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ONTARIO MASSIVE HEMORRHAGE PROTOCOL 2.0: MAJOR CHANGES FROM 2019 RECOMMENDATIONS

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March 26, 2025

MHP 2.0: What is New? Symposium, Collingwood, Ontario

Learning Objectives

- After this presentation, the learner will be able to describe the major updates in the Ontario Massive Hemorrhage Protocol (MHP) from 2019 to 2025 version

Disclosures

- Industry-sponsored clinical trials: Sanofi, Takeda, Roche, SOBI
- Consultancy: Sanofi, Takeda (unpaid)
- Reimbursement for travel: Octapharma
- Participation in advisory board: Alexion Pharmaceuticals

What is Massive Hemorrhage Protocol?

- Protocol/systematic clinical workflow/algorithm/ integrated care pathway to care for a massively bleeding patient
  - **R**ight health care workers, doing the **r**ight things, for **r**ight patients, in the **r**ight order, at the **r**ight time, in the **r**ight place, with the **r**ight outcome
- Massive hemorrhage is most commonly defined as transfusion of ≥10 red blood cell (RBC) units within 24 hours (Lin et al Crit Care 2023)
  - This definition does NOT reflect rate of bleeding, likelihood of achieving rapid control, clinical setting, need for platelet and clotting factor replacement
- Massive hemorrhage protocol (MHP) vs. massive transfusion protocol (MTP)
  - MHP is our preferred term as managing a massively bleeding patient involves many more elements than just transfusion

Are There Proven Benefits of MHP?

- MHP implementation is associated with
  - **Reduction in mortality**, organ failure, post-injury complications
    - Independent of what exactly is in the protocol
  - Decreased length of hospital and critical care stay
  - Faster delivery of blood components to patient
  - Not associated with increase in blood component wastage
  - Less blood component utilization (and less cost)
  - Decreased variability in treatment

Consunji et al Blood Transfusion 2020; Dente et al J Trauma 2009; Cotton et al J Trauma 2009; Riskin et al J Am Coll Surg 2009; Reed et al Injury 2017; Cotton et al J Trauma 2008; O'Keeffe et al Arch Surg 2008; Khan et al Injury 2013; Mothukuri et at EMJ 2015

Ontario MHP Survey 2017:

Marked Variability and Absent in One-third of Hospitals in Ontario

- 150 hospitals surveyed, 100% response rate
- 65% of Ontario hospitals had an MHP
- Of hospitals with an MHP:
  - 15% did not specify activation criteria
  - 35% did not require patient temperature monitoring
  - 39% did not issue blood components in pre-defined packs (i.e. transfused a la carte and on demand)
  - 36% initially managed all patients with O RhD-negative RBC
  - 37% performed laboratory testing at the discretion of a physician (vs. per protocol)
  - 50% did not include targets of hemostatic resuscitation
- 68% did not track any quality metrics

Chin et al. Injury 2019.

cmajOPEN

Research

A regional massive hemorrhage protocol developed through a modified Delphi technique

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Abstract

Background: A massive hemorrhage protocol (MHP) enables rapid delivery of blood components in a patient who is exsanguinating pending definitive hemorrhage control, but there is variability in MHP implementation rates, content and compliance owing to challenges presented by infrequent activation, variable team performance and patient acuity. The goal of this project was to identify the key evidence-based principles and quality indicators required to develop a standardized regional MHP.

Methods: A modified Delphi consensus technique was performed in the spring and summer of 2018. Panellists used survey links to independently review and rate (on a 7-point Likert scale) 43 statements and 8 quality indicators drafted by a steering committee composed of transfusion medicine specialists and technologists, and trauma physicians. External stakeholder input from all hospitals in Ontario was sought.

Results: Three rounds were held with 36 experts from diverse clinical backgrounds. Consensus was reached for 42 statements and 8 quality indicators. Additional modifications from external stakeholders were incorporated to form the foundation for the proposed MHP.

Interpretation: This MHP template will provide the basis for the design of an MHP toolkit, including specific recommendations for pediatric and obstetrical patients, and for hospitals with limited availability of blood components or means to achieve definitive hemorrhage control. We believe that harmonization of MHPs in our region will simplify training, increase uptake of evidence-based interventions, enhance communication, improve patient comfort and safety, and, ultimately, improve patient outcomes.

Provincial Massive Hemorrhage Toolkit

Ontario MHP

A comprehensive toolkit was developed to provide guidance for Ontario hospitals in the implementation of Ontario's Recommendations for Massive Hemorrhage Protocol. The toolkit addresses select patient populations and differences in hospital sizes, resources and geographical challenges.

Released April 30, 2021

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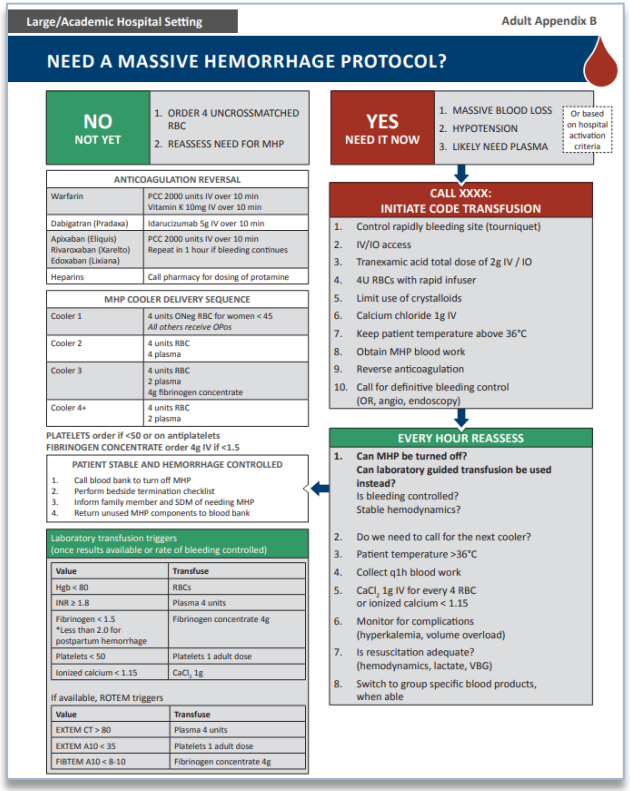


Large/Academic Hospital Setting — Adult Appendix B

NEED A MASSIVE HEMORRHAGE PROTOCOL?

NO NOT YET
1. ORDER 4 UNCROSSMATCHED RBC
2. REASSESS NEED FOR MHP

YES NEED IT NOW
1. MASSIVE BLOOD LOSS
2. HYPOTENSION
3. LIKELY NEED PLASMA

Or based on hospital activation criteria

ANTICOAGULATION REVERSAL	
Warfarin	PCC 2000 units IV over 10 min Vitamin K 10mg IV over 10 min
Dabigatran (Pradaxa)	Idarucizumab 5g IV over 10 min
Apixaban (Eliquis) Rivaroxaban (Xarelto) Edoxaban (Lixiana)	PCC 2000 units IV over 10 min Repeat in 1 hour if bleeding continues
Heparins	Call pharmacy for dosing of protamine

MHP COOLER DELIVERY SEQUENCE	
Cooler 1	4 units ONeg RBC for women < 45 *All others receive OPos*
Cooler 2	4 units RBC 4 plasma
Cooler 3	4 units RBC 2 plasma 4g fibrinogen concentrate
Cooler 4+	4 units RBC 2 plasma

PLATELETS order if <50 or on antiplatelets
FIBRINOGEN CONCENTRATE order 4g IV if <1.5

CALL XXXX: INITIATE CODE TRANSFUSION
1. Control rapidly bleeding site (tourniquet)
2. IV/IO access
3. Tranexamic acid total dose of 2g IV / IO
4. 4U RBCs with rapid infuser
5. Limit use of crystalloids
6. Calcium chloride 1g IV
7. Keep patient temperature above 36°C
8. Obtain MHP blood work
9. Reverse anticoagulation
10. Call for definitive bleeding control (OR, angio, endoscopy)

PATIENT STABLE AND HEMORRHAGE CONTROLLED
1. Call blood bank to turn off MHP
2. Perform bedside termination checklist
3. Inform family member and SDM of needing MHP
4. Return unused MHP components to blood bank

EVERY HOUR REASSESS
1. **Can MHP be turned off?**
   Can laboratory guided transfusion be used instead?
   Is bleeding controlled?
   Stable hemodynamics?
2. Do we need to call for the next cooler?
3. Patient temperature >36°C
4. Collect q1h blood work
5. CaCl, 1g IV for every 4 RBC or ionized calcium < 1.15
6. Monitor for complications (hyperkalemia, volume overload)
7. Is resuscitation adequate? (hemodynamics, lactate, VBG)
8. Switch to group specific blood products, when able

Laboratory transfusion triggers
(once results available or rate of bleeding controlled)

Value	Transfuse
Hgb < 80	RBCs
INR ≥ 1.8	Plasma 4 units
Fibrinogen < 1.5 *Less than 2.0 for postpartum hemorrhage	Fibrinogen concentrate 4g
Platelets < 50	Platelets 1 adult dose
Ionized calcium < 1.15	CaCl, 1g

If available, ROTEM triggers

Value	Transfuse
EXTEM CT > 80	Plasma 4 units
EXTEM A10 < 35	Platelets 1 adult dose
FIBTEM A10 < 8-10	Fibrinogen concentrate 4g

Job Aids
Smart Records
Videos of MHP simulations
Presentations

Rounds
Hospital visits by MOH/CBS
CSTM

https://transfusionontario.org/en/category/massive-hemorrhage-protocol/toolkit-mhp/

MHP = 7T

	The Seven T's
1	Triggering and Treatment of Bleeding
2	Team (incl. Training and Communication)
3	Tranexamic acid
4	Temperature
5	Testing
6	Transfusion
7	Termination and Tracking Performance

Single protocol for all patients with specific guidance for selected patient populations

Ontario MHP: Tracking Performance

How?

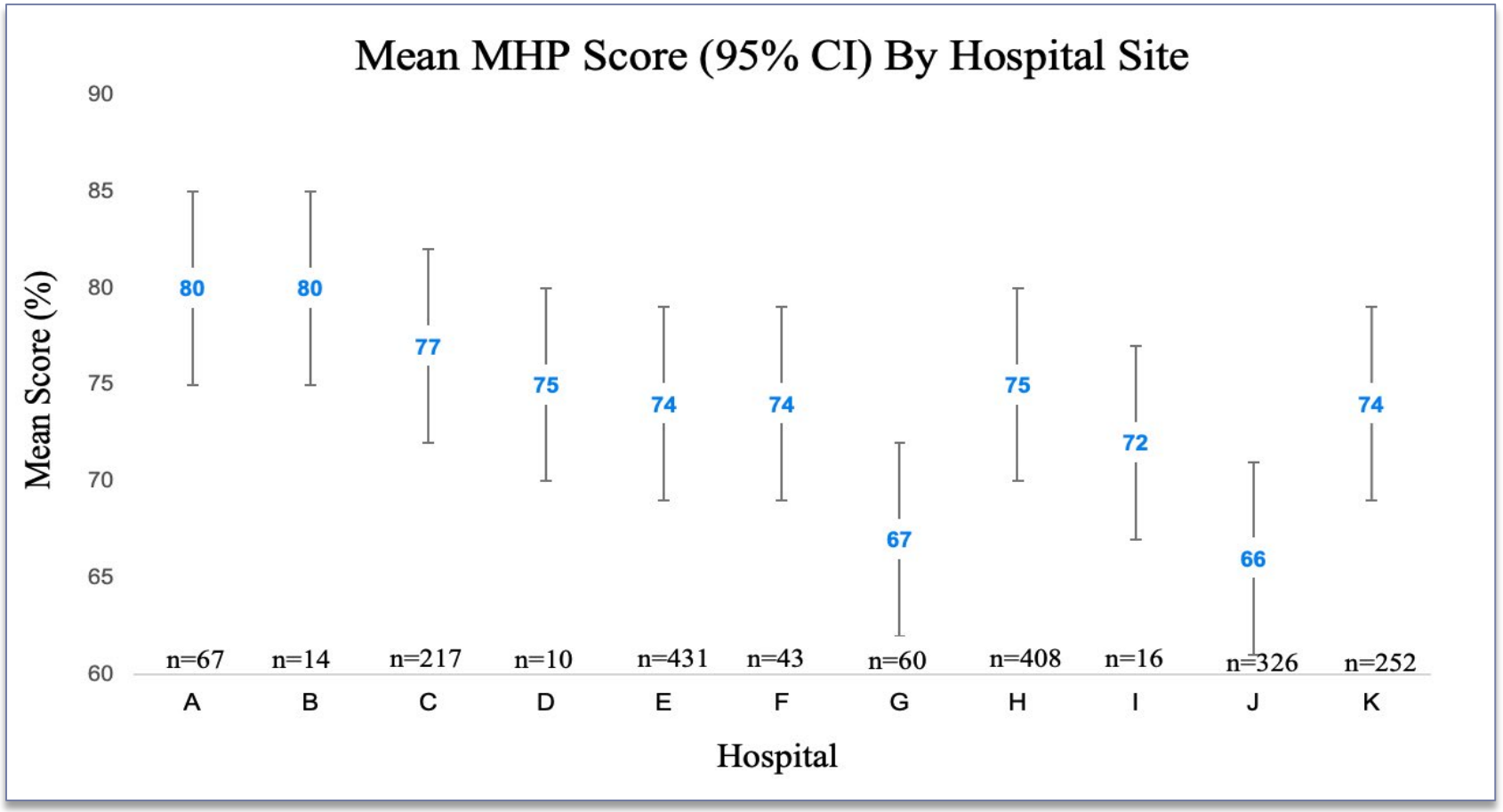
- Audits
- Mortality and morbidity rounds
- Utilization review at a multidisciplinary committee
- **Provincially reported metrics allowing for peer-to-peer comparisons**

Quality Metrics	Completion	Points	Overall Score
Did the patient receive **tranexamic acid** within 1 hour of activation?	Yes	1	6/9 → 66.67%
Was RBC transfusion initiated within **15 minutes** of activation?	Yes	1	
Was the initiation for patient **transfer** within 1 hour of activation?	Yes	1	
Was the patient's temperature ≥ **35°C** at termination?	No	0	
Was the hemoglobin maintained **over 60 g/L** for the first 24 hours?	No	0	
Was the hemoglobin **below 110 g/L** at 24 hours?	Yes	1	
Was the patient transitioned to group specific RBC within **90 minutes** of activation?	Yes	1	
Was the MHP activation **appropriate** for this patient?	Yes	1	
Were any blood products **wasted** during this activation?	Yes	0	

*If data was missing then it was assumed to be not completed → no point awarded.

S. Ali et al, ISBT Regional Congress 2023 Oral Presentation: Retrospective chart review of MHP January 2019 to July 2022, 15 hospitals and 1844 patients

Ontario MHP: Tracking Performance



Ontario Progress Post MHP 1.0

Ontario MHP Survey 2017

- 150 hospitals surveyed, 100% response rate
- 65% of hospitals had an MHP
- Of hospitals with MHP:
  - 61% had pre-defined packs
  - 63% had per protocol lab testing
  - 65% had required temperature monitoring

Ontario MHP Survey 2023

- 158 hospitals surveyed, 100% response rate
- 77% of hospitals had an MHP
- Of hospitals with an MHP:
  - 86% had pre-defined component packs/boxes
  - 87% had pre-defined lab testing
  - 76% had temperature monitoring
- 86% updated or implemented MHP in the last 5 years

Why Ontario MHP 2.0?

- **Fibrinogen concentrate (FC) vs. Cryoprecipitate**
  - **FIBRES** randomized controlled trial (RCT) of cryoprecipitate vs. fibrinogen concentrate for management of bleeding after cardiac surgery in patients with low fibrinogen: FC is non-inferior in terms of efficacy and safety to CRYO and is pathogen-reduced
    - FC becomes the preferred choice for fibrinogen replacement in Canada
- **Empiric fibrinogen replacement in major bleeding**
  - Two RCTs (**CRYOSTAT-2** and **FIDEL**): early, empiric fibrinogen replacement does NOT improve patient outcomes
  - Empiric fibrinogen replacement is no longer recommended where goal-directed treatment is possible

Callum et al JAMA 2019; Davenport et al JAMA 2023; Ducloy-Bouthors et al BJOG 2021

Why Ontario MHP 2.0?

- **Tranexamic acid (TXA) in gastrointestinal bleeding**
  - **HALT-IT** RCT of TXA vs. placebo in patients with major GI hemorrhage: TXA does not reduce mortality and increases the risk of thromboembolic complications
- **Prothrombin complex concentrate (PCC) in major bleeding**
  - **PROCOAG** RCT PCC (25IU FIX/kg) vs. placebo in patients with traumatic bleeding and at risk of major transfusion: no difference in primary outcome – number of blood products in 24 hr and more thromboembolic events in PCC arm
  - **FIIRST2** RCT PCC 2000 IU plus FC 4g vs. plasma in patients with traumatic bleeding and MHP activation – stay tuned for the update
  - **FARES2** RCT PCC 2000IU vs. plasma for management of bleeding after cardiac surgery - just completed, results pending.

HALT-IT Collaborators Lancet 2020; Bouzat et al JAMA 2023

Ontario MHP 2.0

- Multi-disciplinary panel re-assembled
- FTF meeting on November 9, 2023, following by 3 rounds of Delphi via electronic survey
- Reviewed 44 recommendations plus 8 quality metrics from MHP 1.0 + two new statements
- Outcomes
  - 21 recommendations were changed
  - 3 new recommendations were added
  - 2 recommendations were removed

Ontario MHP 2.0

MHP 1.0	MHP 2.0
Recommendation 1. All hospitals shall have a protocol to guide the management of a massively bleeding patient.	All hospitals that may need to treat major hemorrhage (adults and/or children) shall have an age-appropriate protocol to guide the management of a massively bleeding patient.
Recommendation 3. The protocol shall incorporate the principles of damage-control resuscitation, specifically giving highest priority to treating the source of hemorrhage.	The protocol should include prioritizing control of hemorrhage (i.e., damage control surgery and/or embolization) and hemostatic resuscitation to limit further blood loss.
Recommendation 4. The protocol shall consider the available resources at the institution.	The protocol shall consider the available resources and expertise at the institution.

Ontario MHP 2.0

MHP 1.0	MHP 2.0
Recommendation 5. A single protocol for all patients is preferred in order to ensure compliance; there should be specific guidance provided for selected patient populations (e.g., obstetrical patients should receive early fibrinogen replacement).	A single protocol for all patients (trauma and non-trauma) is preferred to ensure high levels of protocol adherence.* . Hospitals that even occasionally look after children must include paediatric considerations in their MHP.
Recommendation 8. Participating team members should have access to formal training and drills to increase awareness, adherence and effective delivery of the MHP.	Participating team members shall have access to formal training and recurring drills to increase MHP adherence, and effective delivery.

Ontario MHP 2.0

MHP 1.0

Recommendation 10. The transport service(s) should be promptly notified if the decision is made to transfer the patient to another hospital for definitive hemorrhage control. If required, the patient should be transferred as soon as and as safely as possible by appropriate staff and transport resources, to an institution where definitive hemorrhage control can be performed.

MHP 2.0

If the decision is made to transfer the patient to another hospital for definitive hemorrhage control, there should be prompt notification to the transport service(s) and a method to communicate that the patient has a life-threatening hemorrhage.

If a patient requires interfacility transfer to an institution where definitive hemorrhage control can be performed, blood components/products, if available, should be sent with the patient.

Ontario MHP 2.0

MHP 1.0

Recommendation 11.
The protocol shall have activation criteria.

MHP 2.0

The protocol shall have activation criteria. A two-step approach to MHP activation is preferred in most cases, balancing the need for timely access to blood products against wastage. This is operationalized with:

Step 1 (administration of 4 units of uncrossmatched RBCs for adults or 20-40cc/kg for pediatric patients) and if additional products are required, then proceed to step 2 (activation of MHP).

In centres with limited resources (e.g. only RBCs available), step 2 may not be feasible. The priority will be administration of adjunct hemostatic products and transfer to a centre for definitive care.

Under certain circumstances, the clinician may activate MHP prior to any blood product administration. In these instances, the use of a validated tool is strongly recommended to guide decision-making (ABC, RABT, Shock Index).

Ontario MHP 2.0

MHP 1.0	MHP 2.0
Recommendation 17. All critical laboratory results and important coagulation parameters (hemoglobin, platelet count, INR and fibrinogen) shall be communicated verbally to the clinical team as soon as they are available.	All critical and important resuscitation laboratory results (e.g., hemoglobin, platelet count, INR, fibrinogen, calcium, potassium and lactate/base deficit) shall be communicated directly to the clinical team as soon as they are available.
Recommendation 19. Patients and/or their substitute decision-maker for whom the massive hemorrhage protocol was activated should be informed. Actual (e.g., transfusion-associated circulatory overload, hyperkalemia) and potential adverse effects should be disclosed. Furthermore, women of child-bearing potential should be informed of the risk of red blood cell alloimmunization.	The healthcare team should discuss potential long-term effects of massive transfusion with surviving patient and/or their family at some point during hospitalization. Specifically, individuals of childbearing potential should be informed of the risk of red blood cell alloimmunization. Post-discharge follow-up and counseling should be considered for all surviving patients.

Ontario MHP 2.0

MHP 1.0

Recommendation 22. The recommended minimum laboratory testing (where the test is available) at each blood draw should be: CBC, INR, activated partial thromboplastin time (aPTT; baseline only), fibrinogen, electrolytes, calcium (ionized), blood gas (pH and base excess) and lactate.

Recommendation 23. The protocol should state the minimum laboratory protocol resuscitation targets for transfusion:

1) Hemoglobin > 80 g/L (RBC);
2) INR < 1.8 (plasma or PCC);
3) Fibrinogen > 1.5 g/L (cryoprecipitate or FC)
4) Platelets > 50 × 10^9/L
5) Ionized calcium > 1.15 mmol/L.

Relevant transfusion targets can also be used if viscoelastic testing is performed.

MHP 2.0

The recommended minimum laboratory testing (where the test is available) at each hourly blood draw should be: CBC, coagulation testing (PT/INR, activated partial thromboplastin time (aPTT; baseline only), and fibrinogen OR viscoelastic testing), electrolytes, calcium (ionized), arterial/venous blood gas (pH and base excess) & lactate

The protocol should state the minimum laboratory protocol resuscitation targets for transfusion:

1) Hemoglobin > 70-90 g/L (RBC)
2) INR<1.8 (plasma or PCC)
3) Fibrinogen > 1.5-2.0 g/L (FC)
4) Platelets > 50 x109/L (>100 for CNS bleeding/injury)
5) Ionized calcium >1.15 mmol/L (calcium chloride or gluconate).

Relevant transfusion targets can also be used if viscoelastic testing is performed.

Ontario MHP 2.0

MHP 1.0	MHP 2.0
Recommendation 29. If the blood group is unknown, O Rh D-negative red blood cells should be used only for female patients of child-bearing potential (age< 45 yr). *The risk of immunization from Rh D-positive platelets is 1% and therefore Rh-immunoglobulin should be provided to Rh D-negative women under the age of 45*	If the blood group is unknown, limit use of O Rh D-negative red blood cells to patients of child-bearing potential (age less than 45 years).
Recommendation 30. Uncrossmatched red blood cells shall be available at the bedside within 10 minutes of MHP activation	Red blood cells shall be available at the bedside within 10 minutes of MHP activation. If crossmatched units are not available within 10 minutes, issue uncrossmatched RBC.

RhIg After RhD Positive Platelet Transfusion

- Consider reported risk of alloimmunization
  - 1.44% of RhD negative recipients developed anti-D after transfusion of RhD positive platelets (either whole blood derived or apheresis) after median 77 days
- Consider number of RBC in platelets
  - Number of RBCs in apheresis platelets: less than 0.0002 mL per unit
  - Number of RBC in BC WBD platelets: about 2 mL of RBCs per unit
  - Number of RBC in apheresis platelets, psoralen treated: 0.115mL
  - **Number of RBC in pooled platelets, psoralen treated: 0.077mL**
- Consider consequences of giving RhIg – exposure to unnecessary blood product, delay in issuing RBC due to positive antibody screen

Cid et al BJH 2015; Nahirniak et al TMR 2015; unpublished data, c/o CBS

Ontario MHP 2.0

MHP 1.0

Recommendation 34. The initial management of the rapidly bleeding patient that precludes the use of laboratory-guided transfusion should begin with immediate red blood cell (RBC) transfusion and then transfusions at an RBC:plasma ratio of 2:1.

MHP 2.0

The initial management of the rapidly bleeding patient that precludes the use of laboratory-guided transfusion should begin with immediate red blood cell (RBC) transfusion and then transfusions at a RBC:plasma ratio of 2:1 followed by lab-guided transfusions when practicable.

Standard approach, Adults:

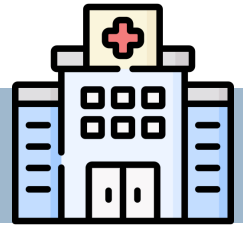
- MHP Pack 1 should contain 4 RBC units (may be issued before trauma patient arrival or before Code Transfusion activation).
- MHP Pack 2 should contain 4 RBC and 4 plasma units
- Subsequent MHP Packs should contain 4 RBC and 2 plasma units
- Platelets and FC should be transfused based on hourly laboratory test results.

Simplified options for smaller organizations without the ability to provide plasma (due to lack of plasma inventory, inability to thaw plasma rapidly, or lack of laboratory personnel):

- As per standard approach, Adults.
- MHP Pack 2 and 3 should contain 4 RBC units, 2000 IU of PCC and 4 g of FC
- Efforts should be made to transfer the bleeding patient to a centre capable of definitive hemorrhage control.
- Platelets, when not stocked in the hospital transfusion laboratory, should be ordered in for transfusion (if patient cannot be promptly transferred out). If the patient is transferred before platelets are transfused and the patient is thrombocytopenic, this should be communicated to the receiving hospital.

MHP 2.0: Transfusion (Packs Every 30 min)

Large Hospital



- Pack 1 : 4 RBC
- Pack 2: 4 RBC , 4 plasma
- Pack 3 and subsequent: 4 RBC, 2 plasma
- Transfuse platelets and FC 4g based on laboratory results

Small Hospital

- Pack 1: 4 RBC
- Pack 2: 4 RBC and where plasma not stocked 2,000IU PCC + FC 4g
- Pack 3 and subsequent: transport out

Switch to lab-based transfusion as soon as practically possible

Ontario MHP 2.0

MHP 1.0	MHP 2.0
Recommendation 36. Fibrinogen concentrate, 4 g (equivalent to approximately 10 units of cryoprecipitate), can be used as a reasonable alternative to cryoprecipitate for fibrinogen replacement.	Empiric administration of fibrinogen replacement is not recommended based on RCT evidence among traumatically-injured and obstetrical patients and observational evidence among other patients. The administration of fibrinogen replacement should occur with evidence of hypofibrinogenemia (laboratory levels or viscoelastic testing). At centres without available fibrinogen testing, the clinician may administer fibrinogen replacement based on clinical evidence of microvascular coagulopathy (e.g. oozing from IV sites) or profound hemodynamic instability where hypofibrinogenemia is likely.
Recommendation 40. Tranexamic acid should be administered as soon as intravenous or intraosseous access is achieved but within 3 hours from time of injury or within 3 hours from MHP activation in all other patients.	Tranexamic acid (TXA) should be administered as soon as possible, within 3-hours from time of injury or within 3-hours from MHP activation. Clinical circumstances (e.g. GI bleeding) may warrant case specific considerations for TXA administration.

MHP 2.0: New Statements

- Among patients who receive pre-hospital blood components/products, a **structured handover** process should be used between pre-hospital teams and in-hospital teams that accurately tracks blood products administered during the pre-hospital or transfer process.
- Ionized **calcium** (iCa^{2+}) is preferred over total calcium (Total Ca^{2+}) testing and should occur at baseline and thereafter at least hourly or after each MHP pack transfused, with a target iCa^{2+} range of 1.15-1.3 mmol/L (Total Ca^{2+} 2.25-2.50 mmol/L). Consider empiric calcium dosing when the patient is symptomatic and/or calcium laboratory results are unavailable.
- In the acute resuscitation phase of major hemorrhage without brain injury, use of a **restrictive volume replacement strategy** is preferred, but remains at physicians' discretion. A low systolic blood pressure of 80-90 mmHg (or MAP 50-60 mmHg) may be permitted as long as adequate clinical perfusion. If fluid resuscitation with transfusion alone is unable to achieve hemodynamic/perfusion targets, use of vasopressor agents can be considered.

MHP 2.0: Summary of Major Changes

- **Changes**
  - ⊕ Added requirement for pediatric MHP
  - ⊕ Added 2 step activation
  - ⊕ Added requirement for a discussion of long-term complications of MHP and counseling for surviving patients
  - ⊕ Added viscoelastic testing
  - ⊕ Added caution about empiric TXA in GI bleeding
  - 🔄 Changed thresholds during goal-directed transfusion
  - ⊖ Removed empiric fibrinogen replacement
- **New statements**
  - Requirement for a structured handover in case of pre-hospital transfusion
  - Requirement to measure and replace calcium
  - Consideration of a restrictive volume replacement

Next Steps and Q&A

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