

# Royal Hospital for Women (RHW)

## NEONATAL BUSINESS RULE

### COVER SHEET



**Health**  
South Eastern Sydney  
Local Health District

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<b>SUMMARY</b>	The critical bleeding in neonates often requires massive transfusion of blood products. This CBR is to assist the clinicians and the POWH Blood Bank to achieve timely intervention.
<b>Key Words</b>	Blood products, critical bleeding, neonate, transfusion

**Contents**

1	BACKGROUND.....	2
2	RESPONSIBILITIES .....	2
2.1	Staff .....	2
3	PROCEDURE .....	3
3.1	Equipment.....	3
3.2	Clinical Practice .....	3
3.2.1	Initiate the Critical Bleeding Protocol Neonate (Appendix A) .....	3
3.2.2	Blood testing .....	4
3.2.3	Transfusion of blood products during critical bleeding .....	5
3.2.4	CTP blood target values* .....	6
3.2.5	Additional treatments to be considered: .....	6
3.2.6	Administration and Documentation.....	7
3.2.7	Patient Information .....	7
3.3	Documentation.....	7
3.4	Education Notes.....	7
3.5	Abbreviations .....	10
3.6	Related Policies/procedures.....	10
4	ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION.....	11
5	CULTURAL SUPPORT .....	12
6	NATIONAL STANDARDS .....	12
7	REVISION AND APPROVAL HISTORY .....	12
	Appendix A.....	13
	APPENDIX B.....	14

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**Critical Bleeding Protocol Neonate (CBP)****RHW CLIN106**

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*Within this document we will use the term woman, this is not to exclude those who give birth and do not identify as female. It is crucial to use the preferred language and terminology as described and guided by each individual person when providing care.*

## **1 BACKGROUND**

The aim of this CBR is to assist clinicians in the process of recognition of the necessity, organisation and administration of blood products in critical bleeding. The aims are early recognition of blood loss, maintenance of tissue perfusion and oxygenation, restoration of blood volume and haemoglobin (Hb), management of coagulopathy, cessation of bleeding and usage of the appropriate blood products.

Critical bleeding in neonates may be defined as either:

- 40mL/kg in 3hr OR
- 80mL/kg in 24hr OR
- Hypovolaemic shock not responding to initial Packed Red Blood Cells (PRBC) 20mL/kg OR
- Evidence or suspicion of ongoing blood loss with haemodynamic/cardiovascular instability

## **2 RESPONSIBILITIES**

### **2.1 Staff**

#### **2.1.1 Medical / Neonatal Nurse Practitioner**

- Timely identification of neonates with critical bleeding
- Initiating the critical bleeding protocol
- Maintain communication with Blood Bank
- Consult with paediatric haematologist

#### **2.1.2 Nursing**

- Collecting bloods for initial and ongoing testing
- Ensure availability of personnel to transport blood product promptly to patient location
- Administration of blood product
- Maintain communication with clinicians
- Informs Blood Bank if patient location changed

#### **2.1.3 Blood bank**

- Prioritise blood testing and blood product dispensing

## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

- Dispatch requested blood products to patient location
- Ensure continuous availability of blood products
- Maintain communication with clinicians including paediatric haematologist

### 2.1.4 Porter

- Transport required blood products to patient location

## 3 PROCEDURE

### 3.1 Equipment

- Transfusion giving set
- 50 mL syringe
- Extension tubing (as required)
- Blood warmer (as required)
- Blood collection tubes
- Blood gas syringe
- Cardiorespiratory monitoring

### 3.2 Clinical Practice

#### 3.2.1 Initiate the Critical Bleeding Protocol Neonate (Appendix A)

- A senior clinician directly or another staff member under the direct instruction from a senior clinician contacting the hospital's Blood Bank to:
  - Initiate the Neonatal CTP and place an order for Pack 1 or Pack 2 blood products depending on the clinical scenario

**Table 1. Suggested Critical Bleeding Packs**

Pack 1	Pack 2
PRBC 20mL/kg	PRBC 20mL/kg
FFP 15mL/kg	FFP 15mL/kg
Cryoprecipitate 5-10mL/kg	Platelets 10-15mL/kg

- If blood is required urgently (<15 minutes) request emergency release of O negative PRBC.

Note

O Negative PRBC stored in fridge in Operating Theatres

- Notify on call Haematologist/haematology registrar and provide the following information:
  - Neonatal bleeding
  - Abnormal neonatal bleeding from intravenous cannulation sites, haemorrhage or bruising
  - Maternal history of:
    - Allo-immune thrombocytopenia

**Critical Bleeding Protocol Neonate (CBP)**

**RHW CLIN106**

- Immune thrombocytopaenia (ITP)
- Maternal thrombocytopaenia
- Familial bleeding disorders
- Warfarin or other anticoagulation other than prophylactic Low Molecular Weight Heparin
- Maternal blood group antibodies
- History of intra-uterine transfusion (IUT)
- Notify the Blood bank with information:
  - Location of patient
  - The name of the designated clinical contact
  - A contact phone number
  - Patient's name (baby of "mothers name")
  - Patient identification number
  - Date of birth
  - Number of units, dose of blood product or pack required
  - A brief clinical scenario
- Inform parents/ carers as soon as possible

**3.2.2 Blood testing**

**3.2.2.1 Initial testing** collected as soon as practicable.

Test	Tube Type
Blood group and Cross match antibody screen	EDTA (Purple)
FBC	EDTA (Purple)
PT/INR/APTT/Fibrinogen*	Citrate Plasma (Blue)
UEC, Ca, Mg, PO4, LFT's	Serum (Gel) [Yellow]
Blood Gas – arterial or venous preferred	Blood gas syringe

**Note**

Umbilical cord samples are not suitable for pre-transfusion testing.

\*Coagulation samples SHOULD NOT be taken from lines that have had heparin infused through as heparin contamination will affect results.

**3.2.2.2 Ongoing testing** repeated every 30-60 minutes where feasible if haemorrhage is ongoing.

Test	Tube Type
FBC	EDTA (Purple)

## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

PT/INR/APTT/Fibrinogen	Citrate Plasma (Blue)
Blood gas including ionized calcium	Blood gas syringe

### 3.2.3 Transfusion of blood products during critical bleeding

- Choose between Pack 1 or Pack 2 and then alternate between 2 packs if ongoing transfusions required
- Packs can be administered rapidly (within 10 minutes) when haemodynamically unstable.
  - Resume typical transfusion infusion timing when clinically stable and bleeding is controlled.
- Alterations may be made to subsequent packs based on coagulation testing – clinical team to liaise with Haematology/Paediatric Haematology and the Blood Bank.
- Blood warmer is to be used when feasible for the rapid administration of large volumes of blood products.
  - **Urgent transfusion should not be delayed waiting for equipment to be present**
  - Red cells should only be warmed as they are being administered to the patient
  - The thermometer should be visible at all time
  - The temperature of the blood warmer must be documented in the patient's clinical notes and must not exceed 40° Celsius
- **Emergency issue of Red Blood Cells**
  - Un-cross matched Group O Rh(D) Negative, CMV negative, <7 days from collection, K factor negative red blood cells should be issued when possible
  - For **emergency transfusions, irradiated cellular components are not required**
- **Emergency issue of plasma products (FFP and Cryoprecipitate)**
  - Group AB plasma products should be selected
  - If group AB is not available, group A, low anti-B titre should be selected
  - ABO compatible plasma should be selected as far as possible
  - **Group O FFP** and cryoprecipitate must only be given to **O recipients**
  - **Extended Life Plasma (ELP) should not be used in neonates**
- **Emergency issue of platelets**
  - CMV negative, group A or O apheresis low titre anti-A/B or pooled Rh(D) negative platelets to be issued if available
  - In a term baby, consider dropping the CMV requirement if unable to source suitable CMV negative platelets
  - If time permits a neonatal sample must be collected and tested. Platelets issued should be ABO and RhD compatible with the patient
  - Caution should be exercised when transfusing non-ABO identical platelets to neonatal and paediatric patients due to the risk of haemolysis from donor anti-A and anti-B antibodies
  - **The use of group O platelets for non-O patients should be avoided as much as possible.**

**Critical Bleeding Protocol Neonate (CBP)****RHW CLIN106****3.2.4 CTP blood target values\***

Hb	Greater than 100 g/L
Fibrinogen	Greater than 1.5 g/L, consider >2.0 g/L
Platelets	Greater than 50 x 10 <sup>9</sup> /L
PT/INR	Less than 1.5x normal (PT <20/INR <2.0)
APTT	Less than 1.5x normal (< 60-80 depending on gestation and day of life)
pH	Greater than 7.2
Base Excess	Less than -6
Lactate	Less than 4 mmol/L
Ionised Ca <sub>2+</sub>	Greater than 1.1 mmol/L in term and 1.0 mmol/L in preterm <sup>#</sup>

**Note**

\*CTP targets are different to elective replacement of blood products.

#Ionised Ca levels may not necessitate active intervention in an asymptomatic neonate and often levels of 0.8-1.0mmol/L in preterm neonates is accepted<sup>3-5</sup>**3.2.5 Additional treatments to be considered:**

- Vitamin K
  - Ensure Vitamin K has been given post-delivery and consider a second dose if ongoing bleeding.
- Tranexamic Acid (see Australasian Neonatal Medicines Formulary [Tranexamic Acid](#))
- Factor Concentrates
  - Activated factor VII (Novoseven), Fibrinogen concentrate (Riastap) or prothrombin complex concentrates (Beriplex) may be indicated in certain bleeding scenarios.
    - Riastap is only licensed in congenital hypofibrinogenaemia associated bleeding. RHW has only approved it for ROTEM-guided obstetric bleeding
  - Suggest discussion between the clinical team and the on-call haematologist/paediatric haematologist for alternate products

**Suggested doses of additional treatments**

Treatment	Dose
Vitamin K	1mg IM or as a slow IV bolus injection
Fibrinogen Concentrate	70 mg/kg
Prothrombin concentrate	25-50 IU/kg

## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

Factor VII	90 micrograms/kg
Tranexamic acid	Loading dose of 10-15 mg/kg, followed by maintenance of 2 mg/kg/hr until bleeding cessation

### 3.2.6 Administration and Documentation

- All clinical staff must be aware of the mandatory requirements for providing safe transfusion according to [NSW Health Policy Directive PD2018\\_042 Blood Management](#).
- Two appropriate staff members must independently identify the patient identification when the transfusion is being set up.
- The patient's identity must be checked against the patient's identification band.
- The following details on the blood pack component label must be checked and must match exactly the details on the blood request form, the prescription order AND the patient's identification band:
  - Patients Surname, Given Name [or Baby of..., if applicable] and Date of Birth
  - Hospital Medical Record Number
  - Unique blood unit number
  - The ABO and Rh (D) group
  - The expiry date on the blood product
  - Any special requirements e.g. specific phenotypes, CMV negative, irradiated.
- In some instances, blood issued may be compatible but not identical to the patient's own ABO and Rh (D) group. *Check for compatibility with the laboratory before commencing transfusion if non identical blood group has been issued.*

### 3.2.7 Patient Information

- Clinical Excellence Commission
  - [Blood Transfusion Guide: Information for Patients and Families](#)
  - [Children Receiving a Blood Transfusion: A Parents' Guide](#)
- Australian Red Cross Lifeblood
  - [Babies receiving a Blood Transfusion](#)
  - [Children receiving a blood transfusion](#)

### 3.3 Documentation

- eRIC
- Blood and blood products administration form
- Authority to Issue Blood Product form
- SEALS Blood Bank Issue Report checklist

### 3.4 Education Notes

- Critical bleeding is defined as half the blood volume loss. Blood volume of a neonate is 80-100 mL/kg.



## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

- Clinically significant bleeding and critical blood loss in neonates is rare<sup>1</sup>, but can be seen in:
  - Acute perinatal blood loss (feto-maternal haemorrhage, vasa praevia, placental abruption)
  - Intra-and extra- cranial haemorrhage (in particular subgaleal)
  - Gastrointestinal haemorrhage
  - Pulmonary haemorrhage
- Neonates are at-risk for critical bleeds due to:
  - Low total blood volume in absolute terms
  - Underdeveloped haemostatic system
  - Low concentration of pro- and anticoagulant proteins
  - Qualitatively dysfunctional fibrinogen existing in fetal form
  - Consequently, the haemostatic changes during massive transfusion in this population are profound, often resulting in an increased bleeding risk.<sup>2</sup>
- Assessment of blood loss is difficult due to unavailable well-established clinical algorithm to diagnose acute blood loss in neonate. Clinical and laboratory data remains a guide for clinicians.
  - Clinical:
    - Evidence of bleeding – subgaleal-, pulmonary- or gastrointestinal haemorrhage, surgical bleeding.
    - Early symptoms/signs including respiratory distress, poor skin capillary refill, skin pallor, cold peripheries and rising heart rate or heart rate >180/minute.
    - Late symptoms/signs including falling SaO<sub>2</sub>/PaO<sub>2</sub> and falling blood pressure.
  - Laboratory:
    - Low Hb and lactic acidosis
  - Ultrasound:
    - Hypovolaemia on cardiac echo with low volume ventricles. In extreme cases, the walls of the ventricles can be seen “kissing” even in diastole.
- **Normal ranges for coagulation testing** in neonates remain contentious as there is limited data available to draw from. There is significant variation in results for very, extremely preterm, preterm and term infants on different days post birth. In the absence of an accepted normal or expected range, we suggest the following as a guideline:
  - PT < 16
  - INR < 1.6
  - APTT <60
  - Fibrinogen > 2
- Coagulation samples SHOULD NOT be taken from lines that have had heparin infused through as heparin contamination will affect testing. Correction of coagulopathy, particularly in asymptomatic neonates is not only based on laboratory investigations, but also on the assessment of the neonate’s clinical condition. (Appendix B)<sup>4</sup>
- **Emergency Treatment**
  - Pursuant to Section 174 of the Children and Young Persons (Care and Protection) Act 1998, consent is not required to treat a child or young person if treatment is required urgently to save the life or prevent serious damage to the health of the child or young person. This means that emergency medical treatment and emergency first aid

## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

treatment, including any procedure, operation or examination, may be provided without the consent of the minor or a parent/guardian.

- In the event of blood or blood component administration being undertaken without prior consent, parents/guardians are to be informed as soon as possible and this conversation documented in the medical record by a medical officer.
- Published data on paediatric massive transfusion are limited to case reports, case series, small retrospective studies and single centre experiences<sup>7</sup>.
- The optimal strategy for the selection of volumes and types of blood components to be administered and for clinical and laboratory monitoring in neonatal patients requiring critical bleeding protocols remains unknown, and much is drawn from paediatric and adult experience.
- Management of the critically transfused neonatal patient, therefore, requires careful and ongoing close monitoring that is best achieved using a standardized management approach<sup>8</sup>.
- PRBC are obtained by removing most of the plasma after centrifuging or by apheresis of whole blood collected into an anticoagulant. They may be resuspended in other additives to prolong storage and filtered to remove most of the leucocytes.
- Platelets are either collected as part of a whole blood donation or by apheresis.
- Whole blood derived platelets are produced by harvesting platelets from ABO and RhD identical whole blood donations. The platelets are resuspended in additive solution to produce the pooled platelet component. In the process of apheresis, platelets are resuspended in a platelet additive solution (PAS).
- Both apheresis and pooled platelets are leucodepleted during or soon after collection and irradiated before release.
- Group and Screen (G&S) or Group and Hold are Routinely performed prior to blood transfusion to detect the presence of potentially clinically significant blood group antibodies. It includes the following:
  - Confirmation that patient details on the blood sample and request form are identical.
  - The checking of historical information on the patient such as previous blood group, previous transfusion and obstetric history
  - ABO and RhD typing of the patient's red cells.
  - Antibody screen to detect antibodies in patient's plasma.
  - Identification of red cell antibodies (performed if positive antibody) screen detected.
  - Crossmatching appropriate donor red cells
- Crossmatch (CXM) is a compatibility test confirming the matching of blood donor and recipient and excludes the possibility of immediate haemolytic transfusion reactions. If a patient has a detectable red cell antibody, more time (potentially several hours) may be required to complete the test.
  - Maternal antibodies can cross over the placenta and be circulating in neonatal blood. Initial pretransfusion testing should be performed on both the mother and infant in the 4 months after delivery. Therefore, donor units are ABO and D compatible with both mother and baby
- Cryoprecipitated Antihemophilic Factor (Cryo) is prepared by thawing fresh frozen plasma between 1–6 °C and collect the precipitate. It contains most of the Factor VIII, fibrinogen, Factor XIII, von Willebrand Factor and fibronectin from fresh frozen plasma.
- Fresh Frozen Plasma (FFP) is the non-cellular fresh frozen plasma (FFP) is either separated from a single unit of whole blood or collected by apheresis where the plasma is retained and the remaining elements are either returned to the donor or harvested for the

## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

appropriate component types. Contains all coagulation factors including approximately 200 IU of Factor VIII plus the other labile plasma coagulation factor, Factor V.

- Irradiation of blood products may be performed (either using gamma irradiation or x-ray) to prevent TA-GVHD). The primary cause of TA-GVHD is the proliferation and engraftment of transfused donor T-lymphocytes in the bone marrow of susceptible recipients.
- Transfusion associated graft versus host disease (TA-GCHD) leads to profound marrow aplasia with a mortality rate >90%.
- Transfusion related acute lung injury (TRALI) is caused by passive transfer of [human leucocyte antigen \(HLA\)](#) or [human neutrophil antigen \(HNA\)](#) antibodies in the donor's plasma are directed against recipient leucocyte antigens. The resulting antigen-antibody reaction activates neutrophils in the lung microcirculation, releasing oxidases and proteases that damage blood vessels and make them leak.
- Leucodepletion is the removal of leucocytes from blood components by filtering at time of collection. The leucocytes present in donated blood play no therapeutic role in transfusion and may be a cause of adverse transfusion reactions.
- RhD (Rhesus D) refers to the D antigen and is the most immunogenic and important Rh antigen. At present, there are 55 antigens in the Rh system, however new antigens continue to be discovered.
- The ABO blood group system, the most important of the blood group classification systems. There are four different ABO blood groups, determined by whether an individual's red cells carry the A antigen, the B antigen, both A and B antigens, or neither antigens.
- Extended Life Plasma (ELP) is FFP thawed and kept in a monitored blood fridge for up to five days. This is to enable the issuing of thawed plasma in time-critical situations. A label must be attached to the ELP showing the change in component name, new component code, thawing date and time, expiry date and time and the identity (initials) of person who re-labelled the product.

### 3.5 Abbreviations

CTP	Critical Bleeding Protocol Neonate	Hb	Haemoglobin
PRBC	Packed Red Blood Cells	FFP	Fresh Frozen Plasma
ITP	Immune thrombocytopenia	IUT	intra-uterine transfusion
CMV	Cytomegalovirus	ELP	Extended life plasma
ROTEM	Rotational Thromboelastometry	PAS	Platelet Additive Solution
G&S	Group and Screen	CXM	Crossmatch
Cryo	Cryoprecipitated Antihemophilic Factor	FFP	Fresh Frozen Plasma
TA-GVHD	Transfusion associated graft versus host disease	TRALI	Transfusion related acute lung injury
RhD	Rhesus D Antigen	ELP	Extended Life Plasma

### 3.6 Related Policies/procedures

- RHW NCC Medical CBR- Surgery at the bedside – Perioperative Guidelines
- RHW NCC Medical CBR- Blood Product Transfusion and Management (Neonate)
- MoH- [PD2018 042 Blood Management](#)

## Critical Bleeding Protocol Neonate (CBP)

RHW CLIN106

- MoH-[IB2020\\_010 Consent to Medical and Healthcare Treatment Manual](#).
- POWH and RHW- CLIN072 Critical Bleeding Protocol (CBP) (Formerly Massive Transfusion Protocol)
- Australasian Neonatal Medicines Formulary.

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## 4 ABORIGINAL HEALTH IMPACT STATEMENT DOCUMENTATION

- Considerations for culturally safe and appropriate care provision have been made in the development of this Business Rule and will be accounted for in its implementation.
- When clinical risks are identified for an Aboriginal and/or Torres Strait Islander woman or family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal liaison officers, health workers or other culturally specific services

**Critical Bleeding Protocol Neonate (CBP)**

**RHW CLIN106**

## 5 CULTURAL SUPPORT

- For a Culturally and Linguistically Diverse CALD woman, notify the nominated cross-cultural health worker during Monday to Friday business hours
- If the woman is from a non-English speaking background, call the interpreter service: NSW Ministry of Health Policy Directive PD2017\_044-Interpreters Standard Procedures for Working with Health Care Interpreters.

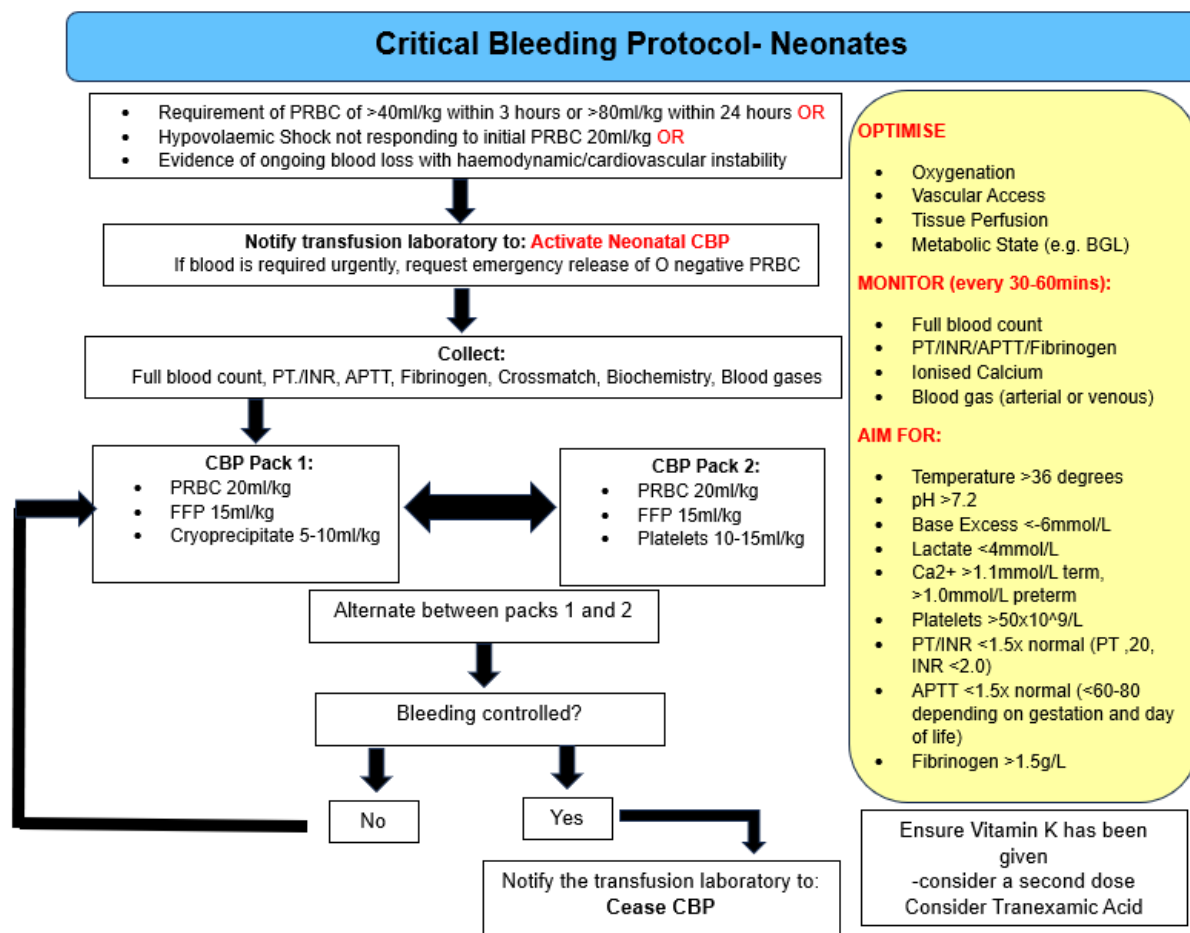
## 6 NATIONAL STANDARDS

- Standard 1 Clinical Governance
- Standard 2 Partnering with Consumers
- Standard 3 Preventing and Controlling Infections
- Standard 4 Medication Safety
- Standard 5 Comprehensive Care
- Standard 6 Communicating for Safety
- Standard 7 Blood Management
- Standard 8 Recognising and Responding to Acute Deterioration

## 7 REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
10/6/2024  24.10.2024	1	S, Bolisetty (Medical Co- Director Neonatal Services) Bryony Ross (Paediatric Haematologist, John Hunter Children's Hospital), Eszter Jozsa (Clinical Nurse Specialist NCC), Ruth Jackson (Nurse Educator NCC)  Endorsed by NCC CBR Committee
2.4.2025	2	Change of terminology from Massive Haemorrhage to Critical Bleeding Protocol
14.4.25	2	RHW BRGC

Appendix A





## APPENDIX B

### Normal ranges for coagulation testing in neonates

#### Full-term Neonates<sup>4</sup>

	Day 1	Day 5	Day 30
PT	13 (10.1 – 15.9)	12.4 (10.0 – 15.3)	11.8 (10.0 – 14.3)
INR	1.00 (0.53 – 1.62)	0.89 (0.53 – 1.48)	0.79 (0.53 – 1.26)
APTT	42.9 (31.3 – 54.5)	42.6 (25.4 – 59.8)	40.4 (32.0 – 55.2)
Fibrinogen	2.83 (1.67 – 3.99)	3.12 (1.62 – 4.62)	2.70 (1.62 – 3.78)

#### Preterm Neonates (30-36 weeks Gestation)<sup>4</sup>

	Day 1	Day 5	Day 30
PT	13.0 (10.6 – 16.2)	12.5 (10.0 – 15.3)	11.8 (10.0 – 13.6)
INR	1.00 (0.61 – 1.70)	0.91 (0.53 – 1.48)	0.79 (0.53 – 1.11)
APTT	53.6 (27.5 – 79.4)	50.5 (26.9 – 74.1)	44.7 (26.9– 62.5)
Fibrinogen	2.43 (1.50 – 3.73)	2.80 (1.60 – 4.18)	2.54 (1.50 – 4.14)