ID Number:

UKOSS

UK Obstetric Surveillance System

Prosthetic Heart Valves in Pregnancy 01/13

Data Collection Form - CASE

Please report all women with an artificial prosthetic heart valve who become pregnant on or after 01/02/2013 and before 01/02/2015

Case Definition:

Any woman with an artificial mechanical prosthetic heart valve who becomes pregnant during the study period, irrespective of the outcome of the pregnancy.

This includes any woman in whom one or more heart valves have been replaced with an artificial mechanical prosthetic heart valve eg Starr-Edwards ball in cage, Bjork-Shiley tilting disc or St Jude's bi-leaflet valve.

EXCLUDED

Women with a bioprosthetic valve eg Carpentier-Edwards, Medtronic Intact or Hancock, women with a homograft or women who have had a valvotomy or valvoplasty (unless they also have an artificial mechanical prosthetic heart valve).

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 ☐

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 pregnancy problems[2]* (including cardiac, thromboembolic or bleeding problems) Yes ☐ No ☐

If Yes, please specify _____

*For guidance please see back cover

Section 3:

Section 3a: Previous Medical History

3a.1 **Does the woman have any thrombogenic risk factors?** Yes ☐ No ☐

If Yes, please tick all that apply Inherited thrombophilia ☐ Lupus ☐ Malignancy ☐
Polycythaemia (Hb>15g/dl) ☐ Thrombocythaemia (platelets>450g/dl) ☐ Other ☐

If Other, please specify _____

3a.2 **Has the woman previously used, or does she currently use intravenous recreational drugs?** Yes ☐ No ☐

3a.3 **Has the woman had a previous thromboembolic stroke?** Yes ☐ No ☐

3a.4 **Does the woman have any other pre-existing medical problems?[3]*** Yes ☐ No ☐

If Yes, please specify details _____

Section 3b: Diagnosis and Treatment Before This Pregnancy

3b.1 **What was the reason for valve replacement?** Congenital heart disease ☐
Rheumatic heart disease ☐ Bacterial endocarditis ☐ Other ☐

If Other, please specify _____

3b.2 **Which heart valve(s) have been replaced with artificial valves?**

	Replaced?		Type of valve	Size	Year of replacement
Mitral	Yes ☐	No ☐	_____	_____	Y Y Y Y
Aortic	Yes ☐	No ☐	_____	_____	Y Y Y Y
Tricuspid	Yes ☐	No ☐	_____	_____	Y Y Y Y
Pulmonary	Yes ☐	No ☐	_____	_____	Y Y Y Y

3b.3 **Was the anticoagulant given immediately prior to pregnancy known?** Yes ☐ No ☐

If Yes, please specify

Agent used	Frequency	Dose (mg)
_____	_____	_____

Was the target INR range known? Yes ☐ No ☐

If Yes, please give range _____

3b.4 **Was the woman given preconception counselling?** Yes ☐ No ☐ Not documented ☐

Section 4: This Pregnancy

Section 4a: Pregnancy diagnosis and treatment

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, specify number of fetuses ☐

4a.3 **What date did the woman first present in pregnancy with any health care professional?** *eg GP, midwife or consultant* D D / M M / Y Y

*For guidance please see back cover

4a.4 Which of the following best describes the pattern of care during pregnancy? *(Please tick only one)*

- Unbooked ☐
- Midwife only care – didn't see a consultant ☐
- Midwife and consultant care in the usual hospital for this woman's area of residence ☐
- Referred to a tertiary centre for an opinion(s) but care continued in the usual hospital for this woman's area of residence ☐
- Care transferred to a tertiary centre which took over the remainder of the pregnancy ☐
- Tertiary care throughout ☐

4a.5 Which treatment regime best describes that planned for the woman *(Please tick only one)*

- Warfarin throughout pregnancy (except around the time of delivery) ☐
- LMWH throughout pregnancy ☐
  - Date LMWH started D D / M M / Y Y
- Converted to LMWH in the first trimester, warfarin during the second and third trimester ☐
  - Date LMWH started D D / M M / Y Y
- Other ☐
  - **If Other**, please specify _____

Section 4b: Anticoagulation Monitoring

4b.1 Was there a planned frequency of anticoagulation monitoring?

Yes ☐ No monitoring – dose based on weight ☐

If No monitoring, please go to Section 4c

4b.2 Details of anticoagulation monitoring

	Monitored?		Planned frequency of monitoring	Range Aimed For	How long post dose was it measured?
INR	Yes ☐	No ☐			N/A
APTT	Yes ☐	No ☐			N/A
Anti Xa – predose	Yes ☐	No ☐			N/A
Anti Xa – postdose	Yes ☐	No ☐			
Other _____	Yes ☐	No ☐			N/A

4b.3 Was the woman still pregnant at 10 weeks? Yes ☐ No ☐

If Yes, please give anticoagulation agent used at 10 weeks _____

And Total daily dose (mg) _____

4b.4 Was the woman still pregnant at 20 weeks? Yes ☐ No ☐

If Yes, please give anticoagulation agent used at 20 weeks _____

And Total daily dose (mg) _____

4b.5 How many times was her anticoagulation monitored in total? ☐☐

4b.6 How many times was monitoring out of range leading to a change in dose of treatment? ☐☐

4b.7 Were any problems with compliance identified? Yes ☐ No ☐

If Yes, please give details _____

*For guidance please see back cover

Section 4c: Cardiac monitoring

4c.1 What was the date of last cardiac review prior to pregnancy? D D / M M / Y Y

or tick if not known ☐

4c.2 Was the woman referred to a specialist obstetric cardiology service? Yes ☐ No ☐

If Yes, which hospital was she referred to? _____

Section 4d: Fetal monitoring

4d.1 Was a 20 week anomaly scan performed? Yes ☐ No ☐

If Yes,

Were any fetal abnormalities detected? Yes ☐ No ☐

If Yes, please give details _____

4d.2 Was a fetal intracranial haemorrhage detected at any point during pregnancy? Yes ☐ No ☐

Section 4e: Other problems

4e.1 Were there any other problems in this pregnancy?[2]* Yes ☐ No ☐

If Yes, please specify _____

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

Was this for Maternal health reasons ☐ Fetal abnormality ☐ Other ☐

If Other, please give details of reason _____

If Yes to 5.1 or 5.2, please now complete sections 6a, 7 and 8

5.3 What is/was the planned place of delivery? *(hospital name)* _____

5.4 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 then *go to Section 7*

_____

5.5 Was a care plan for the management of delivery written in her notes prior to delivery admission? Yes ☐ No ☐

If Yes,

Did this make specific reference to the management of her anticoagulation? Yes ☐ No ☐

5.6 Was delivery induced? Yes ☐ No ☐

If Yes, please state indication _____

5.7 Did the woman labour? Yes ☐ No ☐

If Yes, what pharmacological analgesia was given? Entonox ☐ Oral analgesia ☐

IM opiates ☐ IV opiates ☐ Epidural ☐ Spinal ☐ CSE ☐ None ☐

*For guidance please see back cover

5.8 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 ☐

5.9 How was anticoagulation managed during delivery? *(please tick only one)*

Converted to unfractionated heparin prior to delivery ☐

No change in dose or frequency of administration ☐

LMWH stopped during labour/prior to LSCS ☐

LMWH continued but with reduced dose, a dose omitted, or given with reduced frequency ☐

Reversal of anticoagulation required ☐

If ticked, please specify method *(eg protamine, FFP)* _____

5.10 Was the actual place of delivery different from the planned place of delivery? Yes ☐ No ☐

If Yes, please give

Actual place of delivery _____

Reason for difference _____

Section 6: Outcomes

Section 6a: Woman

6a.1 Was the woman admitted to ITU (critical care level 3)? Yes ☐ No ☐

If Yes, please specify:

Duration of stay ☐☐ days

Or Tick if woman is still in ITU (critical care level 3) ☐

Or Tick if woman was transferred to another hospital ☐

6a.2 Did any other major maternal morbidity occur?[6]* Yes ☐ No ☐

If Yes, please specify _____

6a.3 Was warfarin started/re-started postnatally? Yes ☐ No ☐

If Yes, on what date was it recommenced? D D / M M / Y Y

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) _____

Was a post mortem examination undertaken? Yes ☐ No ☐

If Yes, did the examination confirm the certified cause of death?

Yes ☐ No ☐ Not known ☐

*For guidance please see back cover

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 Mode of delivery Spontaneous vaginal ☐ Ventouse ☐ Non rotational forceps ☐
Rotational forceps ☐ Vaginal Breech delivery ☐ Pre-labour caesarean section ☐
Caesarean section after onset of labour ☐

6b.3 Birthweight ☐☐☐☐ *g*

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 ☐

6b.9 Was any congenital abnormality detected? Yes ☐ No ☐
If Yes, please specify abnormality _____

6b.10 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