Malaysian National Neonatal Registry

TRAINING MANUAL

1st January 2008

Contents

INTRODUCTION

This registry aims to standardise 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 eg. Expected survival rate of infants ventilated for RDS.
6. To study in further detail outcome of very low birth weight babies.
7. To study the frequency and distribution of babies with significant congenital anomalies in the country
8. Stimulate and facilitate research on neonatal critical illness and its management.

METHODOLOGY

Inclusion criteria

All babies admitted to a Neonatal Unit who have any of the following criteria:

1. Have a gestation of <32 weeks ie up to 31 weeks + 6 days.
2. Have a birth weight of 1500 gms or below
3. Are ventilated.
4. Have a major congenital anomaly / anomalies
5. All neonatal deaths (ie newborn babies (<28days) who die in the Neonatal Unit (NNU), 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 > 44/52 will not be considered a neonatal case and hence will be omitted from the study.

Data Collection Technique

The Case Report Forms (CRF) consists of 2 pages. The first page has 3 sections. Section 1 consists of Patient Particulars, Section 2 consists of Birth History and Section 3 consists of Neonatal Events. The second page has 2 sections. Section 4 consist of Outcome of the baby admitted and Section 5, has a list of diagnoses/problems and procedures that require mandatory response as to their presence or absence, other diagnoses.

Babies discharged /transferred out to non-paediatric wards in the same hospital or to other hospitals will have one set of CRFs completed until discharge. **Readmission of the same babies into the NNU will require a new set of CRFs.**

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

A first time admission to the NNU concerned will be considered as a **new case** (even if it has been previously admitted else where) while a subsequent admission to the same NNU will be considered as a **readmission**. This will be accordingly indicated on the 1st sheet of the CRF. Section 2 (Birth History) will not be required again for a readmission while for Section 3 (Neonatal Event) only events occurring during the said admission need to be recorded.
For Section 4 (Outcome) only information pertaining to the respective admission and for Section 5 only Diagnoses and Problems that are encountered or still being encountered during this said admission need to be entered in the data sheet.

Hard copy CRFs will be prepared. Completed CRFs should be sent to the NRU after a defined period. (See enclosed on monthly census and tracking of CRF forms).

When computer facilities are available at the participating site, data can be entered directly into the database software.

Confidentiality

Patient Data
All data are confidential. The data collection center requires the Hospital RN of the patient to facilitate communication between the data center and the participating Paediatricians 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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Case Report Form (Version 5.0)

MALAYSIAN NATIONAL NEONATAL REGISTRY (CRF 08)

Centre Name: _____

Date of Admission: ☐☐/☐☐/☐☐ (dd/mm/yy)

☐ Stillbirth ☐ Livebirth

☐ New Case ☐ Readmission

☐ Referral from, if relevant: .....

Office use: ☐☐ / ☐☐☐

Centre: ☐☐☐

SECTION 1 : PATIENT PARTICULARS

1. Name:			2. RN:	
3. Mother's I/C Number:	New IC:		Passport:	
4. Date of Birth:			(dd/mm/yy)	
5. Ethnic group:	☐ Malay ☐ Indian ☐ Bumiputra Sabah, specify: ..... ☐ Other M'sian ☐ Chinese ☐ Orang Asli ☐ Bumiputra Sarawak, specify: ..... ☐ Non-citizen			
6. Maternal Age:				
7. GPA:	G:	P:	A:	
8. Insulin dependent diabetes in mother:	☐ Yes	☐ No	☐ Not Available	

SECTION 2 : BIRTH HISTORY

Drugs Used In Labour	9. Antenatal Steroid:	☐ Yes	☐ No	☐ Unknown
	10. Intrapartum Antibiotic:	☐ Yes	☐ No	☐ Unknown
11. Birth Weight:				(grams)
12. Gestation:				(weeks)
13. Growth Status:	☐ SGA	☐ AGA	☐ LGA	
14. Gender:	☐ Male	☐ Female	☐ Indeterminate	
15. Place of Birth:	☐ Inborn ☐ Outborn → ☐ University Hospital ☐ General Hospital ☐ Private Hospital ☐ District Hospital with Specialist ☐ District Hospital without Specialist ☐ Private Maternity Home ☐ Home ☐ Others, specify:			
16. Multiplicity: *Check only one*	☐ Singleton ☐ Twin ☐ Triplet ☐ Others, specify:			
17. Mode of Delivery:	☐ SVD ☐ Ventouse ☐ Breech ☐ Caesarean Section ☐ Forceps ☐ Unknown			
18. Apgar score at 1 min and 5 min (1-10) :	a) Score at 1min: _____ b) Score at 5 min: _____ c) ☐ Not Available			
19. Initial resuscitation : *Check all that apply*	a) Oxygen: ☐ Yes ☐ No	d) Cardiac Compression: ☐ Yes ☐ No		
	b) Bag-mask vent: ☐ Yes ☐ No			
	c) Endotracheal tube vent: ☐ Yes ☐ No	e) Adrenaline: ☐ Yes ☐ No		

SECTION 3 : NEONATAL EVENT

20. Respiratory Support: *Check all that apply*	☐ Yes → ☐ Oxygen ☐ CPAP ☐ Conventional Ventilation ☐ HFOV ☐ Nitric Oxide ☐ No			
21. Total Duration of Ventilatory Support:	..... (in days)			
22. Surfactant:	☐ Yes → ☐ < 1 hr ☐ 1- 2 hrs ☐ > 2 hrs ☐ No			
23. Post Natal Steroid for CLD:	☐ Yes ☐ No			
24. Parenteral Nutrition:	☐ Yes ☐ No			
25. Enteral Nutrition on discharge:	☐ Yes → ☐ Exclusive breast feeding / breastmilk feeds ☐ Exclusive formula feeds ☐ Mixed feeds ☐ No			
26. Ultrasound of Brain done at ≤ 28 days of life	☐ Yes ☐ No			

SECTION 4 : OUTCOME

27. Date of Discharge:	(dd/mm/yy)
28. Weight on Discharge / Death / Transfer out:	(grams)
29. Total Duration of hospital stay (Neonatal / Paeds Care):	..... (in completed days)

30. Outcome: **Place of Discharge:**

☐ **Alive** →
- ☐ Home
- ☐ Social welfare home
- ☐ Other Non Paeds Ward
- ☐ Still hospitalized as of 1st birthday
- ☐ Transfer to Other Hospitals →

Name of Hospital:

Post Transfer Disposition (pls fill this section if place transferred to is not part of the NNR Network):
- ☐ Home
- ☐ Death
- ☐ Still hospitalized as of 1st birthday
- ☐ Transferred again to another hospital
- ☐ Readmitted to your hospital

☐ **Dead** →

Died within 12 Hours of Admission ☐ Yes ☐ No

Place of Death: ☐ Labour Room/OT ☐ In Transit ☐ Neonatal Unit ☐ Others, specify: .....

SECTION 5 : PROBLEMS / DIAGNOSES

Mandatory fields for diagnoses / procedures:

1. RDS: ☐ Yes ☐ No

2. PDA: ☐ Yes → ☐ ECHO Done ☐ Indomethacin/Ibuprofen > 24hrs ☐ Ligation ☐ Not Treated
☐ No

3. Pneumothorax: ☐ Yes ☐ No

4. Supplemental oxygen at: Day 28: → ☐ Yes ☐ No | 36 weeks corrected age : → ☐ Yes ☐ No

5. NEC (Stage 2 and above): ☐ Yes → ☐ Surgical Rx
☐ No

6. ROP: Retinal Exam Done: ☐ Yes → *(If yes, worst stage of ROP):* ☐ Stage 0 ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Stage 5 ☐ Laser therapy ☐ Cryotherapy
☐ No → Appointment Given → ☐ Yes ☐ No
☐ Not Applicable / Not Checked

7. IVH: ☐ Yes → *(If yes, worst grade) :* ☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ VP shunt / reservoir insertion
☐ No ☐ Not Applicable

8. Seizures: ☐ Yes ☐ No

9. Infection (Clinical or Confirmed) : ☐ Yes → ☐ On or before day 3 of life ☐ After day 3 of life
☐ No

10. For confirmed sepsis:
- ☐ Group B Streptococcus
- ☐ MRSA
- ☐ CONS
- ☐ Others, specify: .....
- ☐ ESBL organisms
- ☐ Fungal
- ☐ Staphylococcus aureus
- ☐ Klebsiella
- ☐ Pseudomonas
- ☐ Acinetobacter

11. HIE (BW >2000 gm) ☐ None ☐ Mild / Moderate ☐ Severe ☐ Not applicable

12. Congenital Anomalies

12a. Major Congenital Anomalies

☐ Yes ☐ No

☐ Syndrome (known) ☐ Not a Recognised Syndrome ☐ Isolated Major Abnormality
- ☐ Down
- ☐ Edward
- ☐ Patau
- ☐ Others, specify (Please refer to ICD 10):

12b. Types of Abnormalities (Check all that are present. Applies to all including 'known syndromes', 'not a recognised syndrome' or 'isolated major abnormality '
- ☐ CVS → ☐ Cyanotic ☐ Acyanotic ☐ ECHO Done
- ☐ CNS → ☐ Hydrocephalus ☐ Others, check ICD10
- ☐ Neural Tube Defect → ☐ Spina bifida ☐ Anencephaly ☐ Others, check ICD10
- ☐ Skeletal dysplasia
- ☐ Respiratory
- ☐ GIT
- ☐ Hydrops
- ☐ Renal
- ☐ Cleft → ☐ Lip ☐ Palate ☐ Lip and Palate
- ☐ Others, specify

13. Inborn Errors of Metabolism (IEM)

☐ Yes → **a. Clinical Diagnosis?** ☐ Yes
☐ No **b. Confirmed Diagnosis?** ☐ Yes,specify .....

Other Diagnoses :

14. Respiratory :
- ☐ Meconium aspiration syndrome
- ☐ Transient tachypnoea of newborn
- ☐ Pulmonary haemorrhage
- ☐ Pulmonary interstitial emphysema
- ☐ Pneumonia

15. Central Nervous System: ☐ Neonatal encephalopathy (other than HIE) ☐ Neonatal meningitis

16. Cardiovascular: ☐ PPHN

Name : _____ Signature : _____ Date: ☐☐☐ (dd/mm/yy)

DATA DEFINITION AND DATA STANDARDS

Centre Name*:* Name of participating hospital

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

State if it is a Stillbirth or Livebirth

State if it is a new case, a readmission and to specify the referring center (*Referral from :*) if relevant
If the case is transferred from another hospital and never admitted to your hospital, it is a new case and tick and specify referral site

SECTION 1: Patient Particulars

1. ***Name of patient*****:** Name as in hospital record
2. ***RN****:* RN at participating hospital. If the baby dies in Labour room and has no RN, then use the motherôs RN.
3. ***Mother's identity****:* New IC or Passport number
4. ***Date of Birth****:* dd/mm/yy
5. ***Ethnic group*****:** Malay / Chinese / Indian / Orang Asli / Bumiputra Sabah / Bumiputra Sarawak / Non-citizen / Other Malaysian: If Bumiputra Sabah or Bumiputra Sarawak please specify the indigenous group. In the case of mixed marriages, ethnic group of the baby is defined by the ethnic group of the mother.
6. ***Maternal Age****:* Age in completed years.
7. ***GPA*****:** G__P__A (of current pregnancy before delivery of this child)
8. ***State 'yes' or 'no' if mother had insulin dependent diabetes (regardless of whether it is gestational or pregestational)***

SECTION 2: Birth History

9. ***Antenatal Steroid****:* State óyesô or ónoô if this has been given (regardless of number of doses or when it was given).

10. ***Intrapartum Antibiotics****:* If systemic antibiotics were given to the mother in the 24 hours prior to delivery, record as óYesô. This includes antibiotics given only enterally or parenterally, not topical antibiotics.

11. ***Birth weight (grams):*** Weight in grams at birth hospital. If there are discrepant values, use the birth hospital value for out-born babies. If birth weight is unavailable, use the first weight taken up to 24 hours of life. If birth weight is only listed as an estimate, record the estimate, but make a note on the CRF that this is an approximate birth weight.

12. ***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. (US date to be selected if done earlier than 25 weeks if 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

13. ***Growth status:*** based on Intrauterine Growth Curves in training manual (Composite Male / Female) chart. SGA<10th centile; AGA 10-90th centile; LGA >90the centile

14. ***Gender***: Indicate Male, Female or Indeterminate

15. ***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 (unless in the ambulance ï born before arrival)

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.

1. University Hospital
2. General Hospital
3. Private Hospital
4. District Hospital with specialist
5. District Hospital without specialist
6. Private Maternity Home
7. Home
8. Others (e.g. in transit, please specify)

All big city government hospitals are considered as General hospitals and ticked as 2.
District hospitals with specialist pertain to availability of specialist post even if this post is not filled.

16. ***Multiplicity:*** To indicate as singleton, twin, triplet or others i.e. quadruplets, etc.

17. ***Mode of delivery:*** Tick as relevant. Rarely more than 1 may apply. All caesarians are considered as such without differentiation into upper or lower segment. For breech presentation in Caesarian section, tick as Caesarean section only

18. ***Apgar Score at 1 min and 5 min*****:** Enter the apgar score at 1min and at 5 mins as noted in the Labour and delivery record

19. ***Initial resuscitation*****:** Tick ñYes for all intervention that apply

19a**.** Oxygen:
Tick ñYesò if the baby received any supplemental oxygen in the delivery room
Tick ñNoò if the baby did not receive supplemental oxygen in the delivery room.

19b. Bag-mask vent :
Tick ñYesò if the baby received any positive pressure breaths with a bag and face mask in the delivery room.
Tick ñNoò if the baby did not receive any positive pressure breaths with a bag and mask in the delivery room. Tick ñNoò if a bag and face mask were only used to administer CPAP (continuous positive airway pressure) and no positive pressure breaths were given.

19c. Endotracheal tube ventilation:
Tick ñYesò if the baby receive ventilation through an endotracheal tube in the delivery room
Tick ñNoò if the baby did not received ventilation through an endotracheal tube in the delivery room.
If an endotracheal tube was placed only for suctioning and assisted ventilation was not given through the tube, tick ñNoò

19d. Cardiac Compression:

Tick ñYesò if external cardiac massage was given in the delivery room
Tick ñNoò if external cardiac massage was not given in the delivery room

19e. Adrenaline:

Tick ñYesò if adrenaline was given in the delivery room via intravenous, intracardiac or intratracheal routes.
Tick ñNoò if adrenaline was not given in the delivery room via intravenous, intracardiac or intratracheal routes.

SECTION 3: Neonatal Event

20. ***Respiratory support*****:** Tick ñYesò for all ventilation support given.

1. Oxygen ï infant was given supplemental oxygen at any time after leaving the delivery room

2. CPAP ï in the infant was given continuous positive airway pressure applied through the nose at any time after leaving the delivery room

3. Conventional Ventilation ï 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

4. High frequency oscillatory ventilation as delivered by an oscillator.
   High frequency oscillatory ventilation (IMV rate > 240/min) at any time after leaving the delivery room. High frequency oscillatory ventilation via nasal prongs is not considered HFOV

5. Nitric Oxide ï nitric oxide delivered as a gas via a ventilator at any time after leaving the delivery room

6. Others may include High Frequency Jet Ventilation (HFJV) or Liquid ventilation at any time after leaving the delivery room.

21. ***Total Duration of Ventilatory support*****:** State to next complete day i.e. < 24 hours is 1 day and 2 days 4 hours is 3 days, excluding CPAP.

22. ***Surfactant*****:** Indicate whether exogenous surfactant was given or not. If ñYesò indicate whether the infant received it at < 1hr, 1 to 2 hrs. or > 2hrs postnatal age.

23. ***Post Natal Steroid for CLD*****:** Indicate given or not if systemic corticosteroids were used after birth to treat bronchopulmonary dysplasia or chronic lung disease (CLD). Steroids given for other purposes e.g. hypotension and laryngeal oedema will not be included. Inhaled corticosteroids are not considered systemic corticosteroids.

24. ***Parenteral Nutrition*****:** Nutrition given intravenously. Parenteral nutrition must include amino acids with or without fats, hence plain dextrose saline infusion in not parenteral nutrition.

25. ***Enteral Nutrition on discharge:***

Tick óYesô or óNoô whether the infant received any enteral feedings with either formula milk or human milk at discharge.

Tick óExclusive breast feeding/Breast milk feedsô if the infant was discharged receiving human milk as their only enteral feeding, either by being breast fed and/or by receiving expressed breast milk.

Tick óExclusive formula feedsô if the infant was discharged receiving formula milk as their only enteral feeding.

Tick óMixed feedsô if the infant was discharged receiving human milk, plus human milk fortifier and/or formula milk.

26. Ultrasound done at <u>< </u>28 days of age ï Tick óYesô or óNoô whether ultrasound cranium was done <u>at or before</u> 28 days of life .

SECTION 4: Outcome

27 ***Date of discharge: Enter the exact date***

28 ***Weight (grams) of Discharge or Death or Transfer out:*** Weight on Death is the last weight taken when the baby is alive. Enter the exact weight in grams.

29 ***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.

30.***Outcome:*** Alive or Dead ï Alive at discharge or died before discharge.

If Child Alive, state Place of discharge to**:** Home, Social welfare home,Other Non-Paed Ward, óStill hospitalised as of 1st birthdayô or Transferred to other hospitals. If transferred to other hospitals, specify the name of hospital transferred to.

Post transfer disposition**.** If a case is transferred to another hospital in the NNR network, complete the CRF up to current status and <u>send form with the baby</u>. The referral centre would complete a new CRF and this will be analysed together with the CRF of the referring hospital. **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.

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:

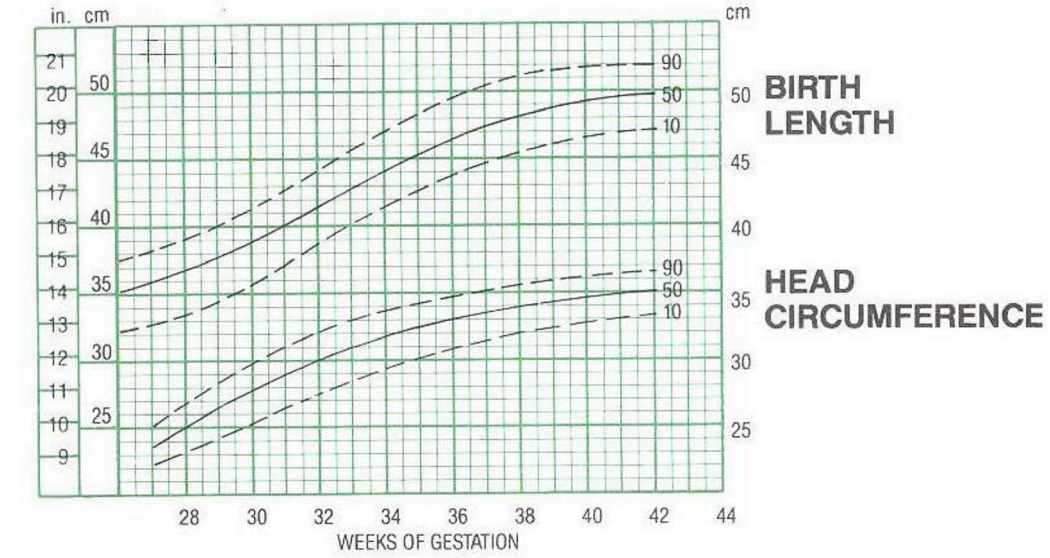
SECTION 5: Problems / Diagnoses

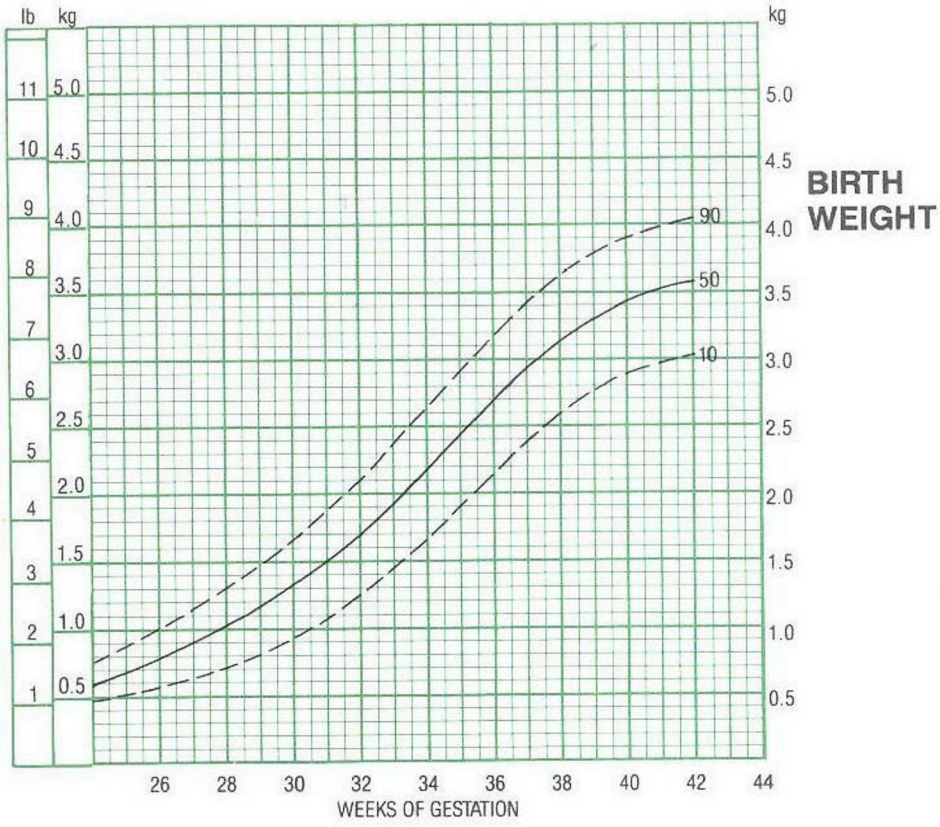
Mandatory fields are included for some diagnoses /procedures that are very important in the care of VLBW and sick infants. Definitions of these conditions are as shown in Appendix 1. Other diagnoses or problems not given in the list can be referred to óWHO 1992 ICD-10; Volume 1 documentô and to be written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

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

APPENDIX 1

INTRAUTERINE GROWTH CURVES (COMPOSITE MALE / FEMALE) (APPENDIX 2)





Data Source: W.H. Kitchen et al *Revised intrauterine growth curves for an Australian hospital population.*
Aust. Paediatr. J. *(1983) 19:157–161.*

APPENDIX 2

Definitions of Certain Specified Diagnoses

Diagnosis	Definition
1. Respiratory distress syndrome (RDS). Tick óyesô or ónoô	Respiratory Distress Syndrome (RDS) is defined as: A. PaO_2 <50 mmHg in room air, central cyanosis in room air, or a requirement for supplemental oxygen to maintain PaO_2 >50 mmHg AND B. A chest radiograph consistent with RDS (low lung volumes and reticulogranular appearance to lung fields, with or without air bronchograms).
2. Patent ductus arterious (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 óYesô, indicate whether ECHO was done and whether treatment (indomethacin/ibuprofen for>24 hours or ligation) was given or not.
3. Pneumothorax Tick óyesô or ónoô	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'.**

4. Supplemental oxygen State if required at Day 28 and 36 weeks corrected gestation	Receipt of continuous enriched oxygen concentration >0.21% by oxyhood, nasal cannula, nasal catheter, facemask or other forms of respiratory support. óContinuousô means that the patient is receiving oxygen throughout the time period and not just in brief episodes as needed i.e. during feeds. óBlow-byô oxygen dose 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.
5. Necrotising enterocolitis (NEC) (Stage 2 and above) Tick óyesô or ónoô If ñYesò and managed surgically tick óSurgical Rxô	NEC according to Bellôs 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)
6. 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. Tick ñYesò if a Retinal exam is done and enter the worst stage. State if laser or cryotherapy was done. If screening was not done, state ñNoò AND indicate whether an appointment for retinal examination was given.	If an indirect ophthalmologic examination was performed at any time, enter the worst stage documented Stage 0 : No Evidence of ROP Stage 1: Demarcation Line Stage 2: Ridge Stage 3: Ridge with Extraretinal Fibrovascular Proliferation Stage 4: Retinal Detachment Stage 5: Vitreous haemorrhage

7.Intraventricular haemorrhage (IVH) Tick ñYesò 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 ñNoò if there was no IVH before or on day 28. If ultrasound is not done before or on 28 days, state ñNot applicableò	If Ultrasound of Brain done <u>on or before</u> 28 days of life, enter the worst grade Grade 1 Subependymal germinal matrix(GM) haemorrhage only Grade 2 IVH without ventricular dilatation Grade 3 IVH with ventricular dilatation Grade 4 IVH with parenchymal involvement
8. Seizures Tick óyesô or ónoô	Clinical evidence of subtle seizures, or of focal or multifocal, clonic or tonic seizures, confirmed by 2 or more clinicians or diagnosed by EEG. Used synonymously with fits or convulsions
9. Infections Tick óYesô if there is evidence of clinical or confirmed sepsis. State whether the onset of the infection was Day 3 and below or after 3 days of birth. NOTE: The date of birth counts as day 1 regardless of the time of birth. For an infant born at 11:59 PM on September 1, day 3 will be September 3.	***Clinical sepsis*** One of the following clinical signs or symptoms with no other recognised cause: Fever (>38^{o}C), hypothermia (<37^{o}C), apnoea, bradycardia *and all of the following:* a. Blood culture not done or no organism or antigen detected in blood b. No apparent infection at another site c. Physician institutes appropriate antimicrobial therapy for sepsis ***Confirmed sepsis*** Clinical evidence of sepsis plus culture-proven infection e.g.: positive blood, urine, or CSF culture or positive bacterial antigen test. Include congenital pneumonia if blood culture was positive.
10. For Confirmed Sepsis State organism as indicated or specify others	Please state the organism cultured: 1 Group B streptococcus 2 MRSA 3 CONS (see below) 4.ESBL organisms 5. Fungal (see below) 6 Staphylococcus aureus 7 Klebsiella 8 Pseudomonas 9 Acinetobacter 10 Others, specify

	For CONS: 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/or is recovered from infantôs CSF 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 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 For FUNGAL infection: 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.
11. Hypoxic ischaemic encephalopathy (HIE) This item only applies to infants with a gestational age of 36 weeks and 0 days or more	HIE requires the presence of all 3 of the following criteria: 1. 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 Dollôs eye or fixed unreactive pupils **AND** 2. Three or more supporting findings 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 ï dysfunction of one or more of the following systems within 72 hours of birth: i. renal: oliguria or acute renalfailure ii. GI: necrotizing enterocolitis, hepatic dysfunction iii. haematologic: thrombocytopaenia, disseminated intravascular coagulopathy iv. endocrine: hypoglycaemia, hyperglycaemia, hypercalcaemia, syndrome of inappropriate ADH secretion (SIADH) v. pulmonary: persistent pulmonary hypertension vi. cardiac: myocardial dysfunction, tricuspid insuffucuency d. evidence of foetal distress on antepartum 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 3. 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 infantôs level of consciousness and response to arousal maneuvers such as persistent gentle shaking, pinching, shining a light or ringing of a bell: Tick óñNone, Mild, Moderate, Severe ò for infants of gestational age 36 weeks or more Tick ñNot applicableò for infants below 36 weeks gestational age at birth	*HIE severity* a. Mild (normal or hyperalert) ï infants in this category are alert or hyperalert with either a normal or exaggerated response to arousal. b. Moderate (lethargic or stupor) ï infants in this category are arousable but have a diminished response to arousal maneuvers c. Severe (deep stupor or coma) ï infants in this category are not arousable in response to arousal maneuvers
12. Major Congenital Anomalies State óYesô or óNoô. Tick ñYesò 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 óKnown Syndromeô, óNot a Recognised Syndromeôor óisolated major abnormalityô in 12a.	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

If the syndrome is known, tick the specific syndromes or specify it. Proceed to 12b. (Type of Abnormalities) Tick all major abnormalities found for recognisable syndrome, non-recognisable ones or isolated major congenital abnormality - tick the abnormalities according to the list provided. Please specify if there are abnormalities not listed.	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 ðlow-set earsô, sacral dimple or single transverse palmar creaseò.
13. Inborn Errors of Metabolism (IEM) Tick ñYesò or ñNoò. If ñyesò, tick either clinical diagnosis or confirmed diagnosis Specify the confirmed diagnosis if any	For clinical diagnosis, tick ñyesò only if tandem spectrometry is not available to confirm diagnosis and there are signs such as encephalopathy not otherwise explained, hypoglycaemia, seizures, with or without associated family history or parental consanguineous marriage
14. Respiratory Meconium aspiration syndrome	Tick ñyesò if all 5 of the following criteria are satisfied: 1. Presence of meconium stained amniotic fluid at birth 2. 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 3. A PaO2<50mmHg in room air, central cyanosis in room air or a requirement for supplemental oxygen to maintain a PaO2 >50mmHg 4. 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 5. 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)

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
Transient Tachypnoea of Newborn	Benign disease of near-term, term or large premature infants with respiratory distress shortly after delivery resolving within 3 days.
Pulmonary interstitial emphysema	Dissection of air into the perivascular tissues of the lung from alveolar overdistention or overdistention of the smaller airways evident on CXR as linear or cast-like lucencies with a history of requiring increasing ventilatory support.
15. Central Nervous System	
Neonatal encephalopathy (other than HIE)	Encephalopathy in the infant at or near term during the first seven days of life, manifested by difficulty in initiating and maintaining respiration, depression of tone and reflexes, altered consciousness, and often seizures **not** fulfilling the criteria for óHypoxic ischaemic encephalopathyô (see above)
Neonatal meningitis	Signs of clinical sepsis and evidence of meningeal infection as shown in cerebrospinal fluid findings (i.e. cytology, biochemistry or microbiologic findings)
16. Cardiovascular	
Persistent Pulmonary Hypertension (PPHN)	Failure of normal pulmonary vasculature relaxation at or shortly after birth, resulting in impedance to pulmonary blood flow which exceeds systemic vascular resistance, such that deoxygenated blood is shunted to the systemic circulation

M o n t h l y B i r t h

C e n s u s

National Neonatal Registry

MONTHLY BIRTH CENSUS

Hospital :……

Month :…… .. Year :……

Total Births :…… Live Births:…… Stillbirths :……

Deliveries Versus Birth Weight

Birth Weight (grams)	No. of Stillbirths	No. of Live Births	No. Admitted to Neonatal Unit	**No who died in delivery room
< 500				
500 ï 600				
601 ï 700				
701 ï 800				
801 ï 900				
901 ï 1000				
1001 ï 1250				
1251 ï 1500				
1501 ï 2000				
2001 ï 2500				
>2500				
TOTAL				

** CRF to be filled for each case

Births Versus Mode of Delivery

Mode of Delivery	No. of Stillbirths	No. of Live Births	No. Admitted to Neonatal Unit	**No who died in delivery room
SVD				
Breech				
Forceps				
Ventouse				
LSCS Elective				
LSCS Emergency				
TOTAL				

*** CRF to be filled for each case*

Births Versus Ethnic Group

Ethnic Group		No. of Stillbirths	No. of Live Births	No. Admitted to Neonatal Unit	**No who died in delivery room
Malay					
Chinese					
Indian					
Orang Asli					
Bumiputra Sabah - specify ethnic group					
Bumiputra Sarawak ï specify ethnic group					
Foreigner					
Other Malaysian					
TOTAL					

*** CRF to be filled for each case*

Remarks:é .é é é é
é é
é é

Name of Site Coordinator:é é

Chop: Date:é é é é é é é é é é

- *Birth census should be sent together with the tracking forms and the completed CRFs of discharges for the month by the end of the following month.*
- *Samples of tracking forms are as follows.*

Tracking
And
Monthly Returns
Of
Case Report
Forms

Track 1

Tracking CRFs (Admissions in month of October 2004)

Name	Hospital RN	***Date of Birth***	***Date of admission***	***Criteria of inclusion***	***Date discharged***	***CRF status***	***Comment***
THY		1st October	1st October	VS	20th October	ã	
NFR		2nd October	2nd October	LRD	2nd October	ã	
YHT		6th October	6th October	ELBW		Still in ward as of 31st October	
THD		15th October	15th October	VS	26th October	ã	
ERT		20th October	20th October	VLBW	28th October	Transferred HKL (CRF sent with case)	
TEN		25th October	26th October	VS		Still in ward	
YTE		26th October	26th October	Died	28th October	ã	
REW		29th October	29th October	VP		Still in ward as of 31st October	

Abrreviations:
ã : CRF completed and attached
Died: Died in NNU
ELBW: Extremely Low Birth Weight
LRD: Labour Room Death
VLBW: Very Low Birth Weight
VP: Very premature (<32 weeks)
VS: Venitlatory 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 this tracking form immediately every working day. Do remember to include cases that have been admitted on your off days, public holidays and weekends too.**

- The óTracking CRFsô list of admissions in a month should be sent to NRU within the following 1month after the month admitted eg list of admissions from 1st to 31st October 2004 should be sent to NRU by the 30th November 2004 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 submitted with this form to NRU

- Also patients admitted in the previous months and discharged between 1st to 31st October should also have their CRFs completed and sent together to the NRU by the 30th November.

An accompanying record (as below) of these cases should be filled and sent together.

Track 2

Crfs From Previous Months

Name	Hospital RN	Date admission	Criteria	Date discharged
GTH	12345	3rd May	VLBW	15th October
SMH	34562	7th July	VLBW	17th October
YIM	56432	2nd September	ELBW	20th October

Nurse coordinators or abstractors should refer to their ôTracking CRFsô admission list of the earlier months and write under the Comment column ôCRF sent in Novemberô for the respective case. *If there are no tracking forms of earlier admissions prior to 1st October 2004, just fill up this Track 2 form as the cases are discharged.*

Track 3

Preliminary Close-out report (in addition to Track 1 and Track 2 Forms for the month January 2005). CRF for case as of 28th January 2005 to be filled and sent by 28th February 2005 for purpose of calculating perinatal and neonatal mortality rates

Please look back at your earlier tracking admission forms for the previous months and select all those where status of CRFs is still not completed and sent as of 28th January 2005

Name	Hospital RN	Date of admission	Status of case	Comments
BGR	76854	1st July 2004	Still in ward > 1 month	CRF incomplete (flagged by sending a phostat copy)
GHU	98765	3rd January 2004	> 1 year	CRF completed and attached

** As the flagged cases get discharged even after the close-out date , complete the original CRF and send the CRFs at the end of the following month as in other cases..

Track 4

(Form to be submitted in addition to Track 1 and 2 Forms for the month of April 2005 by 31st May 2005)

Final close-out as of 30th April 2005 for purpose of Report Writing

Name	Hospital RN	Date of admission	Status of case	Comments
MHT	65743	5th August 2004	Still in ward	CRF incomplete (flagged by sending a photostat copy)
YJU	67543	23rd March 2003	> 1 year	CRF completed and attached

** As the flagged cases get discharged even after the close-out date , complete the original CRF and send the CRFs at the end of the following month as in other cases..

By the end of each month the following should be submitted
1. Birth census record of previous month
2. Track 1 form of previous monthôs admissions
3. Track 2 form of previous monthôs additional discharges
4. Completed CRFs of previous monthôs discharges

In addition to 1,2,3,4 for the month of February, following must be submitted
5. Track 3 form on close-out record
6. Completed and flagged CRFs as of 28th January

In addition to 1,2,3,4 for the month of May, the following must be submitted,
7. Track 4 form on close-out record
8. Completed or flagged CRFs as of 30th April

Please duplicate and keep in your centre a set of all these forms and CRFs before sending them to NRU.

Track 1

Centre Name :……

Admissions in Month / Year

……..

Tracking CRFs

Name	Hospital RN	DOB	DOA	Criteria of inclusion	DOD	CRF attached	Comment

Track 2

Centre Name :……

Additional Discharges for
Month / Year: ……

CRFs of admissions from previous months

Name	Hospital RN	DOA	Criteria	DOD

Track 3

Centre Name : ……..

Cases as of 28th January 2006
Form to be submitted by 28th February 2006

Preliminary Close-out report

(Form to be submitted in addition to Track 1 and Track 2 Forms for the month of January 2006. Completed or flagged CRFs should be submitted together).

Name	Hospital RN	Date of admission	Status of case	Comments

** As the flagged cases get discharged even after the close-out date, complete the original CRF and send the CRFs at the end of the following month as in other cases..

Track 4

Centre name : …….

Cases as of 30th April 2006
Form to be submitted by 31st May 2006

Final close-out as of 30th April 2006 for purpose of Report Writing

(Form to be submitted in addition to Track 1 and 2 Forms for the month of April 2006 Completed or Flagged CRFs should also be submitted together)

Name	Hospital RN	Date of admission	Status of case	Comments

** As the flagged cases get discharged even after the close-out date, complete the original CRF and send the CRFs at the end of the following month as in other cases..