P1106
Expected adverse events

To be completed by the attending doctor (neonatologist)

at each study visit

(week 2, 4, 6, 10, 16 and 24)

Expected Adverse Events

= Common “normal” events that occur in neonates, i.e. jaundice, anemia, apnea etc

20 expected advents listed with a grading system (1-4) for each event

For each study visit – to use a back window of 72 hours/ 3 days

To provide a snapshot
of the infant’s overall clinical condition
at visit

Expected Adverse Event Form

IMPAACT P1106 EXPECTED EVENT REPORTING WORKSHEET FOR NEONATOLOGIST

Patient Number_____ Date of Visit_____ Time of Visit_____ Form Week_____

INSTRUCTIONS: FOR NEONATOLOGISTS:
For each of the targeted parameters, note under "Event" column whether event was identified in participant then record details of event under "Description of Observed Event" column. This information provides a *snapshot* of the infant's overall clinical condition at visit

INSTRUCTIONS: FOR DATA GROUP:
Abstract information documented from this form onto TGW1 - IMPAACT P1106 Expected Event Reporting form. Event type drives which section to report event within the TGW1 form.

Parameter	**Grade 1 Mild**	**Grade 2 Moderate**	**Grade 3 Severe**	**Grade 4 Potentially Life-Threatening**	**Event? Y/N/NE** Y = Yes N = No NE = Not evaluated	**Description of Observed Event (Include AGE in Days or Months for age linked events)**
Apnea* ***Apnea spell defined as apnea event >20s or associated with bradycardia, hypoxia or cyanosis	< 6 spells* per day	6<12 spells* per day or nasal cannula for apnea	12 or more spells* per day or nasal continuous positive airway pressure (NCPAP) for apnea	Requires intubation for apnea		

IMPAACT P1106 EXPECTED EVENT REPORTING WORKSHEET FOR NEONATOLOGIST

Patient Number Pt ID Date of Visit mm/dd/yyyy Time of Visit 10h00 Form Week 2

INSTRUCTIONS: FOR NEONATOLOGISTS:
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Identify the parameter/ event

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Expected Adverse Events - parameters

Apnea	Neonatal abstinence syndrome
Anemia	Neurologic compromise (including HIE)
Congenital abnormalities	Neutropenia
Congenital Heart disease (not PDA)	Patent Ductus Arteriosus
Electrolyte or metabolic disorder	Persistent Pulmonary Hypertension
GI dysfunction (including NEC)	Renal dysfunction
Hypertension	Respiratory insufficiency
Hypotension	Retinopathy of prematurity
Intravascular hemorrhage	Sepsis
Jaundice	Thrombocytopenia

3 STEPS

IMPAACT P1106 EXPECTED EVENT REPORTING WORKSHEET FOR NEONATOLOGIST

Patient Number Pt ID Date of Visit mm/dd/yyyy Time of Visit 10h00 Form Week 2

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Step 1. Identify the parameter

3 STEPS

IMPAACT P1106 EXPECTED EVENT REPORTING WORKSHEET FOR NEONATOLOGIST

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Step 2. Event : Yes , No , Not Evaluated

3 STEPS

WKW1(P1106)/00-00-00
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IMPAACT P1106 EXPECTED EVENT REPORTING WORKSHEET FOR NEONATOLOGIST

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Step 3: If Yes to an event, then grade the event

Grade1 – mild; Grade 2 – moderate; Grade 3-severe; Grade 4 – Life threatening

Recap

Step 2. Identify parameter

Step 2. Event present or not

Step 3. Grading of event

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Anemia	gb 8-10 dL	Hgb ≤ 8 g/dL	Requires packed red cell transfusion, no clinical signs	Requires packed red cell transfusion, clinical signs of shock	Y	
Congenital Anomalies	inor (no pairment function)	Minor (no impairment of function), future treatment may be needed	Major (impairment of function), no immediate treatment needed	Major (impairment of function), immediate treatment needed	N	

Practical examples of Expected Adverse Events

Parameter	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Potentially Life-Threatening	Event? Y/N/NE Y = Yes N = No NE = Not evaluated	Description of Observed Event (Include AGE in Days or Months for age linked events)
Anemia	Hgb 8-10 g/dL	Hgb ≤ 8 g/dL	Requires packed red cell transfusion, no clinical signs	Requires packed red cell transfusion, clinical signs of shock		

Anemia:

Scenario 1:

Patient's scheduled week 4 study visit falls on the 5th of July 2015…..

On the 3rd of July the Hb was 7 g/dL, and on the 4th of July the patient received a red pack cell transfusion……and the Hb improve to 9 g/dL

You see the patient for the first time on the 5 th of July…How would you grade this event?

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Hypertension	Systolic BP> 80-100, no treatment	Systemic BP > 100, no treatment	Treated with one agent	Treatment with multiple agents		
Hypotension	Mild clinical signs, no treatment needed	Symptomatic, treated with IV fluids	Symptomatic, treated with single medication	Clinical signs of shock or requiring use of multiple medications		
Renal Dysfunction	Urine output 1 < 1.5 mL/kg/hr	Urine output 0.5 <1.0 mL/kg/hr	Urine output 0 < 0.5 mL/kg/hr	Prolonged anuria		

Hypertension, Hypotension and Renal dysfunction:

Scenario 2 (Renal dysfunction):

Stable neonate in a low care ward, and the nurse documented 5 wet nappies in the past 12 hours

How would you complete the renal dysfunction section?

Parameter	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Potentially Life-Threatening	Event? Y/N/NE Y = Yes N = No NE = Not evaluated	Description of Observed Event (Include AGE in Days or Months for age linked events)
Hypertension	Systolic BP> 80-100, no treatment	Systemic BP > 100, no treatment	Treated with one agent	Treatment with multiple agents		
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Hypertension, Hypotension and Renal dysfunction

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How would you complete the renal dysfunction section?

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Congenital Heart Disease	Minor (no impairment of function), no treatment needed	Minor (no impairment of function), future treatment may be needed	Major (impairment of function), no immediate treatment needed	Major (impairment of function), immediate treatment needed		
Patent Ductus Arteriosus	Clinical signs, no treatment	Treatment with fluid restriction or diuretics	Treatment with indomethacin or ibuprofen	Surgical ligation		

Congenital heart disease and Patent Ductus Arteriosus

Scenario 3:

Highlight that they are 2 separate entities, and that presence of a PDA is not to be included in the congenital heart disease section

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Elecotrolyte/ Metabolic Disorders	---------- ---	Electrolyte/Metabolic disorder, no systemic signs	----------	Electrolyte/Metabolic disorder with systemic signs		

Electrolyte disorders

Scenario 4:

A baby of a diabetic mother who had a documented hypoglycemia on the 4 th of July, which was followed by a seizure

? Grade

Parameter	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Potentially Life-Threatening	Event? Y/N/NE Y = Yes N = No NE = Not evaluated	Description of Observed Event (Include AGE in Days or Months for age linked events)
Elecotrolyte/ Metabolic Disorders	---------- ---	Electrolyte/Metabolic disorder, no systemic signs	----------	Electrolyte/Metabolic disorder with systemic signs		

Electrolyte disorders

Scenario 4:

A baby of a diabetic mother who had a documented hypoglycemia on the 4 th of July, which was followed by a seizure

Grade 4 event – potentially life-threatening

Parameter	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Potentially Life-Threatening	Event? Y/N/NE Y = Yes N = No NE = Not evaluated	Description of Observed Event (Include AGE in Days or Months for age linked events)
Neurologic compromise	Mildly abnormal neurologic exam, no clinical or EEG seizure activity	Stage I hypoxicischemic encephalopathy (HIE) or possible clinical or EEG seizure activity but no treatment	Stage II HIE or single drug seizure therapy	Stage III HIE or induced hypothermia or multiple drug seizure therapy		
Sepsis	Septic evaluation, no treatment	R/O sepsis, antibiotics for ≤72 hours	Clinical sepsis, >72 hours antibiotics, no septic shock or meningitis	Clinical sepsis, >72 hours antibiotics with septic shock or meningitis		

Neurological compromise and sepsis

Scenario 5:

To highlight that any seizure activity should be classified under neurological compromise, irrespective of the cause, i.e HIE or meningitis

What to do with a neonate that has meningitis and seizures requiring multiple drug seizure therapy?

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Sepsis	Septic evaluation, no treatment	R/O sepsis, antibiotics for ≤72 hours	Clinical sepsis, >72 hours antibiotics, no septic shock or meningitis	Clinical sepsis, >72 hours antibiotics with septic shock or meningitis		

Neurological compromise and sepsis

Scenario 5:

For example: an infant with meningitis and seizures requiring multiple drug seizure therapy, Will have both a neurological compromise grade 4 event, and a sepsis grade 4 event

Additional comments

- It is important to document the worst grade of the event at the study visit, when reviewing the patient's chart, looking back over the last three days

For example – for **thrombocytopenia – study visit day – 5 July**:

	3 July	4 July	5 July
Platelet count	15 000	Not done	30 000

In this case, 15 000 is the lowest value, and this event will be reported as a grade 4 event (< 25 000), even though 30 000 is closest to the study visit

- A column to the right is titled…."Additional comments" (To be completed if needed)

- All entered data will be compiled into reports and evaluated by the team on monthly team calls, and as needed for specific subjects if special concerns arise