ID Number:

INOSS

The International Network of Obstetric Survey Systems

Anaphylaxis in Pregnancy Study 01/16

Data Collection Form - CASE

Please report all pregnant women diagnosed with anaphylaxis on or after 1st September 2016 and before 28th February 2018 during pregnancy and up to 48 hours after delivery

Case Definition:

Anaphylaxis is defined as a severe, life-threatening generalised or systemic hypersensitivity reaction. The following two criteria must be met for a diagnosis of anaphylaxis to be made:

1. A life-threatening airway problem and/or breathing problem and/or circulatory problem

2. Sudden onset and rapid progression of symptoms

Women should not be reported if a diagnosis of anaphylaxis has been excluded by their senior attending obstetrician/anaesthetist.

Please return the completed form to:

INOSS
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Oxford
OX3 7LF
Fax: 01865 617775
Phone: 01865 289744
Email: stephen.mccall@npeu.ox.ac.uk

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. Fill in the form using the information available in the woman's case notes.
3. Tick the boxes as appropriate. If you require any additional space to answer a question please use the space provided in section 7.
4. Please complete all dates in the format DD/MM/YY, and all times using the 24hr clock e.g. 18:37
5. If codes or examples are required, some lists (not exhaustive) are included on the back page of the form.
6. 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 INOSS Administrator. We will send these sections again for you to complete two weeks after the woman's expected date of delivery.
7. **If you do not know the answers to some questions, please indicate this in section 7.**
8. If you encounter any problems with completing the form please contact the INOSS 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 Country of birth: _____

1.3 What was the woman's highest level of education?

No formal schooling ☐
Less than primary schooling ☐ Primary school ☐
Secondary or high school ☐ College, university or higher ☐

1.4 Did the woman or her partner have a steady income during pregnancy (excluding social security)? Yes ☐ No ☐

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: ☐☐
Number of previous caesarean sections: ☐☐

2.2 Did the woman have any other previous pregnancy problems?[1]* Yes ☐ No ☐

If Yes, please specify: _____

*For guidance please see back cover

Section 3: Previous Medical History

3.1 **Does the woman have a previous history of anaphylaxis?** Yes ☐ No ☐

3.2 **Does the woman have a previous history of atopy?** Yes ☐ No ☐

If Yes, *please tick all that apply:* Eczema ☐ Asthma ☐ Hay fever ☐

3.3 **Does the woman have a history of previous allergic reaction to any of the following?** Yes ☐ No ☐

If Yes, *please tick all that apply:* Latex ☐ Food stuffs ☐ Animal fur or bird feathers ☐

Dust mites ☐ Insect stings ☐ Pollen/spores ☐ Other ☐

If Other, please specify: _____

3.4 **Does the woman have a history of previous recorded allergic reaction to any drugs?** Yes ☐ No ☐

If Yes, please state which drug / antibiotic: _____

If Yes, please describe the reaction recorded in the notes:

_____

_____

3.5 **Does the woman have any other pre-existing medical problems[2*]?** Yes ☐ No ☐

If Yes, please specify details: _____

_____

_____

(continue in Section 7 if required)

Section 4: Outcomes

Section 4a: This Pregnancy

4a.1 **Final Estimated Date of Delivery (EDD):[3*]** D D / M M / Y Y

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

If Yes, please specify number of fetuses: ☐

4a.3 **Were there problems in this pregnancy[1*]?**

If Yes, please specify details: _____

Section 4b: Diagnosis and management of anaphylaxis

4b.1 **What was the date and time when symptoms were first experienced?**

D D / M M / Y Y h h : m m (24hr)

4b.2 **When was anaphylaxis diagnosed (date and time)?** D D / M M / Y Y h h : m m (24hr)

4b.3 **Did the woman have a life threatening airway problem?** Yes ☐ No ☐

If Yes, please tick all that apply: Laryngeal or pharyngeal oedema ☐ Hoarse voice ☐

Stridor (laryngospasm) ☐ Other ☐

If Other, please specify: _____

*For guidance please see back cover

4b.4 Did the woman have a life threatening breathing problem? Yes ☐ No ☐

If Yes, please tick all that apply: Shortness of breath and raised respiratory rate (dyspnea) ☐

Wheeze (bronchospasm) ☐ Decreased oxygen saturations ☐

Confusion secondary to hypoxia ☐ Cyanosis ☐

Respiratory exhaustion or respiratory arrest ☐ Other ☐

If Other, please specify: _____

4b.5 Did the woman have a life threatening circulatory problem? Yes ☐ No ☐

If Yes, please tick all that apply: Signs of shock such as faintness, pallor or clammy skin ☐

Tachycardia >100bpm ☐ Signs of ischaemia on ECG ☐

Systolic BP <90mmHg or MBP<60mmHg or measured hypotension ☐

Decreasing level of consciousness ☐ Cardiac arrest ☐

4b.6 Did the woman have skin or mucosal changes (for example pruritus, flushing, urticarial/nettle rash, angioedema)? Yes ☐ No ☐

If Yes, please give details: _____

4b.7 Where was the woman when anaphylaxis occurred? *Please tick:*

Home or Community ☐ Antenatal ward ☐ Postnatal ward ☐

Delivery suite ☐ Theatre ☐ Other ☐

If Other, please specify: _____

4b.8 Was there a suspected causative agent? Yes ☐ No ☐ Unknown ☐

If Yes, was the agent an antibiotic? Yes ☐ No ☐

Tick all that apply: Prophylaxis before/after a caesarean section ☐

Prophylaxis for Group B Streptococcus (GBS) carriage to prevent neonatal infection ☐

Treatment of an infection ☐ Other ☐

If Other, please state reason: _____

If No, what was the causative agent and its indiction for use:

_____

4b.9 Did the woman have any known previous exposure to the causative agent? Yes ☐ No ☐ Unknown ☐

If Yes, please state when: _____

4b.10 Were any regular medications (including over the counter, herbal or recreational) being taken prior to the onset of anaphylaxis? Yes ☐ No ☐ Unknown ☐

If Yes, please list these medications: _____

4b.11 Were vital observations recorded prior to anaphylaxis? Yes ☐ No ☐

If Yes, what were the most recent set of vital observations prior to the diagnosis of anaphylaxis:

	Observation		Date	Time
Oxygen saturations (%)			D D / M M / Y Y	h h : m m (24hr)
Blood pressure (mmHg)	Systolic	Diastolic	D D / M M / Y Y	h h : m m (24hr)
Heart rate (bpm)			D D / M M / Y Y	h h : m m (24hr)
Respiratory rate/min			D D / M M / Y Y	h h : m m (24hr)

4b.12 What were the vital observations at the time of diagnosis of anaphylaxis?

	Observation	Date	Time
Oxygen saturations (%)		D D / M M / Y Y	h h : m m (24hr)
Blood pressure (mmHg)		D D / M M / Y Y	h h : m m (24hr)
Heart rate (bpm)		D D / M M / Y Y	h h : m m (24hr)
Respiratory rate/min		D D / M M / Y Y	h h : m m (24hr)

4b.13 Did the woman have a cardiorespiratory arrest? Yes ☐ No ☐

If Yes, please state the date and time at which this occurred: D D / M M / Y Y h h : m m (24hr)

4b.14 Was any fetal heart rate abnormality noted? Yes ☐ No ☐

4b.15 Following diagnosis of anaphylaxis, was high flow oxygen given? Yes ☐ No ☐

4b.16 Was there orotracheal intubation? Yes ☐ No ☐

If Yes, date and time: D D / M M / Y Y h h : m m (24hr)

4b.17 Following diagnosis of anaphylaxis, were IV fluids given? Yes ☐ No ☐

If Yes, please state:

Name of fluid	Volume	Time started	Time stopped
		h h : m m (24hr)	h h : m m (24hr)
		h h : m m (24hr)	h h : m m (24hr)
		h h : m m (24hr)	h h : m m (24hr)

4b.18 Following diagnosis of anaphylaxis, were any of the following drugs administered? Yes ☐ No ☐

If Yes, please state:

Name of drug	Yes/No	Time given	Dose given	Route
Adrenaline	Yes ☐ No ☐	h h : m m (24hr)		
Chlorphenamine	Yes ☐ No ☐	h h : m m (24hr)		
Hydrocortisone	Yes ☐ No ☐	h h : m m (24hr)		

4b.19 Were any other drugs given during the resuscitation period? Yes ☐ No ☐

If Yes, please state:

Name of drug	Time given	Dose given	Route	Indication
	h h : m m (24hr)			
	h h : m m (24hr)			
	h h : m m (24hr)			

*For guidance please see back cover

4b.20 **Was blood taken for serum tryptase levels?** Yes ☐ No ☐

If Yes, please give date and time D D / M M / Y Y h h : m m (24hr)

If Yes, was the result Normal or raised (please tick one) Normal ☐ Raised ☐

4b.21 **Was blood testing carried out to confirm the suspected allergen?** Yes ☐ No ☐

If Yes, was a specific IgE identified? Yes ☐ No ☐

If Yes, please state what the IgE was specific to: _____

4b.22 **Was skin testing carried out to confirm the suspected allergen?** Yes ☐ No ☐

If Yes, was any causal agent identified? Yes ☐ No ☐

If Yes, please state the agent: _____

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 and time: D D / M M / Y Y h h : m m (24hr)

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 name of hospital providing future care:

_____

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

If No, please indicate name of delivery hospital, _____

5.4 **Was delivery induced?** Yes ☐ No ☐

If Yes, please state indication: _____

If Yes, vaginal prostaglandin was used? Yes ☐ No ☐

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

If Yes, please state:

Grade of urgency:[4]* ☐

Indication for caesarean section: _____

Method of anaesthesia: Spinal ☐ Epidural top-up ☐

CSE ☐ Epidural ☐ General anaesthetic ☐

The time between decision and delivery and delivery of the baby h h : m m (24hr)

*For guidance please see back cover

Section 6: Outcomes

Section 6a: Woman

6a.1 Was the woman admitted to ITU (critical care level 3)?[5]* Yes ☐ No ☐

If Yes, please specify duration of stay: ☐☐ *days*

OR Tick if woman is still in ITU: ☐

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 Did the woman die? Yes ☐ No ☐

If Yes, please specify date and time of death D D / M M / Y Y h h : m m (24hr)

What was the primary cause of death as stated on the death certificate?

(Please state if not known) _____

Section 6b: Infant 1

6b.1 Please state the date and time of delivery: D D / M M / Y Y h h : m m (24hr)

6b.2 Mode of delivery: Spontaneous vaginal ☐ Ventouse ☐ Forceps ☐ Vaginal breech ☐

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, when did the fetus die? Antepartum ☐ **OR** Intrapartum ☐

6b.6 What was the Apgar score? 5 min ☐☐ 10 min ☐☐

6b.7 Were the cord gases measured? Yes ☐ No ☐

If Yes, please state the umbilical arterial pH and base excess: _____

If Yes, please state the umbilical venous pH and base excess: _____

6b.8 Did the infant experience any seizures? Yes ☐ No ☐ Unknown ☐

6b.9 Was an aEEG or a full EEG performed? Yes ☐ No ☐ Unknown ☐

If Yes, please state the results: _____

6b.10 Did the infant have any evidence of neurological imaging? Yes ☐ No ☐ Unknown ☐

If Yes, please state:

Type of imaging used, _____

Date and time used: D D / M M / Y Y h h : m m (24hr)

What damage was identified? _____

6b.11 Did this infant have a neurological examination? Yes ☐ No ☐ Unknown ☐

If Yes, Was there any evidence of neurological deficit on neurological examination? Yes ☐ No ☐

If Yes, please state what this was: _____

*For guidance please see back cover

6b.12 **Was the infant admitted to the neonatal intensive care unit (not SCBU)?** Yes ☐ No ☐

If Yes, please state the duration of stay (days) ☐☐

Or Tick if the infant is still in the neonatal unit ☐

Or was the infant transferred to another hospital? ☐

6b.13 **Was a diagnosis of neonatal encephalopathy made?** Yes ☐ No ☐ Unknown ☐

If Yes, was the baby cooled? Yes ☐ No ☐ Unknown ☐

6b.14 **Did any major infant complications occur[7*]?** Yes ☐ No ☐

If Yes, please specify details: _____

6b.15 **Did this infant die?** Yes ☐ No ☐

If Yes, please specify the date and time of death: D D / M M / Y Y h h : m m (24hr)

If Yes, please state the primary cause of death as documented on the death certificate:

_____

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. Previous or current pregnancy problems, these may include amongst others: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

2. 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

3. Estimated date of delivery (EDD):

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

4. 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

5. Intensive care unit – Level 3:

Patients requiring advanced respiratory support alone or basic respiratory support together with support of at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

6. Major maternal medical complications, these may include amongst others:

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
Other organ dysfunctions (hepatic, cardiac)
Multiple organ failure

7. Fetal/infant complications, these may include amongst others:

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