ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Massive Hemorrhage Protocol

APPLICABILITY

This document is intended for use the following facilities:

Grande Prairie Regional Hospital	Red Deer Regional Hospital
Northern Lights Regional Hospital	Peter Lougheed Hospital
Sturgeon Community Hospital	Alberta Children's Hospital
Royal Alexandra Hospital	Foothills Medical Centre
Misericordia Community Hospital	Rockyview General Hospital
Grey Nuns Community Hospital	South Health Campus Hospital
University of Alberta Hospital	Chinook Regional Hospital
Stollery Children's Hospital	Medicine Hat Regional Hospital

For other facilities in the province of Alberta, initiation of transfusion support and transportation to an alternate facility with more resources to support would be key in managing major bleeding. See *TM40-02.001 Managing a Hemorrhaging Patient Protocol – Rural and Suburban Sites*.

PROTOCOL

Massive hemorrhage is typically defined as:

- the **loss of more than one blood volume in a 24-hour period.**
- Alternate definitions include: **the loss of one-half the patient's blood volume within a 3hr period** OR **bleeding at a rate of 150 mL/minute**.

If these bleeding rates occur during a period of inadequate hemostatic control, significant blood loss requiring massive transfusion can be anticipated. Transfusion support and massive hemorrhage protocols can help to reduce the risk of death in patients who are undergoing exsanguination / massive bleeding or are hemodynamically unstable secondary to prior significant blood loss.

Pre-emptive initiation of the MHP may NOT occur before patient arrival or anticipated patient hemorrhage. However, provision of red cell and fibrinogen support can be given if required.

Red cell transfusion is the most important component in successful resuscitation[1]. No ideal ratio of red cells to other components has been established but a survival benefit of 1:1 red cells to plasma has not been found in randomized control trials[2,3,4]. Starting with ratio-based provision and transitioning to laboratory guided blood component administration as soon as possible is recommended[1,5]. However, MHP is not just provision of ***blood components*** and ***blood products*** (i.e. plasma protein products).

There are **seven critical process elements** associated with MHPs, known as the **7 "Ts**":

1. Triggering & Talking

To activate the MHP, one contact individual in the clinical setting should **contact the site TM lab**. To minimize miscommunication, only that **one designated contact individual** should request blood components and products. Similarly, within the TM lab, the MHP should be coordinated by a single TM technologist. TM is responsible for notifying the hematology/coagulation laboratories.

A Transfusion Medicine physician/pathologist: is a 24/7/365 resource for the clinical team that can help guide transfusion of the most appropriate blood components or products and will ensure that the correct testing is expedited.

The MRHP or their designate is required to **consult with the TM physician/ pathologist prior to issuing of Kit #2** to allow the TM physician to:

a) determine impacts on other patients in the facility;
b) ensure adequate laboratory staff and inventory are available to safely manage the MHP and;
c) to provide clinical decision support regarding the blood components and products being provided.

2. Team

Early notification and preparation of the extended team, including personnel, assigned roles, and equipment is essential. The extended team includes the emergency team, surgical team, interventional radiology team laboratory departments, and other involved departments as appropriate.

Designation of a porter or runner to transport blood components/ products and specimens between the lab and the patient care unit has been identified as a critical component of successful MHPs.

3. Testing

It is critical to **collect a Type and Screen specimen** as needed for TM testing as soon as possible, as well as specimens for regular monitoring of coagulation status.

Although **venous specimens are preferred**, specimens for TM testing in the setting of a MHP can also include shed blood or intraosseous specimens submitted in EDTA tubes. NOTE: if one of these specimen types is provided, it must be indicated on the Connect Care order/requisition.

Patients with an unknown ABO group will be issued group O RBCs and group AB (or low titre A) plasma until a patient ABO group is confirmed. Due to scarcity of supply, a maximum of 2 AB plasma units will be provided at a time. The blood group of components may only be switched as per TM protocols and/or the direction of the TM Physician.

For patients who are Rh-negative, or whose Rh status is unknown, Rh-negative RBCs and platelets will be issued only to patients with child-bearing potential, gender X or of unknown gender and who are less than or equal to 45 years old. Additionally, K negative RBCs will be issued to patients with child-bearing potential, gender X or of unknown gender and who are less than or equal 45 years old.

4. Tranexamic acid (TxA)

Ensure that the patient has received TxA support as appropriate. Tranexamic acid should be administered as soon as intravenous or intraosseous access is achieved but within 3-hours from time of injury in trauma patients or within 3-hours from MHP activation in obstetrical or surgical patients[6,7]. Tranexamic acid use in the setting of major gastrointestinal hemorrhage remain unclear[8,9].

5. Temperature

Ensure that the patient is being actively warmed to keep core temperature greater than 36°C.

6. Transfusion – see Kit contents and general recommendations below.

It is important to remember that the AHS *Transfusion of Blood Components and Blood Products* (PS-59) policy still applies. Blood components may not be issued more than 60 minutes before planned infusion time unless they are issued to a monitored temperature environment such as a validated storage cooler or blood storage refrigerator.

Positive patient identification, **monitoring** of vital signs and **documentation** of transfusion must be performed as per transfusion policy and procedures. This is especially important if there is more than one patient requiring transfusion support.

7. Termination

It is important to **notify the TM lab when the MHP has been terminated**, to allow for resuming of routine testing processes, and care of other patients. It also allows for evaluation and replenishing of stock as required.

It is also important to provide feedback regarding aspects that went well and those that did not. A debrief form will be provided with each activation to allow ongoing quality improvement. All MHP activations will be reviewed by the TM department within 7 days of the event.

PROCESS

1. General

1.1. Identify the hemodynamically unstable patient based on clinical assessment.

1.2. Ensure adequate venous access, using 2 large bore peripheral vascular access devices (PVAD) and/or central venous access device (CVAD), or intraosseous access.

1.3. Collect baseline lab work including type and screen, if not already performed (refer to *Table 2*). If a type and screen was collected at another site, do not remove TSIN band and contact the TM lab for instructions as to whether a Blood Bank Additional specimen is required.

1.4. Select required blood tubing and consider use of rapid infuser.

1.5. Infuse all fluids via blood warmer, when available and use other agents to minimize hypothermia.

1.6. Ensure arrangements for definitive hemorrhagic control are made with appropriate service (Trauma surgery, Vascular surgery, General Surgery, Gastroenterology, Obstetrics & Gynecology and/or Interventional Radiology).

2. Activation

2.1. Activation of MHP requires a physician's order (verbal is sufficient).

2.2. Call TM.

The HCP or designate must contact the TM lab to initiate the MHP. The HCP must provide the TM lab with:

- their name and the name of the MRHP activating the MHP;
- patient name (or alias);
- patient age or estimated age;
- patient gender;
- patient weight or estimated weight;
- pMRN / ULI number;
- location;
- indication for MHP (trauma, GI bleeding, obstetrical or surgical);
- history of anticoagulant or antiplatelet agents, if known.

2.3. Order MHP in Connect Care to initiate the orders for laboratory testing and medications. Use of these orders allows expediated processing and reporting for laboratory tests.

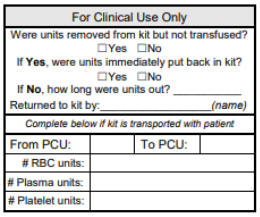
Note: This does not order any blood components or blood products – those must be called to the TM lab. Refer to the *Connect Care Blood Administration Guide*.

2.4. Transport – Dedicated porter or runner to transport lab specimens and MHP kits, coordinated either by clinical area or TM Lab as per site practice.

2.5. Receive MHP kits.

MHP kits are validated storage containers with preset contents based on estimated or actual patient weight as per *Table 1*.
These kits will be designated with the patient demographics and the return date/time on the exterior of the kits and are meant to be transported with the patient when they move between locations.
Kit contents can only be modified by the TM physician/pathologist on-call based on laboratory parameters or clinical information communicated to the TM physician/pathologist by the MRHP or their designate.

- If thawed plasma is not available in the TM laboratory at the time of activation, plasma will follow separately as soon as it is available.
- Platelets will not be provided in the initial kit unless there is laboratory evidence of thrombocytopenia, or the cause of bleeding is cardiovascular or vascular. If there is clinical history of platelet dysfunction or clinical impression of DIC, communication directly to the TM physician/pathologist on call is required.
- Blood components and blood products should not be removed from the cooler until infusion is to be started.
  - Complete the *For Clinical Use Only* section of the Transport Container Slip. (see example on right)
- Adding blood components or blood products to the MHP kits is not allowed except by personnel authorized by TM.



For Clinical Use Only			
Were units removed from kit but not transfused? ☐Yes ☐No If **Yes**, were units immediately put back in kit? ☐Yes ☐No If **No**, how long were units out? _____ Returned to kit by:_____*(name)*			
Complete below if kit is transported with patient			
From PCU:		To PCU:	
# RBC units:			
# Plasma units:			
# Platelet units:			

Table 1: MHP Kit Contents

MHP Kit Delivery Sequence			
	Patient weight 10 kg or less	**Patient weight 10.1 – 25 kg**	**Patient weight Greater than 25 kg**
Kit #1	• RBC: 2 units • Plasma: 2 units* • Fibrinogen concentrate: 1g • Platelets: Per TM MD**	• RBC: 2 units • Plasma: 2 units* • Fibrinogen concentrate: 2g • Platelets: Per TM MD**	• RBC: 4 units • Plasma: 2 - 4 units (2 x low titre A or AB plasma if unmatched)* • Fibrinogen concentrate: 4g*** • Platelets: Per TM MD**
Kit #2	• RBC: 2 units • Plasma: 2 units • Fibrinogen concentrate: Per TM MD • Platelets: 1 unit	• RBC: 2 units • Plasma: 2 units • Fibrinogen concentrate: Per TM MD • Platelets: 1 unit	• RBC: 4 units • Plasma: 2 - 4 units (2 x low titre A or AB plasma if unmatched) • Fibrinogen concentrate: Per TM MD *** • Platelets: 1 unit
Kit #3+ (per TM MD)	• RBC: 2 units • Plasma: 2 units • Fibrinogen concentrate: Per TM MD • Platelets: Per TM MD	• RBC: 2 units • Plasma: 2 units • Fibrinogen concentrate: Per TM MD • Platelets: Per TM MD	• RBC: 4 units • Plasma: 2 - 4 units (2 x low titre A or AB plasma if unmatched) • Fibrinogen concentrate: Per TM MD • Platelets: Per TM MD

* Plasma may be issued separately as soon as available, if it cannot be provided within the kit.
** Cardiovascular and Vascular MHP activations receive platelets in Kit #1 instead of Kit #2.
***Obstetrical MHP activations should receive 4g Fibrinogen concentrate in Kit #1 and #2.

2.6. Reassess

If hemostasis is not being achieved with the first MHP kit and additional blood components/ products or subsequent kits are required, the MRHP or their designate must contact the TM physician / pathologist on call for their site.

The MRHP or their designate must contact the TM Physician/ pathologist on call if there are requests to adjust blood components / products based on patient's laboratory results and clinical condition trajectory.

2.7. Collect and send bloodwork as required (refer to *Table 2*)**.**

Collect and send bloodwork STAT throughout MHP duration to allow TM to modify kit contents as required. Arterial Blood Gases (ABG) and other Point of Care Testing (POCT) (e.g. rotational thromboelastometry [ROTEM], thromboelastography [TEG]) should be performed as per MRHP orders. If ABG testing is not available to provide calcium monitoring, then a calcium should be added to the electrolyte orders.

Table 2: MHP Lab Work

Test	Comments	Frequency
Type and Screen		If needed
• MHP Hemoglobin • MHP Platelet	Only **one** tube needed	At activation and then q30 min
• MHP PT (INR) • MHP Fibrinogen	**One <u>full</u>** tube needed	
Electrolytes		At activation and q1h
Creatinine		Once at activation
Lactate	Not required if part of ABG	Once (if needed)

2.8. Terminate

Inform the TM lab when control of bleeding has been obtained, or when resuscitation efforts have been withdrawn. Return unused blood components and products to TM as soon as possible. Discontinue MHP in Connect Care; see *Connect Care Blood Administration Guide.*

Complete the MHP feedback when patient is stable, and time permits to provide ongoing quality improvement.

3. Other Physiologic Goals and Considerations

3.1. Tranexamic Acid – Should be administered as soon as intravenous or intraosseous access is achieved but within 3-hours from time of injury in trauma patients or within 3-hours from MHP activation in obstetrical or surgical patients. Tranexamic acid is NOT currently recommended in the setting of major gastrointestinal hemorrhage.

- **ADULTS**: 1 gram IV bolus (if not already administered prehospital) followed by 1 gram over 8 hours
- **PEDIATRICS**: 10-15 mg/kg bolus (if not already administered prehospital) followed by 1mg-5mg/kg/h infusion

3.2. Hypocalcemia – Monitor for hypocalcemia and correct calcium levels if less than 1.15 mmol/L.

- **ADULTS**: Calcium Chloride***** 1 gm IV slowly or Calcium Gluconate 3 gm IV slowly
- **PEDIATRICS**: Calcium Gluconate 20-50 mg/kg/dose IV slowly (1 mL/min)

***NOTE:** Calcium Chloride must be infused into a central line to avoid tissue necrosis

3.3. Hyperkalemia – Monitor for hyperkalemia and correct potassium levels.

3.4. Hypothermia – Ensure that the patient is being actively warmed to keep core temperature greater than 36°C.

3.5. Acidosis – Prevent/reverse acidosis.

3.6. Anticoagulation reversal

- Heparin - Protamine 1 mg IV/ 100 Units of heparin
- Warfarin – Vitamin K 10 mg IV plus Prothrombin Complex (PCC) based on INR
- Dabigatran - Praxbind (Idarucizumab) 5 grams IV over 20 minutes
- Direct Factor X inhibitors – 25-50 IU/kg PCC to a maximum of 3000 International Units

Table 3: General Guidelines for Lab Based Blood Component Replacement

General Guidelines for Lab Based Blood Component Replacement *Additional information available on the AHS Transfusion Medicine Website*		
Product	**Threshold**	**General Hemorrhage Dosing Considerations**
RBCs (1 unit ~300 mL)	• Aim for Hgb of at least 80 g/L in actively bleeding patient. • No requirement to maintain above 70 g/L once hemostasis is achieved	20 mL/kg or as required to titrate labs
Plasma (1 unit ~200-280 mL)	• INR greater than 1.8	10- 20 mL/kg or as required to titrate labs
Platelets (1 unit ~200-250 mL) Room temp	• PLT count less than 50 x 10^9/L or projected to soon be less than 50 x 10^9/L • If CNS/ocular bleed <100 x 10^9/L • PLT count is irrelevant if known antiplatelet agents on board.	10 - 20 mL/kg to a max of 1 unit or as required to titrate labs
Fibrinogen Concentrate (1 g/ vial)	• Fib less than 1.5 g/L (trauma, GI or surgical bleeding) or • Fib less than 2.0 g/L (obstetrical or CV surgical bleeding) **or** • evidence of microvascular bleeding	Fibrinogen Concentrate: 60mg/kg to a max of 4 grams in a single dose Separate line infusion over 10-20 mL/min.

DEFINITIONS

Blood components	The therapeutic part of blood used for transfusion, namely, red blood cells, plasma, and platelets. Connect Care may refer to these as “blood products.”
Blood products	The therapeutic part of blood derived from plasma by manufacturing companies. Some sources may refer to these as “plasma protein products.” Examples include albumin, intravenous immune globulin, and prothrombin complex concentrates. Connect Care may refer to these as “derivatives.”
DIC	Disseminated Intravascular Coagulopathy
Health Care Professional (HCP)	An individual who is a member of a regulated health discipline, as defined by the *Health Professions Act* (Alberta), and who practices within scope and role.
Most Responsible Health Practitioner (MRHP)	The health practitioner who has responsibility and accountability for the specific treatment/procedures(s) provided to a patient and who is authorized by AHS to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.
PCC	Prothrombin Complex Concentrate

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Massive Hemorrhage Protocol

APPENDIX A: Greater than or equal to 50kg Massive Hemorrhage Protocol Flowchart

Appropriate Initial Interventions:

- IV/IO access: 2 large bore IVs ± CVC
- Crystalloid: as per attending physician
- **Order MHP labs, Type and Screen (as needed), ABG**
- Continuous Monitoring
- Use blood warmer for transfusions if available
- Prevent/reverse acidosis
- Correct hypocalcemia:
  - **Ca gluconate 3 g IV slowly** or
  - **Ca Chloride 1 g IV slowly ****
    **Calcium chloride is a vesicant. Infuse through central line if available.
- Transfuse with unmatched RBCs, if needed

Other Considerations

- Heparin reversal: **Protamine 1 mg IV / 100 Units of heparin**
- Warfarin reversal:
  - **Vitamin K 10 mg IV**
  - **Prothrombin Complex** (dose as per INR based protocol)
- Direct Factor X inhibitor bypass: **25-50 IU/kg PCC** (to a max of 3000 units)
- Dabigatran reversal – **Idarucizumab** 5 g over 20 minutes
- Consider antifibrinolytics: **Tranexamic Acid 1 g IV bolus** (if not already administered) **followed by 1g over 8 hours**

General Guidelines for Blood Component and Product Replacement in Adults:

RBCs	Aim for Hgb of at least 80 g/L in actively bleeding patient.
Plasma	If INR>1.8 Typical dose: 10-20 mL/kg
Platelets	If Plt <50 x 10^9/L or <100 x 10^9/L if CNS or ocular injury Typical dose: 1 platelet pool
Fibrinogen	If Fibrinogen: ≤1.5 g/L (Trauma, GI, or surgical bleeding) ≤ 2.0 g/L (Obstetrical or CV surgical) Typical dose: Fibrinogen concentrate: 4 grams

GREATER than or equal to 50kg Massive Hemorrhage Protocol Flowchart

Massive Hemorrhage definitions: (1) Blood loss > 150 mL/min; (2) Replacement of 50% of blood volume in 3 h; or (3) Greater than one blood volume in < 24 h.

Identify & Manage Bleeding

- 4 units RBC transfused in ≤ 4 hours and ongoing major bleeding. **Consider** activating MHP
- 6 units RBC transfused in ≤ 4 hours and ongoing major bleeding. **Activate MHP**
- Coordinate with appropriate service intervention for definite hemorrhage control

Dedicated Porter or Designate

1. Arrange **lab specimen transport** and **Kit #1 pick-up** (with pick-up slip or equivalent)
2. Deliver Kit #1 to patient location
3. Arrange transport of follow-up lab specimens and pick-up subsequent Kit(s) as appropriate
4. Remain assigned to patient until MHP is stopped regardless of change in location

Communicate

- TM physician will contact MRHP with actionable lab parameters and changes required to Kit contents
- MRHP/designate to contact TM physician with pertinent clinical info requiring changes to Kit contents and prior to requesting Kit #2.
- Notify TM lab if patient location is changing

- Call TM lab if additional blood components or products are required
- The TM physician can adjust Kits based on labs as needed

Activate MHP

1. **Call** Transfusion Medicine (TM) lab and provide:
   - Patient **Name**/alias, **pMRN/ULI**, **gender**, **weight**, **age**/estimated age
   - Current patient **location**
   - **Indication** for MHP
   - Name of clinical contact and **MRHP**
   - **History** of anticoagulant or antiplatelet agents, if known
2. Record name of TM contact
3. Send dedicated porter or runner to TM lab (Clinical area or TM lab-coordinated per site practice)
4. Order MHP in Epic

GREATER than 50 kg Kit #1 Contents*

Red Blood Cells: 4 units
Plasma: 2 – 4 units (2 units if unmatched)
Fibrinogen: 4g

Q30 min

*Cardiovascular and Vascular MHP activations receive platelets in Kit #1 instead of Kit #2.

Hemostasis & resolution of coagulopathy?

No → Repeat MHP labs

Yes → **Stop MHP:**
- Notify TM lab
- Return unused blood components and products ASAP
- Resume standard ordering practices

Massive Hemorrhage Protocol

APPENDIX B: Less than 50kg Massive Hemorrhage Protocol Flowchart

Appropriate Initial Interventions:

- IV/IO access: 2 large bore IVs ± CVC
- Crystalloid: as per attending physician
- **Order MHP labs, Type and Screen (as needed), ABG**
- Continuous Monitoring
- Use blood warmer for transfusions if available
- Prevent/reverse acidosis
- Correct hypocalcemia:
  - **Adults: Ca gluconate 3 g IV slowly or Ca Chloride 1 g IV slowly ****
    ** Calcium chloride is a vesicant. Infuse through central line if available. .
  - **Pediatrics: Ca gluconate 30 mg/kg/dose IV slowly**
- Transfuse with unmatched RBCs if, needed

Other Considerations:

- Heparin reversal: **Protamine 1 mg IV / 100 Units of heparin**
- Warfarin reversal:
  - **Vitamin K 10 mg IV**
  - **Prothrombin Complex** as per TM protocol dosing for INR and weight
- Direct Factor X inhibitor bypass: **25-50 IU/kg PCC** (to a max of 3000 units)
- Dabigatran reversal – **Idarucizumab** 5 g over 20 minutes
- Consider antifibrinolytics: **Tranexamic Acid 10-15mg/kg bolus** (if not already administered) **followed by 1mg-5mg/kg/h infusion**

General Guidelines for Blood Component and Product Replacement:

RBCs	Aim for Hgb of at least 80 g/L in actively bleeding patient Dose: MD discretion (20 mL/kg reasonable start)
Plasma	If INR>1.8 Dose: 10-20 mL/kg
Platelets	If Plt <50 x 10^9/L or<100 x 10^9/L if CNS or ocular injury Dose: Adult: 1 platelet pool Pediatric: 10-20 mL/kg to max of 1 platelet unit
Fibrinogen	If Fibrinogen: ≤1.5 g/L (Trauma, GI, or surgical bleeding) ≤ 2.0g/L (Obstetrical or CV bleeding) Dose: Fibrinogen: 30-60 mg/kg

LESS than 50kg Massive Hemorrhage Protocol Flowchart

Massive Hemorrhage definitions: (1) Blood loss > 150 mL/min; (2) Replacement of 50% of blood volume in 3 h; or (3) Greater than one blood volume in < 24 h.

Identify & Manage Bleeding

- >10 mL/kg RBC transfused in ≤ 4 hours and ongoing major bleeding. **Consider activating MHP**
- >20 mL/kg RBC transfused in ≤ 4 hours and ongoing major bleeding. **Activate MHP**
- Coordinate with appropriate service intervention for definite hemorrhage control.

Dedicated Porter or Runner

1. Arrange **lab specimen transport** and Kit #1 pick-up (with pick-up slip or equivalent)
2. **Deliver Kit #1** to patient location
3. Arrange transport of follow-up labs specimens and pick-up subsequent Kit(s) as appropriate
4. Remain assigned to patient until MHP is stopped regardless of change in location

Communicate

- TM physician will contact MRHP with actionable lab parameters and changes required to Kit contents
- MRHP/designate to contact TM physician with pertinent clinical info requiring changes to Kit contents and prior to requesting Kit #2.
- Notify TM lab if patient location is changing

- Call TM lab if additional blood components or products are required
- The TM physician can adjust Kits based on labs as needed

Activate MHP

1. **Call** Transfusion Medicine (TM) lab and provide:
   - Patient **name**/alias, **pMRN/ULI**, **gender**, **weight**, **age**/estimated age
   - Current patient **location**
   - **Indication** for MHP
   - Name of clinical contact and **MRHP**
   - **History** of anticoagulant or antiplatelet agents, if known
2. Record name of TM contact
3. Send dedicated porter or runner to TM lab (Clinical area or TM lab-coordinated per site practice)
4. Order MHP in Epic

LESS than 25kg Kit #1 Contents*
Red Blood Cells: 2 units
Plasma: 2 units
Fibrinogen:
1g (Pt weight: 10 kg or less)
2g (Pt weight: 10.1 kg – 25 kg)

GREATER than 25kg Kit #1 Contents*
Red Blood Cells: 4 units
Plasma: 2 – 4 units
(2 units if unmatched)
Fibrinogen : 4g

*Cardiovascular and Vascular MHP activations receive platelets in Kit #1 instead of Kit #2.

Q30 min

Hemostasis & resolution of coagulopathy?

No → Repeat MHP labs

Yes → **Stop MHP:**
- Notify TM lab
- Return unused blood components and products ASAP
- Resume standard ordering practices