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).

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: ____________________________
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

1.2 Ethnic group* (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 problems2* (including cardiac, thromboembolic or bleeding problems) Yes No

If Yes, please specify

*For guidance please see back cover
Section 3: 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?* 
- Yes ☐ No ☐
  If Yes, please specify ___________________________

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?

<table>
<thead>
<tr>
<th>Replaced?</th>
<th>Type of valve</th>
<th>Size</th>
<th>Year of replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aortic</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tricuspid</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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)* 
- DD/MM/YYYY

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 DD/MM/YYYY

*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
- Converted to LMWH in the first trimester, warfarin during the second and third trimester
- 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

<table>
<thead>
<tr>
<th>Monitored?</th>
<th>Planned frequency of monitoring</th>
<th>Range Aimed For</th>
<th>How long post dose was it measured?</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>APTT</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Anti Xa – predose</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Anti Xa – postdose</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Other</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

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 ______________________________
Section 4c: Cardiac monitoring
4c.1 What was the date of last cardiac review prior to pregnancy? 
   DD / MM / YYYY
   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? Yes ☐ No ☐
   If Yes, please specify _______________________________

Section 5: Delivery
5.1 Did this woman have a miscarriage? 
   Yes ☐ No ☐
   If Yes, please specify date 
   DD / MM / YYYY

5.2 Did this woman have a termination of pregnancy? 
   Yes ☐ No ☐
   If Yes, please specify date 
   DD / MM / YYYY
   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?
   If Yes, please state:
   Grade of urgency*  
   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?* 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
   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

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

6b.4 Sex of infant

   Male  Female  Indeterminate

6b.5 Was the infant stillborn?
   If Yes, go to section 7

6b.6 5 min Apgar

6b.7 Was the infant admitted to the neonatal unit?

6b.8 Did any other major infant complications occur?*?

6b.9 Was any congenital abnormality detected?
   If Yes, please specify abnormality

6b.10 Did this infant die?
   If Yes, please specify date of death
   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

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