

NVPO Definitions Project
DATA COLLECTION FORM v0.9(Feb 15_2018)
MILD PRE-ECLAMPSIA (PIH)

ADMINISTRATIVE VARIABLES

Initials of person performing the review: __ __

Outcome code: PIH

Country code: US, AU, UK: __ __

Site code: BC, CC, EM, UW, MO, SG, SU: __ __

Origin code CT=clinical trial MR= medical record : __ __

Subject ID number PIH ____ ____ ____ ____
 Country Site Origin Number (starting with 01)

Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of PIH: (from case identification log): _____

COMMON VARIABLES

1. If clinical trial (tick and list study drug/vaccine):

- Vaccine _____
- Drug _____
- Epidemiologic _____
- Other _____

2. Year of event: _____ (full year)

3. General pregnancy variables

a. Maternal Age (years)

_____ (number)

b. Race (tick one)

- Black
- White
- Asian
- Other _____

c. Ethnicity (tick one)

- Hispanic
- Not Hispanic
- Native Population
- Other _____

d. Infant gender (tick one)

- Male
- Female

e. Mode of delivery (tick one)

- Vaginal
- C-section:
- Other: _____

f. Singleton pregnancy (tick one)

- Yes
- No

g. Parity (fill 1-4 each with full number)

1. Prior Term Pregnancies _____ (number)
2. Prior Preterm Pregnancies (<37 wk) _____ (number)
3. Abortions/miscarriage (<20 wk) _____ (number)
4. Born Alive _____ (number)

GESTATIONAL AGE ASSESSMENT

4. Recorded gestational age (from chart)

_____ (Number: weeks/days)

5. How was gestational age assessed:

- Antenatal Maternal US
- LMP
- Infant Exam,
- Other (describe) _____

6. Elements of GA available in the record (tick one option on each line for a-l)

	Recorded	NOT recorded	Incomplete/ uncertain	Comments/Issues
a. Intrauterine insemination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Embryo transfer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Certain LMP (LMP known)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Uncertain LMP (LMP not known)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e. First trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f. Second trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
g. Third trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
h. Fundal height (any)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
i. Fundal height in 2 nd trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j. Maternal physical exam in 1 st trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

k. Birth weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
l. Newborn GA by physical exam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

7. Assessment of Gestational Age LOC based on GAIA Definition (Use Case Definition Checklist:see appendix 2):

a. Level of certainty _____ (1X,2X,3,4,5 or U: unable to assess)

b. If unable to assign GA LOC, describe the reason(s):

Reason _____

CASE DEFINITION SPECIFIC VARIABLES

8. Elements of the Mild Pre-Eclampsia definition in clinical or study Record (please tick one on each line)

Parameter	Evidence in Medical Record or Study MOP/Protocol			
	Yes	No	Uncertain	Comments
a. Ability to measure blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Blood pressure noted before 20 weeks gestation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Blood pressure noted after 20 weeks gestation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Dip urine for protein	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. 12 or 24 hour urine for protein	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Spot protein:creatinine ratio	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Pregnancy > 20 weeks gestation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. New onset proteinuria diagnosed with >=1+ protein on urine dipstick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. New onset proteinuria diagnosed with >=300 mg protein on 24 hour urine collection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j. Spot protein:creatinine ratio >=0.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

k. New onset hypertension with documented prior normal BP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Systolic blood pressure ≥ 140 mm HG and/or diastolic blood pressure ≥ 90 mm Hg) sustained on two measurements over a minimum of 1 hour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Systolic blood pressure ≥ 140 mm HG and/or diastolic blood pressure ≥ 90 mm Hg) sustained on two measurements over a minimum of 1 hour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

QUALITY ASSESSMENT CASE DEFINITION

9. Case abstractor's best assessment of LOC for Mild Pre-Eclampsia (Use Case Definition Checklist in appendix 1):

a. Level of certainty ____ (1,2, or unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason _____

9. PI's assessment of LOC for Mild Pre-Eclampsia (Use Case Definition Checklist in appendix 1):

a. Level of certainty ____ (1,2, or unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason _____

10. Other comments

Appendix 1: Mild Pre-Eclampsia (PIH)
Guide for LOC assignment for PIH (check all that are present)

“Mild Pre-Eclampsia” (Mild PIH) has been defined as a clinical syndrome characterized by elevation of blood pressure after 20 weeks over baseline. The PIH working group decided that having a baseline blood pressure before 20 weeks, then one after twenty weeks, as well as having a way to measure protein in the urine were key elements of the definition.

Case definition of Mild Preeclampsia

Case definition of Mild Preeclampsia

For all LEVELS:

- 1. Pregnancy \geq 20 weeks gestation AND
- 2. New onset hypertension (systolic blood pressure \geq 140 mm Hg OR
- 2. New onset diastolic blood pressure \geq 90 mm HG AND
- 3. Blood pressure elevation sustained on two measurements over a minimum of 1 h AND
- 4. New onset proteinuria

Level 1 of diagnostic certainty

- 1. New onset proteinuria diagnosed with \geq 300 mg protein on 24 hour urine collection OR
- 1. Spot protein:creatinine ratio \geq 0.3

Level 2 of diagnostic certainty

- 1. New onset proteinuria diagnosed with \geq 1+ protein on urine dipstick

NO Level 3-5 definitions exist for Pre-Eclampsia (PIH)

Insufficient evidence:

- 1. Blood pressure cannot be measured
- 2. No proteinuria evaluation is available

Appendix 2:

Gestational Age Assessment Guide

Definitions of terms used:

Intrauterine insemination (IUI) – A procedure in which a fine catheter is inserted through the cervix into the uterus to deposit a sperm sample directly into the uterus, to achieve fertilization and pregnancy.

Embryo transfer – The procedure in which one or more embryos are placed in the uterus or fallopian tube.

Ultrasound (U/S):

- 1st trimester ($\leq 13 \frac{6}{7}$ weeks).
- 2nd trimester scan ($14 \frac{0}{7}$ – $27 \frac{6}{7}$ weeks).
- 3rd trimester ($28 \frac{0}{7}$ + weeks).

LMP (last menstrual period) – GA is calculated from the first day of the mother’s LMP. If LMP and U/S do not correlate, default to U/S GA assessment.

***Certain LMP:** (LMP date + 280 days): Use LMP if within 7 days at ≤ 14 weeks; within 14 days at ≤ 26 weeks; within 21 days beyond 26 weeks.

***Uncertain LMP – first trimester ($\leq 13 \frac{6}{7}$ weeks by LMP):** Use the approximate date of the last menstrual period (LMP) if corroborated by physical exam, or a first trimester ultrasound. If there is a discrepancy of >7 days between the LMP and the first trimester ultrasound, the ultrasound-established dates will take preference over LMP for gestational age dating.

***Uncertain LMP – second trimester ($14 \frac{0}{7}$ – $27 \frac{6}{7}$ weeks by LMP):** Use the approximate date of the LMP if corroborated by physical exam including fundal height, or a second trimester ultrasound. If there is a discrepancy of >10 days between the LMP and the second trimester ultrasound, the ultrasound-established dates will take preference over LMP for GA dating.

***Uncertain LMP – third trimester >28 weeks –** third trimester ultrasound.

***No LMP date:** If menstrual dates are unknown, the ultrasound established dates will be used for gestational age dating or 2nd trimester fundal height and/or newborn physical examination.

Pregnancy symptoms– nausea, fatigue, tender swollen breasts, frequent urination.

Antenatal Physical Examination– pelvic bimanual examination confirming enlarged uterus.

Newborn Physical Examination– New Ballard Score – physical and neurological assessment.

Fundal Height (FH) in cm

Birth Weight (BW) in grams

GA Levels of Certainty (check all that are present)

Level 1

1. Certain LMP* or intrauterine insemination (IUI) date or embryo transfer (ET) date with confirmatory 1st trimester scan ($\leq 13 \frac{6}{7}$ weeks).

OR

2. 1st trimester scan ($\leq 13 \frac{6}{7}$ weeks).

Level 2A

1. Certain LMP* with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks). If LMP and U/S do not correlate, default to U/S GA assessment.

OR

2. Certain LMP* with 1st trimester physical examination.

Level 2B

Uncertain LMP with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks).

Level 3A

1. Certain LMP with 3rd trimester scan – 28 0/7 weeks +.

OR

2. Certain LMP with confirmatory 2nd trimester FH.

OR

3. Certain LMP with birth weight.

OR

4. Uncertain LMP with 1st trimester physical examination.

Level 3B

1. Uncertain LMP with FH.

OR

2. Uncertain LMP with newborn physical assessment.

OR

3. Uncertain LMP with Birth weight.

