Malaysian National Neonatal Registry

TRAINING MANUAL

1st January 2018

Contents

INTRODUCTION

The Malaysian National Neonatal Registry (MNNR) aims to standardize and formalize neonatal data collection to provide information that will help to identify the strengths and weaknesses of respective neonatal units in the country and to enable steps to be taken to improve on areas of deficiency.

OBJECTIVES OF THE NEONATAL REGISTRY

1. Determine the frequency and distribution of critically ill neonates in Malaysia. These are useful measures of the health burden arising of neonatal critical illness and its care in the country.
2. To study the mortality and some morbidity outcomes of babies admitted to NICU in participating hospitals.
3. To calculate the perinatal, neonatal, and stillbirth mortality rates of inborn babies.
4. To compare outcomes between various centres.
5. To develop indicators for standard of care in various areas e.g. expected survival rate of infants ventilated for RDS.
6. To study in further detail the outcome of very low birth weight babies.
7. Stimulate and facilitate research on neonatal critical illness and its management.

METHODOLOGY

Inclusion criteria

- All babies admitted to a Neonatal Unit(NNU) who have any of the following criteria:
  1. Gestational age of <32 weeks ie up to 31 weeks + 6 days.
  2. Birth weight of 500-1500 gms
  3. Require respiratory support (i.e. ventilated or require Continuous positive airway pressure (CPAP) or high flow nasal cannula (HFNC)).
  4. All infants with hypoxic ischaemic encephalopathy (HIE) (see Appendix 2) with or without requirement of ventilatory support.
  5. All babies with confirmed sepsis i.e positive blood cultures or CSF cultures
  6. All babies admitted with congenital heart disease

- All neonatal deaths (i.e. newborn babies (<28days) who die in the Neonatal Unit delivery room [(includes OT, labour room) and other wards].

- Both inborn and outborn babies will be included.

Exclusion criteria

1. Out born babies who expire before arrival will be excluded.
2. Babies who are admitted to the Neonatal Unit (NNU) at a corrected gestation of > 44 weeks will not be considered a neonatal case and hence will be omitted from the study.
3. Babies who are below 500g birth weight and below 22 weeks gestational age.

4. DATA COLLECTION TECHNIQUE

The **Case Report Forms (CRF)** consists of 7 pages. The first page has two sections - Section 1: Patient Particulars & Maternal History, Section 2: Birth History, Section 3: Neonatal Event, Section 4: Problems/ Diagnoses, Section 5: Outcome. Additional pages are the **Supplementary Form** for the modified Wigglesworth's Classification of perinatal deaths The Readmission form and Intrauterine Growth Curves (Composite Male/Female). Fields that are marked with an asterisk are mandatory.

The top section of the CRF for "New case", "Readmission" and "Previously admitted to another SDP hospital" is to enable tracking the patient from one hospital to another so as to merge the data.

A first time admission to the NNU concerned will be considered as a **new case** (if the baby has never been previously admitted to any Source Data Provider (SDP) hospital within the MNNR network) while a subsequent admission of the same baby to the same NNU will be considered as a **readmission to registry**. If the baby has previously been admitted to another SDP hospital or transferred from another hospital or IJN, the admission will be considered as "**Previously admitted to another SDP**". This will be accordingly indicated on the 1st sheet of the CRF.

Section 2 (Birth History) will not be required again for a readmission or previous admission if already previously filled in, while for Section 3 (Neonatal Event) only events occurring during the said admission need to be recorded. For Section 4, enter only Diagnoses and Problems that are encountered or still being encountered during this current admission, and for Section 5 (Outcome) only information pertaining to the current admission need to be entered in the data sheet for the current admission.

If the patient is still hospitalized up to 1st birthday or on 30th April the following year, the CRF's should be closed. (See enclosed monthly census and tracking of CRF forms).

Hard copy CRFs will be prepared. Where computer facilities are available at the participating site, data can be entered directly into the database software.

Tracking forms should be sent to the MNNR secretariat after 2 months to assist data cleaning. CRF's with data already entered in the database should be kept by the respective hospitals.

Transfer out cases:

- Babies discharged / transferred out to *non-paediatric wards* in the same hospital will have one set of CRF completed until discharge **– maximum hospital stay for which CRF is kept is up to the 1st birthday.**

- A baby who is transferred between *neonatal and paediatric wards* under the same department will be considered same admission and the discharge CRF is to be completed after complete discharge from the hospital.

- Cases that was transferred out / discharged to *other hospitals or readmitted* will have more than one set of CRFs completed. Each SDP hospital must write 'duplicate' on top of the forms to note that another form exists for that particular patient. **Before data entry, search for the patient in the database if it is a readmission or previous admission.** In the database, the two admissions will be merged during analysis once they are identified as the same case. The different admissions can be viewed on the individual hospital website.

CONFIDENTIALITY

Patient Data

All data are confidential. The data collection center requires the Hospital RN of the baby to facilitate communication between the data center and the participating pediatricians should any data clarification be required.

Hospital Identification

A code will be given to each participating site. This code will only be known by the individual site and the data center. Hospital identification by code will not be disclosed in any report or publication. The code will be randomly assigned and all individual hospital data will be anonymous. Comparisons of hospital will only use codes and not the hospital names.

Secretariat

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C ASE REPORT FORM
(version 18.0)

DATA DEFINITION AND DATA STANDARDS

a. ***Centre Name****:* Name of participating hospital.

b. ***Date of Admission (dd/mm/yy)***: Date of first admission to the participating site.

c. State Case Type, if it is a new case, a readmission or 'previously admitted to another SDP hospital'.

New case - if the baby has never been previously admitted to any SDP hospital within the MNNR network or admitted directly to your NNU after birth. If the case is transferred from another non-SDP hospital and never previously admitted to any other SDP hospital, it is also a new case. e.g. 1. inborn preterm 31 weeks baby or eg. 2 - baby born in private hospital and then transferred to your hospital e.g.3 Inborn baby who did not fulfill MNNR criteria discharged home and then admitted at 4 days old to your hospital for ventilation. Tick "New case"

Readmission - the baby previously admitted to your hospital only e.g. 1) inborn ex preterm who fulfills MNNR criteria who has been discharged and then readmitted from home to NICU within 44 weeks postconceptional age (PCA) e.g. 2) inborn baby with congenital heart disease who was ventilated in your NNU, transferred to IJN and then back to your NNU

Previous admission to another SDP - If the patient has been admitted after passing through another SDP hospital e.g. from your NNU to HKL for surgery and then readmitted to your NNU – this is considered a "previous admission from another SDP hospital" for HKL data entry, and "readmission"-for your NNU – so that the system can pick up that there is another CRF for merging from another SDP hospital. Tick "yes" and specify name of other SDP hospital . If a patient was already discharged home from another SDP hospital and admitted to your hospital within 44 weeks gestational age – include as "Previous admission to another SDP hospital" .

Indicate whether the case was admitted to the neonatal ward
e.g. if the baby was born alive but died in labour room.
If case was admitted, complete all sections. If not admitted - proceed to sections 1, 2, 4 (No. 47) and 5

Indicate if the case was admitted to the neonatal ward as an abandoned baby
Abandoned babies, to state by ticking the box. Once this box is ticked, the IT system will allow items 1,4a,6-16 to be not mandatory entries and default entries will be inserted by the system as "not applicable"/ "data not entered"/"9999".

SECTION 1: Patient Particulars & Maternal History

1. ***Name of mother:*** *Name as in hospital record.*
2. ***Name of baby (optional):*** Name as in hospital record, if relevant.
3. ***RN of baby****:* RN at participating hospital. If the baby dies in Labour room and has no RN, then use the mother's RN.

4a. ***Mother's identity card number****:* MyKad number or Other ID document no. If "Other" please specify type of document.

4b. ***Baby's MyKid number:*** add number if available

5a. ***Date of Birth****:* dd/mm/yyyy 5b. ***Time of birth:*** To state in 24 hour format (mandatory for death cases) Estimate time of birth if time not accurately known as in home delivery.

6. ***Ethnic group of mother*****:** Malay / Chinese / Indian / Orang Asli / Bumiputra Sabah / Bumiputra Sarawak / Other Malaysian (e.g. Punjabi, Eurasian or Serani) /Non-citizen (specify country). If Bumiputra Sabah or Bumiputra Sarawak, please specify the indigenous group.

7. ***Maternal Age****:* Age in completed years.

8. ***GPA*****:** Gravida, Parity, Abortion (of current pregnancy **before** delivery of this child) # to state number of ectopic pregnancies (Please note that ectopic pregnancy is also considered as an abortion).

9. ***Maternal Diabetes:*** State 'yes' or 'no' if mother had diabetes (regardless of whether it is gestational or pre-gestational). State 'unknown' if so.

10. ***Maternal Hypertension:*** State 'yes' or 'no' if mother had hypertension (regardless of whether chronic or pregnancy-induced). State 'unknown' if so.

11. ***Maternal Eclampsia:*** State 'yes' or 'no'. State 'unknown' if so.

12. ***Maternal Chorioamnionitis:*** State 'yes' or 'no' if mother had chorioamnionitis. State 'unknown' if so.

13. ***Maternal Anaemia*** – state Yes, No or Unknown. Mother's Hb level < 11 g/dL or noted to have anaemia of pregnancy by O&G

14. ***Maternal abruptio placenta*** – State 'yes' or 'no'.

15. ***Maternal bleeding placenta praevia*** - State 'yes' or 'no'.

16. ***Cord prolapse*** - State 'yes' or 'no'.

SECTION 2: Birth History

17. ***Antenatal Steroid****: **Definition:*** Corticosteroids given antenatal via any route to the mother at a time likely to enhance fetal lung maturation. Excludes steroids given for other reasons.State 'yes' (regardless of number of doses or when it was given) or 'no' if this has not been given If yes, state whether ONE or TWO doses given. ***State 'unknown' if so***

18. ***Intrapartum Antibiotics****:*
Definition: Antibiotic treatment is provided to the mother within the period mother is in labour, with the intent of preventing infection of the fetus. This includes the prophylactic use of parenteral penicillin or ampicillin. State 'Yes' if systemic antibiotics

(enteral or parenteral) were given to the mother from the onset of labour. ***State 'unknown' if so.***

19. ***Birth weight (g):*** The weight of the baby immediately following delivery recorded in grams to the nearest gram and measured within the first hour of life.

20a. ***Gestation (weeks):*** Best estimate of gestational age at birth given in full weeks. Preferences among estimates should be:

1. Obstetric estimate according to delivering obstetrician. (Ultrasound date to be selected if done earlier than 25 weeks and there is a discrepancy with LMP dates. Otherwise use LMP dates.)
2. New expanded Ballard scoring. If there is no definite estimate but baby is referred to as term baby, enter 40. Preferably insert the exact gestation for term infants – i.e. ranging from 37-41 weeks

20b. ***Gestational age based on:*** LMP, Ultrasound, Ballard score or unknown- mandatory to be filled if patient died. Choose only one – the option on which you based the baby's gestational age.

21. ***Growth status:*** based on Intrauterine Growth Curves (Composite Male / Female) chart in page 4 of the CRF. SGA<10th centile; AGA 10-90th centile; LGA >90th centile) . (Autoplot planned but presently still use the growth charts to plot)

22. ***Gender***: Indicate Male, Female or Ambiguous/Indeterminate.

23. ***Place of Birth:***

Inborn- born in the same hospital as the participating site. If born within the wards of the participating hospital to be considered as inborn

Outborn**:** Born in another place (includes BBA) and transferred after birth to the NNU of the participating site. Includes those born in the hospital compound and not wards.

1. Home
2. Health clinic
3. Government hospital with specialist (District/General)
4. Government hospital without specialist
5. University Hospital
6. Private hospital
7. Maternity home with specialist
8. Maternity home without specialist
9. Alternative birthing centre (ABC) – urban or rural.
10. Enroute/during transport (including delivery in ambulance within own hospital grounds)
11. Others - - please specify
12. Unknown

24. ***Multiplicity:*** To indicate as singleton, twin, triplet or others i.e. quadruplets, etc. Fill in the birth order if the baby is other than singleton, e.g. if baby is twin 1 – fill in "01". For triplet three, fill "03". This together with mother's IC no. will act as unique identifier.

25. ***Final Mode of delivery:*** Tick as relevant. All caesarians are considered as such without differentiation into upper or lower segment. For breech presentation in Caesarian section, tick as Caesarean section only. **Tick as "emergency" only if there is a reason for the Caesarian section that has an emergency indication, not whether it is listed as 'semi emergency' or 'emergency' in the OT list.**

26. ***Apgar Score at 1 min and 5 min*****:** A numerical score of the condition of newborn at 1 min and 5 min after birth based on heart rate, colour, respiratory effort, muscle tone and reflex irritability. Enter the apgar score at 1 min & at 5 min as noted in the labour and delivery record. **Please score even if the baby was intubated by 5 minutes of life.** Only tick 'unknown' if truly so and not because it was not scored once baby intubated. Apgar score can be '0' at 1 minute and 5 minutes.

27. ***Initial resuscitation (for inborn babies only)*****:** Tick "Yes for all intervention that applies at birth. Mandatory for inborn cases.

27a. Oxygen:
Tick "Yes" if the baby received any supplemental oxygen in the delivery room.
Tick "No" if the baby did not receive supplemental oxygen in the delivery room.

27b. Early CPAP :
Tick "Yes" if the baby received any CPAP in the delivery room
Tick "No" if the baby did not receive any CPAP in the delivery room

27c. Bag and mask ventilation:
Tick "Yes" if the baby received any positive pressure breaths with a mask in the delivery room through a bag and mask or T-piece resuscitator.
Tick "No" if the baby did not receive any positive pressure breaths in the delivery room. **Tick "No" if a resuscitation device was only used to administer CPAP (continuous positive airway pressure) and no positive pressure breaths were given.**

27d. Endotracheal tube ventilation:
Tick "Yes" if the baby received ventilation through an endotracheal tube in the delivery room.
Tick "No" if the baby did not receive ventilation through an endotracheal tube in the delivery room.
If an endotracheal tube was placed only for suctioning, as for MAS, and assisted ventilation was not given through the tube, tick "No".

27d. Cardiac Compression:
Tick "Yes" if external cardiac massage was given in the delivery room.
Tick "No" if external cardiac massage was not given in the delivery room.

27e. Adrenaline:
Tick "Yes" if adrenaline was given in the delivery room via intravenous, intracardiac or intratracheal routes.
Tick "No" if adrenaline was not given in the delivery room via intravenous, intracardiac or intratracheal routes.

28a. Plastic wrap at birth : Yes /No (for ≤ 1000 gm) .
28b. If yes: was baby wrapped without drying at birth - Yes /No

28c. ***Admission temperature*** – Indicate the first temperature (axillary) on admission to one decimal point in degree Celsius. Mandatory field only if patient admitted to any Neonatal Ward, i.e does not include babies who die in delivery room.

SECTION 3: Neonatal Event

29. ***Respiratory support*:**

29a. Tick "yes" if CPAP (continuous positive airway pressure) given in the ward.

i. Early CPAP during initial stabilisation at birth- State 'yes' or 'no'. - remove

ii. Total duration of CPAP (nCPAP/BiPAP/SiPAP) ; Days. State to next complete half day the number of days on CPAP i.e. < 12 hours is 0.5 day and >12 hours is rounded up to the next completed day e.g. 7 hours is filled in 0.5 day and 14 hours is filled as 1 day. If duration is more than 1 day, round up to next complete day e.g. duration of 2 days and 6 hours be rounded to 3 days.

29b. Tick "yes" if High flow nasal cannula (HFNC) given. give def

Commented [IC1]: Not necessary

i. Total duration of HFNC ; Days. State to next complete half day the number of days on HFNC i.e. < 12 hours is 0.5 day and >12 hours is rounded up to the next completed day e.g. 7 hours is filled in 0.5 day and 14 hours is filled as 1 day. If duration is more than 1 day, round up to next complete day e.g. duration of 2 days and 6 hours be rounded to 3 days.

29c. Conventional ventilation: State 'yes' or 'no'.
Conventional Ventilation – is intermittent positive pressure ventilation through an endotracheal tube with a conventional ventilator (IMV rate <240/min) at any time after leaving the delivery room.

Total duration of Conventional ventilation in Days at your centre. State to the next complete day for the number of days on conventional ventilation i.e. < 12 hours is 0.5 day and >12 hours is rounded up to the next completed day e.g. 7 hours is filled in as 0.5 day and 14 hours is filled as 1 day. **If duration is more than 1 day, round up to next complete day** e.g. duration of 10 days and 2 hours be rounded to 11 days.

29d. High frequency ventilation (HFJ/HFOV) State 'yes' or 'no'

i. Total duration of HFJ/HFOV in Days at your centre. State to the next complete half day for the number of days on HFJ/HFOV as stated similarly above in 29a

29e. Nitric oxide State 'yes' or 'no'.
Nitric Oxide – nitric oxide delivered as a gas via a ventilator at any time after leaving the delivery room.

a) State total duration of Nitric oxide given to the nearest complete half day.

30. Total number of days on ventilation support at your centre: The number of days on conventional ventilation and high frequency ventilation. Do not include days on ''CPAP'' or HFNC (auto calculate)

31. ***Surfactant*****:** A dose of any type of exogenous surfactant was used to treat this baby. Indicate whether exogenous surfactant was given or not. If "Yes" indicate whether the infant received it at < 1hr, 1 to 2 hrs. or > 2hrs postnatal age.

32. ***Parenteral Nutrition*****:** Intravenous infusion of a nutrient solution consisting of a minimum of dextrose and protein but generally providing a complete nutrient infusion including electrolytes, calcium, phosphorus, zinc, trace elements, vitamins and fat. Nutrition given intravenously. Parenteral nutrition must include amino acids with or without fats, hence plain dextrose saline infusion is not parenteral nutrition.

SECTION 4: Problems / Diagnoses

Mandatory fields are included for some diagnoses /procedures that are very important in the care of VLBW and sick infants. Definitions of these conditions are as shown in Appendix 2. Other diagnoses or problems not given in the list can be referred to 'WHO 1992 ICD-10; Volume 1 document' and to be written in the space provided under '*Others'.*

There should not be too many NA (Not available) or 'Unknown' data

Definitions of Certain Specified Diagnoses (In Section 4: Problems/Diagnosis)

Diagnosis	Definition
33. Respiratory	
Meconium aspiration syndrome	Tick "yes" if all 5 of the following criteria are satisfied: Presence of meconium stained amniotic fluid at birth. 1. Respiratory distress with onset within 1 hour of birth. Respiratory distress will be defined as the presence of one of the following signs: tachypnoea, grunting, nasal flaring or intercostals retractions. 2. A PaO_2<50mmHg in room air, central cyanosis in room air or a requirement for supplemental oxygen to maintain a PaO_2 >50mmHg. 3. Abnormal CXR compatible with meconium aspiration: Findings may include coarse irregular or nodular pulmonary densities, areas of diminished aeration or consolidation alternating with areas of hyperinflation, or generalized hyperinflation. 4. Absence of culture proven early onset bacterial sepsis or pneumonia (ie negative blood culture within 72 hours of birth).
Pulmonary haemorrhage	Pulmonary haemorrhage originating in the perinatal period (as diagnosed clinically by pink or red frothy liquid draining from the mouth or arising from the trachea between the vocal cord or suctioned through the endotracheal tube. Diagnosis may also be made on autopsy finding of haemorrhage in the lungs).
Congenital Pneumonia	Infection of the lungs acquired prepartum, intrapartum, at birth or after birth. (Diagnosed with or without cultures). Diagnosis is made clinically and supported by CXR findings.
Nosocomial pneumonia	Infection of the lungs acquired after admission to the ward.
Community acquired pneumonia	Infection of the lungs acquired after discharge home

Transient tachypnoea of Newborn	Self-limiting parenchymal lung disorder characterized by pulmonary edema resulting from delayed resorption and clearance of fetal alveolar fluid. Diagnosed in term or late preterm infant, with onset of tachypnea within 6 hours of life and usually resolves by a week of life. CXR with evidence of retained foetal lung fluid (e.g increased perivascular lung markings, fluid in the transverse fissure) will support the diagnosis.
Pulmonary interstitial emphysema	Dissection of air into the perivascular tissues of the lung from alveolar overdistension or overdistension of the smaller airways evident on CXR as linear or cast-like luscencies with a history of requiring increasing ventilatory support.
34. Respiratory distress syndrome (RDS). Tick 'yes' or 'no'	Respiratory Distress Syndrome (RDS) is defined as: Within the first 24 hours of life, **A.** PaO_2 <50 mmHg or less than 85% in room air, central cyanosis in room air, or a requirement for supplemental oxygen to maintain PaO_2 >50 mmHg or to maintain SaO_2 at more than 85% AND **B.** A chest radiograph consistent with RDS (low lung volumes and reticulogranular appearance to lung fields, with or without air bronchograms)
35. Pneumothorax Tick 'yes' or 'no'	Presence of extrapleural air diagnosed by chest radiograph or needle aspiration (thoracocentesis). 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 CXR taken immediately after thoracic surgery and was not treated with a chest tube, tick **'No'.** For infants who had thoracic surgery and then later developed extrapleural air diagnosed by CXR or needle thoracocentesis, tick **'Yes'.** **Indicate whether pneumothorax developed during CPAP/HFNC, Conventional ventilation or HFV.**
36. Supplemental oxygen & BPD	a) Tick "yes" if the baby received continuous oxygen concentration > 21% or respiratory support for at least 28 continuous days (note not "till 28 days of life"). Otherwise tick "no".

	b) If "yes": -For < 32 weeks GA at birth, tick "yes" if baby still requiring oxygen, CPAP or other forms of respiratory support at 36 weeks. Tick "no" if baby did not require any further support - for babies ≥ 32 weeks GA, tick "yes" if baby still requiring oxygen, CPAP or other forms of respiratory support at day 56[1,2]. 'Continuous' means that the patient is receiving oxygen throughout the time period and not just in brief episodes as needed i.e. during feeds. 'Blow-by' oxygen does not count unless it is the mode of oxygen administration used in a transport situation. Do not score oxygen given as part of a hyperoxia test.
37. Cardiovascular a.Persistent Pulmonary Hypertension (PPHN)	Definitive diagnosis of PPHN is made by echocardiography. In the absence of echo confirmation, pre and postductal pulse oximetry difference of > 10% can be used. Preductal pulse oximetry done on the right hand and post ductal pulse oximetry done on lower limbs.
37b. Heart failure	Failure of the heart to pump characterized by tachypnea, tachycardia, feeding difficulties, hepatic enlargement, and cardiomegaly.
38. Patent ductus arteriosus (PDA).	Clinical evidence of left to right PDA shunt documented by continuous murmur, hyperdynamic precordium, bounding pulses, wide pulse pressure, congestive heart failure, increased pulmonary vasculature or cardiomegaly by CXR, and/or increased oxygen requirement or ECHO evidence of PDA with documentation of left to right ductal shunting. If ticked 'Yes', indicate whether ECHO was done and whether pharmacological closure (indomethacin / ibuprofen / paracetamol) or ligation) was given/done or not.
39. Necrotising enterocolitis (NEC)	***Definition for NEC stage 2 and above :*** **1** Diagnosis at surgery or post mortem, or **2** Radiological diagnosis, a clinical history plus

[1] Jobe, AH, Bancalari, E. Bronchopulmonary dysplasia. *Am J Respir Crit Care Med 2001;* 163:1723.
[2] Bancalari E, Claure N. Definitions and diagnostic criteria for BPD. *Seminars in Perinatology*. 2006:30:164-170

(Stage 2 and above) Tick 'yes' or 'no' If "Yes" and managed surgically tick 'Surgical Treatment' NEC present before admission to your centre?(applies to outborn babies): Tick "yes" or "no"	• pneumatosis intestinalis, or • portal vein gas, **3** Clinical diagnosis, a clinical history plus abdominal wall cellulitis and palpable abdominal mass. NEC according to Bell's criteria stage 2 or higher **Stage 1:** Suspect (History of perinatal stress, systemic signs of ill health ie temperature instability, lethargy, apnoea, GIT manifestations ie poor feeding, increased volume of gastric aspirate, vomiting, mild abdominal distension, fecal occult blood with no anal fissure). **Stage 2:** Confirmed (Any of features of stage 1 plus persistent occult, or gastrointestinal bleeding, marked abdominal distension, abdominal radiograph; intestinal distension, bowel wall oedema, unchanging bowel loops, pneumatosis intestinalis, portal vein gas). **Stage 3:** Advanced (Any of features of stages 1 or 2 plus: deterioration in vital signs, evidence of shock or severe sepsis, or marked gastrointestinal hemorrhage, or abdominal radiograph shows any of features of stage 2 plus pneumoperitoneum).
40. Retinopathy of prematurity (ROP) Maximum stage of ROP in left/right eye as defined by the International Committee on ROP (ICROP). Score according to the grade of ROP assigned on an eye exam done by an ophthalmologist. If there is no explicit grade listed, then score according to the descriptions given by the ICROP (eg threshold) . Tick "Yes" if a Retinal exam is done. State exact date of first screening and post conceptional age at screening. Specify only the	Criteria for screening for ROP are for babies with birth weight < or equal 1500 grams OR gestational < 32 weeks, as well as all preterm babies whose clinical course places them at increased risk for ROP as determined by the attending doctor. If an indirect ophthalmologic examination was performed at any time, enter the worst stage documented: No ROP : No Evidence of ROP Stage 1 : Demarcation Line Prethreshold ROP ("Prethresh") Threshold ROP ("Thresh") Stage 4 : Partial Retinal Detachment Stage 5 : Total retinal detachment PLUS disease : dilated veins and tortuous arteries, papillary rigidity (must also include stages other than No ROP)

worst stage. **Also tick if PLUS disease present** State if laser, cryotherapy, intravitreal anti VEGF or vitrectomy was done. If screening was not done, state "No" **AND** indicate whether an appointment for retinal examination was given, if applicable. State "date of appointment" or "date of first screening" section and postconceptional age will be autocalculated ROP present prior to admission? (applies to outborn babies) Tick 'yes' or 'no' To trace back the outcome of ROP screening on first screening if done after discharge Tick "Not applicable" if does not fulfill criteria	
41. Intraventricular haemorrhage (IVH) If ultrasound done: Tick "Yes" if Intraventricular haemorrhage (IVH) is seen and enter the worst grade before or on 28 days of life. State if VP shunt/reservoir insertion was done. Tick "No" if there was no IVH beforeor on day 28. Tick "Not applicable" for term infants Tick "Ultrasound not done" if it	If Ultrasound of Brain done enter the worst grade: Grade1 IVH Sub-ependymal germinal matrix(GM) haemorrhage only Grade 2 IVH without ventricular dilatation Grade 3 IVH with ventricular dilatation Grade 4 IVH with parenchymal involvement

was not done,	
42. Central venous line 42a Central line - yes or no Date of insertion- Date of removal (autocalculate) 42b. CLABSI	If more than one central line, use data of the central line with the longest duration Central line defined as: (1) Umbilical catheters. (2) Percutaneously inserted central catheters. (3) Surgically placed Broviac catheter that terminates at or close to the heart or in one of the great vessels. Aorta, superior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, inferior vena cava, external iliac veins and common femoral veins are considered great vessels for this study. CLABSI defined as clinical sepsis with positive blood culture in patient with <u>ALL</u> of the following: a. central line in place for at least 48 hours, or within 48 hours after removal b. no other apparent source of infection c. two positive cultures of the same organism from different sites if the organism is a common skin organism (to differentiate from skin contaminant)
43. Confirmed sepsis Tick 'Yes' if there is evidence of <u>confirmed</u> sepsis. Do not include presumed or clinical sepsis State whether the onset of first confirmed sepsis was On or before 72 hours of life or After 72 hours of life State the organism(s) cultured: 1 Group B streptococcus 2 MRSA	***Confirmed sepsis*** Clinical evidence of sepsis plus blood culture-proven infection ONLY <u>For CONS:</u> Place a tick if the infant has ALL 3 of the following: 1. CONS is recovered from a blood culture obtained from either a central line, or a peripheral blood sample AND 2. Signs of generalized infection (such as apnoea, temperature instability, feeding intolerance, worsening respiratory distress or haemodynamic instability) AND 3. Treatment with 5 or more days of IV antibiotics after the above cultures were obtained. If the patient died, was discharged, or transferred prior to completion of 5 days or more of IV

3 CONS (see definition) 4. Staphylococcus aureus 5. Klebsiella 6 Pseudomonas 7 Acinetobacter 8 Fungal (see definition) 9 Others, specify 10 ESBL organisms Can tick more than one	antibiotics, this condition would still be met if the intention was to treat for 5 or more days. Do not place a tick if any or all of the above are not true. <u>For FUNGAL infection</u>: Place a tick only if a fungus was recovered from a blood culture obtained from either a central line or peripheral blood sample after day 3 of life.
44. Neonatal meningitis Tick 'yes' (if CSF biochem or cytology suggestive even if CSF C&S is negative) or 'no' If yes, State if CSF Culture positive **- Yes / No** State the organism(s) cultured: 1 Group B streptococcus 2 MRSA 3 CONS (see definition) 4. Staphylococcus aureus 5. Klebsiella 6 Pseudomonas 7 Acinetobacter 8 Fungal (see definition) 9 Others, specify 10 ESBL organisms Can tick more than one	Tick yes if there are signs of clinical sepsis or neurological signs AND evidence of meningeal infection as shown in cerebrospinal fluid findings (i.e. cytology, biochemistry or microbiologic findings).
45. Hypoxic ischaemic encephalopathy (HIE) **Applies only to <u>gestation >=35weeks</u>**	HIE requires the presence of all 3 of the following criteria: Presence of a clinically recognized encephalopathy within 72 hours of birth. Encephalopathy is defined as the presence of 3 or more of the following findings within 72 hours after birth: a. Abnormal level of consciousness: hyperalertness, lethargy, stupor or coma b. Abnormal muscle tone: hypertonia, hypotonia or flaccidity c. Abnormal deep tendon reflexes: increased, depressed or absent

	d. Seizures: subtle, multifocal or focal clonic e. Abnormal Moro reflex: exaggerated, incomplete or absent f. Abnormal suck: weak or absent g. Abnormal respiratory pattern: periodic, ataxic or apnoeic h. Oculomotor or papillary abnormalities: skew deviation, absent or reduced Doll's eye or fixed unreactive pupils **AND** Three or more supporting findings of an acute intrapartum event (s) from the following list: a. Arterial cord pH<7.00 b. Apgar score at 5 minutes of 5 or less c. Evidence of multiorgan system dysfunction – dysfunction of one or more of the following systems within 72 hours of birth: d. Evidence of foetal distress on antepartum and peripartum monitoring: persistent late decelerations, reversal of end-diastolic flow on Doppler flow studies of the umbilical artery or a biophysical profile of 2 or less e. Evidence of CT, MRI, technetium or ultrasound brain scan performed within 7 days of birth of diffuse or multifocal ischaemia or of cerebral oedema. f. Abnormal EEG: low amplitude and frequency, periodic, paroxysmal or isoelectric. AND 1. The absence of an infectious cause, a congenital malformation of the brain or an inborn error of metabolism, which could explain the encephalopathy.
HIE severity If the infants diagnosed with HIE, record the worst stage observed during the first 7 days following birth based on the infant's level of consciousness	*HIE severity* a. Mild (normal or hyperalert) – infants in this category are alert or hyperalert with either a

and response to arousal maneuvers such as persistent gentle shaking, pinching, shining a light or ringing of a bell: 45a. Tick "none" if there is no HIE Tick '"Mild, Moderate, Severe " according to the definition	normal or exaggerated response to arousal. No seizures. (Sarnat Stage 1) b. Moderate (lethargic or stupor) – infants in this category are arousable but have a diminished response to arousal maneuvers, Such babies frequently have seizures (Sarnat Stage 2) c. Severe (deep stupor or coma) – infants in this category are not arousable in response to arousal maneuvers (Sarnat Stage 3)
45b. Highest Thompson Score before 6 hours of life	To insert highest score
45c. Cooling therapy	Yes/ No if yes , completed 72 hours yes no If yes : cooling blanket or cap / passive cooling + gel pack / both
45d. Seizures in HIE cases	Yes / No
46a. Major Congenital Anomalies State 'Yes' or 'No'. Tick "Yes" if any major congenital anomaly is present even if it is an isolated one (i.e. only one abnormality). If Yes, tick whether it is a 'Known Syndrome', 'Not a Recognised Syndrome' or 'isolated major abnormality' in 45a. If the syndrome is known, tick the specific syndromes or specify it. Proceed to 46b. (Type of Abnormalities) **Tick all major abnormalities found for recognisable syndrome, non-recognisable ones or isolated major congenital abnormality** - tick	A major congenital abnormality is defined as any abnormality of prenatal origin that if uncorrected or uncorrectable, significantly impairs normal physical or social function or reduce normal life expectancy Any abnormalities of prenatal origin that are present at birth, and do not have surgical, medical or cosmetic importance at the time of examination during the newborn period is a minor congenital abnormality and NOT included in this registry. Examples include isolated findings such as 'low-set ears', sacral dimple or single transverse palmar crease". For congenital heart disease, Type Operation yes or no Age of operation _____ (days)

the abnormalities according to the list provided eg. in Down syndrome – tick all the congenital anomalies found in patient. Please specify if there are abnormalities not listed.	

SECTION 5: Outcome on discharge

47a. ***Date of discharge/transfer/death:*** Enter the exact date.

47b. ***Time of death:*** Please use 24-hour format – this will be used to auto-calculate age at discharge. Mandatory item for death cases – give best estimate of time of death if exact time not known.

48. ***Weight (grams) and growth status on discharge/death:***

48a. Enter the exact weight in grams. For Weight on death – it is the last weight taken when the baby was alive.

48b. Indicate growth status as per Intrauterine Growth Curves (Composite Male/Female). (autoplot)

49. ***Exclusive breastfeeding at discharge : Tick yes/no*** Tick "yes" if exclusive breastfeeding for ≥ 72 hours before discharge

50. ***Total Duration of hospital stay (Neonatal/Paeds Care)*****:** State to next complete day i.e. < 24 hours is 1 day, and 10 days 6 hours is 11days.

51. ***Outcome:*** Alive or Dead – Alive at discharge or died before discharge.

If Child Alive, state Place of discharged to after leaving Neonatal Unit**:** Home, Social welfare home, Other Non-Paeds Ward, 'Still hospitalized as of 1st birthday' or 'Transferred to other hospitals', If transferred to other hospitals, specify the Name of Hospital transferred to.

If a case is **transferred to another hospital in the MNNR network**, complete the CRF up to current status and send photostat copy with the baby to assist the referral hospital in obtaining the patient particulars and birth history. The referring hospital still needs to key in the original form into the system. The referral centre should open and complete a new CRF but sections 1 and 2 need not be filled in again if this has already been keyed in by referring centre. This will be **analysed together** with the CRF of the referring hospital.

Post transfer disposition**. If the case is transferred to another hospital out of the NNR network** the referring unit **must get the final 'outcome' of the baby** from the unit that the case was referred to. Click "still in the ward" if patient is still hospitalized in the non-NNR hospital at close out. **ROP findings after discharge can also be updated in the ROP section.**

If Child Died, tick 'Yes' or 'No' whether the infant died within 12 hours or less from the time of admission to the NICU.

Place of Death**:** Labour Room/OT, In Transit, Neonatal Unit and others, specify.

SUPPLEMENTARY FORM

To be filled whenever there is a neonatal death in accordance to the Modified Wigglesworth Classification of Perinatal Mortality:

To fill in only one cause of death under each classification.

Where "to specify" is required, to fill in "ICD code"

This is data additional to that collected in main CRF for neonatal deaths.

1. **Centre name:** State name of reporting hospital.
2. **Name:** State mother's name.
3. **RN of baby:** RN at participating hospital. If the baby dies in Labour room and has no RN, then use the mother's RN.
4. **Mother's new I/C number or passport whichever applicable.**

Patient name label can be used for section 1-4

Immediate Cause of death (Modified Wigglesworth):

(Adapted from *Garis panduan Penggunaan Format PNM1/97 (Pindaan 2000) bagi Melapor Kematian Perinatal*, Jun 2000, Bahagian Pembangunan Kesihatan Keluarga, Kementerian Kesihatan Malaysia).

a. Is there Lethal Congenital Malformation (LCM)/ defect

Severe or lethal congenital malformation that contributed to the death. If Yes, tick specifically the cause of death.

b. If no LCM, is gestation< 37 weeks?

c. – Gestation< 37 weeks: Preterm death without LCM

This includes only livebirths less than 37 weeks gestation after excluding LCM. Tick the immediate secondary cause of death e.g. severe IVH, pulmonary haemorrhage, acute intrapartum event ("asphyxia"). Tick "extreme prematurity" in the subcategory only for babies less than 28 weeks only who died and no immediate secondary cause of death eg. as in palliative care

-Gestation ≥ 37 weeks without LCM, was there an Asphyxial condition?

All term babies who die from birth asphyxia or meconium aspiration syndrome or PPHN.

d. Asphyxial condition absent, was there Infection ?

This refers to term babies (> 37 weeks gestation) whose primary cause of death is an infection. Some examples include meningitis, group B streptococcal infection, intrauterine infections etc.

e. If term and infection present, tick organism

f. If term and infection absent, other specific cause of death
Specify any other cause of death not included in the above classification. This includes kernicterus, haemorrhagic shock /inborn error of metabolism/pneumothorax/ pulmonary haemorrhage. Use ICD 10 code

g. Unknown - Where cause of death is not known.

MONTHLY BIRTH CENSUS

2018

(Please click on the link: https://www.macr.org.my/ennr/pdf/Census_2013.pdf)

TRACKING FORMS

Track 1

Tracking CRFs (e.g Admissions in month of October 201)

Name	Hospital RN	***Date of Birth***	***Date of admission***	***Criteria of inclusion***
THY		1st October	1st October	VS
NFR		2nd October	2nd October	LRD
YHT		6th October	6th October	ELBW
THD		15th October	15th October	VS
ERT		20th October	20th October	VLBW
TEN		25th October	26th October	VS
YTE		26th October	26th October	Died
REW		29th October	29th October	VP

Abrreviations:
Died: Died in NNU
ELBW: Extremely Low Birth Weight
LRD: Labour Room Death
VLBW: Very Low Birth Weight
VP: Very premature (<32 weeks)
VS: Ventilatory support

- **Please try to be as current as possible in registering cases in the study. Look at admissions in your neonatal ward and delivery suite and fill up new admissions that fulfill the criteria into this tracking form immediately <u>every working day</u>. Do remember to include cases that have been admitted on your off days, public holidays and weekends too.**
- **To include all types of cases (New/transfer /readmissions) into this tracking form**

- The 'Tracking CRFs' list of admissions in a month should be sent to NRU by the second week of the following one (1) month after the month baby was admitted eg list of admissions from 1st to 31st October 2017 should be sent to NRU by the second week of November with the status of the CRF stated.

- The completed CRFs of patients on this list who are discharged between 1st October to 31st October should be updated on the MNNR website as soon as possible

Tracking CRFs

Centre Name: ……

Admissions in Month / Year

……..

Tracking CRFs

Name	Hospital RN	DOB	DOA	Criteria of inclusion