ID Number:

World Health Organization

human reproduction programme hrp research for impact

UNDP · UNFPA · UNICEF · WHO · THE WORLD BANK

INOSS

The International Network of Obstetric Survey Systems

Global Maternal Sepsis Study

INOSS GLOSS STUDY
Study 01/17

Data Collection Form - CASE

Please report any pregnant woman or recently pregnant woman (up to 42 days after the end of pregnancy) who has received any investigation or treatment for presumed infection between 00.00 28/11/2017 and 24.00 04/12/2017 and who has been admitted for at least 12 hours.

The following are examples of women who would be expected to be included:

Those with clinical signs suggestive of infection

Those with a sample sent for culture for presumed infection

Those prescribed antibiotics or other antimicrobial at admission or during hospital stay except for prophylaxis at e.g. caesarean section or for GBS or 3rd or 4th degree tear or PROM.

AND/OR Any woman whose death is caused or aggravated by a suspected or confirmed infection.

Exclusion criteria. Women presenting with the following conditions will be excluded, unless they present with systemic repercussions due to infection:

- Any non-severe, localised, uncomplicated infection
  - Candidiasis, Bacterial vaginosis
  - Lower urinary tract infection
  - Fungal infections of the skin (athlete's foot, jock itch, ringworm, and yeast infections)
  - Otitis media
  - Pharyngitis
  - Herpes simplex, Herpes Zoster (Shingles)
- Any uncomplicated chronic infection without evidence of another acute infection
  - Sexually transmitted infections (Gonorrhea, Syphilis, Trichomonas,Chlamydia, Hepatitis, HIV)
  - Tuberculosis
- Any colonisation (presence of microorganisms without clinical signs/symptoms)
  - Known GBS vaginal, urethral and/or rectal colonization
  - Asymptomatic bacteriuria
  - Known oropharyngeal colonization
- Any iatrogenic hypothermia/hyperthermia (e.g. related to epidural, thyroid storm, prostaglandin administration) during hospital stay;
- Use of any prescription of prophylactic antibiotics (e.g. for GBS colonization, after caesarean section, manual removal of the placenta, vaginal delivery);

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 8.
4. Please complete all dates in the format DD/MM/YY, and all times using the 24hr clock e.g. 18:37
5. 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.
6. **If you do not know the answers to some questions, please indicate this in section 8.**
7. If you encounter any problems with completing the form please contact the GLOSS country coordinator or use the space in section 8 to describe the problem.

Section 1: Basic information

1.1 **Age in years:** ☐☐

1.2 **Living with partner:** Yes ☐ No ☐

1.3 **Born in the country?** Yes ☐ No ☐ Not known ☐

If No, please specify country of birth: _____

1.4 **Refugee/asylum seeker/internally displaced?** Yes ☐ No ☐

1.5 **Total number of pregnancies (including current and including pregnancy in the last 42 days)** ☐☐

1.6 **Number of fetuses in current pregnancy:** ☐

1.7 **Total number of pregnancies leading to a birth at 22 weeks or greater gestation (excluding current and excluding childbirth in the last 42 days)** ☐☐

1.8 **Height:** ☐☐☐ *cm*

1.9 **Most recent recorded weight in pregnancy:** ☐☐☐.☐ *kg*

If height and weight are not available, please give BMI: ☐☐.☐

Section 2: Diagnosis of infection

2.1 **Date and time of arrival at hospital (or admission if arrival time not recorded)** D D / M M / Y Y h h : m m (24hr)

2.2 **Date and time first met WHO criteria for suspected or diagnosed infection** *(as specified on front of form)* D D / M M / Y Y h h : m m (24hr)

2.3 At the time of first suspicion or diagnosis of infection, was the woman *(Please tick one only)*:

Admitted from home ☐ Admitted from the emergency department ☐

Transfered from another facility ☐ Already hospitalised in intensive care or high dependency unit ☐

Already hospitalised in other ward ☐ Deceased ☐

2.4 At the time of first suspicion or diagnosis of infection, was the woman *(Please tick one only)*:

Pregnant, not in labour ☐ Pregnant, in labour ☐

Postpartum (up to 42 days) ☐ Post Pregnancy loss or termination (up to 42 days) ☐

If she was pregnant when infection was first suspected or diagnosed, what was the woman's gestational age? ☐☐ weeks ☐☐ days

2.5 Was the primary source of infection identified? Yes ☐ No ☐

If No, go to question 2.6

If Yes, what was the primary source of infection? *(Please tick one only)*

Chorioamnionitis ☐ Endometritis ☐ Abortion-related uterine infection ☐

Lower urinary tract ☐ Upper urinary tract (pyelonephritis) ☐ Respiratory (pneumonia, viral) ☐

Breasts (mastitis/abscess) ☐ Skin (including wound infection) ☐

Meningitis or central nervous system ☐ Infected cannula or line ☐ Other ☐

If Other, please specify: _____

How was the source of the primary infection diagnosed? *(Please tick all that apply)*

Clinical examination alone ☐ Urine dipstick ☐ Other test (e.g. Malaria, HIV, TB, syphilis) ☐

Imaging (x-ray, ultrasound, CT, MRI) ☐ Culture of any body fluid ☐ Other ☐

If Other, please specify: _____

If culture, what was the source of the sample of the first positive culture? *(Please tick one only)*

Blood ☐ Urine ☐ CNS ☐ Wound swab ☐ Vaginal swab ☐

Endometrial swab ☐ Other ☐

If Other, please specify: _____

Date and time first sample was taken D D / M M / Y Y h h : m m (24hr)

What organism (s) were identified? _____

Were any organisms antibiotic resistant? Yes ☐ No ☐

If Yes, please specify resistance pattern, (e.g. methicillin-resistant staphylococcus aureus, extended spectrum beta-lactamase, carbapenem-resistant enterobacteriacae)

_____

_____

2.6 Did the woman have any of the following in the 24 hours before or after meeting the WHO criteria? *(Please tick all that apply)*

Respiratory rate >25/min ☐ O_2 Saturations < 95% ☐ Temperature < 35^0C ☐

Systolic BP < 90mm Hg ☐ Heart rate > 120 BPM ☐ Failure to pass urine for > 18 hours ☐

Change in mental state ☐ Diastolic BP < 40 mm Hg ☐ None of these ☐

If Yes to any of the above, date and time first identified? D D / M M / Y Y h h : m m (24hr)

Section 3: Outcomes

3.1 Did the woman have any of the following in the 14 days prior to first meeting WHO criteria for suspicion/diagnosis of infection? *(Please tick all that apply)*

Abdominal pain (excluding contractions) ☐ Abnormal vaginal discharge ☐

Sore throat/cough ☐ Chest pain ☐ Dysuria ☐ Vomiting/diarrhoea ☐ Flu-like symptoms ☐

Mastitis ☐ Caesarean section wound infection ☐ Other infection ☐ None of these ☐

If Other, please specify: _____

3.2 Did the woman have any of the following treatments during pregnancy? *(Please tick all that apply)*

Any invasive procedure (amniocentesis/cordocentesis/chorionic villus sampling/cervical cerclage) ☐

Blood products/transfusion ☐ Corticosteroids ☐ Immunosuppressants ☐

Chemotherapy (for malignancy) ☐ None of these ☐

3.3 Was the woman prescribed any of the following (for either prophylaxis or treatment) in the 14 days prior to first meeting WHO criteria for suspicion or diagnosis of infection?

Antibiotics ☐ Antivirals ☐ Antifungals (excluding topical) ☐ None of these ☐

If Yes to any, please specify drug prescribed, indication and whether for prophylaxis or treatment: _____

3.4 Did the woman receive any antibiotics to treat infection after meeting the WHO criteria? Yes ☐ No ☐

If Yes, please specify antibiotics received in table below *(Tick all that apply)*

	Start date	Stop date
Amoxicillin ☐	D D / M M / Y Y	D D / M M / Y Y
Ampicillin ☐	D D / M M / Y Y	D D / M M / Y Y
Azithromycin ☐	D D / M M / Y Y	D D / M M / Y Y
Benzyl-Penicillin ☐	D D / M M / Y Y	D D / M M / Y Y
Carbapenems ☐	D D / M M / Y Y	D D / M M / Y Y
Cephalosporin ☐	D D / M M / Y Y	D D / M M / Y Y
Ciprofloxacin ☐	D D / M M / Y Y	D D / M M / Y Y
Clindamycin ☐	D D / M M / Y Y	D D / M M / Y Y
Co-amoxiclav ☐	D D / M M / Y Y	D D / M M / Y Y
Doxycycline ☐	D D / M M / Y Y	D D / M M / Y Y
Erythromycin ☐	D D / M M / Y Y	D D / M M / Y Y
Gentamycin ☐	D D / M M / Y Y	D D / M M / Y Y
Metronidazole ☐	D D / M M / Y Y	D D / M M / Y Y
Piperacillin ☐	D D / M M / Y Y	D D / M M / Y Y

Piperacillin/tazobactum ☐	D D / M M / Y Y	D D / M M / Y Y
Polymyxin B/Colistin ☐	D D / M M / Y Y	D D / M M / Y Y
Vancomycin ☐	D D / M M / Y Y	D D / M M / Y Y
Other, please specify _____ ☐	D D / M M / Y Y	D D / M M / Y Y

What was the date and time the first dose of antibiotic was given?

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

Were any samples taken for culture before antibiotic initiation? Yes ☐ No ☐

Section 4: Management of infection

4.1 Did the woman have any of the following to treat the source of infection? *(Please tick all that apply)*

Laparotomy and washout ☐ Incision and drainage ☐ Caesarean section ☐ Hysterotomy ☐

Hysterectomy ☐ Vacuum aspiration ☐ Percutaneous drainage ☐ Wound debridement ☐

Culdotomy/Colpotomy ☐ Dilatation and curettage or evacuation of retained products ☐

Removal of infected cannula/line ☐ Other ☐ None of these ☐

If Other, please specify: _____

Section 5: Delivery/pregnancy outcome

5.1 Date and time of delivery/miscarriage/termination: D D / M M / Y Y h h : m m (24hr)

If undelivered, please go to Section 6 ***OR*** tick if undelivered ☐

5.2 Place of delivery/miscarriage/termination *(Please tick one only):*

Home ☐ Before arrival/during transfer ☐

At primary healthcare centre ☐ Public hospital ☐ Private hospital ☐

5.3 Did this woman have a miscarriage, ectopic or termination? Yes ☐ No ☐

If Yes, was this: Spontaneous ☐ Induced medical ☐ Surgical ☐ Mixed methods ☐

Not indicated in case notes ☐ laparotomy or laparoscopy for ectopic ☐

If No, was childbirth assisted by *(Please tick one only)*:

Midwife ☐ Obstetrician ☐ Other physician ☐ Nurse ☐

Other skilled birth attendant ☐ Traditional birth attendant ☐ Family member ☐ Other ☐

Was labour onset: Spontaneous ☐ Induced medical ☐

Induced surgical or mixed methods ☐ CS before labour onset ☐

Was membrane rupture? *(Please tick one only)* Spontaneous ☐ **OR** Artificial ☐

Date and time of membrane rupture D D / M M / Y Y h h : m m (24hr)

*Follow-up women until discharge or 6 weeks after diagnosis of infection, whichever is earlier

Was amniotic fluid *(Please tick one only)*:

Clear ☐ Meconium stained ☐ Purulent ☐ Blood-stained ☐

5.4 Was there any evidence of retained products? Yes ☐ No ☐

If Yes, did this require any of the following? *(Please tick all that apply)*

Manual removal of the Placenta ☐ Curettage ☐ Medical management ☐

None of these ☐

5.5 Did the woman have any of the following? *(Please tick all that apply)*

PPH > 500ml (including post miscarriage or termination) ☐ Uterine rupture or perforation ☐

Embolic disease (thrombo/air/amniotic) ☐ 3rd or 4th degree tear ☐

Vulval or perineal haematoma ☐ Postpartum inversion of the uterus ☐

Hysterectomy ☐ Anaphylaxis ☐ Other allergic reaction ☐

Anaesthetic complication ☐ Post-op ileus/bowel obstruction ☐ None of these ☐

Section 6: Maternal outcome

6.1 Status at end of follow-up *(Please tick one only):* Discharged alive ☐

Still in hospital, undelivered ☐ Still in hospital, after end of pregnancy ☐ Dead ☐

If this woman died:

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

Cause of death as stated on the death certificate

_____

Section 7: Infant outcomes

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

7.1 Pregnancy outcome at end of follow-up* *(Please tick one only)*:

Undelivered ☐ Ectopic ☐ Molar pregnancy ☐

Miscarriage ☐ Termination ☐ Stillbirth ☐ Neonatal death ☐ Live birth ☐

If stillbirth, neonatal death or live birth, what was the final mode of birth? *(Please tick one only)*:

Spontaneous vaginal ☐ Instrumental vaginal ☐ Pre-labour CS ☐

1st stage CS ☐ 2nd stage CS ☐

If undelivered, ectopic, molar pregnancy, miscarriage or termination, please go to section 8

7.2 Birth order ☐

7.3 Fetus presentation at delivery *(Please tick one only)* Cephalic ☐ Breech ☐ Other ☐

7.4 Infant sex Male ☐ Female ☐

7.5 Birthweight ☐☐☐☐ *g*

7.6 5 min Apgar score ☐☐

7.7 **Admitted to NICU?** Yes ☐ No ☐

If Yes, Date of admission D D / M M / Y Y Date of discharge D D / M M / Y Y

7.8 **Transferred after birth to another hospital?** Yes ☐ No ☐

7.9 **Suspected early neonatal infection?** Yes ☐ No ☐

7.10 **Culture confirmed early neonatal infection?** Yes ☐ No ☐

If Yes, date of first positive sample D D / M M / Y Y

What organisms were identified (please specify)? _____

Were any organisms antibiotic resistant? Yes ☐ No ☐

If Yes, please specify _____

Was the source of infection identified? Yes ☐ No ☐

If Yes, please specify _____

Was the baby treated with antibiotics? Yes ☐ No ☐

If Yes, please specify which antibiotics, and indicate whether these were used for longer than 48h: _____

7.11 **Infant status at end of follow-up** *(Please tick one only)*

Alive and healthy ☐ Alive with complications ☐ Died ☐

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

Cause of death as stated on the death certificate

_____

Section 8:

Please use this space to enter any other information you feel may be important

_____

_____

_____

_____

_____

_____

_____

Section 9:

9.1 **Name of person completing the form:** _____

9.2 **Designation:** _____

9.3 **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.

Please return the completed form to:

For the UK:

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

Fax: 01865 617775

Phone: 01865 289714

Email: ukoss@npeu.ox.ac.uk

For The Netherlands:

Leiden:

Thomas van den Akker (on behalf of NethOSS)
Department of Obstetrics
Leiden University Medical Center, K6-P-32
Postbus 9600
2300 RC Leiden

Utrecht:

Marcus Rijken (on behalf of NethOSS)
Department of Obstetrics
WKZ- UMC Utrecht
Postbus 85090
3508 AB Utrecht

For Denmark:

Dept. Obstetrics and Gynaecology 4031
Rigshospitalet, University of Copenhagen
Blegdamsvej 9
DK 2100 Denmark

For Belgium:

Brussels and Wallonia:

Nina Van Beirs
CEpiP asbl
Route de Lennik, 808 BP 597
1070 Bruxelles

Phone: 02 / 555.60.30 (CEpiP)
02 / 535.45.97 (Nina)

Mail: ninavanbeirs@hotmail.com
perinatalite@cepip.be

Antwerpen:

Freya Van Avermaete
UZA
Wilrijkstraat 10
2650 Edegem

Phone: 03 / 821 40 70 (Freya)

Mail: Freya.VanAvermaete@uza.be
B.OSSvlaanderen@gmail.com

Oost-Vlaanderen en Limburg:

Mara Bekaert
UZ Gent – Vrouwenkliniek – 0P3
De Pintelaan 185
9000 Gent

Phone: 09/332 68 26 (Mara)

Mail: mara.bekaert@uzgent.be
B.OSSvlaanderen@gmail.com

West-Vlaanderen en Vlaams-Brabant:

Greet Werbrouck
UZ Leuven – Dienst Gynaecologie-Verloskunde
Herestraat 49
3000 Leuven

Phone: 016 / 34 26 14

Mail: greet.werbrouck@uzleuven.be
B.OSSvlaanderen@gmail.com