Definite	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 4 hours apart) AND Evidence of absence of proteinuria by one of the following criteria one of the following: a) < 0.3g / 24h urine, or b) <1+ urine dipstick, or c) urine protein:creatinine ratio documented as "negative" by local lab criteria	1) Meets Definite criteria for preeclampsia (Table 7) AND 2) Documentation of one of the following: a) SBP ≥ 160 or DBP ≥110 at least 4 hours apart b) SBP ≥ 160 or DBP ≥110 and treated with anti-hypertensive medication c) Elevated liver enzymes, defined as twice the upper limit of normal d) Severe, persistent RUQ pain e) Platelets < 100,000/mm2 f) Serum creatinine ≥ 1.1 mg/dL, or doubling of creatinine in absence of other renal disease g) Pulmonary edema by imaging h) New-onset headaches, seizure or visual disturbances
Probable	1) a) Mention of gestational hypertension or pregnancy-induced hypertension in the medical record AND b) Mention of negative laboratory testing for proteinuria	1) Meets probable criteria for preeclampsia (Table 7) AND mention of "Preeclampsia with severe features" or "Severe preeclampsia" in chart OR 2) Mention of "HELLP syndrome" in medical record
Unlikely	Normal documented blood pressure, AND no mention of gestational hypertension for this pregnancy in obstetric records in a record with reasonable documentation	No documentation of SBP ≥ 160 or DBP ≥ 110 AND no mention of severe preeclampsia, and no mention of abnormal values for labs that are criteria for severe features in obstetric records in a record
Unclassifiable	Contradictory information or inadequate medical record such that unable to classify as gestational hypertension or not	Contradictory information or inadequate medical record such that unable to classify as preeclampsia with severe features

Criteria as currently documented in End Point manual:

Table 7. Diagnostic criteria for definite, probable, unlikely and unclassifiable pre-eclampsia and eclampsia		
	Pre-Eclampsia	Eclampsia
Definite	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 6 hours apart) AND 2) Proteinuria by one of the following criteria one of the following: a) ≥ 0.3g / 24h urine , or b) ≥1+ urine dipstick, or c) urine protein:creatinine ratio documented as "positive" by local lab criteria	1) Pregnancy-related hypertension (SBP ≥140 and DBP ≥ 90 on two occasions at least 6 hours apart) AND 2) a grand mal seizure during pregnancy in the absence of other known causes
Probable	1) a) Mention of pre-eclampsia, or other keywords for pre-eclampsia in the medical record AND b) Mention of protein or albumin in the urine in the medical record OR 2) Documentation of intrapartum magnesium for seizure prophylaxis	A grand mal seizure during pregnancy in the absence of other known causes for seizure
Unlikely	Normal documented blood pressure, AND urine protein not documented or <1+, AND no mention of preeclampsia for this pregnancy in obstetric records in a record with reasonable documentation	No mention of seizure or eclampsia during this pregnancy, in a medical record with reasonable documentation
Unclassifiable	Contradictory information or inadequate medical record such that unable to classify as pre-eclampsia or not	Contradictory information or inadequate medical record such that unable to classify as eclampsia or not

13. Pre-gestational diabetes? Review the medical record, SOL visit laboratory studies, and SOL AFU self-report for evidence of diabetes prior to the index pregnancy. Record "Yes" if the patient meets ADA criteria for diabetes at a SOL visit – eg fasting glucose ≥ 126 mg/dL, 2-hour 75g OGTT glucose ≥ 200 mg/dL, or Hemoglobin A1c ≥ 6.5%. Also answer "Yes" if the patient self-reports a diagnosis of Diabetes on a SOL Visit or AFU questionnaire, or if the medical record indicates "Type 1 Diabetes," "Type 2 Diabetes," or "Pregestational Diabetes." Answer "No" if none of these criteria are met. In some cases, women are found to have glucose intolerance in the first half of pregnancy, which likely reflects pre-gestational diabetes. Answer "Unknown" if there is documentation of Hemoglobin A1c ≥ 6.5% or abnormal GTT prior to 20 weeks' gestation in the index pregnancy, or if there is documentation of treatment with insulin, metformin, or glyburide before 20 weeks, in the absence of a diagnosis of pre-gestational diabetes. Similarly, answer "Unknown" if there is contradictory information regarding pre-gestational diabetes.

14. Criteria for pre-gestational diabetes. Select the criteria used to make the diagnosis of pre-gestational diabetes.

15. Diagnostic glucose intolerance during pregnancy. Review the medical record to ascertain whether the patient met laboratory criteria for gestational diabetes during the

index pregnancy. This information may be recorded in a lab report, in the prenatal record, or in the H&P or progress notes for the admission. Answer "Yes" if there is documentation of ≥ 2/4 abnormal OGTT values, even if actual values are not recorded. Answer "No" if glucose testing results are reported that are within normal limits, or if the record states "Normal OGTT" or "negative OGTT." Answer Unknown if there is no documentation regarding GLT or OGTT results.

15a. What type of evidence was documented? Indicate what laboratory values were documented that support diagnostic glucose intolerance.

15b. Abnormal but non-diagnostic glucose intolerance. The purpose of this question is to identify women with impaired glucose tolerance who may have been managed as gestational diabetics, or may have been misclassified as gestational diabetics based on impaired but non-pathologic glucose intolerance. In addition, some patients may be treated empirically for GDM without a GTT if they have a history of GDM and do not tolerate the 100g glucose load, such as women who have undergone gastric bypass surgery. These women may be managed with QID home glucose monitoring. Indicate if there is an abnormal GLT result or elevated fasting or postprandial glucose values in the medical record.

16. Documentation of oral hypoglycemic medication or insulin. Answer "Yes" if the patient is documented to have been taking insulin, glyburide, or metformin during the pregnancy. Note that women with PCOS may be taking metformin in the absence of a diagnosis of GDM or pregestational diabetes; thus metformin alone is not sufficient to classify a woman as having pregestational or gestational diabetes. Answer "No" if the patient is noted have diet-controlled diabetes, diet-controlled GDM, or White Class A1 GDM. Answer "Unknown" if there is no documentation of current medications or treatment of glucose intolerance in the medical record.

17. Documentation of GDM in the medical record. Answer "1" if there is a note by a physician or advanced practice provider indicating that the patient had GDM during this pregnancy. A past history of GDM is not sufficient to answer "Yes." Answer "2 - recorded" if there is no mention of GDM in the medical record.

18. Classify GDM using Table 8 of HCHS/SOL Manual 15 Endpoint Ascertainment Procedures, as detailed below.

Table 8. Diagnostic criteria for Gestational Diabetes Mellitus (GDM)	
Definite	1) Glucose tolerance testing results not available AND documented treatment with insulin or oral hypoglycemic (ie glyburide) OR 2) Laboratory evidence of diagnostic glucose intolerance (one of a-d): a) 3 hour Oral glucose tolerance test (OGTT) with ≥2 abnormal values: fasting glucose ≥95mg/dL; 1 hour ≥180mg/dL; 2 hour ≥155mg/dL; 3 hour ≥ 140mg /dL (Carpenter-Coustan Criteria), OR b) 2 hour 75g oral glucose tolerance test exceeding any one of the following thresholds: fasting glucose ≥ 92 mg/dl, or 1 hour ≥180 mg/dl, or 2 hour ≥ 153 mg/dl (IADPSG criteria), OR c) 50g GLT exceeding 200 mg/dl, OR d) Two or more documented fasting glucoses > 125 mg/dL
Probable	1) Physician or advanced practice provider mention of current gestational diabetes in medical record
Possible	1) Laboratory evidence of abnormal but non-diagnostic glucose intolerance: a) Elevated 1-hour Glucose load testing ≥ 135 mg/dl, OR b) Other evidence of abnormal but non-diagnostic glucose tolerance: fasting glucose ≥ 105 mg/dl, or 1 hour post prandial ≥ 140 mg/dl, or 2 hour post prandial ≥ 120 mg/dl)
Unlikely	No evidence in medical record to suggest deviation from normal glucose tolerance
Unclassifiable	Contradictory information or inadequate medical record such that unable to classify as GDM or not