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Developed by:
The Massive Hemorrhage Working Group (Appendix B)

Recommended Citation:
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Definitions

Massive Hemorrhage

A. Adult or weight of ≥ 50 kg:
   - bleeding at a rate of ≥ 150 ml/min with ongoing hemodynamic instability;
   - the loss of one blood volume in 24 hours; and/or
   - the loss of ≥ 50% blood volume in 3 hours.

B. Pediatric or weight of < 50 kg
   - bleeding at a rate of > 2 ml/min with ongoing hemodynamic instability;
   - the loss of ≥ 80 ml/kg blood volume in 24 hours; and/or
   - the loss of ≥ 50% blood volume in 3 hours.

Massive Transfusion

A. Adult or weight of ≥ 50 kg:
   - transfusion of ≥ 10 units of RBCs in 24 hours; and/or
   - transfusion of ≥ 4 units of RBCs in 1 hours.

B. Pediatric or weight of < 50 kg:
   - transfusion of > 20 ml/kg in 2 hours with an anticipated ongoing need for RBC; and/or
   - transfusion of ≥ 40 ml/kg of all blood components at any time within a 24-hour period.
Nova Scotia Guideline for the Management of Massive Hemorrhage

Introduction

Purpose

The *Nova Scotia Guideline for the Management of Massive Hemorrhage* provides clinical guidance to healthcare professionals for the appropriate control of massive blood loss. This document outlines essential components used to assess, support and stabilize patients experiencing a major hemorrhage. The guideline is intended to facilitate interdisciplinary coordination and communication, streamline access to surgical interventions and ensure rapid delivery of appropriate blood components and blood products. The evidence-based material and consensus-based recommendations in this document support the practices presented in this guideline, which aim to reduce treatment variability and improve patient outcomes.

This guideline provides a template for a standardized approach when managing massively bleeding patients. The content describes current acceptable standards of care that should be applied throughout the Nova Scotia healthcare system. Clinical experts from across the province have approved and support the approaches and treatment options described in this document. This guideline is not meant to replace a massive hemorrhage protocol (MHP), but rather its information is to be used by Emergency Health Services, NSH/IWK hospitals and laboratories in the development of their own MHPs. The goal is to harmonize hemorrhage control measures across the province thereby ensuring all patients receive the best care possible with the available institutional resources.

Scope

This document has been prepared specifically for use in Nova Scotia. Access to medical specialties, surgical capabilities, blood components/products and laboratory testing varies across the province. The guideline’s content is broad to reflect Nova Scotia’s diverse mixture of healthcare settings and resources. Its application is provincial in nature; however, it is not explicitly directed toward any one healthcare institution. The extent of this guideline is limited to its use as a reference for the acceptable standards of care for massive hemorrhage in Nova Scotia and as an adaptable resource for institutions/zonal regions when developing their own massive hemorrhage protocols.

Guideline Development

The Nova Scotia Provincial Blood Coordinating Team (NSPBCT) developed the *Guideline for the Management Massive Hemorrhage in Nova Scotiad* in 2010 in response to the identified need by the Nova Scotia Provincial Blood Contingency Plan to provide guidance and standardization for the use of blood components/products in massively bleeding patients. In 2013, the guideline underwent a revision based on stakeholder feedback to describe the scope of clinical practice more accurately in the document. Since 2013, new advances in hemostatic drugs, diagnostic equipment and massive hemorrhage management have occurred. For this reason, the guideline has been updated to reflect current practices and standards of care.
Management of Massive Hemorrhage

Background

The leading cause of preventable death during surgical procedures, childbirth and in trauma is massive blood loss (Callum, 2019). Successful management of a massive hemorrhage requires a protocol-driven interdisciplinary team approach. The literature clearly indicates improved patient survival when institutions follow a MHP (Cannon, 2017). Massive hemorrhage protocols reduce coagulopathy, hypothermia and acidosis (the ‘Lethal Triad’) by promoting early and aggressive coagulation factor therapy and limiting crystalloid infusion volumes (Shaz, 2009).

Management of massively bleeding patients should be guided by an institution specific MHP. Effective protocols describe the lines of communication between clinicians and the transfusion services, and reflect local practices, logistics, and available medical and human resources (Trudeau, 2017). Massive hemorrhage protocols should be developed by an interdisciplinary team that includes clinicians, transfusion directors, transfusion technologists and any other relevant care providers. The interdisciplinary team provides a comprehensive view of local practices, needs and challenges and are best equipped to incorporate the treatment goals and recommendations in this guideline into institution specific MHPs.

The following recommendations summarize key practice points associated with the successful management of a massive hemorrhage.

Pre-Hospital Management / Scene Transport

Appropriate emergency interventions and prompt transport to a trauma center are associated with better outcomes for major trauma patients (Tansley, 2019). In Nova Scotia, Emergency Health Services (EHS) are a major contributor to the management of massively bleeding patients in the pre-hospital setting. The implementation of pre-hospital transfusion protocols has become common practice among civilian emergency medical services (Van Turenhout, 2020). These protocols aim to establish early hemorrhage control to prevent hypovolemic shock, acidosis, hypothermia and coagulopathy. EHS’s ability to stabilize and rapidly transport patients to a trauma facility are the initial steps in managing major hemorrhage occurring outside a healthcare facility.

The following recommendations should be considered when managing major blood loss in the pre-hospital setting:

- Identify and treat active bleeding, if applicable apply local compression and/or topical treatment to limit blood loss.
  - A tourniquet may be used to stop life-threatening bleeding from open extremity injuries.
  - Hemostatic dressings may be used to limit bleeding in areas where tourniquet
application is not possible due to anatomic limitations.

- A pelvic binder may be used to limit life-threatening bleeding in the presence of a suspected pelvic fracture.

- For blunt or penetrating traumas tranexamic acid (TXA) should be administered as soon as possible. (See Antithrombotic Reversal Strategies and Adjunctive Treatments section for dosing)
  - Note: TXA is contraindicated if injury occurred over 3 hours ago

- In the presence of persistent hemorrhagic shock despite hemorrhage control measures and crystalloid infusion, consider the transfusion of blood components/products when available.

- Transfusion therapy for patients experiencing hemorrhagic shock should include red blood cells RBC and coagulation support.
  - For adult (≥ 50kg) patients with massive blood loss, consider administering 2g Fibrinogen Concentrate (FC), or for pediatric (<50 kg) patients 50mg/kg up to a maximum of 2g; and/or
  - Administer plasma in a 1:1 ratio with packed red blood cells (RBCs).
  - If plasma is not available, consider administering 1000IU Prothrombin Complex Concentrate (PCC) and 2g FC for adult patients or 25IU/kg of PCC to a maximum of 1000IU and 50mg/kg of FC to a maximum of 2g for pediatric patients.
    - Note: dosing intended to mimic 1:1 ratio corresponding to the first four units of RBC

- The following criteria should be used to assess the degree of hemorrhagic shock and guide the decision to initiate or withhold transfusion support:
  - Patient’s response to initial fluid administration
  - Hypotension,
    - Absent radial pulse; or
    - Systolic blood pressure (SBP) of:
      - < 90, for adults and pediatrics > 5 years of age
      - < 80 for pediatrics 1-5 years of age
      - < 70 for infants up to 1 year of age
       - Note hypotension is often a late finding in bleeding pediatric patients. Compensatory mechanisms can maintain SBP with blood volume loses of 30-40%. In pediatrics, tachycardia and signs of poor perfusion are better indicators for the assessment of hemorrhagic shock.
  - Tachycardia (heart rate ≥ 110/min in adults)
  - Clinical signs of poor perfusion (e.g. changes in mental state, not explained by traumatic brain injury, changes in skin color, prolonged capillary refill)
Type of injury (e.g. penetrating torso wound or proximal amputation)

- If available, point-of-care (POC) testing maybe used to help guide pre-hospital transfusion support.
- Any of the following POC results are suggested triggers that would warrant transfusion support in hemodynamically unstable bleeding patients:
  - Lactate $\geq 4$ mmol/L
  - Base excess $\geq -6$ mmol/L; or
  - Hemoglobin less than 90 g/L and ongoing significant blood loss is anticipated
  - INR > 1.7 and ongoing significant blood loss is anticipated
- The decision to transfuse should not only be based on “hard” criteria but should also rely on the clinical judgement of pre-hospital healthcare providers.
- Manage hypothermia by preventing heat loss, use warming equipment if available and increase internal temperature of transport vehicle.
- Transport directly to an appropriate treatment facility, dependent on the nature of injury and hospital resources.
- Contact receiving facility to alert of possible MHP activation.
- In consultation with EHS, the receiving facility’s emergency department clinician should consider activating the MHP prior to the patient’s arrival.
- In advance of arrival, the receiving facility should pre-register patient(s).
- To ensure appropriate blood component/product management and preparation, the receiving facility’s Transfusion Services should be notified of possible MHP activation and the approximate age, gender, number of patients and estimated time of arrival.
- Patients admitted during major hemorrhage or after traumatic injury with a temporary name/identifier or with an incomplete registration (e.g., no date of birth) should not have their demographic /registration changed or updated until after resuscitation efforts are complete.
- Transfusion Services should be notified immediately when patient demographics are updated.

Inter-facility Transport

Primary healthcare services across the Maritime provinces consist of numerous community health centers and hospitals. Relatively few facilities provide all the necessary services to treat major injuries and manage significant blood loss. In Nova Scotia, trauma care is available at eight level-III trauma centers and one adult level-I and pediatric level-I trauma center (Tansley, 2019). The level-I trauma centers serve patients from Nova Scotia, New Brunswick and Prince Edward Island. To ensure severely injured patients receive the appropriate level of care, inter-
hospital transfer may be required when definitive hemorrhage control cannot be achieved at the initial treating facility.

The following recommendations should be considered during the process of transferring a critically bleeding patient to another facility:

- The decision to transfer should be based on the medical needs of the patient and the resources/capabilities of the transferring institution.
- Patients should be transferred as soon and safely as possible to an institution where definitive hemorrhage control can be performed.
- Only those diagnostic studies and procedures that will treat or stabilize immediately life-threatening injuries should be performed before transferring a patient for definitive care.
- The referring doctor should provide all pertinent information regarding the patient’s injuries, care received and patient’s response to care to the receiving facility’s doctor.
- The transport team should be promptly alerted of the possibility of a transport and then notified immediately when the decision is made to transfer the patient.
- The decision to transfer trauma patients, along with the timing and mode of transport, should be done in collaboration with the appropriate (adult or pediatric) Nova Scotia Trauma Team Leader.
- All transport of critical patients should be facilitated through EHS Medical Communications Centre and in collaboration with EHS LifeFlight, and the Nova Scotia Trauma Program, as needed.
  - Note: this includes inter-provincial and intra-provincial transport of Nova Scotia residents and the transport of out-of-province patients to a NS facility.
- When the sending facility’s Transfusion Services is requested to provide blood components, the maximum number of units per package should not exceed 4. Packages containing blood components should not be opened by the transport team or the receiving facility unless immediate transfusion is required. Multiple packages should not be opened to have the contents amalgamated.
- The sending facility’s Transfusion Services should inform the receiving facility of any transfusion testing results, amount/type of blood components/products issued and of any blood components or products being transferred with the patient.
- Upon arrival, all transported blood components/products should remain at the receiving facility.
- Unopen packages should be sent to the receiving facility’s Transfusion Services as soon as possible.
Response Team

Hemorrhage control requires a coordinated response of an interdisciplinary clinical team (Trudeau, 2017). Clinicians (e.g. anesthesiologists, surgeons, emergency physicians, obstetricians), transfusion medicine specialists (hematologists, pathologists, hematopathologists), nurses, laboratory and diagnostic imaging technologists all play a vital role in treating massive blood loss. The composition of the clinical response team and how the team communicates amongst themselves and with the laboratory are critical to the success of hemorrhage management.

The following recommendations should be considered when developing a clinical response team:

- The specific team members/specialties required to respond upon MHP activation should be determined.
- The composition of the team should reflect the various types of hemorrhages, the potential locations of patients, and the institution’s available resources.
- A clinical team leader should be designated to lead the resuscitation efforts.
- The manner in how a team leader is chosen should be clearly outlined.
- The team leader should be chosen based on patient demographics and institutional resources.
- Like the clinical team leader, a single technologist should be designated to coordinate the MHP within Transfusion Services.
- A designated clinical team member(s) should be responsible for blood component/product and specimen transport.
- One single team member should be responsible for communications between the clinical team and Transfusion Services.

MHP Activation

Massive hemorrhage can occur unexpectedly (secondary to injury) or it may be anticipated (intraoperative). Regardless of the context, early identification of patients who may require massive transfusion is critical to successful hemorrhage management (Trudeau J., 2021). When the potential for massive transfusion is recognized, the institution’s massive hemorrhage protocol should be initiated and continued until the risk of massive bleeding has diminished or definitive control of bleeding is achieved. Delaying MHP activation is associated with a longer time in achieving hemostasis and increased patient mortality (Meyer, 2017). Determining when activation is necessary can be a difficult task, as it is often constrained by limited time and information. Despite the critical importance of timely activation, there is no standard approach that will accurately prevent blood component wastage (over-activation), or patient morbidity and mortality (under-activation) (Bell, 2018).
Several validated scoring systems and decision tools have been developed to aid clinicians in predicting the need for MHP activation. Integrating objective triggers into MHP activation criteria leads to a more effective decision-making process with less provider-to-provider subjectivity (Nunez, 2009). However, no scoring system or decision tool has been universally accepted as a standard for identifying which patients will require massive transfusion. Each system has its own set of advantages and limitations. No tool, with both a high degree of sensitivity and specificity or single criteria can identify all patients at risk of significant hemorrhage or predict the need for massive transfusion (Callum, 2019). The decision to activate a MHP requires clinical judgment based on a combination of patient physiology parameters, anatomical injury, mechanism of injury, objective decision tools the patient’s response to initial resuscitation, and when applicable, surgical requirements and underlying conditions (Spahn, 2019).

The following recommendations should be considered when activating a massive hemorrhage protocol:

- Activation of the MHP should occur at the discretion of the Medical Lead and/or Transfusion Medical Director.
- The decision to activate should be based on clinical assessment, risk of massive blood lose and the criteria that comprises the definition of a massive hemorrhage.
- The assessment of hypovolemic shock should evaluate heart rate (HR) and SBP together.
  - The following vital signs may imply the presences of hypovolemic shock in adult patients:
    - SBP < 90 mmHg and HR >110 bpm
  - Note: among pediatrics normal vital signs vary with age and, in comparison with adults are less predictable in cases of hypovolemic shock. Hypotension is often a late finding in bleeding pediatric patients, making SBP less useful in early identification of hypovolemic shock. Tachycardia is often the hall mark indicator used to assess the presences of hypovolemic shock.
- Clinical assessment should include an objective activation trigger, such as a validated predictive scoring system, resuscitation intensity, Critical Administration Threshold or other pre-establish transfusion thresholds.
- A validated massive transfusion predictive scoring system should be incorporated into the activation decision making process for trauma patients not in an obvious state of shock or in need of massive transfusion.
  - Two commonly used predictive tools to help guide MHP activation are the **Assessment of Blood Consumption (ABC) Score** (1 point each for penetrating injury, blood pressure ≤ 90 mm Hg, heart rate ≥ 120 beats/min and positive results of FAST [Focused Assessment with Sonography for Trauma]), and the **Shock Index (SI)** (heart rate divided by systolic blood pressure). Age adjusted values for the SI can be used for pediatric patients. Neither the ABC nor SI scoring system requires laboratory testing and only use
Nova Scotia Guideline for the Management of Massive Hemorrhage

data available during the initial assessment, making the final score obtained in a quick and easy manner.

- The **Revised Assessment of Bleeding and Transfusion (RABT) score** (1 point each for penetrating injury, SI of >1, positive results of FAST and the presence of a pelvic fracture) is a modification of the ABC score that incorporates the SI, instead of isolated vital parameters, along with the presence of a pelvic fracture into the final score. The replacement of hypotension and tachycardia with the SI and the inclusion of a pelvic fracture has been shown to enhance the ABC score in terms of sensitivity and specificity for predicting the need for MT.

- When using the ABC or RABT scoring system, a value of 2 - 4 should be used as the activation trigger.
- When using the SI scoring system, a value of > 0.9 should be used as the activation trigger.
- When using the Shock Index Pediatric Age Adjusted (SIPA) scoring system the following age adjusted values should be used as activation triggers.
  - 1-6 years > 1.2
  - 7-12 years: > 1.0
  - > 12 years: > 0.9
- When an adult patient is not in an obvious state of shock or in need of massive transfusion, Resuscitation Intensity (RI) or Critical Administration Threshold (CAT) may be used as an additional metric to help guide MHP activation.
  - RI is defined as patients requiring four units of any combination of crystalloids or blood components (1 unit defined as 1 unit of RBCs, 1 unit of plasma, 500 ml of colloid or 1 L of crystalloid) to maintain adequate perfusion in the first 30 minutes of resuscitation
  - CAT is defined as the transfusion of 3 or more units of RBCs within a one-hour period
- Alternatively, other pre-established RBC transfusion thresholds may be used as an alert to consider MHP activation.
  - Given a lack of clinical research that has established objective criteria for MHP activation in non-trauma patients, pre-established transfusion thresholds offer a valuable objective method for aiding in the decision to initiate a MHP in the non-trauma setting
  - In cases of adult non-trauma related bleeding the transfusion of 4 or more units of RBCs within one hour may be used to identify hemorrhaging patients that would potentially benefit from MHP activation
- Other criteria that may warrant MHP activation includes the transfusion of emergency issued uncross-matched group O RBCs.
- At minimum, the following laboratory tests should be done upon activation and if possible, prior to fluid resuscitation:
Nova Scotia Guideline for the Management of Massive Hemorrhage

- Group and Screen, CBC, aPTT, PT/INR, fibrinogen (when on-site testing is available), arterial or venous blood gas, lactate, electrolytes, creatinine and ionized Ca2+. Once activated there should be a process in place to ensure that the message is disseminated to all relevant team members and departments.

- Upon activation Transfusion Services should be provided with the following information:
  - Name and contact number of team leader
  - Name and contact number of team member responsible for communications between the clinical team and the Transfusion Services
  - Patient name, age (or approximate age, if unknown), sex, HCN, diagnosis and weight
  - Any known special transfusion requirements, e.g. antigen negative components for patients with known red blood cell antibodies

**Damage Control Resuscitation/Management**

The major principles of damage-control resuscitation (DCR) aim to limit initial interventions to hemorrhage control and homeostasis restoration, with definitive surgical care being delayed until stabilization and hemostatic control are achieved (Cannon, 2017) (Callum, 2019). This is to prevent/mitigate hypothermia, acidosis, and coagulopathy. DCR can significantly improve severely injured bleeding patients’ outcomes and is associated with reduced trauma related morbidity and mortality (Cannon, 2017), (Spahn, 2019).

The following recommendations pertaining to the principles of DRC should be considered during the management of massive blood loss:

- The principles of DCR should guide patient management, specifically giving highest priority to treating the source of hemorrhage.
- The management of metabolic derangements caused by ongoing massive blood loss should supersede definitive surgical care.
- A damage control surgical approach should be used in patients who show signs of hypothermia, acidosis and coagulopathy. Interventions should be limited to those that address life-threatening injuries and to controlling source of hemorrhage.
- Crystalloid fluid resuscitation should be avoided or limited to specific clinical uses, such as carrier fluid for intravenous medication or other non-resuscitative uses.
- In adult patients, permissive hypotension with a target SBP of equal to less than 80 mmHg should be maintained while managing massive bleeding.
- In adult patients with traumatic brain injury, permissive hypotensive should not be used, rather a target SBP greater than 100 mmHg should be maintained while managing ongoing bleeding.
All patients should receive interventions to prevent hypothermia. The following temperature management strategies should be used:

- Ensure the removal of wet clothing and avoid contact with cold surfaces
- Increase room temperature and use heating blankets, heat lamps or other warming equipment
- Use fluid warmers for intravenous fluids (e.g. Level One rapid infuser, or equivalent warming device),
  - Platelets and cryoprecipitate should not be administered through a blood warmer

Patient temperature should be continuously monitored (where available) or at minimum every 30 minutes.

If available, point-of-care blood gas testing should be used over conventional laboratory-based analysis to help monitor the extent of bleeding and shock.

- Note: base deficit and lactate values derived from arterial blood gas analysis are strong predictors of under resuscitation. The use of point-of-care blood gas testing reduces result turnaround times, allowing for quicker patient assessment and clinical decision making.

**Hemostatic Resuscitation (Initial Transfusion Management)**

The initial management for critically bleeding patients requires an aggressive hemostatic resuscitation strategy. In massively bleeding trauma patients, protocol-driven transfusions based on empirical ratios of blood components result in a survival benefit (Holcomb, 2015, Noland, 2019). However, the optimal ratio of plasma, red blood cells and platelets remains a debate. Regardless, the empiric phase of hemostatic resuscitation is intended to provide quick initial hemostatic support during critical bleeding when laboratory results may not be available or accurately reflect the true clinical condition. An up-front hemostatic supportive approach aims to replace patient blood loss in a way that will preserve/restore homeostasis until a laboratory guided, goal-directed therapy can be used.

Note: In the **non-trauma setting**, hemostatic resuscitation strategies and the empiric use of blood components have not been tested in randomized controlled trials (Callum, 2019). Specific ratios of blood components and their empiric use, a practice seen in trauma-related transfusion resuscitation, **may not be appropriate for all bleeding patients**.

The following recommendations should be considered during initial transfusion management when a laboratory guided approach is not available or practical:

- No single approach to the initial transfusion management of critically bleeding patients should be imposed as an absolute standard of care. The clinical situation should dictate the amount and type of blood components/products needed for transfusion.
• Only blood components/products with a clear order from the team leader or delegate should be transfused.

• All required pre-transfusions checks must be performed prior to the transfusion of any blood components/products.

• The collection and testing of the patient’s blood group must be expedited to ensure group-specific RBC and plasma are provided as quickly as possible.

• When a patient’s blood group is unknown, group O RhD negative, Kell antigen negative RBCs should be transfused to individuals of 45 years of age or younger with child-bearing potential.

• Transfusion should not be withheld in circumstances where group O RhD negative and/or Kell antigen negative RBC inventory is limited or unavailable.

• In exceptional circumstances, when an adult patient’s blood group is unknown, group A plasma may be considered a reasonable alternative to group AB.

• Institutions should define the maximum volume of group A plasma to be transfused to a patient with an unknown blood group.

  – Note: Surveys show 1000 -2000ml of group A plasma is commonly used in the initial resuscitation stages of hemorrhage management for adult trauma patients with unknown blood groups.

• When a patient receives ABO incompatible plasma there should be a procedure in place to monitor for potential hemolytic associated adverse events post-transfusion.

• Unless there are specific contraindications, cell salvage should be used where available.

• To ensure quick and easy access to a variety of blood components/products during initial hemorrhage management, predetermined quantities of specified blood components/products should be delivered to the patient area in standardized packages.

• Packages should be prepared in a manner that permits a RBC: Plasma resuscitation strategy between 1:1 and 2:1, or when platelets are available, a RBC: Plasma: Platelet resuscitation strategy between 1:1:1 and 2:1:1.

• Modifications to the contents in the pack(s) should only be made by the team leader or TM Medical Director.

• The initial management of the rapidly bleeding patient should begin with immediate RBC transfusion.

• Packed red blood cells should be available in the patient area within 10 minutes of MHP activation.

• Early administration of FC should be considered during initial hemorrhage management.

  – FC should be available in the patient care area early in the resuscitation process.
• When platelets are not stocked in the transfusion laboratory, they should be requested, unless imminent transfer to an institution capable of definitive hemorrhage control is required.
  – Where CBS cannot supply platelets to a facility within 90 minutes, and where it is logistically appropriate, arrangements with an alternative facility should be in place to facilitate platelet support.

• The delivery mechanism for blood components/products should be specified and chosen in a manner that ensures they will arrive to the patient care area in a quick, consistent and reliable manner.

• If access to a blood refrigerator in the patient care area is not available or access is impractical, blood components/products should be packaged, when time permits, in validated temperature-controlled containers.

• The procedure for requesting/sending the next package or additional blood components/products should be specified and be easy to perform in the setting of a massive hemorrhage.

• The delivery of the upfront components/products should continue until the rate of blood loss has decelerated and transfusion support can be guided by laboratory analysis.

• For pediatric patients < 50 kg blood components/products should be administered on a weight basis to avoid inadvertent volume overload. The following weight base dosing should guide transfusion:
  – RBCs 10-20 ml/kg
  – Plasma 10-20 ml/kg
  – Platelets 10-15 ml/kg (transfused as needed based on platelet count)

• Institutions should develop pediatric MHP for specific blood component/product requirements. Given the wide range of patient weights and sizes within the pediatric population and limited pediatric specific evidence on appropriate blood product ratios, no “one size fits all” approach is appropriate.
  – The following may be used as a reference for the development of pediatric MHP blood component/products requirements during the initial critical bleeding phase:

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Adapted from “An update on the ORBCoN Standardized Pediatric Massive Hemorrhage Protocol 2021”

<table>
<thead>
<tr>
<th>Weight</th>
<th>Package 1</th>
<th>Package 2</th>
<th>Package 3</th>
<th>Package 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>41-50Kg</td>
<td>4 RBCs</td>
<td>4 RBCs, 1000ml plasma</td>
<td>4 RBCs, 500ml plasma, 4g FC</td>
<td>4 RBCs, 500ml plasma,</td>
</tr>
<tr>
<td>31-40Kg</td>
<td>3 RBCs</td>
<td>3 RBCs, 750ml plasma</td>
<td>3 RBCs, 500ml plasma, 4g FC</td>
<td>3 RBCs, 500ml plasma,</td>
</tr>
<tr>
<td>10-30Kg</td>
<td>2 RBCs</td>
<td>2 RBCs, 500ml plasma</td>
<td>2 RBCs, 250ml plasma, 2g FC</td>
<td>2 RBCs, 250ml plasma</td>
</tr>
<tr>
<td>&lt;10Kg</td>
<td>1 RBCs</td>
<td>1 RBCs, 250ml plasma</td>
<td>1 RBCs, 250ml plasma, 2g FC</td>
<td>1 RBCs, 250ml plasma</td>
</tr>
</tbody>
</table>
For institutions where the management of pediatric hemorrhages is uncommon, there should only be one standard MHP for all patients who are less than 50kg.

For pediatrics, platelets should not be administered empirically or as part of an initial formula driven approach; rather, they should only be administered based on a result guided approach.

Adult and pediatric patients should be switched to a goal directed result guided transfusion approach as soon as practically possible.

Antithrombotic Reversal Strategies and Adjunctive Treatments

Antithrombotic agents include heparin, vitamin K antagonists (VKA), direct oral anticoagulants (DOAC) and antiplatelet agents. These medications are used to reduce the risk of a thrombotic event. During a massive hemorrhage the rapid reversal of heparin, VKAs and DOACs is critical in mitigating patient morbidity and mortality. Additionally, adjunctive treatments should also be used to assist with hemorrhage management.

The following recommendations should be considered when managing massively hemorrhaging patients on antithrombotic agents and for the administration of Tranexamic acid:

- All antithrombotic treatment should be discontinued.
- Dosing for reversal agents should be reduced and in consultation with hematology if the antithrombotic agent has already been held for several hours.
  - Note: due to the relatively short half-lives of direct oral anticoagulants and their quick offset of anticoagulants effects reversal agents may not be indicated in all patients.
- Tranexamic acid must be administered within 3 hours of bleeding onset in patients with traumatic or post-partum hemorrhage.
  - **Adults:** Loading dose: 1000 mg/dose IV followed by continuous IV Infusion: 125 mg/hour for 8 hours or until bleeding stops (whichever occurs first)
  - **Pediatric:** Loading dose: 15 mg/kg/dose IV (Maximum 1000 mg/dose); followed by continuous IV Infusion: 2 mg/kg/hour (Maximum 125 mg/hour) for 8 hours or until bleeding stops (whichever occurs first)
  - **Post-Partum Hemorrhage:** 1000 mg IV over 10 minutes. Second dose may be repeated if bleeding continues after 30 minutes or stops and restarts within 24 hours after the first dose
- The anticoagulant reversal strategies in table 1 and 2 should be considered.
Table 1 Antithrombotic agents and reversal strategies
Adapted from University Health Network, Policy & Procedure Manual, Massive Transfusion Protocol-Clinical and Recommendations for the Use of Blood Components/Products in the Bleeding Patient on Direct Oral Anticoagulants

<table>
<thead>
<tr>
<th>Antithrombotic</th>
<th>Example</th>
<th>Reversal Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heparin Sodium</td>
<td>Unfractionated Heparin</td>
<td>Protamine - 1 mg/90 Units of Heparin (Note: Protamine does not fully reverse Low Molecular Weight Heparin)</td>
</tr>
<tr>
<td>Low Molecular Weight Heparin</td>
<td>Dalteparin (Fragmin®)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enoxaparin (Lovenox®)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tinzaparin (Innohep®)</td>
<td></td>
</tr>
<tr>
<td>Vitamin K Antagonists</td>
<td>Acenocoumarol (Sintrom®)</td>
<td>Phytonadione (vitamin K₁) 10 mg IV (5-10 mg IV for pediatrics) AND Prothrombin Complex Concentrate (Octaplex and Beriplex)</td>
</tr>
<tr>
<td></td>
<td>Warfarin (Coumadin®)</td>
<td>• INR 1.7 to 5 – administer 40 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• INR greater than or equal to 5.1 or unknown or Intracranial Hemorrhage – administer 80 ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refer to table 2 for Pediatric Dosing</td>
</tr>
<tr>
<td>Direct Thrombin Inhibitors</td>
<td>Argatroban (Argatroban®)</td>
<td>No specific antidote</td>
</tr>
<tr>
<td></td>
<td>Bivalirudin (Angiomax®)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dabigatran (Pradaxa®)</td>
<td>Idarucizumab (Praxbind®) 5 g IV bolus (administer in 2 infusions of 2.5 g each no more than 15 minutes apart) Consult hematology for pediatric dosing</td>
</tr>
<tr>
<td>Factor Xa Inhibitors</td>
<td>Direct</td>
<td>Apixaban (Eliquis®)</td>
</tr>
<tr>
<td></td>
<td>Edoxaban (Lixiana®)</td>
<td>No approved antidote. Prothrombin Complex Concentrate (Octaplex and Beriplex)</td>
</tr>
<tr>
<td></td>
<td>Rivaroxaban (Xarelto®)</td>
<td>Dosage: 80 ml (2000 Units)</td>
</tr>
<tr>
<td></td>
<td>Indirect</td>
<td>Fondaparinux (Arixtra®)</td>
</tr>
<tr>
<td>Antiplatelet agents</td>
<td>Acetylsalicylic Acid</td>
<td>No approved reversal agents, consider platelet transfusion* (1 unit)</td>
</tr>
<tr>
<td></td>
<td>(Aspirin®)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clopidogrel (Plavix®)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prasugrel (Effient®)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ticagrelor (Brilinta®)</td>
<td></td>
</tr>
</tbody>
</table>

* The platelet inhibition effects of aspirin, clopidogrel and Prasugrel can be partially reversed with platelet transfusion. However, platelet transfusion appears less effective for ticagrelor reversal.

Table 2 PCC Dosing for Pediatrics for Vitamin K Antagonist (Noga T., 2016)

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>INR &lt; 3</th>
<th>INR ≥ 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10</td>
<td>10 ml</td>
<td>20 ml</td>
</tr>
<tr>
<td>10 - 25</td>
<td>20 ml</td>
<td>30 ml</td>
</tr>
<tr>
<td>25 - 50</td>
<td>30 ml</td>
<td>40 ml</td>
</tr>
</tbody>
</table>
Goal-Directed and Result-Guided Transfusion

Transfusion support during a massive hemorrhage will vary from patient to patient based on the nature and degree of injury. The transition from initial transfusion management to a goal-directed, result-guided approach minimizes transfusion associated complications and mortality. Ratio-driven protocols are intended to provide quick initial hemostatic support during critical bleeding when laboratory results may not be available or accurately reflect the true clinical condition. Protocols that rely solely on this approach can cause over-transfusion, resulting in either no additional benefit or added toxicity (Dzik, 2011). Transitioning transfusion support based on clinical course and laboratory results allows accurate correction of the individual’s specific hemostatic needs, reduces product wastage and lowers the risk of unnecessary transfusion and transfusion associated complications (Nascimento, 2013).

The following recommendations should be considered when transitioning to a goal-directed result-guided transfusion:

- Bleeding rate should be reassessed between doses of blood components/products.
- At a minimum, the following testing should be repeated hourly until protocol is terminated.
  - CBC, PT/INR, fibrinogen (when on-site testing is available), arterial or venous blood gas, lactate, electrolytes, creatinine and ionized Ca2+,
  - Depending on the severity of the hemorrhage, repeat testing at 30-minute intervals is an appropriate measure to guide transfusion requirements.
- The order/entry of testing should incorporate the use of order sets.
- The laboratory resuscitation targets in table 3 should be used to guide transfusion.
  - Relevant transfusion targets can also be used if viscoelastic testing is performed

Table 3: Transfusion trigger based on laboratory result

<table>
<thead>
<tr>
<th>Laboratory Results</th>
<th>Products</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin less than 80 g/L</td>
<td>RBC</td>
<td>Adults - as per rate of blood loss</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pediatrics - 10-20 ml/kg - up to a maximum single dose of 4 units</td>
</tr>
<tr>
<td>Platelet count less than 50 x 10⁹ /L or</td>
<td>Platelets</td>
<td>Adults – 1 apheresis or pooled unit</td>
</tr>
<tr>
<td>less than 100 x 10⁹ /L in CNS injury</td>
<td></td>
<td>Pediatrics – 10-15 ml/kg - up to a maximum single dose of one apheresis or pooled unit</td>
</tr>
<tr>
<td>INR greater than 1.7</td>
<td>Plasma</td>
<td>Adults - 1000 ml or 15ml/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pediatrics - 10-20 ml/kg - up to a maximum single dose of 1000 ml</td>
</tr>
<tr>
<td>Fibrinogen less than 1.5 g/L or</td>
<td>Cryoprecipitate</td>
<td>Adults - 10 units</td>
</tr>
<tr>
<td>Less than 2.0 g/L in postpartum hemorrhage</td>
<td></td>
<td>Pediatrics – 1-2 unit/10 kg - up to a maximum single dose of 10 units</td>
</tr>
<tr>
<td></td>
<td>Fibrinogen</td>
<td>Adults - 1-4 g</td>
</tr>
<tr>
<td></td>
<td>Concentrate</td>
<td>Pediatrics - 30-60 mg/kg - up to a maximum single dose of 4 grams</td>
</tr>
</tbody>
</table>
Calcium should be administered for every 4 units of RBCs transfused or every 40 ml/kg RBC transfused in pediatric patients and when ionized calcium is less than 1.14 mmol/L. The following dosing should be used to correct for hypocalcemia:

- Calcium chloride – adults -1g; pediatrics 10-20 mg/kg up to a maximum of 1g
- Calcium gluconate – adults - 3g; pediatrics 30-60 mg/kg up to a maximum of 3g

To counter the complications associated with massive transfusion, the physiological parameters in table 4 should be maintained.

### Table 4: Parameter targets to counter complications associated with massive transfusion

<table>
<thead>
<tr>
<th>Physiological Parameters</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>&gt; 36°C</td>
</tr>
<tr>
<td>Arterial pH</td>
<td>&gt; 7.2</td>
</tr>
<tr>
<td>Ionized Calcium</td>
<td>&gt; 1.13 mmol/L</td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>80-100 mmHg</td>
</tr>
</tbody>
</table>

**Termination**

Massive hemorrhage protocols can result in the transfusion of large volumes of blood components and products. This puts patients at risk of developing complications such as volume overload, hypothermia, coagulopathy, acidosis, hypocalcemia, hyperkalemia, transfusion related immunomodulation (TRIM), alloimmunization and transfusion reactions (Trudeau, 2017). Although the clinical response team must be careful to limit these complications, the decision to terminate the protocol must not be made prematurely. Premature protocol termination can lead to a decrease in the number of response team members at the bedside or in the frequency of laboratory testing and in the availability of blood components, all of which ultimately increase the risk of failing to adequately resuscitate the patient (Callum, 2019). The decision to terminate the protocol needs be made in a way that balances the negative effects of over-transfusing with the benefits of attaining hemodynamic stability.

The following recommendations should be considered when terminating the massive hemorrhage protocol:

- The response team leader should be responsible for declaring the protocol terminated.
- Termination should be based on clinical judgement and the fulfillment of the following criteria:
  - Bleeding source control has been attained
  - Hemodynamic stability has been achieved
Once termination is declared, Transfusion Services, and any other supporting laboratory services should be promptly notified.

All unused blood components/products and corresponding coolers/containers should be immediately returned to Transfusion Services.

A team debrief of the resuscitation efforts should be held shortly following termination.

- Although, it may not be possible to hold a formal meeting with all team members, those directly involved should be provided an opportunity to ask questions or provide feedback about the resuscitation efforts.

Special Considerations

Hospitals must not only consider their resources when developing local massive hemorrhage protocols, but also the population they serve. The recommendation in this guideline is for individual institutions to have one protocol. However, protocols should provide specific guidance for select patient populations and have the flexibility, to easily meet the needs of specific patient groups.

Furthermore, protocols must examine the quality of evidence supporting treatment options and take into consideration the use of hemostatic control measures that fall outside the accepted standards of care. When best practice use of conventional hemostatic measures fails to control bleeding, alternative control measures are often used as a last resort to save the patient’s life. Protocols should recognize that these deviations occur and provide guidance on “off-label” but indicated use of alternative hemostatic control measures.

The following recommendations pertain to the management of a massive hemorrhage in specific patient populations as well as the use of “off-label” but indicated treatment options that fall outside of conventional standards of care.

Neonatal and Pediatric Hemorrhage

- Transfusion support and hemostatic adjuncts should be provided on weight-based dosing.
- The protocol should state single maximum dosing for all blood components/products and hemostatic adjuncts.
- The protocol should state requirements for appropriately sized equipment.
- The protocol should stress the increased risk for hyperkalemia and hypothermia.
- The transfusion of older RBC and irradiated units > 24 hours should be avoided for neonates and children under the age 2.
Obstetrical Hemorrhage

- Consideration should be given to measuring fibrinogen levels early and repeatedly.
- Consideration should be given to aggressive fibrinogen replacement.
- Consideration should be given to the use of an intrauterine balloon device as a bridge to definitive bleeding control.

Gastrointestinal Hemorrhage

- Caution should be applied to the use of tranexamic acid in gastrointestinal bleeding
- Caution should be applied to the aggressive use of plasma

Cardiac Surgery Related Hemorrhage

- The protocol should stress the use of viscoelastic testing to guide hemostatic support.

Adjunctive Treatments

- Depending on the urgency of treatment and available resources, 2,000 IU of PCC and 4 g of FC may be used as a substitute for coagulation factor (e.g. plasma therapy) replacement in adult patients. This strategy should be viewed as a temporary solution for the correction of coagulopathy prior to transport to a facility capable of definitive hemorrhage control.
- The decision to stock PCC and FC in a facility lacking the resources to store and issue thawed plasma should be based on the patient having access to coagulation support in a reasonable amount of time. Facilities must consider their geographical location and the response time of the transport team when determining if stocking PCC and FC is necessary.
- The use of rFVIIa should only be considered in rare circumstances where there is a reasonable expectation the patient will survive and after all other transfusion and therapeutic measures previously stated have been carried out unsuccessfully.
- Factor VIIa should not be given to patients who are hypothermic or have an arterial pH that is outside a near normal range.
- In the setting of massive hemorrhage, desmopressin (DDAVP) should only be considered in cases involving mild hemophilia A or Von Willebrand’s disease. Apart from these indications, the evidence supporting the use of desmopressin to manage massive blood loss is weak and the risks associated with its use in the setting of massive bleeding are unclear.
- In the presence of life-threatening hypotension and an inadequate response to fluid/volume replacement therapy, a vasopressor may be administered to help maintain target blood pressure.
System Performance Monitoring

Identifying opportunities for improvement in any patient management strategy is a continual task; massive hemorrhage protocols are no exception. Protocol implementation is just the first step to improving the care of massively bleeding patients (Callum, 2019). Tracking and measuring quality metrics during each MHP activation is an important step in ensuring patients receive the best care possible. System performance monitoring provides an opportunity to gauge the protocol’s effectiveness and identify elements that can be improved.

The following recommendations should be considered when developing a MHP quality assurance program or when assessing system performance:

- Protocols should be reviewed at minimum every three years.
- All institutions should have a mechanism in place to evaluate their performance.
- All massive hemorrhages and MHP activations should be tracked.
- At a minimum, the following metrics should be tracked for every activation:
  - The number of RBC, Plasma and platelets transfused during each resuscitation
  - Proportion of patient deaths occurring before the transfusion of 10 RBC units over a 24-hour period
  - Time from activation to when first blood components were dispensed from Transfusion Services.
  - Time from activation to first RBC transfusion.
  - Time from activation to first plasma transfusion.
  - Time required to transition patients to group-specific blood components.
  - Proportion of patients transitioned to group O Rh-positive RBCs.
  - Blood product wastage rates related to MHP.
- At a minimum these metrics should be reviewed bi-annually by a hospital transfusion committee and the provincial massive hemorrhage working group.
- MHP drills should be held on periodic basis especially for locations that experience infrequent activations.

Massive Hemorrhage Guideline Summary

A summary of the treatment steps discussed in the guideline can be found in Appendix A. This summary and can be displayed in high-risk clinical areas, i.e. emergency departments, intensive care units, operating rooms, labor/delivery/recovery unit and blood transfusion laboratories. The summary provides a description of treatment goals, practice steps and utilization of blood components/products during the treatment of massive bleeding.
References


# Appendix A: Massive Transfusion Guideline Summary

| I. Initial Resuscitation and Prevention of Further Bleeding | Initial Management of Bleeding and Coagulopathy  
***  
Identify and treat active bleeding, administer tranexamic acid, provide red blood cells and coagulation support for patients experiencing hemorrhagic shock  
Transport  
***  
Transport directly to an appropriate treatment facility, contact receiving facility to alert of possible MHP activation |
|---|---|
| II. Assessment of Bleeding and Risk of Massive Transfusion | Clinical Assessment  
***  
Assess blood loss using a combination of patient physiology, anatomical injury, mechanism of injury, response to initial resuscitation and objective decision tools  
Protocol Activation  
***  
Alert all relevant team members and departments of MHP activation, provide transfusion services with all pertinent information |
| III. Damage Control Resuscitation | Rapid Control of Bleeding  
***  
Address metabolic derangements caused by ongoing blood loss, limited interventions to only those that are required for source hemorrhage control  
Temperature Management  
***  
Apply measures to reduce heat loss, warm hypothermic patients |
| IV. Hemostatic Resuscitation | Initial Transfusion Management  
***  
Provide care team with plasma and pRBCs in at least a 1:2 ratio, offer platelets when available, ensure fibrinogen concentrate is available early in resuscitation  
Reversal of Antithrombotic Agents  
***  
Reverse vitamin K antagonists and Factor Xa inhibitors with Prothrombin Complex Concentrate, and direct thrombin Inhibitors with Idarucizumab |
| V. Goal-Directed and Result Guided Transfusion | Testing  
***  
Perform CBC, PT/INR, fibrinogen (when on-site testing is available), blood gas, lactate, electrolytes, creatinine and ionized Ca²⁺ testing every 30 - 60 minutes  
Resuscitation Targets  
***  
Continue resuscitation using a goal directed strategy guided by standard laboratory values and/or viscoelastic tests |
| VI. System Performance Monitoring | Protocol Assessment  
***  
Track quality metrics for every protocol activation, review metrics bi-annually and protocol every three years  
Simulation  
***  
Periodically conduct mock MHP drills, provided team members an opportunity to ask questions and offer feedback about the protocol and resuscitation efforts. |
Appendix B: Massive Transfusion Working Group

The Nova Scotia Provincial Blood Coordinating Team (NSPBCT) acknowledges the tremendous and diligent work of the provincial MTWG for providing valuable expertise and contributions in the development of this guideline.

<table>
<thead>
<tr>
<th>MASSIVE TRANSFUSION WORKING GROUP</th>
</tr>
</thead>
</table>
| **Dr. Blaine Kent**               | Chief, Division of Cardiac Anesthesia  
Surgical Director, Perioperative Blood Management Program QEII  
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IWK Transfusion Services |
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| **Dr. David Conrad**              | Acting Head, Division of Hematopathology  
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| **Dr. Frank Cragg**               | Medical Director Transfusion Services  
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| **Dr. Robert Green**              | Medical Director of Trauma  
Nova Scotia Trauma Program |
| **Dr. Robert Liwski**             | Medical Director of the HLA Laboratory  
Nova Scotia Health Authority, Central Zone |
| **Dr. Samuel Minor**              | Associate Professor General Surgery, Critical Care  
QEII Health Sciences Centre  
American College of Surgeons Committee on Trauma Chair for the Maritime Provinces |
| **Mr. Michael Farrell**           | Utilization Management Coordinator  
Nova Scotia Provincial Blood Coordinating Team |
| **Ms. Emily Durant**              | Transfusion Practice Nurse  
Nova Scotia Provincial Blood Coordinating Team |