CLINICAL BUSINESS RULE COVER SHEET

Health
South Eastern Sydney
Local Health District

Prince of Wales Hospital and The Royal Hospital for Women

NAME OF DOCUMENT	**Critical Bleeding Protocol (CBP)** **(Formerly Massive Transfusion Protocol)**
TYPE OF DOCUMENT	**Business Rules**
DOCUMENT NUMBER	**POWH CLIN072**
FUNCTIONAL GROUP/ SUBGROUP	**Clinical/Patient Services** **Medications and Administration of Blood and Blood products**
DATE OF PUBLICATION	**August 2018, Updated August 2019**
RISK RATING	**High**
REVIEW DATE	**June 2020**
FORMER REFERENCE(S)	**Clinical Procedures Manual,** **Massive Transfusion Protocol February 2016,** **Updated: March 2016, April 2016**
NATIONAL STANDARD ALIGNMENT	**Standard 7: Blood and Blood Products**
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	**Director of Clinical Services (Medical)** **Director of Nursing and Clinical Services**
AUTHOR	**Senior Haematologist/Transfusion CNC** **Randwick Campus Transfusion Committee**
KEY TERMS	**Critical Bleeding Episodes** **Massive Transfusion** **ROTEM**
SUMMARY	**Describes the process for the management of blood transfusion requirements in major bleeding episodes occurring in adult patients at the POWH. It aims to assist the interactions of the treating clinicians and the Blood Bank.**

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

Feedback about this document can be sent to SESLHD-POWHPolicy@health.nsw.gov.au

Critical Bleeding Protocol (Formerly Massive Transfusion Protocol) POWCLIN072

1. PURPOSE & SCOPE

To streamline the management of blood transfusion requirements in critical bleeding episodes occurring in adult patients at the Randwick Campus, assisting the interactions of the treating clinicians and the Blood Bank. It should be noted that any instance of massive transfusion may have unique clinical features and the Protocol may need to be tailored to the individual patient circumstances.

Special Considerations:

- Sydney Children's Hospital (SCH)
  - Refer to Massive Transfusion Protocol (Paediatric) or contact SCH on call Haematologist/ Blood Bank
- Royal Hospital for Women Maternity
  - Refer to Post-Partum Haemorrhage (PPH) Prevention and Management
- Point of Care Testing (ROTEM) guided algorithm for use in specialised areas
  Cardiothoracic Theatres, Cardiothoracic Intensive Care and General Theatres
  - Refer to Cardiac / Vascular ROTEM Algorithm
  - Refer to General Surgical / Obstetric Haemorrhage ROTEM Algorithm

  Remainder of the hospital eg Emergency Department, Medical and Surgical wards
  - Refer to the Non-ROTEM Guide

2. RESPONSIBILITIES

Consultant in charge of the case
(eg. anaesthetist, intensivist, emergency physician, trauma team leader)
Blood Bank Technician on Duty
Haematology Registrar/Consultant on-call
After Hours Nursing Nurse Manager
Advanced Practice Nurse
After Hours Clinical Support Nurse
Domestic Services Supervisor

3. DEFINITIONS

1 pooled bag of platelets = 4 units of platelets
PRBC = packed red blood cells
FFP = fresh frozen plasma
Adult blood volume = ~ 70mL/kg
Apheresis Cryoprecipitate = 2 units whole blood cryoprecipitate
ROTEM = point of care whole blood haemostasis testing method

4. COMPETENCY/ASSSESEMENT

Not required.

5. PROCEDURE

5.1 PRINCIPLES OF CRITICAL BLEEDING MANAGEMENT

The administration of blood and blood products must be in accordance with POW Clinical Business Rule - Blood Component Management and Administration [1].

5.1.1 Criteria for Identifying Patients at Risk of Massive Haemorrhage (any) (B) [2]

- Patients likely to need replacement of their entire blood volume in 24 hours
- Patients who have at least one (1) of severe thoracic, abdominal or pelvic injury
- Patients who are receiving or have received transfusion of 4 units RBC in <4 hours (In addition to Haemodynamic instability and/or ongoing blood loss).

5.1.2 Damage Control During Resuscitation (B) [3]

- Early consultant input to arrest haemorrhage and minimize macrovascular bleeding
- Minimise macrovascular bleeding (surgical assessment/intervention, tourniquet, packing and compression as appropriate).
- Minimise microvascular bleeding and coagulopathy – aggressive fluid resuscitation; use active warming measures (i.e. thermal control devices) to try and avoid hypothermia and acidosis

5.1.3 Activation of the Critical Bleeding Protocol (CBP)

- Consultant in charge of the case (e.g. anaesthetist, intensivist, emergency physician, trauma team leader) notifies Blood Bank directly (ext 29145) once patient is identified to be at risk by fulfilling criteria in 5.1.1. And activates CBP verifying if using ROTEM guided or Non-ROTEM management.
- Blood Bank scientists may also identify a patient and ask if the team wishes to activate the CBP
- Blood component therapy, after the initial four (4) units of PRBC, is then administered according to the ROTEM trace or the non-ROTEM Guide depending on the patient's location and diagnosis.
- Haematological and coagulation monitoring is performed according to CBP, and guides ongoing component therapy. See Appendix 1.
- Component therapy administration may be altered by the consultant in charge particularly in the event of abnormal initial haematological and coagulation values, clinical conditions (e.g. liver failure) suggesting coagulopathic risk or the patient having received blood components prior to arrival at POWH.

- The decision to cease the CBP is that of the consultant in charge and must be communicated directly to Blood Bank.

5.1.4 Principles of Coagulopathy Management in Critical Bleeding

- The endpoint of the coagulation cascades is fibrinogen being converted to fibrin. Coagulopathy will not tend to correct, even with adequate factor replacement, unless fibrinogen is adequately present. Cryoprecipitate is the appropriate choice for hypofibrinogenaemia (B) [3].
- Platelets tend to approach inadequate levels only after transfusion of 8 – 10 units packed red blood cells (PRBCs). Despite adequate levels, platelet function is affected by hypothermia and acidosis. Damage control resuscitation minimising hypothermia and acidosis is therefore critical to survival (B) [2].

5.2 CRITICAL BLEEDING PROTOCOL (CBP)

Refer to Appendix 1 for Critical Bleeding Protocol Flowchart

5.2.1 Consultant in Charge

- Ensure adherence to 'damage control during resuscitation'. See Section 5.1.2.
- Activate CBP by direct communication with Blood Bank technician/scientist (ext number 29145).
- Ensure haematological and biochemical monitoring of replacement therapy and resuscitative efforts occurs approximately every 30 - 60 minutes during resuscitation (B) [2].
- Ensure ROTEM trace is repeated 10 minutes after each intervention and the results are recorded in patient's notes
- Assume responsibility for the order, rate and recording of component therapy replacement, guided by clinical impression and resuscitative end points.
- Cease the CBP by direct communication with on duty Blood Bank technician.

5.2.2 Blood Bank/Haematology Role (see also separate blood bank protocol [4])

- Supply initial 4 units PRBC
- Once supplied immediately enquire of requesting Medical Officer as to the need for CBP activation. If activated, determine if it is ROTEM Guided **OR** Non-ROTEM Guided. Record activating Medical Officer's name, dispense blood components as per MTP pack.
- Ensure emergent grouping and cross match of recipient's blood.
- Ensure adequate thawing of frozen product. Note: FFP takes 30 minutes to thaw
- Ensure emergent processing of haematological and coagulation parameters initially

and during resuscitation by notifying specimen reception and main lab of the CBP
- Advise consultant in charge of variances from haematological end points.
- Additional advice may be sought from Haematologist / Haematology Registrar on call.

5.2.3 Nursing Role at POWH

The Nurse-in-charge is responsible for assisting with the coordination and communication of the CBP.

- Notify the Domestic Services Supervisor of the activation of the CBP **afterhours**. Extension 22884/5 or pager 44248 (Monday - Friday) pager 44885/6 (weekends)
- Ensure the After Hours Nurse Manager is notified from 4pm (pager 44194)
- Ensure the Advanced Practice Nurse is notified (pager 45387)

Nursing / Midwifery Role at RHW

- Notify the porter Extension 26784 (Monday – Friday) or pager 44000 (afterhours)
- Notify the Nurse Manager pager 44020 if the porter is unavailable to transport blood products and they will make alternative arrangements.

5.2.4 ROTEM Guided

Staff must send an 'Authority to Issue Blood Products' Form (pink form) **for all products requested** with the staff member collecting the products. This is important in ensuring the correct products are delivered to the right patient
There may be more than one CBP activated throughout the Campus at any one time

- PRBC to be requested based on estimated blood loss and Haemoglobin results from blood gas machine and formal FBC
- Refer to Cardiac / Vascular ROTEM Algorithm – **OR** -
- Refer to General Surgical / Obstetric Haemorrhage ROTEM Algorithm
- Ensure ROTEM trace is repeated 10 minutes after each intervention and the results are recorded in the patient's notes

5.2.5 NON-ROTEM Guided

Staff must send an 'Authority to Issue Blood Products' Form (pink form) for requested pack, either MTP 1 or MTP 2 including patient identification and department.
If bleeding continues, alternate MTP 1 and MTP 2

MTP 1

- 4 units PRBC, 4 units FFP, 3 units apheresis cryoprecipitate (Or 6 units whole blood derived cryoprecipitate) (B) [2]

Alternating with
MTP 2

- 4 units PRBC, 4 units FFP, 1 pooled bag of platelets (B) [2]
  NOTE: Australian Red Cross Blood Service may experience platelet shortage – Every effort will be made to supply patients on the MTP protocol (B) [5]

Suggest additional (B) [2]*:*

- Platelets – if platelets < 50 X 10^9/L *or* < 100 X 10^9/L with head injury.
- Cryoprecipitate – if fibrinogen < 1.0 g/L
- FFP – if PT, APTT prolonged and provided fibrinogen > 1.0 g/L
- PRBC – if Hb< 80 g/L and ongoing blood loss (anticipated or actual)
- Calcium chloride – if ionised calcium < 2.0 mmol/L

5.2.6 Haematological / Biochemical Monitoring (B) [2]

- FBC, EUC, LFT, ionised calcium, PT/APTT, Fibrinogen, ABG, Group/crossmatch initially.
- FBC, EUC, PT/APTT, fibrinogen, arterial venous blood gases (A/VBG) every 60 mins during resuscitation. Ionised calcium measurements may also be require

5.2.7 Resuscitative End points for NON-ROTEM Management (B) [2]

- INR < 1.5; PT less than 16 seconds; APTT less than 42 seconds.
- Fibrinogen greater than 1.0g/L
- Platelets greater than 50 x 10^9/L
- PH 7.35 - 7.45
- Core Temperature greater than 35.5°C
- Base Deficit less than -3
- Poor prognostic values = Temp < 34°C, Base Deficit > -6, PH < 7.1, Lactate > 4mmol/L, ionised calcium <1.1 mmol/L

5.2.8 Tranexamic Acid

- A randomised controlled trial of trauma patients who received tranexamic acid demonstrated improved survival both from all-cause mortality and death from bleeding within 3 hours (B) [7]
- In trauma patients with significant haemorrhage, consider intravenous (IV) tranexamic acid (B) [7]

  Tranexamic Acid 1g IV loading dose over 10 minutes followed by tranexamic acid 1g IV infusion over 8 hours
- Tranexamic acid is safe and effective if given early in postpartum haemorrhage [8]
- POWH Availability: ampoules containing 500mg/5mL and 1g/10mL in **pharmacy and Afterhours Drug Room (AHDR)**. Contact either the Advanced Practice Nurse (pager # 45387) or After Hours Nurse Manager (pager # 44194) for access to the AHDR. Additionally 500mg/5mL ampoules are available as imprest stock in Cardiothoracic ICU, Cardiothoracic Theatre, Emergency, Operating Theatres, Urology Theatre and Vascular (DB2N).

5.2.9 Recombinant Activated Factor (rFVIIa)

- There has been no randomised trial demonstrating a survival advantage of rFVIIa use in life-threatening bleeding. Use of rFVIIa in life threatening bleeding is 'off label' (B) [2].
- Patient pH should be > 7.2 for procoagulant effect and every effort has been made to correct surgical bleeding (B) [2].
- Authorisation required by consultant haematologist on call [6]
- Dose: 90 microg/kg (1mg for every 11kg body weight), rounded to the nearest whole vial to minimise wastage, given as an intravenous bolus over 2 to 5 minutes. A second dose may be required 2 to 4 hours after the first dose [6].
- **Recombinant rFVIIa is kept in Blood Bank**

  Refer to POW Clinical Business Rule

  Recombinant Factor VIIa (Novoseven RT®) for Life-threatening Bleeding

6. DOCUMENTATION

Recombinant VIIa registry for off-label use (POWH contributes to a National and International registry)
Blood Bank log of MTP activation and Randwick Transfusion Committee review

7. COMPLIANCE/ EVALUATION

The Randwick Campus Transfusion Committee will review all episodes where the MTP protocol was activated to evaluate compliance with Appendix 1.

8. RELATED POLICIES/PROCEDURES/GUIDELINES/BUSINESS RULES

Number	Policy/Procedure/Guideline/Business Rule
1.	POWH Clinical Business Rules: Blood Component Management and Administration
4.	POWH Blood Bank Procedures Manual.
6.	POWH Clinical Business Rules: Recombinant Factor VIIa (Novoseven RT®) for Life- threatening Bleeding

9. EXTERNAL REFERENCES

Number	Reference
2.	National Blood Authority Australia. Patient Blood Management Guidelines: Module 1 – Critical bleeding/Massive Transfusion. March 2011.
3.	American Association of Blood Banks Technical Manual: Seventeenth edition. 2011.
5.	Australian Red Cross Blood Service Massive Transfusion. Available at https://transfusion.com.au/disease_therapeutics/transfusion
7.	CRASH-2 trial collaborators. Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial. TheLancet. 2010; 376(9734): 23-32.
8.	Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. TheLancet. 2017; 389(10084): 2105-2116.

10. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
2006	Drafts	Dr Susan MacCallum & Randwick Campus Transfusion Committee.
January 2007	0	Written by Dr Susan MacCallum & Randwick Campus Transfusion Committee. Approved by POWH Policy & Procedure Committee.
October 2011	1	Dr Susan MacCallum & Randwick Campus Transfusion Committee.

December 2011	1	Updated. Changes to Sections 5.2.3, 5.2.6 and 5.2.7 Approved by POW/SSEH Policy and Procedure Review Committee for distribution. Approved by POW Drug & Therapeutics Committee.
February 2015	2	Updated by Transfusion Specialist (Dr Susan MacCallum) and Transfusion CNC. Summary of practice changes: • Inclusions of responsibilities for Domestic Services- See Section 5.2.3 • Requirement for request form to accompany staff member collecting MTP pack. • Additional Criteria for Identifying Patients at Risk of Massive Haemorrhage now includes patients who are receiving or have received transfusion of 4 units RBC in <4 hours (In addition to Haemodynamic instability and/or ongoing blood loss). • Updated Section 5.1.2 to include suggestions for minimizing macrovascular bleeding • Added Section 5.2.3 to include the Nurses' role. • Section 5.2.4- changes to MTP pack now included • Appendix 1 updated- alteration to MTP pack contents and order of administration.
March 2015	2	Approved by POW Drug & Therapeutics Committee. Approved by POW/SSEH Policy and Procedure Review Committee for distribution.
February 2016	3	Updated by CNC Transfusion (Elizabeth McGill) • From February 1st 2016 Randwick Campus Blood Bank will stock apheresis cryoprecipitate and will eventually replace whole blood (WB) derived cryoprecipitate – 1 unit apheresis cryoprecipitate = 2 units WB derived cryoprecipitate Section 5.2.4 and Appendix 1 updated to include this information Interim approval by P. Bolton (Director of Clinical Services- Medical) and H. Walker (Director of Nursing and Clinical Services).
March 2016	3	Approved by POW/SSEH Policy and Procedure Review Committee.
April 2016	3	Appendix 1 updated to reflect current pager number for Domestic Services. Approved by POW Drug & Therapeutics Committee.
May 2017	4	Updated by Transfusion Specialist (Dr Susan MacCallum) and Transfusion CNC. • ROTEM guided algorithm added to special considerations • Definition Apheresis Cryoprecipitate

July 2018	5	Updated by Transfusion Specialist (Dr Susan MacCallum) and Transfusion CNC (Leanne Crnek) • Change to document name - Critical Bleeding Protocol • Updated Section 1 special considerations to include areas using ROTEM algorithms and Non-ROTEM management of critical bleeding episode • Section 5.2 Updated Critical Bleeding Protocol Flowchart • Section 5.2.3 Include Nursing Role at POWH in heading • Incorporation of ROTEM Guide 5.2.4 and Non-ROTEM Guide 5.2.5 sections • Section 5.2.7 Replace Massive Haemorrhage with Non ROTEM Management to ensure consistency with terms • Swap sections 5.2.8 & 5.2.9 due to preference of use • Section 5.2.9 Inclusion of statement Tranexamic Acid is safe & effective if given early in postpartum haemorrhage • New reference included in section 9 regarding Tranexamic Acid & postpartum haemorrhage • Appendix 1 Replaced MTP Flowchart with Critical Bleeding Flowchart
August 2018	5	1st August 2018 Approved by POW/SSEH Policy and Procedure Review Committee.
August 2018	5	14th August 2018 Approved by POW Drug & Therapeutics Committee.
July 2019	6	Update only, full review not completed. Updated by CNC Transfusion (Leanne Crnek) • 1. Purpose & scope: change POWH to Randwick Campus • Special Considerations: Replace RHW Massive Transfusion in Obstetrics & Gynaecology (Code Pink) with Post-Partum Haemorrhage (PPH) Prevention & Management

Appendix 1- POWH Adult Critical Bleeding Protocol

POWH Adult Critical Bleeding Protocol (CBP)

Actual or anticipated 4 units RBC in < 4 hours, + haemodynamically unstable, +/– anticipated ongoing bleeding
Severe thoracic, abdominal, pelvic or multiple long bone trauma, major gastrointestinal, surgical or obstetric bleeding

Senior clinician determines that patient meets criteria for **CRITICAL BLEEDING PROTOCOL** activation

Baseline:
Group & Screen/cross match, full blood count, coagulation screen (PT, INR, APTT, fibrinogen), biochemistry, arterial blood gases
If using ROTEM order EXTEM, INTEM, FIBTEM & HEPTEM (HEPTEM cartridges are used for all algorithms)

Notify Blood Bank Ext 29145 to:
Activate CRITICAL BLEEDING PROTOCOL requesting 'Non ROTEM' or 'ROTEM'
Send porter Ext 22884/5 pager 44208 to Blood Bank with completed 'Authority to Issue Blood Products' pink form to collect 4 units Red Blood Cells

NON ROTEM

MONITOR (every 30–60 mins):
Full Blood Count
Coagulation Screen
Ionised Calcium
Arterial Blood Gases

AIM FOR:
- Temperature > 35^{0}C
- pH > 7.2
- Base excess< – 6
- Lactate < 4 mmol/L
- Ca^{2+} > 1.1 mmol/L
- Platelets > 50 x 10^{9}/L
- PT/APTT < 1.5 normal
- INR ≤ 1.5
- Fibrinogen > 1.5 g/L

Senior Clinician Requests NON ROTEM:
MTP1
• 4 units PRBC (initially provided) • 4 units FFP • 3 units Apheresis Cryopreciptate
MTP2
• 4 units PRBC • 4 units FFP • 1 pooled bag of platelets
If still bleeding continue alternating MTP1 and MTP2

Consider: IV Tranexamic Acid 1g loading over 10 minutes followed by 1g infusion over 8 hours
For further advice on managing critical bleeding contact Haematologist on call

Bleeding controlled?

NO

YES

Notify Blood Bank Ext 29145 to:
Cease Massive Transfusion Protocol
Return unused products to Blood Bank immediately

ROTEM

Refer to the following Algorithms for critical bleeding
RBC requested as per blood loss or Hb (blood gas or FBC)

Cardiac/Vascular Algorithm

General Surgical/Obstetric Haemorrhage Algorithm

Special Considerations
- Vitamin K & Prothrombinex for warfarin reversal
- Protamine for heparin reversal
- Contact Haematologist on call for NOAC reversal

POWH Adult Massive Transfusion Protocol and ROTEM algorithm for critical bleeding endorsed by the Randwick Blood Transfusion Committee August 2018

Massive Transfusion Protocol Sir Charles Gairdner Hospital Western Australia. April 2017