ID Number:

UKOSS

UK Obstetric Surveillance System

Cholestasis in Pregnancy
Study 05/10

Data Collection Form - CASE

Please report any woman delivering on or after 1st June 2010 and before 1st July 2011.

Case Definition:

All pregnant women identified as having severe obstetric cholestasis, defined as having pruritus without a rash in association with raised serum bile acids ≥ 40 µmol/L at any point in the pregnancy.

Exclude:

Women with obsteric cholestasis with bile acid levels <40 µmol/L.

Please return the completed form to:

UKOSS
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Oxford
OX3 7LF
Fax: 01865 617775
Phone: 01865 289714

Case reported in: _____

Royal College of Obstetricians and Gynaecologists

npeu National Perinatal Epidemiology Unit

Instructions

1. Please do not enter any personally identifiable information (e.g. name, address or hospital number) on this form.
2. Please record the ID number from the front of this form against the woman's name on the Clinician's Section of the blue card retained in the UKOSS folder.
3. Fill in the form using the information available in the woman's case notes.
4. Tick the boxes as appropriate. If you require any additional space to answer a question please use the space provided in section 7.
5. Please complete all dates in the format DD/MM/YY, and all times using the 24hr clock e.g. 18:37
6. If codes or examples are required, some lists (not exhaustive) are included on the back page of the form.
7. If the woman has not yet delivered, please complete the form as far as you are able, excluding delivery and outcome information, and return to the UKOSS Administrator. We will send these sections again for you to complete two weeks after the woman's expected date of delivery.
8. **If you do not know the answers to some questions, please indicate this in section 7.**
9. If you encounter any problems with completing the form please contact the UKOSS Administrator or use the space in section 7 to describe the problem.

Section 1: Woman's details

1.1 Year of birth Y Y Y Y

1.2 Ethnic group[1]* *(enter code, please see back cover for guidance)* ☐☐

1.3 Marital status single ☐ married ☐ cohabiting ☐

1.4 Was the woman in paid employment at booking? Yes ☐ No ☐

If Yes, what is her occupation

_____

If No, what is her partner's (if any) occupation

_____

1.5 Height at booking ☐☐☐ cm

1.6 Weight at booking ☐☐☐.☐ kg

1.7 Smoking status never ☐ gave up prior to pregnancy ☐ current ☐ gave up during pregnancy ☐

Section 2: Previous Obstetric History

2.1 Gravidity

Number of completed pregnancies beyond 24 weeks ☐☐

Number of pregnancies less than 24 weeks ☐☐

If no previous pregnancies, *please go to section 3*

2.2 Please indicate if any of the following were present in previous pregnancies:

Pre-eclampsia ☐ HELLP ☐ Obstetric Cholestasis ☐

2.3 Did the woman have any other previous pregnancy problems?[2]* Yes ☐ No ☐

If Yes, please specify _____

*For guidance please see back cover

Section 3: Previous Medical History

3.1 Please indicate whether any of the following were present: *(Tick all that apply)*

- Hepatitis C infection ☐
- Epstein Barr infection ☐
- Cytomegalovirus infection ☐
- Autoimmune hepatitis ☐
- Primary biliary cirrhosis ☐
- Primary sclerosing cholangitis ☐
- Gallstones
  - **If Yes**, please state if Symptomatic ☐ Asymptomatic ☐
- Drug induced hepatic impairment ☐
  - **If Yes**, please specify drug causing impairment _____
- Cyclical itch / cholestasis ☐
- Other episodes of cholestasis e.g. drug-induced ☐
- Jaundice ☐

3.2 Did the woman have any other previous or pre-existing medical problems?[3]* Yes ☐ No ☐

If Yes, please give details _____

Section 4: This Pregnancy

Section 4a: Diagnosis of Cholestasis

4a.1 Final Estimated Date of Delivery (EDD)[4]* D D / M M / Y Y

4a.2 Was this a multiple pregnancy? Yes ☐ No ☐

If Yes, please specify number of fetuses ☐

4a.3 Date of diagnosis D D / M M / Y Y

4a.4 Were any of the following present at or immediately preceding diagnosis?

	Yes	No	Date of onset	Date of resolution
Pruritus	☐	☐	D D / M M / Y Y	D D / M M / Y Y
Vomiting	☐	☐	D D / M M / Y Y	D D / M M / Y Y
Abdominal pain	☐	☐	D D / M M / Y Y	D D / M M / Y Y
Skin rash	☐	☐	D D / M M / Y Y	D D / M M / Y Y

4a.5 Did the woman have hypoglycaemia? Yes ☐ No ☐

If Yes, please specify glucose levels (mmol/L) ☐☐☐

4a.6 Was an ultrasound scan performed? Yes ☐ No ☐

If Yes, were gallstones or biliary sludge found on ultrasound? Yes ☐ No ☐

What was the date of scan? D D / M M / Y Y

Were any abnormalities found? Yes ☐ No ☐

If Yes, please give details _____

*For guidance please see back cover

4a.7 Was additional imaging performed? Yes ☐ No ☐

If Yes, please give type of imaging _____

And date of imaging D D / M M / Y Y

Were any abnormalities found? Yes ☐ No ☐

If Yes, please give details _____

4a.8 Was a liver biopsy performed? Yes ☐ No ☐

If Yes, please specify date of biopsy D D / M M / Y Y

And major findings _____

4a.9 Was pre-eclampsia diagnosed in this pregnancy? Yes ☐ No ☐

If Yes, please specify

Maximum diastolic BP ☐☐☐

Maximum proteinuria (+ of protein) ☐☐☐☐

4a.10 Were there any other problems in this pregnancy?[2]* Yes ☐ No ☐

If Yes, please specify _____

Section 4b: Biochemistry before delivery *(please indicate if not recorded)*

Marker	Level at diagnosis	Worst recorded level	Date worst level recorded
Serum bile acids (µmol/L)	☐☐☐	☐☐☐	D D / M M / Y Y
AST (iu/L)	☐☐☐☐	☐☐☐☐	D D / M M / Y Y
ALT (iu/L)	☐☐☐☐	☐☐☐☐	D D / M M / Y Y
Bilirubin (µmol/L)	☐☐☐	☐☐☐	D D / M M / Y Y
γGT (iu/L)	☐☐☐	☐☐☐	D D / M M / Y Y
Creatinine (µmol/L)	☐☐☐	☐☐☐	D D / M M / Y Y
Urate (µmol)	☐☐☐☐	☐☐☐☐	D D / M M / Y Y
Platelets (x10^9/L)	☐☐☐	☐☐☐	D D / M M / Y Y
PT (sec)	☐☐☐	☐☐☐	D D / M M / Y Y
APTT (sec)	☐☐☐	☐☐☐	D D / M M / Y Y
White cell count (x10^9/L)	☐☐.☐	☐☐.☐	D D / M M / Y Y

4b.1 What was sample type of the worst recorded level of bile acids?

Fasting ☐ Random ☐ Not known ☐

Section 4c: Management

4c.1 Did the elevation of serum bile acids resolve spontaneously? Yes ☐ No ☐

If Yes, please specify date of spontaneous resolution D D / M M / Y Y

4c.2 Was the woman recruited to the PITCH trial? Yes ☐ No ☐

If Yes, please specify which arm(s) of the trial Drug vs placebo ☐ Timing of delivery ☐

4c.3 Was treatment with ursodeoxycholic acid (UDCA) started? Yes ☐ No ☐

If Yes, please give date started D D / M M / Y Y

And dose (mg) ☐☐☐

Did symptoms improve? Yes ☐ No ☐

*For guidance please see back cover

4c.4 Was treatment with vitamin K started? Yes ☐ No ☐

If Yes, please give date started D D / M M / Y Y

4c.5 Was treatment with any other drugs started? Yes ☐ No ☐

If Yes, Please give

Drug name	Indication	Dose	Start Date
			D D / M M / Y Y
			D D / M M / Y Y
			D D / M M / Y Y
			D D / M M / Y Y

4c.6 How are bile acids routinely measured in your unit?

Fasted ☐ Non fasted ☐ Not known ☐

Section 4d: Antenatal Fetal Monitoring

4d.1 Were any of the following employed during this pregnancy? Yes ☐ No ☐

Monitoring Type	Number of times monitored
Cardiotocography	
Fetal movement charts	
Fetal blood sampling	
USS for fetal growth	
Doppler ultrasound scan	
Other	
If Other, please specify monitoring type _____	

Section 5: Delivery

5.1 Did this woman have a miscarriage? Yes ☐ No ☐

If Yes, please specify date D D / M M / Y Y

5.2 Did this woman have a termination of pregnancy? Yes ☐ No ☐

If Yes, please specify date D D / M M / Y Y

5.3 Is this woman still undelivered? Yes ☐ No ☐

If Yes, will she be receiving the rest of her antenatal care from your hospital? Yes ☐ No ☐

If No, please indicate name of hospital providing future care

_____

Will she be delivered at your hospital? Yes ☐ No ☐

If No, please indicate name of delivery hospital, then *go to Section 7*

_____

5.4 Was delivery induced? Yes ☐ No ☐

If Yes, please state indication _____

What method was used? _____

*For guidance please see back cover

5.5 Did the woman labour? Yes ☐ No ☐

If Yes, was labour augmented? Yes ☐ No ☐

What date and time was 1st stage of labour diagnosed? D D / M M / Y Y h h : m m (24hr)

What date and time was 2nd stage of labour diagnosed? D D / M M / Y Y h h : m m (24hr)

5.6 Was delivery by caesarean section? Yes ☐ No ☐

If Yes, please state:

Grade of urgency[5]* ☐

Indication for caesarean section _____

Method of anaesthesia: Regional ☐ General anaesthetic ☐

Section 6: Outcomes

Section 6a: Woman

6a.1 Was the woman admitted to ITU/HDU? Yes ☐ No ☐

If Yes, duration of stay ☐☐ days

Or Tick if woman is still in ITU/HDU ☐

Or Tick if woman was transferred to another hospital ☐

6a.2 Biochemistry at delivery *Dates of these tests should be not more than 7 days before delivery*

Marker *(please indicate if not recorded)*	Level at delivery	Date level recorded
Serum bile acids (μmol/L)	☐☐☐	D D / M M / Y Y
AST (iu/L)	☐☐☐	D D / M M / Y Y
ALT (iu/L)	☐☐☐	D D / M M / Y Y
Bilirubin (μmol/L)	☐☐☐	D D / M M / Y Y
γGT (iu/L)	☐☐☐	D D / M M / Y Y

6a.3 Did any other major maternal morbidity occur?[6]* Yes ☐ No ☐

If Yes, please specify _____

6a.4 Did the woman die? Yes ☐ No ☐

If Yes, please specify date of death D D / M M / Y Y

What was the primary cause of death as stated on the death certificate?
(Please state if not known.) _____

Section 6b: Infant 1

NB: If more than one infant, for each additional infant, please photocopy the infant section of the form **(before filling it in)** and attach extra sheet(s) or download additional forms from the website: www.npeu.ox.ac.uk/ukoss

6b.1 Date and time of delivery D D / M M / Y Y h h : m m (24hr)

6b.2 Mode of delivery

Spontaneous vaginal ☐ Ventouse ☐ Lift-out forceps ☐ Rotational forceps ☐

Breech ☐ Pre-labour caesarean section ☐ Caesarean section after onset of labour ☐

*For guidance please see back cover

6b.3 **Birthweight** ☐☐☐☐ g

6b.4 **Sex of infant** Male ☐ Female ☐ Indeterminate ☐

6b.5 **Was the infant stillborn?** Yes ☐ No ☐

If Yes, *please go to section 7.*

6b.6 **5 min Apgar** ☐☐

6b.7 **Was the infant admitted to the neonatal unit?** Yes ☐ No ☐

If Yes, please specify:

Duration of stay ☐☐ days

What was the indication for admission? _____

6b.8 **Were any CTG abnormalities noted during labour?** Yes ☐ No ☐

If Yes, please specify type of abnormality _____

6b.9 **Was the umbilical arterial or venous pH measured?** Yes ☐ No ☐

If Yes, what was the umbilical arterial pH? ☐☐.☐

What was the umbilical vein pH? ☐☐.☐

6b.10 **Was there meconium staining of the amniotic fluid, placenta or membranes?** Yes ☐ No ☐

6b.11 **Did any other major infant complications occur?[7]*** Yes ☐ No ☐

If Yes, please specify _____

6b.12 **Did the infant have a congenital anomaly?** Yes ☐ No ☐

If Yes, please specify _____

6b.13 **Did this infant die?** Yes ☐ No ☐

If Yes, please specify date of death D D / M M / Y Y

What was the primary cause of death as stated on the death certificate?
(Please state if not known.) _____

Section 7:

Please use this space to enter any other information you feel may be important

_____

_____

_____

_____

_____

Section 8:

8.1 **Name of person completing the form** _____

8.2 **Designation** _____

8.3 **Today's date** D D / M M / Y Y

You may find it useful in the case of queries to keep a copy of this form.

*For guidance please see back cover

Definitions

1. UK Census Coding for ethnic group

WHITE
- 01. British
- 02. Irish
- 03. Any other white background

MIXED
- 04. White and black Caribbean
- 05. White and black African
- 06. White and Asian
- 07. Any other mixed background

ASIAN OR ASIAN BRITISH
- 08. Indian
- 09. Pakistani
- 10. Bangladeshi
- 11. Any other Asian background

BLACK OR BLACK BRITISH
- 12. Caribbean
- 13. African
- 14. Any other black background

CHINESE OR OTHER ETHNIC GROUP
- 15. Chinese
- 16. Any other ethnic group

2. Previous or current pregnancy problems, including:

Thrombotic event
Amniotic fluid embolism
Eclampsia
3 or more miscarriages
Preterm birth or mid trimester loss
Neonatal death
Stillbirth
Baby with a major congenital abnormality
Small for gestational age (SGA) infant
Large for gestational age (LGA) infant
Infant requiring intensive care
Puerperal psychosis
Placenta praevia
Gestational diabetes
Significant placental abruption
Post-partum haemorrhage requiring transfusion
Surgical procedure in pregnancy
Hyperemesis requiring admission
Dehydration requiring admission
Ovarian hyperstimulation syndrome
Severe infection e.g. pyelonephritis

3. Previous or pre-existing maternal medical problems, including:

Cardiac disease (congenital or acquired)
Renal disease
Endocrine disorders e.g. hypo or hyperthyroidism
Psychiatric disorders
Haematological disorders e.g. sickle cell disease, diagnosed thrombophilia
Inflammatory disorders e.g. inflammatory bowel disease
Autoimmune diseases
Cancer
HIV

4. Estimated date of delivery (EDD): Use the best estimate (ultrasound scan or date of last menstrual period) based on a 40 week gestation

5. RCA/RCOG/CEMACH/CNST Classification for urgency of caesarean section:

1. Immediate threat to life of woman or fetus
2. Maternal or fetal compromise which is not immediately life-threatening
3. Needing early delivery but no maternal or fetal compromise
4. At a time to suit the woman and maternity team

6. Major maternal medical complications, including:

Persistent vegetative state
Cardiac arrest
Cerebrovascular accident
Adult respiratory distress syndrome
Disseminated intravascular coagulopathy
HELLP
Pulmonary oedema
Mendleson's syndrome
Renal failure
Thrombotic event
Septicaemia
Required ventilation

7. Fetal/infant complications, including:

Respiratory distress syndrome
Intraventricular haemorrhage
Necrotising enterocolitis
Neonatal encephalopathy
Chronic lung disease
Severe jaundice requiring phototherapy
Major congenital anomaly
Severe infection e.g. septicaemia, meningitis
Exchange transfusion