UKOSS

UK Obstetric Surveillance System

Biological agents in pregnancy
Study 02/22

Data Collection Form - CASE

Please report any woman delivering on or after the 01/05/2022 and before 30/04/2024

Case Definition:

All pregnant women identified as having taking one of the following biological agents for the indication of treatment of an inflammatory disorder in pregnancy:

Natulizumab, Dupilimab, Mepolizumab, Ustekinumab, Belimumab, Rituximab, Secukinumab, Ixekizumab, Tociluzumab, Canakinumab, Anakinra, Sarilumab, Abatacept, Guselkumab, Omalizumab, Dupilumab, Mepolizumab, Vedolizumab, Rinsakizumab, Anifrolumab and ' other ' novel biological agent (excluding Etanercept, Adalimumab, Infliximab, Certolizumab, and their biosimilars)

Please note, we are not including data collection for biological agents for the indication of severe COVID-19 infection

Case ID Number: | | | | | | |

Royal College of Obstetricians and Gynaecologists

Bringing to life the best in women's health care

Please return the completed form to:

ukoss@npeu.ox.ac.uk

UKOSS
National Perinatal Epidemiology Unit
University of Oxford, Old Road Campus, Oxford, OX3 7LF

Phone: 01865 617764 / 617774

Reporting Month: _____

Reporting Hospital: _____

NPEU

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 for your own reference.
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.
   If you do not know the answers to some questions, please indicate this in section 7.
   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]* Yes ☐ No ☐

If Yes,

Did the woman have pre-eclampsia or pregnancy hypertension? Yes ☐ No ☐

Was the pregnancy associated with fetal growth restriction? Yes ☐ No ☐

Did the woman deliver preterm? Yes ☐ No ☐

Section 3: Previous Medical History

If necessary, please liaise with your local medical or obstetric physician when completing this section

Which inflammatory condition/s does this woman have? *(tick all that apply)*

Rheumatoid arthritis ☐ Psoriatic arthritis ☐ Still's disease or Juvenile Idiopathic Arthritis ☐

Spondyloarthritis ☐ Inflammatory polyarthropathy ☐ Systemic lupus erythematosus ☐

Psoriasis ☐ Ulcerative colitis ☐ Crohn's disease ☐ Severe asthma ☐

Multiple sclerosis ☐ Takayasu arteritis ☐ Microscopic polyangiitis ☐

Granulomatosis with polyangiitis (formerly Wegener's granulomatosis) ☐

Eosinophilic granulomatosis with polyangiitis (formerly Churg-Strauss syndrome) ☐

Polyarteritis nodosa ☐ Kawasaki disease ☐ Eczema ☐ Other systemic vasculitis ☐

If Other systemic vasculitis, please specify _____

3.2 When was the condition diagnosed? D D / M M / Y Y **OR tick if not known** ☐

3.3 Which inflammatory condition is the woman taking a biological agent for?

Some women may have more than one inflammatory condition, therefore please state the primary indication for treatment with the biologic agent.

_____

3.4 Which biological agent is the woman taking?

Natulizumab ☐ Dupilimab ☐ Mepolizumab ☐ Ustekinumab ☐ Belimumab ☐

Rituximab ☐ Secukinumab ☐ Ixekizumab ☐ Tociluzumab *(for use in rheumatoid arthritis)* ☐

Canakinumab ☐ Anakinra ☐ Sarilumab ☐ Abatacept ☐ Guselkumab ☐

Omalizumab ☐ Dupliumab ☐ Mepolizumab ☐ Vedolizumab ☐

Rinsakizumab ☐ Anifrolumab ☐ Other ☐

If Other, please specify _____

3.5 What date did the treatment with this biological agent commence?

D D / M M / Y Y *OR* tick if not known ☐

3.6 Was the biological agent started in pregnancy? Yes ☐ No ☐

If Yes, what was the indication? _____

3.7 Was the biological agent stopped in pregnancy? Yes ☐ No ☐

If Yes, what was the reason? _____

3.8 When was this biological agent taken? *(tick all that apply)*

Pre-pregnancy ☐ 1st trimester ☐ 2nd trimester ☐ 3rd trimester ☐ Post partum ☐

3.9 **Did the woman take any other disease modifying treatments for her inflammatory condition in the six months before, or during pregnancy?** Yes ☐ No ☐

If Yes, tick all that apply and indicate when they were used

	6 months before pregnancy	1st trimester	2nd trimester	3rd trimester	Post partum
Hydroxychloroquine	☐	☐	☐	☐	☐
Sulfasalazine	☐	☐	☐	☐	☐
Leflunomide	☐	☐	☐	☐	☐
Azathioprine	☐	☐	☐	☐	☐
Mercaptopurine	☐	☐	☐	☐	☐
Methotrexate	☐	☐	☐	☐	☐
Cyclophosphamide	☐	☐	☐	☐	☐
Cyclosporin	☐	☐	☐	☐	☐
Mycophenolate mofetil	☐	☐	☐	☐	☐
Anti-TNF-Alpha agent (infliximab, etanercept, adalimumab, certolizumab pegol, golimumab)	☐	☐	☐	☐	☐

3.10 **Did the woman receive any of the following treatments in the six months before, or during pregnancy?** Interferon beta ☐ Steroids (inhaled) ☐ Theophilline ☐ Non-steroidal anti-inflammatory drugs ☐ Oral hypoglycaemics ☐ Insulin ☐ Antihypertensives ☐ Folic acid ☐ Aspirin ☐ None of these ☐

3.11 **Does the woman have pre-existing diabetes?** Yes ☐ No ☐

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

If Yes, please specify _____

3.13 **Was the woman taking any other regular medication immediately prior to conception or during pregnancy?** Yes ☐ No ☐

If Yes, please state which _____

Section 4: This Pregnancy

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

4.2 **Was this pregnancy a multiple pregnancy?** Yes ☐ No ☐

If Yes, specify number of fetuses ☐

4.3 **Were there problems in this pregnancy?[2]*** Yes ☐ No ☐

If Yes, did the woman have pre-eclampsia? Yes ☐ No ☐

If Yes, was fetal growth restriction or small for gestational age diagnosed antenatally? Yes ☐ No ☐

Any other problems in the pregnancy, 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 the pregnancy terminated due to a congenital abnormality? Yes ☐ No ☐

If Yes, please state the name and describe the anomaly

_____

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

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 _____

Was vaginal prostaglandin used? Yes ☐ No ☐

5.5 **Did the woman labour?** Yes ☐ No ☐

5.6 **Did the woman give birth preterm (<37 weeks gestation)?** Yes ☐ No ☐

If Yes, was the birth spontaneous or iatrogenic? Spontaneous ☐ Iatrogenic ☐

If Yes, was there associated preterm prelabour rupture of membranes? Yes ☐ No ☐

5.7 **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 (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 **Was the woman admitted to HDU (Critical care Level 2)?** Yes ☐ No ☐

If Yes, please specify

Duration of stay ☐☐ days

Or Tick if woman is still in HDU (Critical care Level 2) ☐

Or Tick if woman was transferred to another hospital ☐

6a.3 **Was the woman admitted to enhanced maternal care on delivery suite?** Yes ☐ No ☐

If Yes, please specify

Duration of stay ☐☐ days

Or Tick if woman is still in enhanced care ☐

Or Tick if woman was transferred to another hospital ☐

6a.4 **Did any other major maternal morbidity occur?[6*]** Yes ☐ No ☐

If Yes, please specify _____

6a.5 **Was the woman treated for sepsis?** Yes ☐ No ☐

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

If Yes, did she have positive blood cultures? Yes ☐ No ☐

If Yes, please describe any bacteria grown from the cultures _____

6a.6 **Did the women have any other postnatal complications?** Yes ☐ No ☐

If Yes, please specify _____

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 certified cause of death/diagnosis? Yes ☐ No ☐ 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

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 ☐ 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, *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

Or Tick if infant is still in neonatal unit ☐

Or Tick if infant was transferred to another hospital ☐

6b.8 **Did any other major infant complications occur?[7]*** Yes ☐ No ☐

If Yes, please specify _____

6b.9 **Was the infant treated for sepsis?** Yes ☐ No ☐

If Yes, did the infant have positive blood cultures? Yes ☐ No ☐

If Yes, please describe the bacteria grown from the cultures _____

6b.10 **Did the infant have a congenital anomaly?** Yes ☐ No ☐

If Yes, please the name and describe the anomaly _____

6b.11 **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.

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
Secondary infection e.g.pneumonia
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