“EURONEONET 2011 PERINATAL DATASET MANUAL”

January 2011

Version 1.0

INDEX

A) 2011 EuroNeoNet DATABASE ELIGIBILITY CRITERIA

Any infant born alive at your hospital, whether or not was admitted to your NICU, should be reported if his/her:

1) Birth Weight (BW) is less than **1501** g

OR

2) Gestational Age (GA) is less than **32** wks (**31 + 6** days inclusive).

All livebirths must be reported, **no matter** if his/her gestational age is below 22 weeks or the birth weight is below 401g.

All outborn infants of same BW and GA as above, admitted to any location in your hospital within 28 days of birth should also be included, only if the baby has never been discharged home.

Outborn babies admitted to the Neonatal Unit after the 28th day of life, should not be included in the Database, since by international definitions those babies are no longer "newborn" but "infants".

B) 2011 EuroNeoNet DATASET Forms.

There are three different Data Forms:

1) **Death in Delivery Room Form**
2) **General Data Form**
3) **Transferred Infants Form**

Fill in them depending on:

If infant **DIED** in **Delivery Room**, please, fill in **the Death in Delivery Room Form ONLY.**

If infant **DID NOT DIE** in **Delivery Room,** and was **NOT transferred** to another hospital, please fill in **ONLY** the **General Data Form**.

If infant **DID NOT DIE** in **Delivery Room** and **WAS transferred** to another Hospital, please, fill in **BOTH**, **General Data Form** and **Transferred Infants Form**.

DATA COLLECTION POSSIBLE PATTERNS

Infants born with
Birth weight below 1501 g
OR
Gestational age below 32 weeks
(31 weeks and 6 days inclusive)

Died in Delivery Room → Fill in the **Death In Delivery Room Form** ONLY

NOT Died in Delivery Room → Fill in the **General Data Form**

NOT Transferred
(Initial disposition: died, home or still hospitalised as of first birthday) → **DO NOT** fill in any more Forms

Transferred to another Hospital → Fill in the **Transferred Collection Form** too

C) 2011 EuroNeoNet DATASET Definitions

C. 1) 2011 EuroNeoNet DATASET Definitions for the Death in Delivery Room Form.

Remember that the Death in Delivery Room Form ONLY must be filled in when infant died in Delivery Room, before admission to NICU.

CODE

Each infant will be assigned a unique identification number (CCC/RR/HH/YY/N). (that is, Country code/Regional code/Hospital code/last 2 digits of the year of birth/consecutive number of patients admitted). **To obtain the identification number you should proceed as following:**

CCC: Enter 3 digits for country code (first 3 digits of international telephone code of each participating country, with an initial 0 if code has only two digits).
RR: Enter 2 digits for region, province, country, land, …(first 2 digits of postal code).
HH: Enter 2 digits for hospital following a correlative order of access in the study (assigned by the Bilbao Coordination Office).
YY: Enter the last 2 digits of the year of birth (2011 = 11).
NNN: Enter 3 digits per each infant, following a correlative order of its admission to NICU (e.g. 001 to the first admitted child in the year, 002 to the 2º, and so on).

❑ PERINATAL ITEMS

1. - GESTATIONAL AGE

The gestational age (GA) is recorded from the first day of the last menstrual period. When there are clinical doubts or the gestational age is unknown, it can be estimated with ultrasound, obstetric and physical examination.
The best estimate of GA should be recorded in weeks and days. If the best estimate of gestational age is an exact number of weeks, enter the number of weeks in the space provided for weeks and enter 0 in the space provided for days. DO NOT LEAVE THE NUMBER OF DAYS BLANK.

2. - BIRTH WEIGHT

Record the birth weight (BW) in grams obtained in the delivery room. If infant died in delivery room and there is study of autopsy, record the weight obtained on autopsy.

3. - BIRTH LENGTH

Record the birth length (BL) in centimeters and tenth of a centimeter obtained in the delivery room.

4. - BIRTH HEAD CIRCUMFERENCE

Record the birth head circumference (HC) in centimeters and tenth of a centimeter obtained in the delivery room.

5. - DEATH IN DELIVERY ROOM?

Check **YES** if infant died in delivery room or prior to NICU admission and use Delivery Room Death form if submitting paper data forms.
Check **NO** if the infant did not die in the delivery room or prior to NICU admission and continue filling out the data form.

6. - LOCATION OF BIRTH (INBORN VS. OUTBORN)

Check **INBORN** if the infant was delivered at your Hospital.
Check **OUTBORN** if the infant was delivered outside your Hospital and indicate the name of the institution of birth, city and country.

6a. Location of birth (description). If the infant was delivered outside your Hospital, please indicate the name of the institution of birth, city and country.

7. - PRENATAL CARE

Check **YES** if the mother received any prenatal obstetrical care prior to the admission for delivery.
Check **NO** if the mother did not receive any prenatal obstetrical care.

8. - PRENATAL STEROIDS (Betamethasone, dexamethasone or hydrocortisone)

Check **NONE** if no corticosteroids were administered prior to delivery.
Check **INCOMPLETE** if delivery occurred less than 24 hours after the first dose of corticosteroids, or more than one week after the last dose of corticosteroids.
Check **COMPLETE** if delivery occurred more than 24 hours and less than one week after a dose of corticosteroids.

8a. Number of steroid courses: Check the total number of steroid courses (None, Incomplete, Complete)

9. - MODE OF DELIVERY

Check **VAGINAL** for any vaginal delivery (spontaneous or induced).
Check **CAESAREAN SECTION** for any caesarean delivery (elective or emergency).

10. - GENDER (SEX)

The assigned, male or female gender.

11. - MULTIPLE BIRTH

Check **NO** for a singleton birth.
Check **YES** for any birth involving more than a one infant.

11a. Total number of fetuses: For any multi-fetal gestation enter the number of fetuses.

11b. Order at delivery: Enter the order of babies in which it were delivered (1, 2…).

12. - APGAR SCORES

Enter the value of the Apgar score assigned at 1 and at 5 minutes as noted in the labor and delivery record.

13. - DELIVERY ROOM RESUSCITATION

a) OXYGEN

Check **YES** if infant received any supplemental oxygen in the delivery room.
Check **NO** if infant did not receive supplemental oxygen in the delivery room.

b) ANY NON AGGRESSIVE POSITIVE VENTILATION

Check **YES** if infant received any positive pressure breaths with a bag and face mask in the delivery room.
Check **NO** if infant did not receive any positive pressure breaths with a bag and mask face or laryngeal in the delivery room. Check NO if a bag and face mask were only used to administer CPAP (continuous positive airway pressure) and no intermittent positive pressure breaths were given.

c) ENDOTRACHEAL INTUBATION

Check **YES** if the infant received ventilation through an endotracheal tube.
Check **NO** if an endotracheal tube was placed only for suctioning and assisted ventilation was not given through the tube.

d) ADRENALINE / EPINEPHRINE

Check **YES** if these drugs were given in the delivery room via intravenous, intracardiac or intratracheal routes.
Check **NO** if these drugs were not given in the delivery room by any route.

e) CARDIAC COMPRESSION

Check **YES** if external cardiac massage was given in the delivery room.
Check **NO** if external cardiac massage was not given in the delivery room.

Note: There are situations in which infants receive their initial neonatal resuscitation in locations other than a delivery room. These include cases in which birth occurs outside of a delivery room (home, automobile, ambulance, hospital room, emergency room, etc…) and cases in which resuscitation is provided in locations adjacent to or close by the delivery room. In such situations, the responses to item 13 should be based on the initial resuscitation provided immediately after birth, regardless of where the resuscitation manoubres took place.

14. - SURFACTANT

a) Surfactant at delivery room

Check **YES** if the infant received exogenous surfactant at any time.
Check **NO** if the infant never received exogenous surfactant.

15 b. If Yes to 15 a. Enter TIME at the first surfactant dose

Enter the completed hours and minutes at the first surfactant dosing.

15. - LIMITATION OF THERAPEUTIC EFFORTS

Check **YES** if a decision not to initiate new therapies or to withdraw already established therapies in infants judged to have a minimal chances for an intact survival was taken.

16.- CAUSE OF DEATH

Check only one of the possible listed causes of death (Respiratory failure, Sepsis, Neurological, Congenital malformation, Unknown, **Other**).

16a. Cause of death (description).

Please specify the cause of death if other was checked in item **16.**

16b. Autopsy / Necropsy.

Check **YES** or **NO** if the autopsy / necropsy was or was not done.

17. - MAJOR BIRTH DEFECT

Check **YES** if the infant had one or more of the birth defects listed in Appendix II. In the spaces provided, you may enter the code of birth defects from the list.

Check **NO** if the infant was not diagnosed as having one or more of the birth defects listed in Appendix II.

18. - NOTES

Please, include any comment you feel necessary.

C.2) 2011 EuroNeoNet DATASET Definitions for the General Data Form.

Remember that the General Form must be ALWAYS filled in, EXCEPT FOR babies who died in the Delivery Room.

CODE

Each infant will be assigned a unique identification number (CCC/RR/HH/YY/N). (that is, Country code/Regional code/Hospital code/last 2 digits of the year of birth/consecutive number of patients admitted). **To obtain the identification number you should proceed as following:**

CCC: Enter 3 digits for country code (first 3 digits of international telephone code of each participating country, with an initial 0 if code has only two digits).
RR: Enter 2 digits for region, province, country, land, … (First 2 digits of postal code).
HH: Enter 2 digits for hospital following a correlative order of access in the study (assigned by the Bilbao Coordination Office).
YY: Enter the last 2 digits of the year of birth (2008 = 08).
NNN: Enter 3 digits per each infant, following a correlative order of its admission to NICU (e.g. 001 to the first admitted child in the year, 002 to the 2º, and so on).

AGE AT ADMISSION (days and hours)

Enter the age of the patient in completed days and hours at the time of admission to the Neonatal Unit. NOT APPLICABLE if baby died before admission.

❑ PERINATAL ITEMS

1. - GESTATIONAL AGE

The gestational age (GA) is recorded from the first day of the last menstrual period. When there are clinical doubts or the gestational age is unknown, it can be estimated with ultrasound, obstetric and physical examination.
The best estimate of GA should be recorded in weeks and days. If the best estimate of gestational age is an exact number of weeks, enter the number of weeks in the space provided for weeks and enter 0 in the space provided for days. DO NOT LEAVE THE NUMBER OF DAYS BLANK.

2. - BIRTH WEIGHT

Record the birth weight (BW) in grams obtained in the delivery room. If unavailable or judged to be inaccurate, use the weight on admission to the neonatal unit.

3. - BIRTH LENGTH

Record the birth length (BL) in centimeters and tenth of a centimeter obtained in the delivery room or at admission. If unavailable or judged to be inaccurate, use the length on admission to the neonatal unit.

4. - BIRTH HEAD CIRCUMFERENCE

Record the birth head circumference (HC) in centimeters and tenth of a centimeter obtained in the delivery room. If unavailable or judged to be inaccurate, use the head circumference on admission to the neonatal unit.

5. - DEATH IN DELIVERY ROOM

Check **YES** if infant died in delivery room or prior to NICU admission, and use Death in Delivery Room Form if submitting paper data forms.
Check **NO** if the infant did not die in the delivery room or prior to NICU admission, and continue filling out the data form.

6. - LOCATION OF BIRTH (INBORN VS. OUTBORN)

Check **INBORN** if the infant was delivered at your Hospital.
Check **OUTBORN** if the infant was delivered outside your Hospital.

6a. Location of birth (description). If the infant was delivered outside your Hospital, please indicate the name of the institution of birth, city and country.

7. - PRENATAL CARE

Check **YES** if the mother received any prenatal obstetrical care prior to the admission for delivery.
Check **NO** if the mother did not receive any prenatal obstetrical care.

8. - PRENATAL STEROIDS (Betamethasone, dexamethasone or hydrocortisone)

Check **NONE** if no corticosteroids were administered prior to delivery.
Check **INCOMPLETE** if delivery occurred less than 24 hours after the first dose of corticosteroids, or more than one week after the last dose of corticosteroids.
Check **COMPLETE** if delivery occurred more than 24 hours and less than one week after a dose of corticosteroids.

8a. Additional steroid courses: If more than one course was administered check the number of courses. (None, Incomplete, Complete).

9. - MODE OF DELIVERY

Check **VAGINAL** for any vaginal delivery (spontaneous or induced).
Check **CAESAREAN SECTION** for any caesarean delivery (elective or emergency).

10. - GENDER (SEX)

The assigned, male or female gender.

11. - MULTIPLE BIRTH

Check **NO** for a singleton birth.
Check **YES** for any birth involving more than a one infant.

11a. Total number of fetuses: For any multi-fetal gestation enter the number of fetuses.

11b. Order at delivery: Enter the order of babies in which it were delivered (1, 2…).

12. - APGAR SCORES

Enter the value of the Apgar score assigned at 1 and at 5 minutes as noted in the labor and delivery record.

13. - DELIVERY ROOM RESUSCITATION

a) OXYGEN

Check **YES** if infant received any supplemental oxygen in the delivery room.
Check **NO** if infant did not receive supplemental oxygen in the delivery room.

b) ANY NON AGGRESSIVE POSITIVE VENTILATION

Check **YES** if infant received any positive pressure breaths with a bag and face mask in the delivery room.
Check **NO** if infant did not receive any positive pressure breaths with a bag and mask face or laryngeal in the delivery room. Check NO if a bag and face mask were only used to administer CPAP (continuous positive airway pressure) and no intermittent positive pressure breaths were given.

c) ENDOTRACHEAL INTUBATION

Check **YES** if the infant received ventilation through an endotracheal tube.
Check **NO** if an endotracheal tube was placed only for suctioning and assisted ventilation was not given through the tube.

d) ADRENALINE / EPINEPHRINE

Check **YES** if these drugs were given in the delivery room via intravenous, intracardiac or intratracheal routes.
Check **NO** if these drugs were not given in the delivery room by any route.

e) CARDIAC COMPRESSION

Check **YES** if external cardiac massage was given in the delivery room.
Check **NO** if external cardiac massage was not given in the delivery room.

Note: There are situations in which infants receive their initial neonatal resuscitation in locations other than a delivery room. These include cases in which birth occurs outside of a delivery room (home, automobile, ambulance, hospital room, emergency room, etc…) and cases in which resuscitation is provided in locations adjacent to or close by the delivery room. In such situations, the responses to item 13 should be based on the initial resuscitation provided immediately after birth, regardless of where the resuscitation manoubres took place.

14. - RESPIRATORY SUPPORT AFTER LEAVING THE DELIVERY AREA:

a) OXYGEN

Check **YES** if the infant was given supplemental oxygen at any time after leaving the delivery room.
Check **NO** if the infant was never given supplemental oxygen after leaving the delivery room.

b) VENTILATORY SUPPORT

If the infant received any type of respiratory assistance, check as many options as needed:

- **Nasal CPAP**
- **Conventional Ventilation via a tracheal tube** after leaving the delivery room.
- **Non-aggressive Conventional Ventilation** after leaving the delivery room, **without endotracheal intubation**.
- **High Frequency Ventilation via a tracheal tube** after leaving the delivery room.
- **Non-aggressive High Frequency Ventilation** after leaving the delivery room.

If the infant did **NOT** received any type of respiratory assistance, please, leave in blank.

c) ENDOTRACHEAL INTUBATION

Check **NO** if the infant was not intubated at admission neither during the hospital stay.
Check **YES** either the infant was intubated at admission or during the hospital stay.

15. - SURFACTANT

a) Surfactant at any time

Check **YES** if the infant received exogenous surfactant at any time.
Check **NO** if the infant never received exogenous surfactant.

15 b. If Yes to 15 a. Enter TIME at the first surfactant dose

Enter the completed hours and minutes at the first surfactant dosing.

c) Total number of surfactant dose

Enter the total number of surfactant doses.

16. - SUPPLEMENTAL OXYGEN ON DAY 28

Check **YES** if the infant was still in hospital and received any supplemental oxygen on day 28.
Check **NO** if the infant was still in hospital on day 28 and did not receive supplemental oxygen at that age.
Check **NOT APPLICABLE** if the infant died or was discharged prior to day 28, and was not readmitted on or before day 28.

17. - OXYGEN AT 36 WEEKS ADJUSTED GESTATIONAL AGE

Check **YES** if the infant was still in hospital and received any supplemental oxygen on the date when the infant was 36 weeks post-conceptional age.
Check **NO** if the infant was still in hospital and did not receive supplemental oxygen on the date the infant was 36 weeks adjusted gestational age.
Check **NOT APPLICABLE** if the infant was not alive in your hospital on the date at which the infant was 36 weeks adjusted gestational age or if the infant had a gestational age after rounding off to the nearest week, of 36 weeks or more at birth.

18.- STEROIDS FOR BRONCHOPULMONARY DYSPLASIA/CHRONIC LUNG DISEASE (BPD-CLD)

Check **YES** if corticosteroids were used after birth to treat or prevent BPD-CLD.
Check **NO** if corticosteroids were not used after birth to treat or prevent BPD-CLD.

19.- INDOMETHACIN/IBUPROFEN PROPHYLAXIS OF PATENT DUCTUS ARTERIOSUS (PDA)

Check **YES** if indomethacin or ibuprofen was administered after birth without evidence of PDA.
Check **NO** if indomethacin or ibuprofen was not administered as a Prophylaxis of PDA.

20. - INDOMETHACIN/IBUPROFEN THERAPEUTIC USE FOR PDA

Check **YES** if indomethacin or ibuprofen was administered after birth as a treatment of PDA.
Check **NO** if indomethacin/ibuprofen was not administered after birth as a treatment of PDA.

21. - SURGERY

a) PDA SURGICAL LIGATION

Check **YES** if surgical ligation of the ductus arteriosus was performed either in the operating room or NICU.
Check **NO** if surgical ligation of the ductus arteriosus was not performed.

b) SURGERY FOR RETINOPATHY OF PREMATURITY (ROP)

Check **YES** if retinal cryosurgery and/or laser surgery were performed for ROP.
Check **NO** if retinal cryosurgery and/or laser surgery were not performed for ROP.

c) NECROTIZING ENTEROCOLITIS (NEC) SURGERY

Check **YES** if one or more of the following procedures: laparotomy, bowel resection or intraperitoneal drain placement were performed for NEC, suspected NEC or bowel perforation.
Check **NO** if none of the following procedures: laparotomy, bowel resection or intraperitoneal drain placement were performed for NEC, suspected NEC or bowel perforation.

d) OTHER MAJOR SURGERY

Check **YES** if a major surgical procedure other than PDA ligation, NEC surgery or ROP surgery was performed in the operating room or the NICU.
The following procedures are not considered major surgical procedures:
Pyloromyotomy, unilateral or bilateral inguinal hernia repair, central line placement or circumcision.
Check **NO** if these are the only surgical procedures an infant has had or if no other major surgical procedures were performed.

If multiple laparotomies or bowel resections are required within a one week period for NEC, these procedures are all considered NEC surgery and only NEC Surgery should be checked.

e) OTHER MAJOR SURGERY (DESCRIPTION)

Please specify the type of major surgical procedure other than PDA ligation, NEC surgery or ROP.

DIAGNOSES

22. - RESPIRATORY DISTRESS SYNDROME (RDS)

Check **YES** if the infant had RDS defined as:

A: A PaO2 <50 mmHg (<6.6 Kpa) in room air, central cyanosis in room air, or a requirement for supplemental oxygen to maintain PaO2 >50 mmHg (>6.6 Kpa).

AND

B: A chest radiogram consistent with RDS (low lung volumes and reticulogranular appearance of lung fields, with or without air bronchograms).

Check **NO** if the infant did not satisfy both criteria A and B.

23. - PNEUMOTHORAX

Check **YES** if the infant had extrapleural air diagnosed by chest radiograph or needle aspiration (thoracentesis).
Check **NO** if the infant did not have extrapleural air diagnosed by chest radiograph or needle aspiration (thoracentesis).

For infants who had thoracic surgery and a chest tube was placed at the time of surgery OR if free air was only present on a Chest Radiograph taken immediately after thoracic surgery and was not treated with a chest tube, check **NO**.
For infants who had thoracic surgery and then later developed extrapleural air diagnosed by Chest Radiograph or needle thoracentesis, check **YES**.

24. - NECROTIZING ENTEROCOLITIS (NEC)

Check **YES** if the infant had NEC diagnosed at surgery, at postmortem examination or clinically and radiographically using the following criteria:

A. - One or more of the following clinical signs present:

1. - Bilious gastric aspirate or emesis
2. - Abdominal distension
3. - Occult or gross blood in stool (no fissure)

AND

B. - One or more of the following radiographic findings present:

1. - Pneumatosis intestinalis (cystic or linear)
2. - Hepato-biliary gas
3. - Pneumoperitoneum

Check **NO** if the infant did not satisfy the above definition of NEC.

Note: Infants should be coded as having FOCAL GASTROINTESTINAL PERFORATION, not as NEC even if satisfying the definition of NEC but, are found at surgery or postmortem examination for that episode to have a Focal Gastrointestinal Perforation.

25. - FOCAL GASTROINTESTINAL PERFORATION

Check **YES** if the infant had a Focal Gastrointestinal Perforation separate from NEC. This diagnosis will be based on visual inspection of the bowel at the time of surgery or postmortem examination that demonstrates a single focal perforation with the remainder of the bowel appearing normal.
Check **NO** if the infant did not have a Focal Gastrointestinal Perforation as defined above.

26. - CRANIAL IMAGING

Check **NO** if cranial imaging (ultrasound, MRI or CAT scan) was not performed on or before day 28.
Check **YES** if at least one cranial imaging technique was performed on or before day 28.

26a. Periventricular Intraventricular Hemorrhage (PIVH) Grade. If a cranial imaging was performed, enter grade based on criteria below:

Grade 0 - No subependymal or intraventricular hemorrhage.
Grade 1 – Subependymal germinal matrix hemorrhage only.
Grade 2 – Intraventricular blood, no ventricular dilation.
Grade 3 - Intraventricular blood, ventricular dilation.
Grade 4 – Intraparenchymal hemorrhage.

If multiple ultrasounds were done on or before day 28 record the most severe grade.

27. - PERIVENTRICULAR LEUKOMALACIA (PVL)

Check **NO** if there was no evidence of cystic or non-cystic periventricular leukomalacia (PVL) on any cranial ultrasound or other imaging technique.

If CYSTIC PVL, NON-CYSTIC PVL OR BOTH were diagnosed, please check the type as diagnosed by cranial ultrasound or other imaging technique.

Check **NOT APPLICABLE**, if a cranial ultrasound or other imaging technique was never done.

Note: To be considered cystic PVL there must be multiple small periventricular cysts identified. Periventricular echogenicity without cysts should not be coded as cystic PVL. A porencephalic cyst in the area of previously identified intraparenchymal hemorrhage should not be coded as cystic PVL.

27a. If cystic or non-cystic PVL, enter the age in days.

Enter the age of the patient in days when cystic or non-cystic PVL was first diagnosed.

28. - EARLY BACTERIAL SEPSIS AND/OR MENINGITIS (ON OR BEFORE DAY 3 OR 72 HOURS OF BIRTH)

Note: The date of birth counts as day 1 regardless of the time of birth.

Check **YES** if a bacterial pathogen from the list in Appendix I was recovered from a blood and/or cerebrospinal fluid culture obtained before day 3 of life.
Check **NO** if a bacterial pathogen from the list in Appendix I was not recovered from a blood and/or cerebrospinal fluid culture obtained before day 3 of life.

28a. Bacterial pathogen of early sepsis and/or meningitis early (before day 3). If the patient developed an early sepsis, check the bacterial pathogen recovered from a blood and/or cerebrospinal fluid culture obtained on day 1, 2 or 3 of life. Enter the code of pathogen (Appendix I).

> **Note:** If a bacterial pathogen and a Coagulase Negative Staphylococcus are recovered during the same sepsis workup performed before day 3, check only bacterial pathogen for that episode. If Coagulase Negative Staphylococcus is the only bacteria recovered and is associated to the three clinical criteria listed below check Coagulase Negative Staphylococcus.
>
> ***** Coagulase negative staphyulococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.
>
> ***** Signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).
>
> ***** Treatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.

29. – LATE SEPSIS AND/OR MENINGITIS (AFTER DAY 3 OR 72 HOURS OF BIRTH)

Note: The date of birth counts as day 1 regardless of the time of birth.

Check **YES** if a pathogen from the list in Appendix I is recovered from a blood and/or cerebrospinal fluid culture obtained after day 3 of life.
Check **NO** if a pathogen from the list in Appendix I is not recovered from a blood and/or cerebrospinal fluid culture obtained after day 3 of life.

29a. Bacterial pathogen first episode.

- Enter the code number of the **bacterial pathogen** responsible **for the first late sepsis episode** (Appendix I).

  Note: If a bacterial pathogen and a Coagulase Negative Staphylococcus are recovered during the same sepsis workup performed after day 3, check only bacterial pathogen for that episode. If a bacterial pathogen is recovered during one episode of sepsis after day 3 and Coagulase Negative Staphylococcus is recovered during another episode of sepsis after day 3 (associated with the three clinical criteria listed below) check both bacterial pathogen and Coagulase Negative Staphylococcus.

  ***** Coagulase negative staphyulococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.

  ***** Signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).

  ***** Treatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.

29b. Bacterial pathogen second episode.

- Enter the code number of the **bacterial pathogen** responsible **for the second late sepsis episode** (Appendix I).

  Note: If a bacterial pathogen and a Coagulase Negative Staphylococcus are recovered during the same sepsis workup performed after day 3, check only bacterial pathogen for that episode. If a bacterial pathogen is recovered during one episode of sepsis after day 3 and Coagulase Negative Staphylococcus is recovered during another episode of sepsis after day 3 (associated with the three clinical criteria listed below) check both bacterial pathogen and Coagulase Negative Staphylococcus.

  ***** Coagulase negative staphyulococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.

  ***** Signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).

  ***** Treatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.

29c. Bacterial pathogen third episode.

- Enter the code number of the **bacterial pathogen** responsible **for the third late sepsis episode** (Appendix I).

Note 1: If a bacterial pathogen and a Coagulase Negative Staphylococcus are recovered during the same sepsis workup performed after day 3, check only bacterial pathogen for that episode. If a bacterial pathogen is recovered during one episode of sepsis after day 3 and Coagulase Negative Staphylococcus is recovered during another episode of sepsis after day 3 (associated with the three clinical criteria listed below) check both bacterial pathogen and Coagulase negative Staphylococcus.

***** Coagulase negative staphyulococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.

***** Signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).

***** Treatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.

Note 2: If the patient develop more than three late sepsis episode, please, **make a comment at the end of the protocol** (*Notes*).

30. - RETINOPATHY OF PREMATURITY (ROP)

Check **NO** if an indirect ophthalmologic examination for ROP was not performed.
Check **YES** if an indirect ophthalmologic examination for ROP was performed at any time.

30a. ROP Grade (0-5). If Yes, enter the WORST grade, according to the following classification:

Grade 0 – No evidence of ROP lesions
Grade 1 – White demarcation line between vascular and avascular retina
Grade 2 – Elevated demarcation line or ridge
Grade 3 – Ridge with extraretinal fibrovascular proliferation
Grade 4 – Subtotal retinal detachment
Grade 5 – Total retinal detachment

30b. "PLUS disease":

Check **YES** if ROP stages II or III is diagnosed, and venous dilatation and arteriolar tortuosity in the central and posterior retinal areas are also present.
Check **NO** in all other cases.

31. - LIMITATION OF THERAPEUTIC EFFORTS

Check **YES** if a decision not to initiate new therapies or to withdraw already established therapies in infants judged to have a minimal chances for an intact survival was taken.

32. - AGE AT DEATH (days and hours)

Enter the age at death in completed DAYS and HOURS.

32a. Cause of death.

Check only one of the possible listed causes of death (Respiratory failure, Sepsis, Neurological, Congenital malformation, Unknown, **Other**).

32b. Cause of death (description).

Please specify the cause of death if other was checked in item **32a.**

32c. Autopsy / Necropsy

Check **YES** or **NO** if the autopsy / necropsy was or was not done.

33. - MAJOR BIRTH DEFECT

Check **YES** if the infant had one or more of the birth defects listed in Appendix II. In the spaces provided, you may enter the code of birth defects from the list.

Check **NO** if the infant was not diagnosed as having one or more of the birth defects listed in Appendix II.

34. - DISCHARGE

For infants who were transferred and were readmitted before 28 days, this question should be answered if the infant was hospitalised continuously in your center.

a) OXYGEN AT DISCHARGE / DISPOSITION

Check **YES** if the infant was discharged on supplement oxygen.
Check **NO** if the infant was not discharged on supplement oxygen.

For infants who remained in your hospital on his/her first birthday, check **YES** if the infant was on supplemental oxygen on the date of the infant's first birthday. Check **NO** if the infant was not on supplemental oxygen on his/her first birthday.

For infants who died prior to discharge, check **YES** if the infant received supplemental oxygen at any time on the day of death, check **NO** if the infant did not receive supplemental oxygen at any time on the day of death.

b) APNEA MONITOR OR CARDIO-RESPIRATORY MONITOR

Check **YES** if the infant was discharged on an apnea monitor or cardio-respiratory monitor.
Check **NO** if the infant was not discharged on an apnea monitor or cardio-respiratory monitor.

For infants who remained in your hospital on his/her first birthday, check **YES** if the infant was on an apnea monitor or cardio-respiratory monitor on the date of the infant's first birthday. Check **NO** if the infant was not on an apnea or cardio-respiratory monitor on his/her first birthday.

For infants who died prior to discharge, check **YES** if the infant was on an apnea monitor or cardio-respiratory monitor at any time on the day of death, check **NO** if the infant was not on an apnea or cardio-respiratory monitor at any time on the day of death.

35. - INITIAL DISPOSITION FROM YOUR HOSPITAL

Check **TRANSFERRED** to another hospital if the infant was transferred to another hospital or chronic care facility on or before his/her first birthday and before going home.
Check **HOME** if the infant was discharged home on or before his/her first birthday from your hospital without ever transferring to another hospital.
Check **DIED** if the infant died on or before his/her first birthday at your hospital prior to being discharge home or transferred.
Check **STILL HOSPITALISED AS OF FIRST BIRTHDAY** if the infant was still at your hospital on the date of the infant's first birthday.

36. - AGE AT DISPOSITION

Age at disposition/discharge in completed days.

37. - WEIGHT AT INITIAL DISPOSITION

Enter weight in grams obtained on the day of initial disposition. If the infant was not weighted on the day of discharge or death, enter the weight from the previous day. If answer to initial disposition from your hospital is still hospitalised as of first birthday, enter the infant's weight on the infant's first birthday. If the infant was not weighed on the date of his/her first birthday, enter the weight from the previous day.

38. - LENGTH AT INITIAL DISPOSITION

Enter length in centimeters and tenth of centimeter obtained on the day of initial disposition. If the infant was not measured on the day of discharge or death, enter the length from the previous day. If answer to initial disposition from your hospital is still hospitalised as of first birthday, enter the infant's length on the infant's first birthday. If the infant was not measured on the date of his/her first birthday, enter the length from the previous day.

39. - HEAD CIRCUMFERENCE AT INITIAL DISPOSITION

Enter head circumference in centimeters and tenth of a centimetre obtained on the day of initial disposition. If the infant's head was not measured on the day of discharge or death, enter the head circumference from the previous day. If answer to initial disposition from your hospital is still hospitalised as of first birthday, enter the infant's head circumference on the infant's first birthday. If the infant's head was not measured on the date of his/her first birthday, enter the head circumference t from the previous day.

40.- ENTERAL FEEDING AT DISPOSITION.

Check "Human Milk Only" if the infant was discharged receiving human milk as their only enteral feeding, either by being breast fed or by any tube feeding technique.

Check "Formula Only" if the infant was discharged receiving formula milk as their only enteral feeding.

Check "Human Milk in Combination With Either Fortifier or Formula" if the infant was discharged receiving human milk, plus human milk fortifier and/or formula milk.

Check "None" if the infant was not receiving any enteral feedings with either formula milk or human milk at discharge.

The answer to this item should be based on enteral feedings received during the 24 hour period prior to discharge, transfer, or death at disposition (home, transfer to another hospital or death). For infants who remained in your hospital on their first birthday, complete the item, Enteral Feeding at Discharge, based on enteral feedings received on that day.

41. - NOTES

Please, include any comment you feel necessary.

C.3) 2011 EuroNeoNet DATASET Definitions for the Transferred Infants Form.

Remember that the Transferred Infants Form must be filled in TOGETHER with the General Form when an infant is transferred to another hospital

CODE

Each infant will be assigned a unique identification number (CCC/RR/HH/YY/N). (That is, Country code/Regional code/Hospital code/last 2 digits of the year of birth/consecutive number of patients admitted). **To obtain the identification number you should proceed as following:**

CCC: Enter 3 digits for country code (first 3 digits of international telephone code of each participating country, with an initial 0 if code has only two digits).
RR: Enter 2 digits for region, province, country, land, … (First 2 digits of postal code).
HH: Enter 2 digits for hospital following a correlative order of access in the study (assigned by the Bilbao Coordination Office).
YY: Enter the last 2 digits of the year of birth (2008 = 08).
NNN: Enter 3 digits per each infant, following a correlative order of its admission to NICU (e.g. 001 to the first admitted child in the year, 002 to the 2º, and so on).

1. - REASON FOR TRANSFER

Check only one of the possible listed reasons for transfer (Growth/Discharge Planning, Surgery, Chronic Disease, Medical/Diagnostic Services, Other).

1a. Reason for transfer (description). Please specify the reason for transfer if it is not listed above.

2. - UNIT'S TRANSFER NAME, CITY AND COUNTRY

Please specify the Name, City and Country of the hospital where the baby was transferred.

3. - LAST TRANSFER DISPOSITION

Please, get this information from the hospital to which the infant was transferred from your hospital.

Check **HOME** if the infant was discharged home on or before his/her first birthday from the transferred Hospital.
Check **DIED** if the infant died on or before his/her first birthday at the transferred Hospital.
Check **STILL HOSPITALISED AS OF FIRST BIRTHDAY** if the infant was still at transferred Hospital on the date of the infant's first birthday.

4. - TOTAL LENGTH OF STAY (days)

Age at last disposition/discharge in completed days.

5. - WEIGHT AT LAST DISPOSITION

Enter weight in grams obtained on the day of last disposition. If the infant was not weighted on the day of discharge or death, enter the weight last recorded day. If answer to last transfer disposition from transferred hospital is still hospitalised as of first birthday, enter the infant's weight on the infant's first birthday. If the infant was not weighed on the date of his/her first birthday, enter the last recorded weight day.

6. - LENGTH AT LAST DISPOSITION

Enter length in centimeters and tenth of centimeter obtained on the day of last disposition. If the infant was not measured on the day of discharge or death, enter the length last recorded day. If answer to last transfer disposition from your transferred hospital is still hospitalised as of first birthday, enter the infant's length on the infant's first birthday. If the infant was not measured on the date of his/her first birthday, enter the last recorded length day.

7. - HEAD CIRCUMFERENCE AT LAST DISPOSITION

Enter head circumference in centimeters and tenth of a centimetre obtained on the day of last disposition. If the infant's head was not measured on the day of discharge or death, enter the head circumference last recorded day. If answer to last transfer disposition from transferred hospital is still hospitalised as of first birthday, enter the infant's head circumference on the infant's first birthday. If the infant's head was not measured on the date of his/her first birthday, enter the head circumference last recorded day.

8.- ENTERAL FEEDING AT DISPOSITION.

Check "Human Milk Only" if the infant was discharged receiving human milk as their only enteral feeding, either by being breast fed or by any tube feeding technique.

Check "Formula Only" if the infant was discharged receiving formula milk as their only enteral feeding.

Check "Human Milk in Combination With Either Fortifier or Formula" if the infant was discharged receiving human milk, plus human milk fortifier and/or formula milk.

Check "None" if the infant was not receiving any enteral feedings with either formula milk or human milk at discharge.

The answer to this item should be based on enteral feedings received during the 24 hour period prior to discharge, transfer, or death at disposition (home, transfer to another hospital or death). For infants who remained in your hospital on their first birthday, complete the item, Enteral Feeding at Discharge, based on enteral feedings received on that day.

9. - NOTES

Please, include any comment you feel necessary.

APPENDIX I. BACTERIAL PATHOGENS

1. - Group B β-hemolytic streptococcus
2. - Staphylococcus aureus
3. - Enterococcus faecalis (Streptococcus faecalis)
4. - Listeria monocytogenes
5. - Escherichia coli
6. - Klebsiella pneumoniae
7. - Pseudomonas aeruginosa
8. - Haemophilus influenzae
9. - Neisseria meningitidis
10. - Streptococcus pneumoniae
11. - Enterobacter cloacae
12. - Proteus mirabilis
13. - Serratia marcescens
14. - Salmonella species
15. - Citrobacter species
16. - Staphylococcus epidermidis
17. - Ureaplasma urealiticum
18. - Clamidia
19. - Pheumocystic carinii
20. - Cándida albicans
21. - Others (Specify)

APPENDIX II. BIRTH DEFECTS CODES by EUROCAT

Code	Central nervous system defects
Q00	Anencephaly
Q05	Meningomyelocele
Q04.35	Hydranencephaly
Q003	Congenital Hydrocephalus
Q04.2	Holoprosencephaly
1Q	Other CNS defects

Code	Congenital Heart defects
Q20.0	Truncus arteriosus
Q20.3	Transposition of the great vessels
Q21.3	Tetralogy of Fallot
Q20.4	Single ventricle
Q20.1	Double outlet right ventricle
Q21.21	Complete atrio-ventricular canal
Q22.0	Pulmonary atresia
Q22.1	Pulmonary stenosis
2Q	Other cardiac
Q22.4	Tricuspid atresia
Q23.4	Hypoplastic left heart syndrome
Q25.1	Coarctation of the aorta
Q26.2	Total anomalous pulmonary venous return
Q21.0	Ventricular septal defect
Q25.2	Interrupted aortic arch
Q24.6	Congenital heart block

Code	Gastro-intestinal defects
Q35	Cleft palate
Q39.1	Tracheo-esophageal fistula
Q39.0	Esophageal atresia
Q41.0	Duodenal atresia
Q41.1	Jejunal atresia
Q41.2	Ileal atresia
Q42	Atresia of large bowel or rectum
Q42.3	Imperforate anus
Q79.2	Omphalocele
Q79.3	Gastroschisis
E84.1	Meconium ileus
3Q	Other GI defects

Code	Genito-urinary defects
Q60.1	Bilateral renal agenesis
Q61	Bilateral polycystic, multicystic or dysplastic kidneys
Q62.0	Obstructive uropathy with congenital hydronephrosis
Q64.1	Exstrophy of the urinary bladder
4Q	Other GU defects

Code	Chromosomal abnormalities
Q91.3	Trisomy 13
Q91	Trisomy 18
Q90	Trisomy 21
5Q	Other chromosomal abnormality

Code	Other birth defects
Q65	Skeletal dysplasia
Q79.0	Congenital diaphragmatic hernia
E70	Inborn error of metabolism
6Q	Other defects of metabolism and other origin

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(We would like to acknowledge the support given by Vermont Oxford Neonatal Network, by allowing us to use some definitions of their dataset in our project)