



Diabetes in pregnancy

Study 01/21

Case Report Form – CONTROL

Instructions:

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This is a Sample Data Collection Form for information only. **Please do not use this form to provide us with information on a control.** Data should be entered using our OpenClinica system [here](#).

Section 1. Control selection

Please read the following instructions for selecting controls for this study.

1. Identify the date and time of **admission** for the woman with a diagnosis of diabetes in pregnancy (gestational diabetes or pre-existing diabetes) admitted for labour care in the midwifery unit (the **CASE**).
2. From the unit birth register or electronic records identify the woman who was **admitted for labour care in the midwifery unit/birth centre immediately before** the CASE, **who did not meet the case definition**.

Please note, this woman:

- Must have **been admitted to** the midwifery unit/birth centre for labour care **immediately before** the case
- Must **not** have had a diagnosis of diabetes

This woman is the **CONTROL**.

1.1 Please confirm that this woman was admitted for labour care in the midwifery unit/birth centre immediately before the case

Yes/No

If Yes, go to **1.1.1** If No, this woman may not be correctly selected as a control. Please contact the UKMidSS office. Do NOT enter any further data for this woman at this point.

1.1.1 In which month was this woman admitted for labour care in the midwifery unit/birth centre?

Month and year

1.2 Please confirm that this woman did NOT have a diagnosis of diabetes (pre-existing or gestational) on admission to the midwifery unit/birth centre for labour care.

Yes (i.e, no diagnosis of diabetes)

No (i.e. diagnosis of diabetes)

If Yes, go to **Section 2** If No, **this woman may not be correctly selected as a control. Please contact the UKMidSS office. Do NOT enter any further data for this woman at this point.**

Section 2. Woman's details

2.1 What was the woman's age at delivery (years)?

2.2 What was the woman's ethnic group?

[Drop-down menu]

01. White British
02. White Irish
03. Any other White background
04. Mixed White & Black Caribbean
05. Mixed White & Black African
06. Mixed White & Asian
07. Any other mixed background
08. Indian
09. Pakistani
10. Bangladeshi
11. Any other Asian background
12. Black Caribbean
13. Black African
14. Any other Black background
15. Chinese
16. Any other ethnic group
17. Not recorded

2.3 Is the woman currently in paid employment?

Yes/No/Not recorded

If Yes, Woman's occupation _____ OR Not recorded

2.4 Is the woman's partner currently in paid employment?

Yes/No/No partner/Not recorded

If Yes, Partner's occupation _____ OR Not recorded

2.5 Children in Low-income Families Measure score

0.000 [note: link to an external look-up website where users can enter postcode to derive the CLFM score which can then be entered in the form – use same validation as PPH Study]

2.6 What was the woman's height at booking (cm)?

_____ OR Not recorded

2.7 What was the woman's weight at booking (kg)?

_____ OR Not recorded

If 2.6=not recorded & 2.7=not recorded, go to **2.7.1**

2.7.1. What was the woman's body mass index (BMI)?

_____ OR Not recorded

2.8 What was the woman's smoking status at delivery?

Please tick one only

- 01. Never smoked
- 02. Gave up prior to pregnancy
- 03. Gave up during pregnancy
- 04. Current smoker
- 05. Not recorded

Section 3. Pregnancy/antenatal history**3.1 Has this woman had any previous pregnancies?**

Yes/No [If Yes, go to **3.1.1**; if No, go to **3.2**]

3.1.1. How many completed pregnancies ≥ 24 weeks has this woman had, prior to this pregnancy?

3.1.2. How many pregnancy losses <24 weeks has this woman had, prior to this pregnancy?

3.1.3. Was this woman known to have had any complications in previous pregnancies?

Please tick all that apply [at least one option must be ticked, "none of the above" cannot be ticked with any other option]

- 01. Gestational diabetes
- 02. Previous macrosomic baby ≥ 4.5 kg
- 03. Previous shoulder dystocia
- 04. Other, please specify _____
- 05. None of the above

3.2 Was this pregnancy conceived through assisted conception?

Yes/No/Not recorded

3.3 What was the final Estimated Date of Delivery (EDD)?

[Note: Use the best estimate (ultrasound scan or date of last menstrual period) based on a 40 week gestation]

DD/MM/YY

3.3.1. What was the gestation at admission (in completed weeks)?

Two-digit whole number

3.4 Did this woman have a random blood glucose test during pregnancy?

Yes/No/Not recorded

3.5 Did this woman have an oral glucose tolerance test during pregnancy?

Yes/No

3.6 Immediately prior to admission in labour was this woman known to have any medical conditions?

Please tick all that apply [at least one option must be ticked, “none of the above” cannot be ticked with any other option]

01. Essential hypertension
02. Confirmed cardiac disease
03. Thromboembolic disorder
04. Atypical antibodies
05. Hyperthyroidism
06. Renal disease
07. Epilepsy
08. Other, please specify _____
09. None of the above

3.7 Were any current pregnancy risk factors identified antenatally, prior to admission in labour?

Please tick all that apply [at least one option must be ticked, “none of the above” cannot be ticked with any other option]

Please tick all that apply:

01. BMI at booking $>35\text{kg/m}^2$
02. Anhydramnios
03. Polyhydramnios
04. Suspected fetal growth restriction
05. Suspected macrosomia
06. Post-term (>42 weeks)
07. Anaemia (haemoglobin $<105\text{g/litre}$)
08. Group B Streptococcus
09. Antepartum haemorrhage
10. Pre-eclampsia / pregnancy induced hypertension
11. Malpresentation (breech or transverse lie)
12. Other, please specify _____
13. None of the above

Section 4. Labour and birth care

4.1 Was this woman's labour induced?

Yes/No/Not recorded

4.2 On initial assessment at the start of labour care were any of the following identified?

Please tick all that apply [at least one option must be ticked, "none of the above" cannot be ticked with any other option]

01. Abnormal blood glucose readings
02. Maternal tachycardia
03. Hypertension
04. Proteinuria
05. Maternal pyrexia
06. Vaginal blood loss
07. Prolonged rupture of membranes (>24 hours before onset of established labour)
If Yes, please specify duration _____ hrs
08. Significant meconium
09. Reported pain differing from pain normally associated with contractions
10. Abnormal presentation, including cord presentation
11. Transverse or oblique lie
12. High or free-floating head
13. Suspected fetal growth restriction
14. Suspected macrosomia
15. Suspected anhydramnios
16. Suspected polyhydramnios
17. Fetal heart rate abnormality
18. Deceleration in fetal heart rate
19. Reduced fetal movements in the last 24 hours
20. None of the above

4.3 Did this woman use immersion in water for pain relief at any time during labour?

Yes/No

4.4 Were any of the following identified during labour care (after initial assessment) before birth?

Please tick all that apply [at least one option must be ticked, "none of the above" cannot be ticked with any other option]

01. Abnormal blood glucose readings
02. Maternal tachycardia
03. Hypertension
04. Maternal pyrexia

05. Vaginal blood loss
06. Prolonged rupture of membranes
If Yes, please specify duration
07. Significant meconium
08. Reported pain differing from pain normally associated with contractions
09. Confirmed/suspected delay in first stage of labour
10. Confirmed/suspected delay in second stage of labour
11. Obstetric emergency
If Yes, please specify
12. Abnormal presentation, including cord presentation
13. Transverse or oblique lie
14. High or free-floating head
15. Fetal heart rate abnormality
16. Deceleration in fetal heart rate
17. None of the above

4.5 Was this woman transferred to the care of an obstetrician at any time during labour care or immediately after the birth?

Yes/No [If Yes, go to **4.5.1**; if No, go to **4.6**]

4.5.1 When was the woman transferred?

01. Before birth
02. After birth

4.5.2 What was the primary reason for transfer?

01. Abnormal blood glucose readings
02. Maternal tachycardia
03. Hypertension
04. Maternal pyrexia
05. Significant meconium
06. Confirmed delay in first stage of labour
07. Confirmed delay in second stage of labour
08. Epidural/other pain relief request
09. Fetal heart rate abnormalities in first stage
10. Fetal heart rate abnormalities in second stage
11. Retained placenta
12. Repair of perineal trauma
13. Other, please specify _____

4.5.3 Was labour augmented with syntocinon?

Yes / No

4.5.4 Did this woman have an epidural or spinal?

Yes / No

4.5.5. Did this woman have a general anaesthetic?

Yes / No

4.6 Where did this woman give birth?

[only one option must be ticked]

- 01. Midwifery unit, under midwifery care
- 02. Midwifery unit, under care of obstetrician
- 03. Obstetric unit, under midwifery care
- 04. Obstetric unit, under care of obstetrician

4.7 What was the mode of birth?

[only one option must be ticked]

- 01. Spontaneous vertex birth
- 02. Vaginal Breech
- 03. Ventouse
- 04. Forceps
- 05. Caesarean section [Go to **4.7.1**]

4.7.1. Grade of urgency of Caesarean section

[only one option must be ticked]

- 01. Category 1: Immediate threat to life of woman or fetus
- 02. Category 2: Maternal or fetal compromise, not immediately life-threatening
- 03. Category 3: Needing early delivery, no maternal or fetal compromise
- 04. Category 4: At a time to suit the woman and maternity team

4.7.2. Primary reason for Caesarean section

[only one option must be ticked]

- 01. Abnormal presentation
- 02. Fetal compromise
- 03. Maternal compromise
- 04. Slow progress
- 05. Other, please specify _____
- 06. Not known

4.8 Did this woman give birth in water?

Yes/No

4.9 Was shoulder dystocia documented?Yes / No (if yes, go to **4.9.1**)**4.9.1. How was the shoulder dystocia managed?**

Please tick all that apply

- 01. McRoberts
- 02. Episiotomy
- 03. Suprapubic pressure
- 04. Internal manoeuvres
- 06. Removal posterior arm
- 07. All fours position
- 08. Other (e.g. Cleidotomy, Zavanelli, Symphysiotomy), please specify

4.10 Did this woman receive syntocinon or syntometrine as a component of active management of the 3rd stage?

Yes/No

Section 5. Maternal outcomes**5.1 Did this woman have any perineal trauma involving the anal sphincter (3rd/4th degree tear)?**

Yes/No

5.2 Within the first 48 hours after giving birth did this woman receive a higher level of care, e.g. enhanced maternity care or intensive care?Yes/No [if yes go to **5.2.1**; if no go to **5.3**]**5.2.1. What was the highest level of care the woman received?**

[Drop down menu]

- 01. Enhanced maternity care (high dependency)
- 02. Intensive care
- 03. Other higher level care, please specify (free text) _____

5.2.2. What was the main reason for higher level care?

Free text _____

5.2.3. What was the total duration of higher level care?

Note: Hours OR Days – validation to ensure that only hours or days is entered

Hours (if less than 24 hours) OR Days (if at least 24 hours)

5.3 Was this woman recorded as having a PPH of 1500ml or more?

Yes / No

5.4 Did this woman receive a blood transfusion within 48 hours of giving birth?

Yes/No [If Yes, go to **5.4.1**; if No go to Error! Reference source not found.]

5.4.1. When was the first blood transfusion given?

[Drop down menu]

01. End of third stage – 23 hours after birth
02. 24-48 hours after birth
03. More than 48 hours after birth

5.4.2. How many units of whole blood or packed cells did this woman receive?

5.5 Was there any other maternal morbidity?

Yes/No If Yes, please specify _____

5.6 Did this woman die?

Yes/No. If Yes go to **5.6.1** If No go to **5.7**

5.6.1. What was the underlying cause of maternal death?

Free text _____/Not yet known

5.7 How long after delivery was the woman discharged home?

Note: Hours OR Days – validation to ensure that only hours or days is entered

Hours (if less than 24 hours) OR Days (if at least 24 hours)

Section 6. Baby outcomes

6.1 What was the baby's birthweight?

_____ g [acceptable range 1500-5500g]

6.2 What was the sex of the baby?

Please tick one only

01. Male
02. Female
03. Indeterminate

6.3 Was the baby stillborn?

Yes/No [If Yes, go to **6.3.1**; if No, go to **6.4**]

6.3.1. When did the baby die?

[Drop down menu]

01. Before the start of care in labour
02. After the start of care in labour

6.4 What was the Apgar score at 5 minutes?

[0-10] or not recorded

6.5 Was the baby fed within 30 minutes of birth?

Yes/No [If yes, go to Error! Reference source not found.]

6.5.1 What type of milk did the baby receive?

[please tick all that apply]

- 01. Breast milk
- 02. Formula milk

6.6 Was the baby breastfed at least once before discharge home?

Yes/No

6.7 Did the baby complete a blood sugar monitoring protocol?

Yes/No [If Yes, go to 6.7.1; if No, go to 6.8]

6.7.1 Did the woman exclusively breastfeed during the blood sugar protocol?

Yes/No

6.7.2 Did the baby receive formula/glucoGel for glycaemic control?

Yes/No

6.7.3 What was the reason for monitoring the blood sugar?

[Drop down menu- tick all that apply]

- 01. Maternal beta-blocker use
- 02. Pre-term
- 03. Small for gestational age
- 04. Low birth weight
- 05. Abnormal feeding behaviour
- 06. Perinatal acidosis (cord arterial or infant pH)
- 07. Hypothermia
- 08. Suspected / confirmed early onset sepsis
- 09. Cyanosis
- 10. Apnoea
- 11. Altered level of consciousness
- 12. Seizures
- 13. Hypotonia
- 14. Lethargy
- 15. High pitched cry

6.8 Was the baby admitted to a neonatal unit or any other paediatric high level care within 48 hours of birth?

Yes/No [If Yes, go to 6.8.1; if No, go to 6.9]

6.8.1. What was the duration of stay in the neonatal unit?

Note: Hours OR Days – validation to ensure that only hours or days is entered

Hours (if less than 24 hours) OR Days (if at least 24 hours)

6.8.2. What was the main reason for admission to the neonatal unit?

[Drop down menu]

01. Respiratory problems

02. Suspected perinatal asphyxia

03. Hypoglycaemia

- Lowest blood glucose level before admission (mmol/l) [acceptable range 0-3]
- Did the baby receive intravenous blood glucose? Yes/No

04. Physical trauma/birth injury

05. Feeding problems

06. Suspected infection

07. Meconium aspiration

08. Jaundice

09. Congenital anomaly (please specify _____)

10. Maternal admission to higher level care

11. Other, please specify _____

6.9 Was there any other neonatal morbidity?

Yes/No If Yes, please specify _____

6.10 Did this baby die after birth?

Yes/No [If Yes, go to **6.10.1**; if No, go to **6.11**]

6.10.1. How old was the baby when they died?

Hours OR days _____

6.10.2. What was the primary cause of neonatal death?

[Drop down menu]

01. Congenital anomaly

02. Antepartum infection

03. Immaturity related conditions

04. Intrapartum asphyxia, anoxia or trauma

05. Infection

06. Other _____

07. Not yet known

6.11 How long after delivery was the baby discharged home?

Note: Hours OR Days – validation to ensure that only hours or days is entered

Hours (if less than 24 hours)OR Days (if at least 24 hours)

Section 7. Any other information

- 7.1 Please enter any other information you feel may be important (please do not add any personal identifiable data here- e.g. date of birth, NHS numbers, hospital numbers, etc.)**

Sample Control