ID Number:

UKOSS

UK Obstetric Surveillance System

Severe Primary Immune Thrombocytopenia in Pregnancy Study 02/13

Data Collection Form - CASE

Any women delivering on or after 01/07/2013 and before 01/07/2014

Case Definition:

Please report any pregnant woman:

1. who has been diagnosed with thrombocytopenia with a platelet count of <50 x 10^9/l at any point in her pregnancy prior to delivery where obstetric and hereditary causes for thrombocytopenia have been excluded (ie. Pre-eclampsia, HELLP syndrome, acute fatty liver of pregnancy, known antiphospholipid antibody syndrome or other hereditary thrombocytopenias)

OR

2. Any pregnant woman diagnosed with an isolated thrombocytopenia where a clinical decision to treat the thrombocytopenia prior to delivery of the infant has been made.

EXCLUDE

Women with secondary immune thrombocytopenia to systemic lupus erythematosus (SLE) Hepatitis C, CMV, HIV and HAART therapy or any condition where treatment of thrombocytopenia is focused on treatment of the causative disease are excluded from the study.

Royal College of Obstetricians and Gynaecologists

Bringing to life the best in women's health care

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: _____

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 ☐

1.8 Blood group ☐☐

1.9 Rhesus D status Positive ☐ Negative ☐

Section 2: Previous Obstetric History

2.1 Gravidity

Number of previous completed pregnancies beyond 24 weeks ☐☐
Number of previous pregnancies less than 24 weeks ☐☐

If no previous pregnancies, please go to section 3

2.2 Did the woman have any previous caesarean section(s) Yes ☐ No ☐

If Yes, how many previous Caesarean Sections has this woman had? ☐☐

*For guidance please see back cover

Section 3: Previous Medical History

Section 3a: ITP related

3a.1 **Was the woman known to have ITP *prior to pregnancy*?** Yes ☐ No ☐

If No, *please go to section 3c*

3a.2 **What year was Immune Thrombocytopenia diagnosed?** Y Y Y Y

3a.3 **What type of ITP was diagnosed ?** Primary (idiopathic) ☐

Secondary (associated with other autoimmune condition) ☐

Section 3b: Treatment of ITP prior to pregnancy

3b.1 **Has the woman ever been hospitalized due to ITP?** Yes ☐ No ☐ Unknown ☐

3b.2 **Did the woman receive treatment for ITP at any point prior to this pregnancy?**

Yes ☐ No ☐ Unknown ☐

If Yes, please give details of any treatments ever received **prior** to this pregnancy:

	Prior to conception	At conception	Neither	Not known
Corticosteroid therapy	☐	☐	☐	☐
Intravenous immunoglobulin	☐	☐	☐	☐
IV anti-D	☐	☐	☐	☐
Azathioprine	☐	☐	☐	☐
Cyclosporin A	☐	☐	☐	☐
Cyclophosphamide	☐	☐	☐	☐
Danazol	☐	☐	☐	☐
Dapsone	☐	☐	☐	☐
Mycophenolate mofetil	☐	☐	☐	☐
Rituximab	☐	☐	☐	☐
TPO receptor agonists (eg eltrombopag/romiplostin)	☐	☐	☐	☐
Vinka alkaloid regimen (eg. Vincristine / vinblastine)	☐	☐	☐	☐
Platelet transfusion	☐	☐	☐	☐

3b.3 **Did the woman have a splenectomy to treat this condition?** Yes ☐ No ☐ Unknown ☐

3b.4 **What is the lowest recorded platelet count prior to pregnancy:** ☐☐ x 10^9/l

Or please tick if unknown ☐

Section 3c: Pre-existing Medical Disorders

3c.1 **Did the woman have any other pre-existing medical problems?**[3*] Yes ☐ No ☐

If Yes, please specify _____

*For guidance please see back cover

Section 4: This Pregnancy

Section 4a:

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

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

If Yes, please specify number of fetuses ☐

Section 4b: Diagnosis of ITP

4b.1 Was ITP first diagnosed during this pregnancy? Yes ☐ No ☐

If No, *please go to 4b.2*

If Yes, what date was ITP diagnosed? D D / M M / Y Y

What investigations were performed to exclude other causes of thrombocytopenia:

Full Blood Count	Yes ☐	No ☐	Unknown ☐
Liver Function Tests	Yes ☐	No ☐	Unknown ☐
Urea and Electrolytes	Yes ☐	No ☐	Unknown ☐
Coagulation	Yes ☐	No ☐	Unknown ☐
C-reactive protein	Yes ☐	No ☐	Unknown ☐
Peripheral Blood Film	Yes ☐	No ☐	Unknown ☐
Antiphospholipid antibodies	Yes ☐	No ☐	Unknown ☐
Other	Yes ☐	No ☐	

If Other tests done, please specify which (e.g. bone marrow, anti-platelet antibodies): _____

4b.2 Did this woman suffer with maternal symptoms of ITP during this pregnancy? Yes ☐ No ☐

If Yes, please specify Bruising ☐ Purpura ☐ Epistaxis ☐ Intracranial haemorrhage ☐

Melaena ☐ Frank Haematuria ☐ Intra-abdominal bleeding ☐ Gingival bleeding ☐

Other ☐ **If Other,** please specify: _____

4b.3 Was the woman hospitalized for symptoms of major bleeding? Yes ☐ No ☐

If Yes, number of admissions: ☐☐

Total number of days as inpatient: ☐☐

4b.4 What was the lowest recorded platelet count this pregnancy? ☐☐☐ x 10^9/l

4b.5 Were there other problems in this pregnancy?[2*] Yes ☐ No ☐

If Yes, please specify: _____

Section 4c: Treatment of ITP during pregnancy

4c.1 Did this patient require treatment antenatally for low platelets? Yes ☐ No ☐

If No, *please go to section 5*

4c.2 What was the primary clinical reason for starting treatment? *(please tick only one)*

Symptoms of bruising/bleeding? ☐

Prophylactic treatment to prevent bleeding due to platelet count? ☐

Asymptomatic but treated to reach a target platelet count for normal vaginal delivery? ☐

Asymptomatic but treated to reach a target platelet count for planned caesarean section? ☐

Asymptomatic but treated to reach a target platelet count for other non-delivery surgical procedure? ☐

Other reason ☐

*For guidance please see back cover

4c.3 What treatments were given?

	First line	Second line	Date started	Date stopped	Responded? *(tick if yes)*
Standard dose corticosteroids	☐	☐	D D / M M / Y Y	D D / M M / Y Y	☐
IVIg	☐	☐	D D / M M / Y Y	D D / M M / Y Y	☐
IV anti-D	☐	☐	D D / M M / Y Y	D D / M M / Y Y	☐
High dose methyl prednisolone (HDMP)	☐	☐	D D / M M / Y Y	D D / M M / Y Y	☐
Splenectomy	☐	☐	N/A	N/A	N/A

4c.4 Were there any reported maternal side effects to any treatment? Yes ☐ No ☐

If Yes, please give specify the name of treatment and symptoms noted

_____

_____

4c.5 Was any further treatment required? Yes ☐ No ☐

If Yes, please give details? _____

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 the woman receive the remainder of her antenatal care at your hospital? Yes ☐ No ☐

If No, please indicate the name of the hospital providing future care: _____

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

If No, please indicate the name of delivery hospital: _____

5.4 Did the woman labour? Yes ☐ No ☐

If Yes, what was the onset of labour? *(please tick only one)* Spontaneous ☐ Induced ☐

Did the woman have an epidural during labour? Yes ☐ No ☐

5.5 Was a fetal blood sample(FBS) performed in labour? Yes ☐ No ☐

If Yes, how many FBS's were performed in labour? ☐

If No, what was the reason *(please tick only one)*

No indication for FBS ☐ Concern about low fetal platelets ☐ Other ☐

If Other, please specify: _____

5.6 Was the platelet count recorded during labour/at time of delivery? Yes ☐ No ☐

If Yes, What was the platelet count ☐☐☐ x 10^9/l

*For guidance please see back cover

5.7 **Did the woman receive any treatment for thrombocytopenia during labour?** Yes ☐ No ☐

If Yes, please give details *(e.g. platelet transfusion + number units transfused)*

_____

5.8 **Was delivery by caesarean section?** Yes ☐ No ☐

If Yes, please state:

Grade of urgency[5]* ☐

Indication for caesarean section _____

5.9 **Mode of Anaesthesia / Analgesia for delivery** *(please tick only one)*

General anaesthetic ☐ Spinal ☐ CSE ☐ Epidural ☐

None ☐ Opiates ☐ Entonox ☐

5.10 **What was the estimated blood loss at delivery?** ☐☐☐☐ ml

Section 6: Outcomes

Section 6a: Woman

6a.1 **Did the woman have a postpartum haemorrhage?** Primary ☐ Secondary ☐ No ☐

6a.2 **Did the woman have a caesarean section wound haematoma?** Yes ☐ No ☐ Unknown ☐

6a.3 **Did the woman have a perineal haematoma?** Yes ☐ No ☐ Unknown ☐

6a.4 **Did the woman have a diagnosed epidural haematoma?** Yes ☐ No ☐ Unknown ☐

6a.5 **Did any other major maternal morbidity occur?**[6]* Yes ☐ No ☐

If Yes, please specify _____

6a.6 **Was the woman admitted to ITU (critical care level 3)?** Yes ☐ No ☐

If Yes, please specify indication: _____

Duration of stay ☐☐ days

Or Tick if woman is still in ITU ☐

Or Tick if woman was transferred to another hospital ☐

6a.7 **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)

Was a post mortem examination undertaken? Yes ☐ No ☐

If Yes, did the examination confirm the diagnosis? Yes ☐ No ☐ Not known ☐

Section 6b: Infant

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 **Birthweight** ☐☐☐☐ *g*

*For guidance please see back cover

6b.3 Mode of delivery Spontaneous vaginal ☐ Ventouse ☐ Lift-out forceps ☐
Rotational forceps ☐ Breech ☐ Pre-labour caesarean section ☐
Caesarean section after onset of labour ☐

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

6b.5 Was the infant stillborn? Yes ☐ No ☐
If Yes, *go to section 7*

6b.6 5 min Apgar ☐☐

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

6b.8 Did any other major infant complications occur?[7]* Yes ☐ No ☐
If Yes, please specify _____

6b.9 Was the cord blood platelet count measured? Yes ☐ No ☐
If Yes, What was the cord blood platelet count at birth? ☐☐☐ x 10^9/l

6b.10 Did neonatal thrombocytopenia subsequently develop or worsen? Yes ☐ Not known ☐
If Yes, please give details _____
Was there evidence of neonatal sepsis or other cause for thrombocytopenia? Yes ☐ No ☐
If Yes, please give details _____
Was any treatment administered for neonatal thrombocytopenia? Yes ☐ No ☐ Unknown ☐
If Yes, please give name of drugs used (e.g. IVIg or platelet transfusion combined with IVIg)
_____

6b.11 Was a transcranial USS performed? Yes ☐ No ☐
If Yes, was there any evidence of intracranial haemorrhage? Yes ☐ No ☐

6b.12 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:

Name of person completing the form _____

Designation _____

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 morbidity, 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