Emergency framework for rationing of blood for massively bleeding patients during a red phase of a blood shortage

Working group on emergency disposition of blood during a red phase blood shortage

National Advisory Committee on Blood and Blood Products | Comité consultatif national sur le sang et les produits sanguins

2012-04-14

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Section 1 - Purpose

When the original version (dated 2009-09-28) of the *National Plan for the Management of Shortages of Labile Blood Components* was sent out for external consultation, it was criticized because it did not include a plan for patients requiring massive transfusion. Many examples cited were the lack of preparedness for Hurricane Katrina and although best intentions on behalf of the decision makers present, many inappropriate decisions were made. This document is the first attempt to address this deficiency in the National Blood Shortages Plan. This document was prepared by a multidisciplinary group with a broad range of expertise (See Appendix C). This document was developed to guide healthcare professionals in triaging patients in need of massive transfusion during a red phase blood shortage, where demand for blood greatly exceeds supply, and where all other measures to increase the supply of blood have been exhausted. The definition of a red phase for red blood cells is that there is less than 48 hours worth of red blood cell (RBC) units available in Canada and there is no foreseeable ability to avert the shortage by increasing collections or by reducing elective surgical procedures further. This document is intended to guide all transfusion rationing decisions made in the red phase in Canada for patients predicted to need massive transfusion due to massive hemorrhage (defined as expected blood loss of one blood volume over less than a 24 hour period; 0.5 blood volume in 3 hours; or four or more units of red blood cells in one hour). This tool applies to all decisions regarding all blood components (red blood cells, frozen plasma, and platelets), although it is expected that red blood cells will likely be the product in greatest scarcity, since in massively bleeding patients there are no available alternatives to red blood cells. The triage tool is designed to assist with standardizing care across all jurisdictions to allow for fair and just distribution of blood during a red phase.

Section 2 - Background

A) Blood Inventory Management in Canada 2004-2010

The availability of blood for transfusion has not been limited by supply and patients receive transfusion as deemed necessary by their physicians. Transfusions are administered knowingly to brain dead patients while awaiting decisions to be made regarding eligibility for organ donation. A core concern with the management of patients requiring massive transfusion in a blood shortage is that a single patient with a very poor chance of survival could potentially consume 10 or more units of blood that could be alternatively diverted to save other patients with a much better chance of survival.

Between April 2004 and March 2009, Canadian Blood Services averaged 17,372 RBC units in inventory across the country, with the target of 5 days or more on hand (>15,425 units on hand). During this time period, there was 1 day when inventory dipped below 10,000 units, 10 days below 11,000 units, and 38 days below 12,000 units. Hence, only 2.5% of the time (out of a total of 1500 days measured) did the inventory level drop below 12,000 units in Canada (<4 days on hand). On all but one occasion Canadian Blood Services was able to reverse the decline in inventory by increasing collection of blood. On one occasion, it was also necessary to issue a public appeal to donors in the face of double the usual growth in demand. In addition, Canadian Blood Services pro-actively ramps up collection activities to build inventories prior to anticipated

blood shortages, such as was done in preparation for the H1N1 pandemic influenza outbreak in 2009. Since the development of the *National Plan for the Management of Shortages of Labile Blood Components*, there has never been an amber or red phase declared (personal communication, Mr. David Howe, Canadian Blood Services).

In the Province of Quebec, since 2004, Hema-Quebec has maintained approximately 5700 RBC units in inventory, corresponding to an inventory of 8 days. This allows Hema-Quebec to meet the needs of the 98 hospitals throughout the Province. From April 2004 to March 2009, the daily inventory fell below the optimal target of 8 days for a total of 13 days: 2 days below 3600 RBC units (less than 5 days), 2 days below 3900 RBC units (less than 5.5 days) and 9 days below 4600 RBC units (less than 6.5 days). All these events occurred in 2004 and 2005. The inventory was maintained at its optimal level continuously for all blood groups from 2006 to 2009. However, Hema-Quebec is monitoring the demand for O negative RBC units which has increased from 10.8% in 2004 to 12.6% in 2011. Hema-Quebec has developed a recruitment process adapted to the level of inventory to prevent it from falling below its optimal target. (Personal communication, Mrs Sylvie Thibault, Hema-Quebec).

It has been predicted that as the proportion of the population over age 65 years increases over the next 4 decades, that our blood supply could become seriously compromised due to insufficient donors. Between 2010 and 2050, the per capita use of blood is expected to rise from current levels of 31 per 1000 to 65 per 1000 population.(1) In addition, in the same time period, the blood dependency ratio is expected to increase from 0.60 to 0.95 (the number of age non-eligible donors each age eligible donor will have to support, in addition to their own needs).

B) Effectiveness of screening during an acute blood shortage

There is very little known on the effectiveness of screening orders for transfusion and cancelling surgery during a blood shortage. No work as yet has been done on rationing of blood components to massively bleeding patients. Galloway et al (2) reported on the yield that would be achieved with the implementation of an emergency blood contingency plan during a blood shortage. They simulated the impact of enacting the National UK Blood Shortage Plan over a 21 day period with a table top exercise. They estimated after retrospectively reviewing 661 elective surgeries that they would have cancelled a mere 22 operations, of which only 7 required blood. In addition, 22 non-surgical anemia patients would have been managed without transfusion and 34 bone marrow failure patients could have had their transfusions delayed by 2 to 7 days during a short-term shortage. Overall, the savings were minimal compared to a total of 251 patients transfused during their 21-day audit period.

C) Examples of non-transfusion triage protocols

Most of the literature on resource rationing frameworks during scarcity comes from the critical care and public health spheres addressing response to pandemics. Christian et al. reported in the Canadian Medical Association Journal in 2006 the Ontario triage protocol for critical care during an influenza pandemic.(3). This triage tool was developed by a multidisciplinary team

(critical care, infectious diseases, military medicine, disaster medicine, and triage management) after an extensive literature review and broad consultation process. The key parts of this triage protocol include a colour-coded triage tool, inclusion criteria, and exclusion criteria. The authors chose the SOFA score because it assesses daily organ dysfunction, uses simple physiologic and laboratory parameters, is easy to calculate and has been widely validated (see Table 1) (4) The SOFA score cut-off (>11 points) was set for a predicted mortality rate of 80%. Their exclusion criteria includes, but is not limited to, severe trauma and burns, advanced disease states, cardiac arrest, end-stage organ failure and elective palliative surgery. (5) Christian et al (3) had not included age as an exclusion criterion however, the authors received strong and consistent feedback from stakeholders and during expert consultation that an age criteria should be included in the exclusion criteria. An age criterion of 85 years was chosen.

Similar exclusion criteria were used by Devereaux et al in a triage tool for allocation in mass critical care in 2008 (6) and the Utah Department of Public Health triage tool. (7) Devereaux also added the following additional exclusion criteria: SOFA score >15, SOFA >5 for more than 5 days with a flat or rising trend, $\geq$6 organ failures, and advanced or irreversible neurological event or condition (6). The triage tool categorizes patients into 4 colours (blue, red, yellow and green). Patients with a poor chance of survival were designated 'blue' and critical care resources are not to be allocated to these patients. Patients with the highest chance of survival were designated 'red' and critical care resources were prioritized to these patients. Patients designated 'yellow' were next on the priority list, followed by 'green' patients who are to be deferred or reassessed as needed. These investigators also required prioritization reassessment at 48 and 120 hours.

Devereaux et al detailed the results of a Task Force for Mass Critical Care Summit Meeting that occurred in January of 2007.(6) They also utilized inclusion and exclusion criteria as detailed above. Patients meeting these criteria were subjected to daily reassessments of the inclusion and exclusion criteria. Patients were prioritized by SOFA score. They listed four reasons why resources may be re-allocated, even for patients meeting the inclusion/exclusion criteria, given the available resources at the time of triage, including: 1. Patients with the highest SOFA scores or a SOFA score that is rising or flat; 2. A high degree of patient acuity with poor chance of survival and a likely long duration of critical care resources; 3. A moderate degree of acuity but a prolonged duration of critical care resource needed; 4. Severe underlying chronic illness in conjunction with any of the above factors leads a decision maker to feel the prognosis is poor, and/or the patient's duration of critical care will be prolonged. Their document also included key recommendations, including but not limited to: 1. All hospitals must operate uniformly and cooperate in order to successfully implement a triage process; 2. Patients not eligible for critical care will continue to receive supportive/palliative medical care; 3. The task force suggests that a triage officer and support team implement and coordinate the distribution of scarce resources; 4. Providers should be legally protected for providing care during allocation of scarce resources when following accepted protocols.

The Utah Department of Public Health triage tool for hospital and ICU triage for adults and children is very similar to the above two triage protocols. (7) It utilizes exclusion criteria and the

modified-SOFA (M-SOFA) score to triage patients. (8) The M-SOFA score does not require a platelet count or bilirubin result to apply, making it somewhat easier to use, although the creatinine and arterial oxygen saturation are required.

D) Validation of non-transfusion triage tools

There are no publications detailing the validation of transfusion triage tools. The following studies describe the extent of the literature on the validation of triage tools for other aspects of medical care. Christian et al performed a retrospective validation of their triage tool for critical care resources. (5) The objective was to determine the usability of the Ontario triage protocol. (3) Four triage officers retrospectively reviewed consecutive patients admitted to two ICUs during an 8 week period. Each patient was triaged as per the colour coded prioritization tool. Each patient was triaged separately by two triage officers and where there was a disagreement; arbitration was used to resolve the discrepancy. Overall, 234 patients were included in the cohort, of whom 39.7% met the exclusion criteria and would have been triaged to expectant or palliative management. Of the 65 patients triaged to expectant management, only 24.6% survived to discharge. The most common exclusion criteria triggering a triage to this category in those patients who survived to hospital discharge was the presence of metastatic cancer. The triage tool was able to reduce the demand for ventilators by 49.3%. Arbitration was required in 54.9% of the cases, however, the majority of cases requiring arbitration related to a single triage officer, suggesting that not all clinicians will be able to function as triage officers. Overall, their triage tool performed well in this retrospective study.

Guest et al in an observational cohort study utilized the Ontario triage protocol (3) in a 26 bed ICU in the United Kingdom over a 2 month period.(9) The only modification to the triage protocol was the 'severe trauma' exclusion criteria was modified to 'a trauma with a TRISS (Trauma Injury Severity Score) score predicting >80% mortality'. Overall, 29 patients were triaged to palliative care. Of these 29 patients, only 10 (34%) survived to discharge. In comparison, of 20 patients triaged to highest priority, 75% survived. They concluded that the triage tool did not perform well enough to triage ICU resources. One of the limitations to this report is the lack of 6-month follow-up for detailing survival of patients with metastatic cancer. Since patients with metastatic cancer would be triaged to palliative care because of a predicted poor 6-month survival, not in-hospital survival. Clearly in follow-up studies longer term survival will be a key variable.

Kahn et al evaluated the 'Simple Triage and Rapid Treatment (START)' tool in a retrospective analysis of a commuter train massive casualty event involving 265 patients.(10) Overall, 163 patients required triage, of whom 148 patient charts were sufficiently complete for inclusion in the analysis. Their objective was to determine the proportion of patients who were 'over triaged' and 'under triaged' with this triage tool, compared to the goal standard modified Baxt criteria (patients needing emergency procedures or care). They found considerable 'over triage'. Of 22 patients triaged to 'red' requiring emergency intervention, only 2 were retrospectively considered 'red'. Overall, the tool performed poorly.

E) Limitations of the existing literature

Currently, allocation frameworks are primarily based on expert opinion and disease scores that were not designed for the purpose of rationing. Many frameworks have not been prospectively validated and others performed poorly in prospective validation studies. Utilization of scoring systems, such as the SOFA score, have been criticized for needing the results of laboratory testing, which may be unavailable in a disaster or not available in a timely fashion, and this is particularly relevant to massive transfusion.

Section 3 - Framework Development

The individuals involved in the development of this draft framework are listed in Appendix C. The working group members had broad expertise to provide input on the vast majority of patients at risk for massive transfusion. The group was convened in 2009. The working group members were from large tertiary care centres in Canada and have expertise in transfusion medicine, trauma, anesthesiology, heart/lung/liver transplantation, obstetrics, cardiovascular surgery, allied health, medical ethics, law and methodology. The group also included members of the National Advisory Committee on Blood and Blood Products. The group did not include patient representatives.

The group identified salient clinical questions to guide the systematic search for the rationing of blood for massively bleeding patients during red phase blood shortages. Massively bleeding patients were identified as patients undergoing heart/lung/liver transplantation, patients with trauma, gastrointestinal hemorrhage, ruptured aortic aneurysm, obstetrical patients, and patients requiring ventricular assist devices or extracorporeal membrane oxygenation.

A systematic search of the Medline, Cochrane Central Register of Controlled Trials, EMBASE and In Process databases until September 2009 and a bibliographical search was used to generate recommendations. The search strategy focused on predictors of massive blood loss and predictors of mortality, ethical frameworks, and allocation protocols to guide the working group in the development of this document. The full search strategies from Medline and inclusion and exclusion criteria are illustrated in Appendix G.

Face to face meetings, teleconferences and electronic correspondence were used to generate recommendations. Recommendations were developed based on the best evidence available. The levels of evidence and grading of recommendations were adapted from the Canadian Task Force on Preventative Health Care (available at www.canadiantaskforce.ca). Areas of disagreement were resolved through consensus verification with all working group members.

National and International experts, professional societies and patient representatives were asked to review the recommendations to validate their relevance. Refer to Appendix D for the results and findings from the stakeholder consultation. This framework and its recommendations is supported by the working group members, members of the National Advisory Committee on Blood and Blood Products, Canadian Blood Services (via the National Emergency Blood Management Committee), and is currently pending support from the Provincial and Territorial Ministries of Health including the Deputy

and Ministers of Health. The intention is for this framework to be implemented as a supplement to the existing *National Plan for the Management of Shortages of Labile Blood Components* and will be disseminated to all physicians involved in the treatment of patients requiring massive blood transfusion in Canada.

This framework will require prospective validation after publication in massively bleeding patients to ensure: 1. Adequate inclusion of the vast majority of massively bleeding patients; 2. Its ability to identify patients with poor in-hospital and 6-month survival; 3. Its value and usability to the triage teams; 4. The ability of the tracking logs to capture the necessary data for evaluation of the framework; 5. Its ability to curtail the use of blood components to reduce utilization.

Section 4 - Red Phase Blood Shortage

The *National Plan for the Management of Shortages of Labile Blood Components* describes four phases of blood shortage: green (supply generally meets demand), amber (blood inventory is insufficient to continue usual transfusion practice; e.g. high blood loss surgeries must be delayed), red phase and recovery phase. The National Plan for blood shortages was developed by a multidisciplinary team and is posted on the National Advisory Committee on Blood and Blood Products' website (www.nacblood.ca). A red phase implies that blood inventory levels are insufficient to ensure that patients with non-elective indications for transfusion will receive the required blood. During the amber phase, patients requiring massive transfusion will receive standard medical care. During the red phase, it is anticipated that there will be insufficient blood to support all patients. An amber or red phase blood shortage will only be declared when all strategies for increasing blood collections have been exhausted. Patients not requiring large amounts of blood components will be managed with increasing restrictive strategies. For example, in the red phase, all red cell transfusions for hemoglobin levels in excess of 70 g/L will be deferred until the recovery phase of the blood shortage. However, patients presenting with significant hemorrhage or those that the attending physician, on the basis of their clinical acumen, determines may require large amounts of blood components will be triaged according to this framework. The current National Plan for blood shortages does not stipulate how to triage patients in need of massive transfusion when there is insufficient blood to continue usual transfusion practices.

Section 5 - Levels of Triage

There will be several levels of rationing of blood components across Canada that will occur in a blood shortage. These are defined in this document as primary, secondary and tertiary triage. Primary triage refers to National redistribution of blood components between Canadian Blood Services centres across Canada. There needs to be fair, equitable, and transparent distribution of blood components at this level during a shortage. This has been termed 'macro-rationing' in the literature.(11) Secondary triage refers to fair, equitable, and transparent distribution of blood components from a blood centre to the hospitals it serves. Lastly, tertiary triage refers to the rationing of blood components to individual patients at the hospital level. Allocation at the patient level is termed 'micro-rationing'. This document refers primarily to tertiary triage, but the overall strategy requires that primary and secondary triage processes are in place in Canada. Although most of the complicated triage decisions will be made at the patient level, to

be fair and equitable, such decisions must be part of a National coordinated effort at all triage levels. All individuals involved in primary, secondary and tertiary triage must be committed to complying with the *National Plan for the Management of Shortages of Labile Blood Components* to ensure fair and equitable access to blood components during a blood shortage across all jurisdictions in Canada.

Section 6 - Ethical Issues

Resource rationing is one of the most challenging ethical issues faced in health care. Rationing frameworks (triage tools) raise numerous ethical concerns about the decision-making process used to ensure a fair and just distribution of scarce resources when the demand for health care exceeds the available resources. From an ethics perspective "fairness" is the key goal of any resource allocation exercise; however, the determination of what constitutes a fair rationing process is a matter of debate. Should the sickest be given priority over the most urgent? Should resources be allocated to achieve the most benefit for the greatest number or for the larger benefit to a small number? Ultimately these are value-based decisions for which no overall consensus exists among stakeholders.

The working group was assigned the formidable task of developing a resource rationing strategy (triage tool), dealing specifically with patients requiring massive transfusions during the red phase of a blood shortage. At the initial Working Group meeting in December 2009, the ethical framework: Accountability for Reasonableness (A4R) was presented and approved as the preferred approach that would best serve to guide the working group by fostering conditions for the development of a fair decision-making process.(12)

The A4R framework is composed of conditions that describe an open, practical and transparent priority setting process that can incorporate the relevant range of decision-specific contextual factors (frequently determined based on best evidence), encourages appropriate engagement from stakeholders, and supports public accountability for managing limited resources.(13)

The five conditions (14) of the A4R framework, which served to direct the Working Group deliberations, were:

1. Relevance: Decisions should be based on clear and explicit reasons and the collection of relevant and accurate data.
2. Publicity: The decisions and their rationales should be made publicly accessible as part of formal communication plan.
3. Revision: There should be opportunity to revisit criteria developed as part of a preliminary prospective analysis and post red phase critical review.
4. Empowerment: The plan will be circulated extensively to ensure effective participation of all affected stakeholders.
5. Enforcement: The plan will be endorsed by the National Advisory Committee on Blood and Blood Products, Provincial and Territorial Ministries of Health including the Deputy and Ministers of Health, and be used across the country in parity.

Ultimately the goal of any triage tool is to support decision-making by detailing a procedure for making triage decisions that protects the community by maximizing benefits and minimizing harms. In development of this triage tool, the working group outlined that any system of resource rationing must be evidenced-based and prospectively validated in advance of the disaster or resource shortage. Input should be sought from relevant stakeholders and the content should be publicly debated. The content and recommendations of the triage protocol should be endorsed by stakeholders from the major medical societies involved. There should be transparency in the aims and procedures involved in the document development process to prevent misunderstanding or mistrust. The triage process should protect patients against ethnic, racial, and socioeconomic inequity. Individual physicians, administrators, and patients should not be able to overturn a triage decision in compliance with the triage process. A contemporaneous appeals process for the rationing of blood during massive bleeding is impractical, where decisions must be made within minutes of the onset of hemorrhage. The appeals process for this document will be replaced by wide stakeholder consultation, extensive layperson input, and review of triage decisions by the Hospital / Regional and the National Emergency Blood Management Committee in the event of a red phase blood shortage. 'Ad hoc' departures from the process are inadvisable and will lead to inequitable access to blood components across the country. Clinicians or institutions who decide to depart from the triage tool could lead to adverse outcomes for patients with a high probability of a good outcome, should the blood inventory be depleted by widespread administration of blood to patients with very poor predicted outcomes.

The working group reviewed a number of principle-based decision-making criteria (see Table 2) and considered each in the preparation of the primary triage plan and the supplemental criteria which will be used for rationing patients needing massive transfusion. As result of this deliberation, the working group felt that no single principle was sufficient to incorporate all morally relevant considerations when dealing with massive transfusions, and so the overall triage plan includes consideration of a number of ethical principles: first come/ first served and maximization of the numbers of life years saved (usually the youngest first). Additionally, the working group also focused on the creation of a decision-making process that relied on a fair process (procedural fairness) to establish the ethical legitimacy of any resource allocation decision. Table 3 outlines the procedural values which guided the working group's review of the available data and literature as it related to the development of the inclusion and exclusion criteria for a triage tool. This procedural fairness was met by widespread consultation within the health care sector and with laypersons (see Appendix D).

Age was initially included in the triage tool as a variable, similar to the Ontario ICU triage protocol (3). Age based rationing is controversial.(15-19) Age was included in the tool to allow for incorporation of the ethical principle of maximizing the 'life-cycle' opportunity of every individual. This principle is based on the belief that each person should have his or her own fair chance at 'fair innings' in life and to live through most stages in life. The working group proposed an age limit of 80 years as the overall exclusion cut-off as this represents the approximate median survival of adults in Canada. However, in the stakeholder engagement, the working group reviewed considerable feedback expressing concern over this criterion and a specific general age criterion was removed as an overall exclusion criteria.

Section 7 – Alternatives to Blood Transfusion

Patients for whom the decision is made not to allocate a certain resource must be offered all available therapies, including palliative care where appropriate, and be treated with dignity. In the case of transfusion, a patient not allocated to transfusion must be offered all non-transfusion therapies available and blood conservation strategies/alternatives. Blood conservation strategies should include any or all of the following: erythropoiesis-stimulating agents, intravenous / oral iron, antifibrinolytics, intraoperative cell salvage, interventional radiologic procedures, rapid access to endoscopy, and non-invasive surgeries. Palliative care should include pain and symptom relief, spiritual and psychosocial support.(20) In addition, continued monitoring of all assessed patients at regular intervals is required to re-assess eligibility in the event that clinical indicators suggest a need to re-triage the patient to active transfusion management.

Section 8 – Gastroenterology

The majority of patients admitted to hospital with a gastrointestinal (GI) hemorrhage do not require transfusion, with one series reporting only 23.3% of patients requiring one or more units.(21) In case series of patients undergoing massive transfusion, GI hemorrhage accounts for 21% to 31% of all massive transfusions.(22)(23) In a case series of 100 episodes of 'massive upper gastrointestinal hemorrhage' (which was defined as at least 2 units of blood, >1000 ml of estimated blood loss, and hemodynamic instability) the most common causes for bleeding were: varices (30%), duodenal ulcer (20%), and gastric ulcer (18%).(24) The mortality rate in this series for patients that required admission was 70% and overall the patients received a mean of 16 units of RBC (non-survivors received a greater number of units - mean 27 units). Hence, this triage process will apply to a highly selected group of gastrointestinal bleeding patients with a very poor chance of survival. The vast majority of GI bleed patients will be managed as dictated by the National Blood Shortages Plan and will not require triage as per this document.

Section 9 - Pediatrics

The ethical issues surrounding rationing in children are very complex and have been reviewed recently by Kanter and Cooper.(25) Their review calls for more work to be done before we will be ready to ration health care resources in pediatric patients (i.e., age less than 16).

The working group strongly recommended that triage priority at the level of the blood supplier should be given to pediatric institutions to ensure adequate supplies are maintained at these hospitals, since most children will meet the criteria for continued transfusion support.

Section 10 – Transplantation

Prior to a red phase blood shortage being declared (preferably as a green phase activity), all organ transplant centres across Canada in jurisdictions serviced by Canadian Blood Services should collate data regarding the rate of transfusion for specific transplant procedures. Having data on the current rates of transfusion for each procedure (pre, during, and post-transplant), readily available will allow for

transplant procedures to be categorized as high versus low risk for transfusion. Knowing the risk of transfusion for each transplant procedure will aid in individualizing the informed consent discussion with the patient to determine the risks of proceeding or not proceeding with a transplant procedure during a red phase blood shortage.

Section 11 - Legal Implications

Patient implications: During a red phase blood shortage, patient access to blood components will be limited by supply. The clinical triage team must ensure that all measures are taken to ensure individual patient rights are respected and patients are given access to all available medical therapies to ensure the best possible outcome, given the circumstances. In this setting of altered standard of care, however, some transfusion limitations may be placed on certain patients as dictated by the triage tool and the availability of blood.

Provider liability: To date none of the existing Canadian triage frameworks for allocation of resources during a pandemic have had to withstand the rigorous dissection in the court room during a legal proceeding. Triage plans attempt to fairly and impartially provide every person the opportunity to survive, however, they do not guarantee either treatment or survival. To remain fair and impartial, triage plans reduce the autonomous clinical judgment authority afforded healthcare facilities and providers. While some people will not receive all the care (in this case, transfusion) that they could possibly need, this does not by default make triage an unfair or negligent process. Healthcare facilities and providers who deliver care in accordance with the triage tool are considered by National / Provincial / Territorial Emergency Blood Management Committees as to have provided the best possible care in this setting of altered level of care. Healthcare facilities and providers have a duty to use a degree of care and skill which is expected of a reasonably competent facility/provider, acting in the same or similar circumstances. Triage decision makers at local/patient level are not however accountable for validating the ongoing quality of evidence utilized to derive this triage tool, including its inclusion and exclusion criteria. Those facilities and providers who utilize this tool in good faith and in a competent manner, should not be found negligent for triage decisions dictated by this is tool.

Section 12 - National Emergency Blood Management Committee

The National Emergency Blood Management Committee (NEBMC) is comprised of transfusion medicine experts from the National Advisory Committee on Blood and Blood Products, members from Canadian Blood Services, blood recipient representation, and Provincial and Territorial Ministry Representatives. This group will be convened in the event of a possible National blood shortage to provide guidance on the need to call an amber or red phase. In the event of an amber or red phase, this group will provide guidance to the Provincial and Territorial Provincial Emergency Blood Management Committees (P/TEBMC) on blood management issues. The NEBMC will dictate in a red phase when this massive transfusion rationing framework is required. In addition, in extreme red phase blood shortages, the NEBMC may be required to adjust the framework for the following variables: 1. Disease severity score cut-offs (e.g., MELD score – see below); 2. Re-assessment level (currently set at every 10^{th} unit of red blood cells transfused – see below). Following the recovery phase, the NEBMC will be required to review

the Provincial and Territorial data on triage decisions to determine if modification to the framework or tracking tools will be required. A brief report from the NEBMC to the National Advisory Committee on Blood and Blood Products should follow every red phase use of this framework. For further information, refer to the *National Plan for the Management of Shortages of Labile Blood Components.*

Section 13 - Communication Plan

The *National Plan for the Management of Shortages of Labile Blood Components* includes an Appendix detailing the communication plan for blood shortages in Canada. The communication plan covers the notification of the general public via media releases and direct communication to hospitals, health care practitioners, and transfusion recipients via Provincial and Territorial Ministries of Health. In the event of a red phase where the NEBMC declares that this framework is required, its use will be included in the communication documents to individuals as listed above. This communication is critical to ensuring that the need for blood rationing for massively bleeding patients in a red phase is openly disclosed to the public, all hospitals, health care practitioners, and patients. This communication plan can be found in the National Blood Shortage Plan at www.nacblood.ca .

Section 14 - Triage Team

It is recommended that triage teams be established in advance of a shortage. The role of the triage team is to provide a structure that formally oversees the triage process be it provincial /regional or at the hospital level during a crisis. The triage team should receive comprehensive information on the triage framework in advance of a blood shortage being declared. The triage team must be a multidisciplinary team with adequate background knowledge in terms of patient triage and managing patients under a 'crisis standard of care'.

14.1 – Membership

The triage team should be comprised of any of the following and be appointed by the regional/hospital transfusion committee or regional/hospital emergency blood management committee (the number of team members should be proportional to the transfusion volume of the institution or region):

1. Triage Team Leader. The triage team leader should be an experienced physician with familiarity in triaging critically ill patients, broad based knowledge of resources and capabilities of healthcare organizations. The triage team leader will have final responsibility and authority over clinical decisions.

2. A Management Representative. A management representative is required to provide guidance on the capability of the organization regarding resources, personnel, external support, and internal and external communications.

3. An ethicist.(26)

4. A nursing supervisor to provide direction on alternate care.

5. Representative from the emergency room, trauma, transplantation, cardiovascular surgery, gastroenterology, and obstetrics to provide updates on demand, impact and assist in decision making.

6. Palliative care nurse or physician for patients not triaged to receive blood.

7. Social worker.

8. Chaplain.

9. Medical laboratory technologist.

In addition, the triage team leader should have another triage physician available to them for assistance with decision making for difficult cases. The regional/hospital transfusion committee or Regional/Hospital Emergency Blood Management Committee should appoint members of the triage teams with the number of individuals proportional to the transfusion volume of the institution or region. It will be the responsibility of the triage teams to report back to the transfusion committee or emergency blood management committee all triage decisions made.

The triage teams must be educated on the background information and how to apply the triage tool in advance of a blood shortage. The responsibility for education of physicians and triage teams rests with the Regional Emergency Blood Management Committee in collaboration with the Hospital/Regional/District Health Authority. Specific training at dedicated intervals is difficult to achieve as there is varying frequency with which simulation exercises occur, the level of involvement of various medical services during a simulation and a large turnover of physicians throughout the system. However, through simulation exercises, continuous education, and dissemination of the National Blood Shortages Plan and this emergency framework, physicians would be more inclined to align with the National Blood Shortages Plan to ensure all patients receive quality levels of care during a shortage. Post simulation reporting may provide the best training opportunities in that lessons learned can be addressed at the Medical Advisory Committee level. Training and development modules should occur in collaboration with Canadian Blood Services as they will be instrumental in invoking the National Blood Shortages Plan. A core part of this pre-shortage education should clearly focus the triage team on their role in ensuring the best care for the community of patients that they serve, rather than the needs of individual patients.

14.2 - Responsibilities

The responsibilities of the triage team are to ensure

- documentation of the state of emergency (i.e., that an emergency has been activated, that all existing resources are exhausted, the rationale for withholding transfusion, and that all supportive care and blood conservation strategies will be instituted);

- documentation of inclusion/exclusion criteria;

- adherence to decisions and alternate levels of care;

- efficient and regular re-evaluation of patients;
- reevaluation of triaged patients daily and every 10th red blood cell transfusion;
- physicians receive the required assistance; and,
- the public receive information about the status of the emergency and where to obtain further information.

14.3 - Implications

The triage team should not be directly involved in the care of the patient. The triage team assigned to allocate blood components needs to be clearly cognizant that their duty is to the population, not just to the individual patient. The triage teams should be blinded to identifying patient information when presented with clinical information in determining if a patient is eligible to receive transfusion as per the triage criteria. It is suggested that the triage team convene in an area not within the immediate vicinity of the patient bedside. Typically given the acute and emergent nature of the presenting cases, it is anticipated that there will be no ability to manage an appeals process in the middle of the mass casualty situation or other disaster. In addition, decisions during a massive hemorrhage must be made within minutes and therefore a formal appeals process is not clinically feasible as such the triage decisions must be final with no appeal process. The triage teams should be offered adequate administrative and psychological support.

There must be sufficient coverage of the triage team to allow for 24 hour coverage. The triage team decisions need to be reported daily to the Regional/Hospital Emergency Blood Management Committee to ensure 'over triage' and 'under triage' errors are minimized. Consideration needs to be given by the hospital of having a joint intensive care and transfusion triage teams, where possible, to maximize the use of resources. The triage decisions need to be transparently communicated to the patient, the patient's family, the clinical team caring for the patient and recorded clearly in the patient's chart. Patients should be re-assessed at a minimum of daily, every 10th unit of red blood cells, or sooner if their clinical status improves or deteriorates substantially prior to 24 hours.

In the setting of a scarcity of multiple hospital resources, the blood triage tool should be utilized sequentially with the other rationing tools. It is possible that a blood shortage may occur as an isolated event or in the setting of multiple resource scarcity (e.g., ventilators or critical care beds). In the setting of an isolated blood shortage, all other available therapies, including blood conservation strategies, should be offered to all patients. In addition, ensuring pain and symptom management should be a core part of the triage team's oversight responsibility so that patients and their families do not feel abandoned.

14.4 - Documentation

Clear and complete documentation will be essential for a complete patient record and for evaluation after the red phase. In the patient chart, the triage team shall document the following: phase of blood shortage, triage decision, reason for exclusion if applicable, date/time of next planned re-evaluation, a copy of the triage documentation tool, and the number to page if the clinical status of the patient substantially improves or deteriorates before the next planned re-assessment. Extensive clinical notes will not be possible, or appropriate, as the triage team will be required to triage multiple patients. Documentation can be delegated to any member of the triage team and need not be done by the triage physician. Documentation on the triage documents should include a triage tracking log of all cases and a triage sheet for each patient. Efforts should be made to be as complete as possible to allow for the best possible review of triage decisions after the resolution of the red phase. At the end of each shift, a copy of the documents should be given to the chair of the Regional/Hospital Emergency Blood Management Committee, or their designate, and the original documents given to the next triage team with appropriate verbal handover. At the completion of the red phase, copies of all triage tools should be forwarded to the Provincial Emergency Blood Management Committee for review and analysis.

Figure 1 – Algorithm for the Triage Team (page 1)

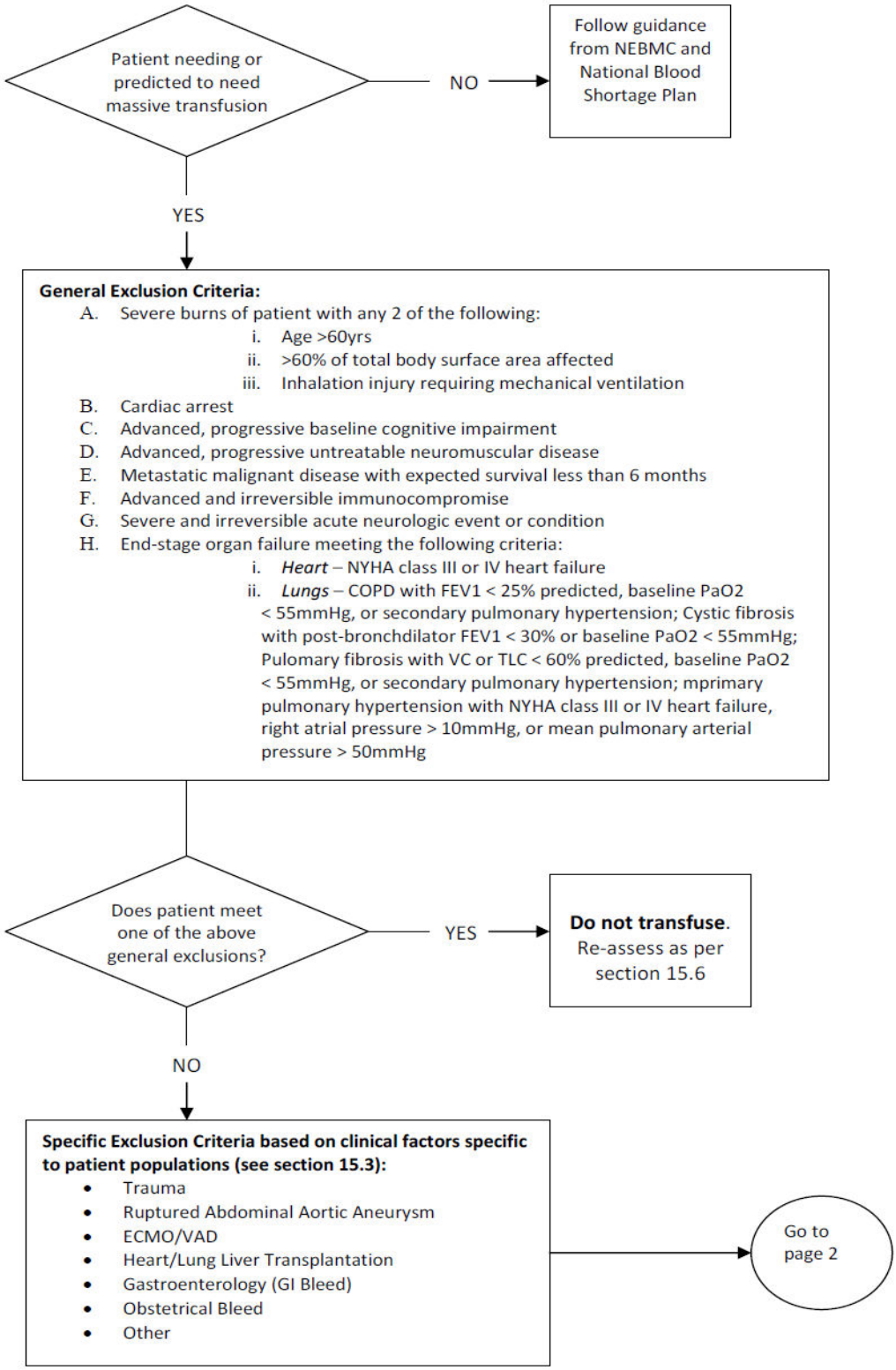
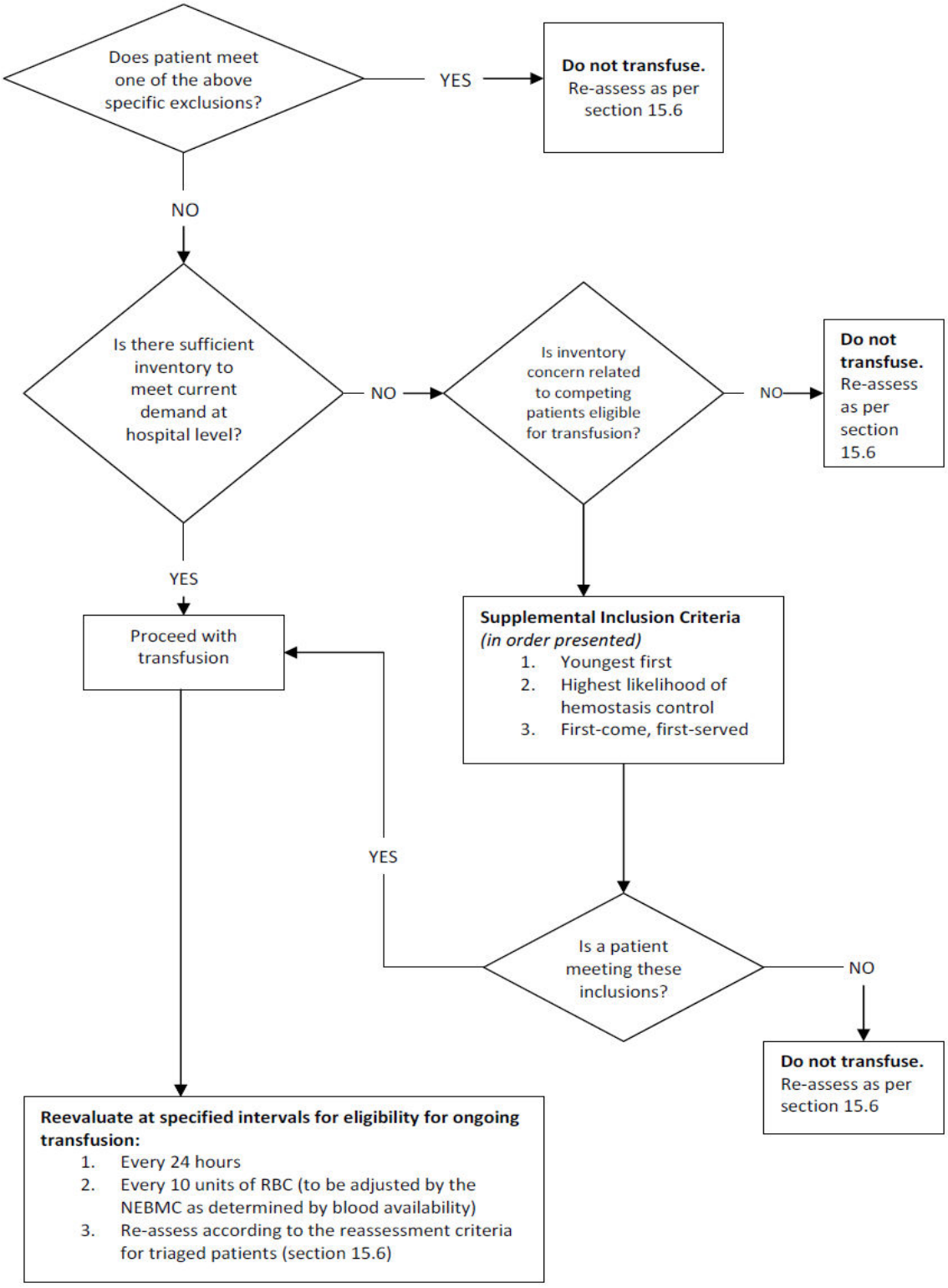


Figure 1 – (page 2)



Section 15 – Recommendations

The emergency framework for rationing of blood for patients predicted to need massive transfusion

Goal: To provide blood transfusions to Canadians in an ethical, fair, and transparent way to ensure that the greatest number of life years are saved and to minimize the suffering and maximize the use of blood alternatives for those who are triaged to no transfusion due to insufficient availability of blood.

15.1 - Inclusion Criteria: All patients needing or predicted to need massive transfusion due to massive hemorrhage (defined as expected blood loss of one blood volume over less than a 24 hour period; 0.5 blood volume in 3 hours; or four or more units of red blood cells in one hour) during a red phase blood shortage.

All patients should receive access to all available blood conservation strategies including but not limited to:

- Thrombopoietin mimetics, erythropoiesis-stimulating agents, intravenous/oral iron, antifibrinolytics, intraoperative cell salvage, interventional radiologic procedures, rapid access to endoscopy, and non-invasive surgeries.

15.2 - General Exclusion Criteria (adapted from Table 3):

Note: These general exclusion criteria only apply to patients needing massive transfusion support.

A. Severe burns of patient with any 2 of the following:
   - Age > 60 yr
   - > 60% of total body surface area affected
   - Inhalation injury requiring mechanical ventilation

B. Advanced, progressive baseline cognitive impairment
C. Advanced, progressive untreatable neuromuscular disease
D. Metastatic malignant disease with expected survival less than 6 months
E. Advanced and irreversible immunocompromise
F. Severe and irreversible acute neurologic event or condition
G. End-stage organ failure meeting the following criteria:
   - *Heart* - NYHA class III or IV heart failure
   - *Lungs*
     i. COPD with FEV1 < 25% predicted, baseline PaO2 < 55 mm Hg, or secondary pulmonary hypertension
     ii. Cystic fibrosis with post-bronchodilator FEV1 < 30% or baseline PaO2 < 55 mm Hg;
     iii. Pulmonary fibrosis with VC or TLC < 60% predicted, baseline PaO2 < 55 mm Hg, or secondary pulmonary hypertension;
     iv. Primary pulmonary hypertension with NYHA class III or IV heart failure, right atrial pressure > 10 mm Hg, or mean pulmonary arterial pressure > 50 mm Hg

Abbreviations: SpO2 = oxygen saturation measured by pulse oximetry, FIO2 = fraction of inspired oxygen, NYHA = New York Heart Association, COPD = chronic obstructive pulmonary disease, FEV1 = forced expiratory volume in 1 second, PaO2 = partial pressure

15.3 - Specific Exclusion Criteria for Massively Bleeding Patients:

15.3.1 - Trauma

1. **During a red phase, do not administer transfusions to children or adults with non survivable brain injury.**
   Level of evidence: III
   Grade of recommendation: A
   Clinical Consideration: CT scanning should be done as soon as possible to confirm the diagnosis of a non survivable brain injury.

2. **During a red phase, do not administer transfusion to children or adults with a Glasgow Coma Scale =3 who have hypotension not attributable to reversible factors and who have fixed and dilated pupils.**
   Level of evidence: III
   Grade of recommendation: A

3. **During a red phase, do not transfuse patients after the declaration of brain death for the purpose of deceased organ donation.**
   Level of evidence: III
   Grade of recommendation: A

4. **During a red phase, do not administer transfusions to adults or children with penetrating cranial trauma and a Glasgow coma scale =3 that is not attributable to reversible factors.**
   Level of evidence: III
   Grade of recommendation: B

5. **During a red phase, do not administer transfusions to adults or children with penetrating cranial trauma, a Glasgow coma scale <8 that is not attributable to reversible factors, hypotension and severe thoracoabdominal trauma.**
   Level of evidence: III
   Grade of recommendation: B

6. **During a red phase, do not administer transfusions to adults or children with blunt trauma, and a Glasgow Coma Scale =3 that is not attributable to reversible factors.**
   Level of evidence: III
   Grade of recommendation: B

7. **During a red phase, do not administer transfusions to adults or children with blunt trauma who have lost vital signs pre-hospitalization.**
   Level of evidence: III
   Grade of recommendation: A

8. **During a red phase, do not administer transfusions to patients with transcranial gunshot injuries.**
   Level of evidence: III
   Grade of recommendation: A

9. **During a red phase, do not administer transfusions to patients >65 years with severe brain injury and profound shock and severe thoracic or abdominal trauma.**
   Level of evidence: III
   Grade of recommendation: B

10. **During a red phase, do not administer transfusions to patients >75 years with moderate brain injury, a Glasgow Coma scale of <12, who are in profound shock and who have thoracoabdominal injury.**
    Level of evidence: III
    Grade of recommendation: B

15.3.2 - Ruptured Abdominal Aortic Aneurysm (RAAA)

1. **During a critical blood shortage, do not transfuse patients with RAAA who have a cardiac arrest preoperatively.**
   Level of evidence: III
   Grade of recommendation: B

2. **During a critical blood shortage, do not transfuse patients with RAAA with a systolic blood pressure less than 70mmHg who are unresponsive to fluid resuscitation and have lost consciousness.**
   Level of evidence: III
   Grade of recommendation: B

3. **During a critical blood shortage, do not transfuse patients with RAAA that do not meet criteria for emergent vascular repair.**
   Level of evidence: III
   Grade of recommendation: I

15.3.3. - ECMO/VAD

1. **During a red phase, do not transfuse patients who require ECMO/VAD and who have multi-organ (> 1 organ) failure.**
   Level of evidence: III
   Grade of recommendation: B

2. **During a red phase, ensure that physicians and patients/families that patients receiving ECMO/VAD support who have multi-organ failure are aware that they may not receive transfusion support if massively bleeding.**
   Level of evidence: III
   Grade of recommendation: B

15.3.4 – Organ Transplantation

1. **Deceased Donor Organ Recovery - During a red phase, deceased donor organ recovery for transplantation should proceed, with the understanding that the deceased donor will not be transfused in the process of deceased donor stabilization.**
   Level of evidence: III
   Grade of recommendation: B

2. **Deceased Donor Transplantation - During a red phase, deceased donor solid organ transplants may proceed with informed consent regarding increased risk from restriction of blood transfusion, and with the understanding (among patient and all involved physicians) that blood may not be available for transfusion.**
   Level of evidence: III
   Grade of recommendation: B

3. **Living Donor Transplantation – During a red phase, living donor transplantation should be deferred.**
   Level of evidence: III
   Grade of recommendation: B

15.3.5 – Gastroenterology (refer to Section 8 for further information)

1. **During a red phase do not administer transfusions to patients with gastrointestinal bleeding and a Rockall score >8.**
   Level of evidence: III
   Grade of recommendation: B

2. **During a red phase do not administer transfusion to patients with liver cirrhosis and gastrointestinal (i.e. variceal) bleeding who have a Child Pugh score more than 10 (MELD score of more than 18) and who are not on the list for transplantation.**
   Level of evidence: III
   Grade of recommendation: B

3. **During a red phase, triage patients with gastrointestinal bleeding to centers with endoscopy to minimize the use of blood products.**
   Level of evidence: III
   Grade of recommendation: B

15.3.6 - Obstetrics

1. **In a red phase, red cell transfusion should not be withheld from the bleeding obstetrical patient.**
   Level of evidence: II-2-III
   Grade of recommendation: B

15.3.7 - Other massively bleeding situations not listed above

1. **In a red phase, for patients massively bleeding for reasons not listed above, do not transfuse patients for whom the triage team believes the mortality rate exceeds 80%.**

15.4 - Levels of Evidence

I Evidence from randomized controlled trial(s)
II-1 Evidence from controlled trial(s) without randomization
II-2 Evidence from cohort or case-control analytic studies, preferably from more than one centre or research group
II-3 Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could be included here
III Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees

15.5 - Recommendation Grades

A There is **good** evidence to recommend the action.
B There is **fair** evidence to recommend the action.
C The existing evidence is **conflicting** and does not allow making a recommendation for or against the use of the action, however other factors may influence decision-making.
D There is **fair** evidence to recommend against the action.
E There is **good** evidence to recommend against action.
I There is **insufficient** evidence (in quantity and/or quality) to make a recommendation, however other factors may influence decision-making

15.6 - Reassessment for Triaged Patients

1. Patients triaged to no blood components:

Patients triaged to no transfusion care will be re-assessed at a minimum of every 24 hours. The triage team will review requests from the most responsible physician if an improvement in a patient's status would now qualify them to be triaged to active transfusion management. In addition, the triage team will assure that the patient and their family are given adequate access to psychological support and that adequate symptom management is given to minimize pain and distress.

2. Patients triaged to blood components:

For patients triaged to active transfusion care, they will be re-assessed at a minimum of every 10 units of red blood cells (including pediatrics) or every 24 hours for patients receiving less than 10 units of blood or until cessation of hemorrhage(or more frequently – e.g. every 5 units - if deemed necessary by the NEBMC). At each assessment, the triage team will utilize the following variables to

guide their decisions regarding the value of continued transfusions: SOFA score, total blood products used, need for ongoing transfusion support and ability to control bleeding with either surgery or other procedure (e.g. interventional radiology, endoscopy). Patients with a SOFA score >11, continued need for large amounts of blood components, and with no foreseeable ability to control blood loss will be triaged to palliative care.

Transfusion decisions will be documented on the patient tracking tool shown in Appendix E.

15.7 - Competing patients triaged to active transfusion care – Supplemental Criteria

If two or more patients are competing for blood components at the same hospital for whom both qualify for active transfusion management by the triage team (based on their equal status at the conclusion of the general exclusion criteria **and** clinical factors specific to patient population exclusion criteria stages of the triage process), and current inventory levels necessitates further triage – the following principles (in order) will be used to make the very difficult decision regarding who will get priority for transfusion resources: 1.Youngest first; 2. Highest likelihood of hemostasis control; (based on clinical decision making by the triage team), and 3. First-come, first-served. In the event that two or more patients are competing for blood components at different hospitals and the blood still resides at the local blood centre, the same aforementioned principles will be applied jointly by the blood centre physician and the triage team leader from the hospitals involved.

Section 16 - Dissemination of this Rationing Framework

Pending support from the Provincial and Territorial Ministries of Health, this emergency framework will be implemented as a supplement to the *National Plan for the Management of Shortages of Labile Blood Components* and will be disseminated by the National Advisory Committee on Blood and Blood Products to relevant stakeholders. In addition, this document as well as a truncated version will be disseminated by each Provincial/Territorial Representative or Provincial Blood Office/Program to each hospital through their normal communication channels. Also, efforts will be made to ensure that the framework is presented at relevant stakeholder annual meetings to ensure widespread dissemination. The framework will also be submitted for peer-reviewed publication.

Section 17 - Implementation Barriers

There are numerous barriers that have potential to derail this framework during a red phase blood shortage. These are the anticipated concerns of the committee:

a) Inadequate dissemination of the framework.
    - At the present time, not all Provinces/Territories have PEMBC or Provincial Blood Offices and some Provinces have insufficient resources to ensure both dissemination and education of the relevant clinical groups. Adequate resources must be allocated at the Provincial/Territorial level to ensure the adequacy of dissemination.

b) Triage team reluctance to withhold therapy due to difficulty transitioning from caring for individual patients to making decisions in the best interest of the whole hospital population in need of transfusion resources.
c) Fear of legal liability.
    - The triage team must be given assurance that the best way to prevent legal liability is to follow the framework to ensure 'over triage' and 'under triage' are minimized. Clinicians should face legal liability only if they withhold blood components from patients that clearly meet the inclusion criteria for transfusion or if they transfuse patients with an obvious very poor chance of long-term survival and subsequently cause harm to other patients who would have clearly benefited from blood had it been available.
d) Pressure from families, clinicians, and hospital administrators/staff to deviate from the framework for individual patients.
    - Any pressure from any hospital staff to deviate from the framework for specific patients should be immediately reported the HEBMC. The chair of the HEBMC shall resolve such issues so that the triage team can focus on triage decisions and patient care.
e) Non-disclosure of transfusion activity by the hospital transfusion service.
    - At the present time, there is no information system to allow for real-time monitoring of transfusion activity in Canada (excluding Quebec). Once the blood leaves Canadian Blood Services, its final status is unknown, therefore it is possible for a hospital to underreport transfusion inventories to Canadian Blood Services and thus manipulate the system to maintain better inventory than are dictated by the inventory set out in the National Blood Shortages Plan.

Section 18 - Next Steps and Future Research

This framework is the first attempt to develop a strategy for fair and equitable distribution of blood to massively bleeding patients during a red phase blood shortage. The working group recognizes that the majority of the recommendations are based on expert opinion, in conjunction with a detailed review of the literature, and that over time the framework will be revised to reflect new knowledge in this area. The working group recommends the following to improve the ability to fairly triage blood for these patients:

1) Prospective or retrospective validation of the framework to determine the effectiveness of the tool to decrease the use of blood products.
2) Prospective validation of the documentation tool.
3) Development of training material for triage teams.
4) Development and execution of mock drills.
5) Survey of intensive care and emergency room clinicians regarding their attitudes towards triaging blood for massively bleeding patients to determine their willingness to act as triage officers, their acceptance of explicit rationing criteria, and their acceptance of the recommendations.

6) Real-time hospital inventory available nationally to determine where and when blood products are being issued across Canada. This would assist with transparency as all transfusion activity would be visible electronically.
7) Validate the utility of the SOFA score for massively bleeding patients and for pediatric patients.
8) Planned revision after every red phase and every three years.

The working group felt strongly that we have a 'duty to plan' for severe blood shortage for patients who will need a large number of blood components and that this document is a work in progress. Harwood RJ(27) stated in a letter to the editor on planning for shortages in a pandemic, *"The requirement to plan properly cannot be emphasized strongly enough. It is unreasonable to burden medical staff with a dilemma when it lies in society's power to help resolve these issues ahead of time. Whatever the moral obligation that doctors have to society, it is not sufficient to try to resolve these issues 'on the hoof' in the midst of a pandemic. They must be settled before a pandemic arrives."*

Appendix A - Terminology

Allocation vs. Rationing – The terminology used to describe the triaging of scarce resources is currently under debate. Allocation is the most commonly used term, although its use has been scrutinized.(28) Allocation refers to the 'the action or process of allocating or distributing something'. Rationing refers to 'the controlled distribution of resources and scarce goods and services'. Matas(28) argues that when we hide behind the word 'allocation', we forget that there will be winners and losers with each triage decision that is made. We have utilized the term 'rationing', where appropriate, throughout this document to acknowledge Matas' concerns regarding these two terms.

Implicit vs. Explicit Rationing – 'Implicit' rationing refers to rationing based on an individualized approach. In contrast, 'explicit' rationing refers to rationing based on strict criteria. A systematic review of studies on how physicians ration healthcare resources concluded that implicit rationing is already happening (e.g. delay in treatment, early discharge) and that we need ethically sound criteria to support explicit rationing strategies.(29) Implicit rationing results in role conflict, where physicians must make decisions that are not necessarily best for their patient, but best for the community of patients that they serve. In addition, implicit rationing decisions will vary clinician to clinician for the same clinical scenario.

Over triage vs. Under triage – 'Over triage' refers to rationing scarce resources to a patient who is unlikely to survive or benefit from the resources. In contrast, 'under triage' refers to failing to allocate resources to a patient who is likely to benefit and has a high likelihood of a good outcome if allocated resources.

Crisis standard of care - The optimal level of health care that can be delivered during a catastrophic event, requiring a substantial change in usual health care operations.(30)

Appendix B – Tables

Table 1. The SOFA score as described by Vincent et al.(4)

SOFA Score	**0**	**1**	**2**	**3**	**4**
PaO2/FIO2 Ratio	>400	≤400	≤300	≤200 and mechanically vented	≤100 and mechanically vented
Platelet Count	>150	≤150	≤100	≤50	≤20
Bilirubin umol/L	<20	20-32	33-101	102-204	>204
Hypotension (ug/kg/min)	None	MAP<70	Dopamine ≤5 or dobutamine (any dose)	Dopamine >5 or epinephrine ≤0.1 or norepinephrine ≤0.1	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1
Glasgow Coma Scale	15	13-14	10-12	6-9	<6
Creatinine (umol/L)	<110	110-170	171-299	300-440 or <500 mL/day	>440 or <200 mL/day

Table 2. Ethical principles and their role in blood triage decisions. Adopted from Persad et al for blood transfusion triage decisions.(31)

Principle	Advantages	Disadvantages	Recommendation
Treat people Equally			
Lottery	Easy to apply, no patient information required	Ignores all other ethical principles	Exclude as it requires stewards to be blind to other relevant facts
First-come, first-served	Easy to apply, no patient information required	Patients with greater resources may be able to access medical resources faster and hence may not be fair	Include as supplemental, blood will not be hoarded in anticipation of a patient with better expected outcomes
Favour the worst off			
Sickest first	Provides resources to patients suffering the most	Ignores prognosis	Exclude as it ignores post treatment prognosis
Youngest first	Benefits those who have had the least life	Ignores prognosis which may be extremely poor even for a child	Include for patients in same triage zone for prioritization and for exclusion criteria
Maximize total benefits			
Number of lives saved	Benefits the greatest number	Ignores long term prognosis	Exclude
Number of life-years saved (prognosis)	Maximizes life-years produced	Discriminates against older patients	Include via triage criteria
Social usefulness			
Instrumental value	Future oriented (i.e. health care workers and emergency personnel get priority access)	Patients unlikely to be back to work before the end of the scarcity	Exclude
Reciprocity	Past oriented (i.e. previous blood donors get priority)	Blood donor criteria are very restrictive (e.g. residence in the UK between 1980 and 1996)	Exclude

Table 3. Procedural values to guide ethical decision-making. Adopted from the Stand on Guard for Thee document (32)

Procedural Value	**Description**
Reasonable	Decisions should be based on reasons (i.e. evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a blood shortage. The decisions should be made by people who are credible and accountable.
Open and transparent	The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.
Inclusive	Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.
Responsive	There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.
Accountable	There should be mechanisms in place to ensure that decision makers are answerable for their actions and inactions.

Appendix C - Blood Shortage and Massive Transfusion Working Group.

The NAC Blood Shortage Working Group (BSWG) serves as the technical, medical and scientific working group, on behalf of the National Advisory Committee on Blood and Blood Products (NAC) in the development of a national framework for responding to any crisis which impacts the adequacy of the blood supply in Canada.

The NAC BSWG established this sub-group to develop this document that is intended to guide healthcare professionals in triaging patients in need of massive transfusion during a red phase blood shortage, where demand greatly exceeds supply and where all other measures to increase the supply of blood have been exhausted.

The following have made significant contributions to the development of this document:

Dr. Jeannie Callum	Working Group Chair, National Advisory Committee on Blood and Blood Products
Dr. Nadine Shehata	Canadian Blood Services
Dr. Susan Nahirniak	National Advisory Committee on Blood and Blood Products
Dr. Lucinda Whitman	National Advisory Committee on Blood and Blood Products (Chair)
Dr. Heather Hume	Pediatric Hematologist, St. Justine Hospital, Montreal
Mr. Ahmed Coovadia	Canadian Blood Services
Dr. Brian Muirhead	National Advisory Committee on Blood and Blood Products
Dr. Keyvan Karkouti	Anesthesiologist, University Health Network
Dr. Shuen Tan	Fellow in Transfusion Medicine
Dr. Homer Tien	Chief of Trauma, Sunnybrook Health Sciences Centre; Lt.-Col. Canadian National Defense
Dr. Sharvesh Logsetty	Trauma Association of Canada
Dr. Barto Nascimento	Trauma & Transfusion Fellow
Dr. Morad Hameed	Trauma Association of Canada
Dr. Amanda Skoll	Society for Obstetrics and Gynecology
Mr. Blair Henry	Clinical and Research Ethicist, Sunnybrook Health Sciences Centre
Ms. Joanna Noble	Risk Management, Healthcare Insurance Reciprocal of Canada
Ms. Jodi Murray	Legal, Canadian Blood Services
Dr. Daryl Kucey	Canadian Association of Vascular Surgery
Dr. Prosanto Chaudhury	Canadian Society of Transplantation
Dr. Nalin Ahluwalia	Canadian Association of Emergency Physicians
Dr. Paul Moayyedi	Gastroenterologist, McMaster University
Ms. Teddie Tanguay	Canadian Association of Critical Care Nurses
Dr. Gurmeet Singh	Cardiac Surgeon, University of Alberta
Dr. Marc de Perrot	Lung transplantation, Thoracic Surgeon, University Health Network
Dr. Vincent Laroche	Public Health Ministry of Quebec; Member, National Advisory Committee

Appendix D - Community and Stakeholder Engagement

Community and stakeholder engagement is critical to garner support and objectively review the proposed rationing process, and to validate the triage criteria. Public engagement is critical for procedural justice since a contemporaneous appeals process is not feasible in a disaster setting or during a massive hemorrhage. Hence, a pre-emptive community and stakeholder engagement process has been conducted to allow for feedback on the triage protocol well in advance of a red phase blood shortage.

For this document, the community and stakeholder engagement strategy was divided into two components. Firstly, in the development of the triage tool, clinicians with expertise in the treatment of patients requiring massive transfusions were invited to be members of the working group (2009). Following the development of the draft document, a planned consultation process involving the National Liaison Committee and the Regional Liaison Committees of Canadian Blood Services (NLC/RLC) was conducted (33). Members of these committees include blood recipients, patient group representatives, blood donors, blood system volunteers and healthcare professionals. The committees were asked to review the entire draft document and provided input. Additionally, a wider lay community consultation process was conducted. Several groups were contacted to ensure widespread lay consultation during the development of the draft emergency framework, including the NLC/RLC as detailed above.

The following are lists of those organizations and societies who were requested to provide written feedback and/or complete a survey regarding the content of the draft emergency framework document in 2011.

Stakeholder Organization	**Response Received**	**Individual Member Response (s)**	**Stakeholder Official Response**
Aplastic Anemia and Mylelodysplasia Association of Canada	Yes	Yes	No
Canadian Anaesthesiologists Society	Yes	Yes	No
Canadian Association of Critical Care Nurses	Yes	No	Yes – Board of Directors
Canadian Association of Emergency Physicians	Yes	Yes	No
Canadian Bioethics Society	Yes	Yes	No
Canadian Cancer Society	Yes	Yes	No
Canadian Critical Care Society	Yes	Yes	No
Canadian Liver Foundation	Yes	No	Yes – Medical

			Advisory Council
Canadian Medical Association	Yes	No	Yes – analysis provided by the Office of Ethics
Canadian Society for Medical Laboratory Science	Yes	No	Yes - President
Canadian Society for Transfusion Medicine	Yes	No	Yes – Board of Directors
Canadian Society for Transplantation	Yes	No	Yes – Board of Directors
Canadian Society for Vascular Surgery	Yes	Yes	No
National Advisory Committee on Blood and Blood Products	Yes	Yes	Yes
Healthcare Insurance Reciprocal of Canada	Yes	Yes	Yes – working group member
Neutropenia Support Association Inc.	Yes	No	Yes
Trauma Association of Canada	Yes	Yes	No

The following organizations did not provide comment or feedback:

Canadian Association of Gastroenterology, Society of Obstetricians and Gynaecologists of Canada, Canadian Pediatric Society, Canadian Bone & Marrow Transplant Group, Canadian Association of Transplantation , Childhood Cancer Foundation Candlelighters Canada, Canadian Medical Protective Association, Sickle Cell Disease Parents Support Group (CHEO). Thalassemia Foundation of Canada, Anemia Institute for Research and Education, Arthritis Society of Canada, Association of Hemophilia Clinic Directors of Canada, Bruce Denniston Bone Marrow Society, Canadian Association of Neuroscience Nurses, Canadian Cancer Society. Canadian Critical Care Society, Canadian Hematology Society Canadian Hemophilia Society, Canadian Immunodeficiencies Patient Organization, Canadian Neurosciences Federation, Canadian Nurses Association, Canadian Society of Cardiac Surgeons National Emergency Nurses Affiliation, Physicians and Nurses for Blood Conservation,The Leukemia and Lymphoma Society of Canada, Advocacy Centre for the Elderly (Ontario), Canadian Thoracic Society Kidney Foundation of Canada, Crohn's and Colitis Foundation of Canada, Canadian Lung Association, Heart and Stroke Foundation of Canada, Canadian Diabetes Association.

The emergency framework working group members also widely disseminated the draft framework to individuals with particular expertise in the management of massively bleeding patients, blood

management and ethics. Comments and feedback received was compiled and discussed by the core working group members and after consultation with the larger working group the framework was extensively revised and reformatted.

For ease of review, main feedback was categorized as follows:

- Positive feedback
- Minor grammatical
- Legal implications / Ethical considerations
- Transplantation
- Age as an Exclusion Criteria
- Use of Pre-hospital data
- Consensus process
- Triage team
- Failure of hospitals to comply resulting in inequity
- Other

Positive feedback- The majority of those organizations and individuals that provided feedback indicated that the rationale for developing the emergency framework document was clear and they also confirmed that there is a need for a framework outlining a process for emergency disposition of blood components should a red phase blood shortage be declared. The literature review was deemed to be thorough and the draft framework was comprehensive.

Minor / Grammatical - In consideration of the end-users of the emergency framework, it has been reformatted, sectioned and a number of appendices created for ease of reading and reference.

Legal Implications / Ethical Considerations – As a result of feedback, the section on ethics (Section 6) has been strengthened, in particular the considerations given to supplementary triage criteria. In terms of legal protection for those in decision making positions under the guidance of this emergency framework, it is anticipated that support and endorsement of this framework by the provincial ministries of health will in turn result in this framework being the temporary standard of care when implemented during a red phase blood shortage. Support at all levels of government and the system is imperative to ensure maximum compliance which ultimately means maximum blood components available for the greatest number of patients. The provincial /territorial representatives have been asked to consider incorporating or linking provincial contingency plans with other existing provincial contingency plans in an attempt to ensure that triage tools developed separately are not contradictory and reflect potential for multiple resource scarcity.

Transplantation – Significant feedback was received with regard to the recommendations to not transfuse for the purpose of harvesting organs for transplant. Harvested organs can save lives and if this process is not done (for some organs) during a red phase blood shortage extra lives would potentially be lost. The Canadian Society for Transplantation presented alternate recommendations for consideration

by the working group. The revised recommendations were welcomed and incorporated into the final document.

Age as an exclusion criterion – The working group had originally proposed an age limit of 80 years as an overall exclusion cut-off for receipt of blood components in a red phase blood shortage. Stakeholders expressed considerable concern over the inclusion of this criterion. As a result, the age limit of 80 years has been removed (Section 6 – Ethical Issues)

Use of pre-hospital data – Comments were received regarding the validity of using pre-hospital data (vitals etc.) to make end-of-life decisions. With respect to pre-hospital cardiac arrest, the literature does not indicate that the diagnosis of pre-hospital cardiac arrest in trauma patients is unreliable. The pre-hospital diagnosis of cardiac arrest and the actual duration of patient transport are often used as criteria for stopping resuscitation (personal e-mail correspondence – Dr. H. Tien).

Consensus Process – Stakeholders recognized that successful application of the emergency framework is contingent on awareness and support for the proposed triage process across all jurisdictions and at all decision-making levels (hospitals and provincial governments). As such, support for the framework is being sought by the provincial Deputy Ministers and Ministers of Health. Support from all jurisdictions will ensure that the framework is available and processes are in place prior to a red phase blood shortage being declared. Cross-jurisdictional support will aid in consistency of patient treatment and triage across the country. A truncated version of the emergency framework has been developed to highlight this needed consistency as it is recommended that it be incorporated verbatim into all provincial blood contingency plans. Consistency across the country is imperative. Efforts will be made to ensure that the framework is presented at relevant stakeholder annual meetings to ensure widespread dissemination.

Triage Team – As a result of feedback, the role of the triage team has been expanded and this section contains more detail with regard to the documentation, implications and various roles and responsibilities of the proposed triage team members. It is important for the triage team to apply the recommendations objectively and away from the direct care of the patient. As such, the concept of a 'blinded' triage process is recommended to mitigate potential bedside biases. Clarification on how a triage team would work in a smaller hospital has been provided. These teams can be regional or provincial – each province can address this in their own provincial plans in terms of how this would work. Triage team characteristics have been expanded upon to ensure the team is functional and members have the skills necessary to ensure the triage process is applied appropriately. The Provincial / Territorial representatives were consulted on the education and training of the triage teams. An approach is outlined in Section 12.1.

Failure of hospitals to comply resulting in inequity - Stakeholders highlighted that it is imperative to ensure fair access to the limited blood supply and that all jurisdictions and physicians be required to follow these guidelines in a red phase blood shortage. To ensure fair access, this document is being prepared in advance of an actual shortage and communicated to stakeholders. Support is being sought

at the Deputy and Ministerial levels of government. Support at all levels will ensure jurisdictional compliance to this framework. It is recommended that a truncated version of this framework be incorporated verbatim into provincial blood contingency plans ensuring consistency across all jurisdictions in terms of process. The members of the National Emergency Blood Management Committee are such that accountability and transparency are supported. This is addressed in the National Plan for the Management of Shortages of Labile Blood Components.

Other – Other revisions or considerations included (but not limited to): the definition for massive bleeding / hemorrhage, the importance of access to erythropoietin during a blood shortage (communicated to the provincial/territorial representatives), clarification on what constitutes a massive GI bleed, and priority given to stocking pediatric facilities with blood components during a red phase shortage.

The extensive community and stakeholder engagement resulted in a saturation of comments and feedback received. Many comments from stakeholders were similar and repetitive and as a result the working group concluded that all relevant comments and feedback had been captured and addressed appropriately in this engagement process. The need for ongoing refinement and revision as new data becomes available is vital and as such this emergency framework will be reviewed on a regular basis and after every activation ensuring it adequately addresses the requirement for consistent, fair and equitable provision of blood components to Canadian patients during a red phase blood shortage.

Appendix E – Documentation Tools

Triage Tracking Log – Emergency Disposition of Blood during Red Phase Blood Shortage

Tracking Number	Medical Record Number	Last Name	First Name	Location	Blood Group
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
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Patient Triage Record' – Emergency Disposition of Blood during Red Phase Blood Shortage

Patient Tracking Number	Hospital	
Reason for Massive hemorrhage	Date of Triage	Time of Triage
Predicted to need >10 units in the next 24 hours ☐ Yes ☐ No(if no refer to standard tracking tool) Has patient received product in the previous 24 h? ☐ Yes ☐ No If yes, list products:	Age Hemoglobin Platelet INR PTT Fibrinogen	Blood Group pH Lactate Temp
Meets any exclusion criteria ☐ Yes ☐ No If yes, which one(s)?	Product Required	Units of ABO compatible product available
Meets any specific exclusion criteria ☐ Yes ☐ No If yes, which one(s)?	Date/Time of assessment	SOFA score
Decision made to administer blood? ☐ Yes ☐ No	Date/Time	Number of units & products transfused
Patient outcome at 24 hours	Date/Time	Re-assessment Decision
Comments by Triage Team	Comments regarding patient and family concerns	
Triage Documentation completed by	Signature	
Triage Officer Name	Signature	
Follow-up		
Patient Outcome at Discharge	Patient Outcome at 6 months	

Appendix F

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Appendix G - Identification and Selection of Studies

Inclusion/Exclusion Criteria

We included studies that were 1) original reports, 2) systematic reviews or guidelines and were 3) published in English. We excluded studies that were 1) case reports or 2) abstracts. For the trauma literature, we excluded reports that were from 1) Developing countries (defined as countries outside North America and the European Union) as trauma care in those countries was deemed to be dissimilar to developed countries, 2) reports that included less than 100 patients, 3) reports published earlier than year 2000 as the care of trauma patients has advanced over the years and 4) reports of combat trauma. For the literature search for patients undergoing heart/lung/liver transplantation and patients requiring ventricular assist devices and extracorporeal membrane oxygenation, we excluded reports from 1) reports that included less than 100 patients, 2) reports published earlier than year 2000 as transplant regimens have evolved and 3) reports from the journal Transplantation Proceedings as the reports are not peer reviewed. For the literature search for obstetrical care, reports from developing countries were excluded as obstetrical care is not well developed in those countries. Summaries of included and excluded reports are illustrated in Tables 1 to 3. Table 3 summarizes reports excluded for reasons not stated above and the rationale for exclusion.

One reviewer (NS) assessed the citations for inclusion and extracted data to generate tables containing data on trial design, quality, and outcome results. Tables 1-3 describe the reports.

Table 1: Citations Reviewed

Disease Category	Electronic Database			
	Medline	**Medline in Process**	**EMBASE**	**CCTR**
Trauma	706	496	2593	186
Trauma and Massive Bleeding		19	358	21
Heart and Lung Transplantation	1648	95	1919	68
Heart and Lung Transplantation and Massive Bleeding	11	0	14	0
Liver Transplantation	2380	163	468	113
Liver Transplantation and Massive Bleeding	59	9	71	2
Ventricular Assist Device	660	18	698	33
Ventricular Assist Device and Massive Bleeding	3	0	5	0
Extracorporeal Membrane Oxygenation	465	22	634	22
Extracoporeal membrane oxygenation and Massive Bleeding	10	0	9	0
Ruptured Aortic Aneurysm	848	118	669	33
Ruptured Aortic Aneurysm and Massive Bleeding	19	2	19	0
Obstetrics	718	1	484	148
Obstetrics and Massive Bleeding	131	2	47	2
Gastrointestinal bleeding	857	69	325	102
Gastroenterology and Massive Bleeding	285	7	159	12

CCTR, Cochrane Clinical Trials Registry

Table 2: The Number of Reports Used to Generate Recommendations

Disease Category	Number
Trauma	97
Trauma and Massive Bleeding	2
Heart Transplantation	36
Lung Transplantation	27
Liver Transplantation	42
Liver Transplantation and Massive Bleeding	15
Ventricular Assist Device	10
Extracorporeal Membrane Oxygenation	17
Ruptured Aortic Aneurysm	79
Obstetrics	8
Gastrointestinal bleeding	54

Table 3: Reports Excluded After Review

Rationale for Exclusion	Number
Trauma	
No predictors of mortality stated	5
Combined outcome of death or vegetative state	1
Mortality risk score development for use in studies using administrative databases	1
No relevant outcomes	2
No statistical analysis	2
Only assessed patients who died	2
Glasgow coma score used as the outcome	1
Systematic review of improvements necessary for prognostic models	1
Heart Transplantation	
No predictors of mortality	5
Predictors of survival for patients on the waiting list	1
Composite outcome	1
Compared only one predictor (age)	1
Risks bridging to transplantation	**1**
Risks for heart failure	1
Personality predictors of mortality	1
Risk factors of death with and without transplantation	1
Lung Transplantation	
No predictors of survival	5
Duplicate report	1
Compared only one predictor (patient volume, and graft ischemic time, HLA)	3
Only analyzed donor characteristics	3
Systematic review of predictors for "outcomes"	1

Rationale for Exclusion	Number
Liver Transplantation	
Composite outcome of graft loss and death	1
Predictors of patients who can benefit from transplantation	1
Review of study previously published	1
Assessed predictors after ICU admission	1
Assessed predictors of no transfusion	1
Assessed postoperative predictors of mortality	1
Sample size not stated	1
Assessed predictors for mortality patients on the waiting list	1
Assessed predictors of graft survival	1
Patients having hepatic resection	1
Effect of Aprotinin on outcomes	2
Economic study	1
Predictors of transplantation without transfusion	1
Assessed a behavioral scale as predictor of mortality	1
Assessed MELD score for non transplant mortality	1
VAD	
No predictors of survival	7
Patient population was not a transplant population (cardiac surgery)	1
Only donor characteristics were analyzed	1
Patient group analyzed not specified	1
Abstract	1
Analyzed patients with VAD and inotropic support separately	1
Only predictors of inotropic support analyzed	1

Table 3: Reports Excluded (continued)

Rationale for Exclusion	Number
ECMO	
Only assessed predictors of ARDS	1
Ruptured Abdominal Aortic Aneurysm	
No predictors stated	4
Assessed postoperative variables and mortality	2
Association with one variable and mortality (i.e. age/sex)	3(age) 1(sex)
Combined ruptured and elective or emergent	7
Compared outcomes for patients with COPD	1
No statistical tests used	1
Obstetrics	
Descriptive studies	14
Association with one variable and mortality (age)	1
No predictors of mortality stated	6
Association between predictors and morbidity	2
Combined outcome of mortality and "near miss"	1

Table 3: Reports Excluded (continued)

Rationale for Exclusion	Number
Gastroenterology	
No predictors of mortality	7
Descriptive studies	11
Only one predictor assessed (age)	1
Composite outcome used	3
Gastric cancer	1
Assessed association between PUD and liver cirrhosis	1
Case series of achalasia	1
No statistical tests	1

Systematic Review II

Medline Search Terms for Gastroenterology

1 gastrointestinal bleed$.mp. (8568)
2 gastrointestinal blood loss$.mp. (336)
3 gastrointestinal tract blood loss$.mp. (5)
4 exp Gastrointestinal Hemorrhage/ (37489)
5 gastrointestinal hemorrhage$.mp. (31115)
6 gastrointestinal haemorrhage$.mp. (917)
7 hemorrhage$, gastrointestinal.mp. (17)
8 haemorrhage$, gastrointestinal.mp. (7)
9 hematochezia$.mp. (640)
10 Hematemesis/ (1673)
11 hematemesis.mp. (2556)
12 hematemeses.mp. (48)
13 Melena/ (1603)
14 melena$.mp. (2493)
15 rectal bleed$.mp. (2095)
16 rectal blood loss$.mp. (27)
17 rectal hemangioma$.mp. (20)
18 rectum bleed$.mp. (5)
19 rectal haemorrhage$.mp. (32)
20 rectal hemorrhage$.mp. (106)
21 colon bleed$.mp. (9)

22 colonic bleed$.mp. (115)
23 duodenal bleed$.mp. (70)
24 Peptic Ulcer Hemorrhage/ (6341)
25 peptic ulcer hemorrhage$.mp. (6356)
26 peptic ulcer haemorrhage$.mp. (40)
27 hemorrhage$, peptic ulcer.mp. (3)
28 stomach ulcer hemorrhage$.mp. (2)
29 duodenal ulcer hemorrhage$.mp. (38)
30 duodenal ulcer haemorrhage$.mp. (9)
31 or/1-30 (43968)
32 exp Mortality/ (212912)
33 32 and 31 (1719)
34 limit 33 to english language (1378)
35 limit 34 to case reports (521)
36 34 not 35 (857)

Medline Search Terms for Gastroenterology and Massive Bleeding

1 gastrointestinal bleed$.mp. (8572)
2 gastrointestinal blood loss$.mp. (336)
3 gastrointestinal tract blood loss$.mp. (5)
4 exp Gastrointestinal Hemorrhage/ (37508)
5 gastrointestinal hemorrhage$.mp. (31136)
6 gastrointestinal haemorrhage$.mp. (917)
7 hemorrhage$, gastrointestinal.mp. (18)
8 haemorrhage$, gastrointestinal.mp. (7)
9 hematochezia$.mp. (642)
10 Hematemesis/ (1674)
11 hematemesis.mp. (2558)
12 hematemeses.mp. (48)
13 Melena/ (1603)
14 melena$.mp. (2494)
15 rectal bleed$.mp. (2098)
16 rectal blood loss$.mp. (27)
17 rectal hemangioma$.mp. (20)
18 rectum bleed$.mp. (5)
19 rectal haemorrhage$.mp. (32)
20 rectal hemorrhage$.mp. (106)
21 colon bleed$.mp. (9)
22 colonic bleed$.mp. (115)
23 duodenal bleed$.mp. (70)
24 Peptic Ulcer Hemorrhage/ (6341)
25 peptic ulcer hemorrhage$.mp. (6356)
26 peptic ulcer haemorrhage$.mp. (40)

27 hemorrhage$, peptic ulcer.mp. (3)
28 stomach ulcer hemorrhage$.mp. (2)
29 duodenal ulcer hemorrhage$.mp. (38)
30 duodenal ulcer haemorrhage$.mp. (9)
31 or/1-30 (43994)
32 massive blood transfusion$.mp. (253)
33 massiv$ transfus$.mp. (642)
34 massive blood loss$.mp. (378)
35 acute blood loss$.mp. (563)
36 massive blood replacement$.mp. (30)
37 whole blood transfus$.mp. (228)
38 (massive$ bleed$ adj3 patient$).mp. (160)
39 massive transfusion protocol$.mp. (20)
40 massive transfusion practice$.mp. (6)
41 large volume blood transfusion$.mp. (6)
42 large volume transfusion$.mp. (13)
43 massive bleed$.mp. (1326)
44 massive hemorrhage$.mp. (1556)
45 Blood Transfusion/ (47115)
46 Blood Component Transfusion/ (2192)
47 Erythrocyte Transfusion/ (4602)
48 Platelet Transfusion/ (3638)
49 or/45-48 (54046)
50 ((massive$ or whole) adj4 (transfus$ or replacement$)).mp. (5774)
51 50 and 49 (1458)
52 or/32-44,51 (5452)
53 52 and 31 (913)
54 limit 53 to english language (567)
55 limit 54 to case reports (282)
56 54 not 55 (285)

Medline Search Terms for Trauma

1 civilian trauma$.tw. (179)
2 exp "Wounds and Injuries"/ (574532)
3 Military Medicine/ (28722)
4 exp Naval Medicine/ (9376)
5 Military Personnel/ (19725)
6 War/ (20961)
7 iraq war, 2003 -/ (360)
8 or/3-7 (63914)
9 2 not 8 (565905)
10 1 or 9 (566029)
11 exp Mortality/ (213079)

12 massive blood loss$.mp. (378)
13 acute blood loss$.mp. (563)
14 (massive$ bleed$ adj3 patient$).mp. (160)
15 massive bleed$.mp. (1326)
16 massive hemorrhage$.mp. (1556)
17 exp Hemorrhage/ (197818)
18 Hemorrhage$.mp. (175553)
19 Haemorrhage$.mp. (22516)
20 bleed$.mp. (101691)
21 or/12-20 (295986)
22 11 and 21 and 10 (1608)
23 exp Neoplasms/ (2078572)
24 exp Carcinoma/ (392867)
25 or/23-24 (2078572)
26 22 not 25 (1482)
27 limit 26 to english language (1191)
28 limit 27 to case reports (485)
29 27 not 28 (706)

Medline In Process Search Terms for Trauma and Massive Bleeding

1 massive blood transfus$.tw. (9)
2 massive transfus$.tw. (30)
3 massive blood loss$.tw. (15)
4 acute blood loss$.tw. (8)
5 whole blood transfus$.tw. (6)
6 (massive$ bleed$ adj3 patient$).tw. (11)
7 massive bleed$.tw. (69)
8 massive hemorrhage$.tw. (62)
9 or/1-8 (188)
10 blood transfusion$.tw. (1039)
11 blood component transfusion$.tw. (5)
12 erythrocyte transfusion$.tw. (13)
13 platelet transfusion$.tw. (92)
14 or/10-13 (1139)
15 ((massive$ or whole) adj4 (transfus$ or replacement$)).tw. (76)
16 15 and 14 (28)
17 16 or 9 (193)
18 civilian trauma$.tw. (16)
19 trauma$.tw. (8739)
20 "Wounds and Injuries".tw. (6)
21 or/18-20 (8743)
22 Military.tw. (1129)
23 Naval Medicine.tw. (1)
24 war.tw. (1055)
25 or/22-24 (2073)
26 21 not 25 (8519)
27 26 and 17 (21)

28 limit 27 to english language (19)
29 limit 28 to case reports (0)
30 from 28 keep 1-19 (19)

Medline Search Terms for Liver Transplantation

1 Liver Transplantation/ (33822)
2 liver transplant$.tw. (29153)
3 transplant$, liver.tw. (752)
4 hepatic transplant$.tw. (898)
5 transplant$, hepatic.tw. (98)
6 graft$, liver.tw. (252)
7 liver graft$.tw. (2451)
8 Transplants/ (1384)
9 Transplantation/ (6763)
10 or/8-9 (8128)
11 Liver/ (336160)
12 11 and 10 (162)
13 or/1-7,12 (39498)
14 exp Mortality/ (212912)
15 and/13-14 (3179)
16 limit 15 to english language (2862)
17 limit 16 to case reports (482)
18 16 not 17 (2380)

Medline Search Terms for Liver Transplantation and Massive Bleeding

1 massive blood transfusion$.tw. (247)
2 massiv$ transfus$.tw. (611)
3 massive blood loss$.tw. (370)
4 acute blood loss$.tw. (549)
5 massive blood replacement$.tw. (30)
6 whole blood transfus$.tw. (226)
7 (massive$ bleed$ adj3 patient$).tw. (148)
8 massive transfusion protocol$.tw. (17)
9 massive transfusion practice$.tw. (6)
10 large volume blood transfusion$.tw. (6)
11 large volume transfusion$.tw. (13)
12 massive bleed$.tw. (1270)
13 massive hemorrhage$.tw. (1517)
14 Blood Transfusion/ (46385)
15 Blood Component Transfusion/ (2117)
16 Erythrocyte Transfusion/ (4435)
17 Platelet Transfusion/ (3561)
18 or/14-17 (53054)
19 ((massive$ or whole) adj4 (transfus$ or replacement$)).mp. (5691)
20 18 and 19 (1413)
21 or/1-13,20 (5295)

22 Liver Transplantation/ (32931)
23 liver transplant$.tw. (28287)
24 transplant$, liver.tw. (732)
25 hepatic transplant$.tw. (886)
26 transplant$, hepatic.tw. (96)
27 graft$, liver.tw. (246)
28 liver graft$.tw. (2390)
29 Transplants/ (1315)
30 Transplantation/ (6657)
31 or/29-30 (7954)
32 Liver/ (330804)
33 32 and 31 (161)
34 or/22-28,33 (38432)
35 34 and 21 (104)
36 limit 35 to english language (84)
37 limit 36 to case reports (25)
38 36 not 37 (59)

Medline Search Terms for Heart and Lung Transplantation

1 Heart Transplantation/ (25081)
2 Heart-Lung Transplantation/ (1767)
3 cardiac transplant$.tw. (7355)
4 transplant$, cardiac.tw. (148)
5 heart transplant$.tw. (13048)
6 transplant$, heart.tw. (778)
7 graft$, heart.tw. (61)
8 heart-lung transplant$.tw. (1545)
9 transplant$, heart-lung.tw. (15)
10 graft$, heart-lung.tw. (0)
11 or/1-10 (30168)
12 Transplants/ (1384)
13 Transplantation/ (6763)
14 or/12-13 (8128)
15 Heart/ (108165)
16 (heart adj2 lung).tw. (11378)
17 or/15-16 (118537)
18 17 and 14 (130)
19 or/11,18 (30255)
20 exp Mortality/ (212912)
21 19 and 20 (2207)
22 limit 21 to (english language and humans) (1927)
23 limit 22 to case reports (279)
24 22 not 23 (1648)

Medline Search Terms for Lung Transplantation

1 Lung Transplantation/ (9057)

2 graft$, lung$.mp. (61)
3 lung$ graft$.mp. (290)
4 transplant$, lung$.mp. (651)
5 lung transplant$.mp. (11588)
6 lung$ transplant$.mp. (11592)
7 or/1-6 (11671)
8 exp Lung/ (191346)
9 exp Bronchi/ (30809)
10 Bronchioles/ (58)
11 exp Pulmonary Alveoli/ (20902)
12 bronchus$.mp. (8261)
13 or/8-12 (195758)
14 Transplants/ (1432)
15 Transplantation/ (6701)
16 Organ Transplantation/ (7272)
17 or/14-16 (15116)
18 13 and 17 (121)
19 or/7,18 (11772)
20 exp Mortality/ (214838)
21 19 and 20 (1013)
22 limit 21 to (english language and humans) (893)
23 limit 22 to case reports (175)
24 22 not 23 (718)

Medline Search Terms for Heart and Lung Transplantation and Massive Bleeding

1 massive blood transfusion$.tw. (247)
2 massiv$ transfus$.tw. (611)
3 massive blood loss$.tw. (370)
4 acute blood loss$.tw. (549)
5 massive blood replacement$.tw. (30)
6 whole blood transfus$.tw. (226)
7 (massive$ bleed$ adj3 patient$).tw. (148)
8 massive transfusion protocol$.tw. (17)
9 massive transfusion practice$.tw. (6)
10 large volume blood transfusion$.tw. (6)
11 large volume transfusion$.tw. (13)
12 massive bleed$.tw. (1270)
13 massive hemorrhage$.tw. (1517)
14 Blood Transfusion/ (46385)
15 Blood Component Transfusion/ (2117)
16 Erythrocyte Transfusion/ (4435)
17 Platelet Transfusion/ (3561)
18 or/14-17 (53054)
19 ((massive$ or whole) adj4 (transfus$ or replacement$)).mp. (5691)
20 18 and 19 (1413)
21 or/1-13,20 (5295)
22 Heart Transplantation/ (24622)

23 Heart-Lung Transplantation/ (1736)
24 cardiac transplant$.tw. (7219)
25 transplant$, cardiac.tw. (137)
26 heart transplant$.tw. (12742)
27 transplant$, heart.tw. (769)
28 graft$, heart.tw. (59)
29 heart-lung transplant$.tw. (1520)
30 transplant$, heart-lung.tw. (15)
31 graft$, heart-lung.tw. (0)
32 or/22-31 (29580)
33 Transplants/ (1315)
34 Transplantation/ (6657)
35 or/33-34 (7954)
36 Heart/ (106350)
37 (heart adj2 lung).tw. (11092)
38 or/36-37 (116452)
39 38 and 35 (129)
40 or/32,39 (29667)
41 21 and 40 (21)
42 limit 41 to english language (20)
43 limit 42 to case reports (9)
44 42 not 43 (11)

Medline Search Terms for Ruptured Aortic Aneurysm

1 exp Mortality/ (212912)
2 Aortic Aneurysm, Abdominal/ (9872)
3 abdominal aortic aneurysm$.tw. (9129)
4 aortic aneurysm$, abdominal.tw. (10)
5 aneurysm$, abdominal aortic.tw. (11)
6 or/2-5 (12766)
7 6 and 1 (1184)
8 limit 7 to english language (1035)
9 limit 8 to case reports (187)
10 8 not 9 (848)

Medline Search Terms for Ruptured Aortic Aneurysm and Massive Bleeding

1 massive blood transfusion$.tw. (247)
2 massiv$ transfus$.tw. (611)
3 massive blood loss$.tw. (370)
4 acute blood loss$.tw. (549)
5 massive blood replacement$.tw. (30)
6 whole blood transfus$.tw. (226)
7 (massive$ bleed$ adj3 patient$).tw. (148)
8 massive transfusion protocol$.tw. (17)
9 massive transfusion practice$.tw. (6)
10 large volume blood transfusion$.tw. (6)

11 large volume transfusion$.tw. (13)
12 massive bleed$.tw. (1270)
13 massive hemorrhage$.tw. (1517)
14 Blood Transfusion/ (46385)
15 Blood Component Transfusion/ (2117)
16 Erythrocyte Transfusion/ (4435)
17 Platelet Transfusion/ (3561)
18 or/14-17 (53054)
19 ((massive$ or whole) adj4 (transfus$ or replacement$)).mp. (5691)
20 18 and 19 (1413)
21 or/1-13,20 (5295)
22 Aortic Aneurysm, Abdominal/ (9563)
23 abdominal aortic aneurysm$.tw. (8871)
24 aortic aneurysm$, abdominal.tw. (10)
25 aneurysm$, abdominal aortic.tw. (11)
26 or/22-25 (12414)
27 21 and 26 (40)
28 limit 27 to english language (33)
29 limit 28 to case reports (14)
30 28 not 29 (19)

Medline Search Terms for Obstetrics

1 massive blood loss$.tw. (378)
2 acute blood loss$.tw. (563)
3 (massive$ bleed$ adj3 patient$).tw. (160)
4 massive bleed$.tw. (1326)
5 massive hemorrhage$.tw. (1556)
6 exp Hemorrhage/ (197818)
7 hemorrhage$.mp. (175553)
8 haemorrhage$.mp. (22516)
9 bleed$.mp. (101691)
10 or/1-9 (295986)
11 exp Mortality/ (213079)
12 Mothers/ (18584)
13 mother$.mp. (126700)
14 maternal$.mp. (171567)
15 or/12-14 (254417)
16 11 and 10 and 15 (1528)
17 exp Carcinoma/ (392867)
18 exp Neoplasms/ (2078572)
19 or/17-18 (2078572)
20 16 not 19 (1492)
21 limit 20 to case reports (110)
22 20 not 21 (1382)
23 limit 22 to english language (1135)
24 from 23 keep 1-100 (100)
25 neonate mortality.mp. (8)

26 exp Infant, Newborn/ (429678)
27 23 not 26 (718)

Medline Search Terms for Obstetrics and Massive Bleeding

1 massive blood transfusion$.tw. (247)
2 massiv$ transfus$.tw. (611)
3 massive blood loss$.tw. (370)
4 acute blood loss$.tw. (549)
5 massive blood replacement$.tw. (30)
6 whole blood transfus$.tw. (226)
7 (massive$ bleed$ adj3 patient$).tw. (148)
8 massive transfusion protocol$.tw. (17)
9 massive transfusion practice$.tw. (6)
10 large volume blood transfusion$.tw. (6)
11 large volume transfusion$.tw. (13)
12 massive bleed$.tw. (1270)
13 massive hemorrhage$.tw. (1517)
14 Blood Transfusion/ (46385)
15 Blood Component Transfusion/ (2117)
16 Erythrocyte Transfusion/ (4435)
17 Platelet Transfusion/ (3561)
18 or/14-17 (53054)
19 ((massive$ or whole) adj4 (transfus$ or replacement$)).mp. (5691)
20 18 and 19 (1413)
21 or/1-13,20 (5295)
22 Obstetrics/ (13026)
23 obstetric$.tw. (51232)
24 exp Obstetric Surgical Procedures/ (86979)
25 obstetric$ surgical procedure$.tw. (11)
26 obstetric$ surger$.tw. (248)
27 procedure$, obstetric$ surgical.tw. (0)
28 surgical procedure$, obstetric$.tw. (1)
29 surger$, obstetric$.tw. (83)
30 exp Pregnancy Complications/ (274045)
31 or/22-30 (362539)
32 21 and 31 (398)
33 limit 32 to english language (248)
34 limit 33 to case reports (117)
35 33 not 34 (131)

Medline Search for Extracorporeal Membrane Oxygenation

1 Extracorporeal Membrane Oxygenation/ (3581)
2 Extracorporeal Membrane Oxygenat$.mp. (4331)
3 oxygenat$, extracorporeal membrane.mp. (5)
4 membrane oxygenat$, extracorporeal.mp. (9)
5 ECMO.mp. (2104)
6 or/1-5 (4489)
7 exp Mortality/ (215587)
8 6 and 7 (616)
9 limit 8 to english language (584)
10 limit 9 to case reports (119)
11 9 not 10 (465)

Medline Search for Ventricular Assist Device

1 Heart-Assist Devices/ (6089)
2 heart assist device$.mp. (6130)
3 vascular assist device$.mp. (1)
4 vascular assist pump$.mp. (0)
5 heart assist pump$.mp. (3)
6 left ventric$ assist device$.mp. (2138)
7 LVAD.mp. (1115)
8 ventric$ assist device$.mp. (3608)
9 artificial ventric$.mp. (111)
10 (artificial adj1 ventric$).mp. (119)
11 ventric$, artificial.mp. (9)
12 artificial heart ventric$.mp. (27)
13 exp Assisted Circulation/ (10960)
14 assist$ circulation.mp. (3274)
15 circulation, assist$.mp. (20)
16 (assist$ adj circulation).mp. (3274)
17 or/1-16 (11659)
18 exp Mortality/ (218784)
19 17 and 18 (843)
20 limit 19 to english language (779)
21 limit 20 to case reports (119)
22 20 not 21 (660)

Appendix H– References Used to Generate Recommendations

Trauma: predictors of massive transfusion

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