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Futility and Potentially Inappropriate Treatment in Massive Transfusion

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Futility and Potentially Inappropriate Treatment in Massive Transfusion

KEY POINTS

- There are numerous predictors of potentially inappropriate treatment, but none are fully reliable.
- Prospective discussions and shared decision-making must be routine during ongoing assessment of the massively bleeding patient at regular intervals and should include communication among surgery, anesthesiology, and transfusion medicine specialties.
- Blood suppliers are responsible to many hospitals and patients, and it may be difficult to support one patient's ultramassive transfusion (UMT), especially in times of shortages.

INTRODUCTION

Recognition of clinical futility and potentially inappropriate treatment in the context of massive transfusion protocols is a complex and multifaceted concept requiring a pragmatic approach to balance aggressive resuscitation efforts with ethical commitments of beneficence, non-maleficence, responsible blood stewardship and ethical resource allocation.

The term "futile" should only be used in the rare circumstance that "an intervention simply cannot accomplish the intended physiologic goal."[1] Uses of blood that are strictly futile may be withheld or withdrawn solely on standard clinical decision-making and without additional due process requirements.[1]

Potentially inappropriate treatments are defined as "treatments that have at least some chance of accomplishing the effect sought by the patient, but clinicians believe competing ethical considerations justify not providing them."[1] In critical care settings, potentially inappropriate treatments are further characterized as treatments "when there is no reasonable expectation that the patient will improve sufficiently to survive outside the acute care setting, or when there is no reasonable expectation that the patient's neurologic function will improve sufficiently to allow the patient to perceive the benefits of treatment."[2]

A position statement from five critical care societies has recommended that the withdrawal or withholding of potentially inappropriate treatment after a fair decision-making process is ethically defensible.[1]

The discussion of the subject is particularly crucial in severe blood shortages, where the judicious use of limited blood products becomes paramount.

The determination of potentially inappropriate treatment requires a multidisciplinary decision that considers the patient's overall clinical condition, response to resuscitation efforts, and the availability of blood products while possibly considering predetermined time-outs or transfusion volumes.

In these scenarios, prompt surgical intervention, hemostatic agents, and aggressive resuscitative measures beyond transfusion are essential for patient salvage. The availability and feasibility of these resources may influence transfusion support.

When determining potentially inappropriate treatment in massive transfusion, key considerations include:

1. whether the available resources will likely salvage the patient based on injury patterns, physiological derangements, and response to resuscitation;
2. responsible stewardship of the scarce blood product resource, especially during shortages. However, the justification for withholding treatment in cases of potentially inappropriate treatment differs significantly from the rationale for rationing limited resources. Treatment decisions to withhold potentially inappropriate treatment focus on obligations to balance benefits and burdens of treatment for an individual patient, while decisions to withhold treatment from one patient to benefit others in a community are rationing decisions based on justice and population health considerations[3]; and
3. proactive planning through multidisciplinary discussions, ethical frameworks, and predefined processes rather than reactive decision-making.

An explicit, evidence-based approach balancing patient factors, resource availability, and ethical principles is preferred for these high-stakes decisions.

POSSIBLE INDICATORS OF POTENTIALLY INAPPROPRIATE TREATMENT

Numerous candidate indicators of potentially inappropriate treatment in the setting of massive transfusion have been evaluated including:[4-9]

1. physiological parameters (e.g., systolic blood pressure,

heart rate, oxygen saturation, arterial base deficit, peak lactate level, nadir pH, urine output, visible evidence of tissue ischemia (pulseless extremities, visible dead bowel, visible hepatic infarction);

2. cause of critical bleeding (trauma, cardiac surgery, organ transplantation);
3. likelihood of gaining surgical control of bleeding;
4. severity scores (e.g., Glasgow Coma Scale, Injury Severity Score);
5. surgical interventions (e.g., aortic clamping, thoracotomy);
6. patient age;
7. number of red blood cell units (RBCs) transfused; and
8. total blood products transfused and the ratio of different components.

However, no single indicator has been identified as a reliable predictor of futile, or inappropriate treatment. The number of clinical variables, differences in patient management, and other factors make study design challenging. Even the definition of critical bleeding, massive or ultramassive transfusion (UMT) are inconsistent across studies.[10-12]

PREDICTIVE MODELS AND THROMBOELASTOGRAPHY

A variety of proposals have been made for different markers of transfusion futility. These include defining a set number of red blood cell (RBC) units transfused within a certain time period, identification of the 'Death Diamond' pattern through thromboelastography (TEG), and the implementation of STOP Criteria based on arrival lab values, physiology, and rapid TEG.[13-17] Furthermore, predictors of mortality that have been described include peak lactate above 10 mmol/L, nadir arterial blood gas pH < 7.0, age >65 years, and diagnostic group – with higher mortality in trauma than in cardiac/vascular surgery, with the lowest mortality in transplant surgery.[12,18] To date, no single approach has proven sufficiently valid to gain wide acceptance.

ETHICAL CONSIDERATION AND DECISION-MAKING PROCESS

Given the complexity of massive transfusion scenarios and the lack of a 'one-size-fits-all' tool to estimate potentially inappropriate treatment, it is essential to develop an explicit decision-making process in which fair and due process elements are incorporated. This process should involve input from hospital ethics committees, multidisciplinary clinical teams, and other stakeholders to ensure the ethical provision of care and responsible resource allocation. Although some healthcare facilities may have established futility or potentially inappropriate treatment policies, these tend to be time consuming and resource intensive. Developing an expedited fair process decision-making policy must be a priority for real-time decision-making in contingency and crisis conditions.[1,3]

The goal of prospective discussions and shared decision-making is to reach a local consensus regarding when to reassess prolonging continued emergency care, including ongoing transfusion, of massively bleeding patients. This discussion should incorporate the following factors:[18,19]

1. clinical markers of critical injury;
   a. central nervous system (CNS) status and signs of irreversible brain damage (e.g., fixed dilated pupils, extreme anisocoria);
   b. pressor requirement;
   c. ventilation mechanics (e.g., FiO2, lung compliance);
   d. visible severe ischemia of bowel/liver;
   e. pulseless cold extremities;
2. current and anticipated ongoing blood loss;
3. number of blood products already transfused;
4. laboratory parameters (e.g., lactate, complete blood count, chemistry, coagulation tests, blood gases, liver function tests); and
5. likelihood of gaining bleeding control.

Ongoing assessment of the massively bleeding patient should occur at regular intervals during resuscitation. Real-time communication with the patient's family or significant others is crucial, focusing on functional outcomes, the patient's wishes, and the possible withdrawal or withholding of treatment deemed inappropriate.

BLOOD SUPPLY CONSIDERATIONS

The number of units of blood provided by the local supplier will depend on available stocks and the needs of other patients. One goal for a massively bleeding patient is to not jeopardize the blood supplier's ability to provide transfusion support for more viable patients who are also in urgent need of the limited supply of blood and components. Multiple casualty situations, such as can occur in mass shootings, are likely to require triage of blood resources to those most likely to survive their injuries.[5,20]

Blood suppliers may need to pull products from unshipped inventory or request other hospitals to return products to meet a specific patient's needs. These actions can cause shortages at other hospitals, impairing patient care. Blood suppliers face

the difficult task of balancing the needs of one patient at one hospital against those of many patients from many hospitals. This demands effective supplier communication to in these situations.

CONCLUSION

Inappropriate treatment in massive transfusion protocols is a multifaceted issue requiring a pragmatic, multidisciplinary approach. No single factor reliably predicts inappropriate treatment. Decisions should consider the patient's condition, response to resuscitation, blood product availability, and ethical principles. An explicit decision-making process involving ethics committees, multidisciplinary teams, and stakeholders is preferred, incorporating the diagnosis, prognosis, blood loss, laboratory parameters, treatments, and blood supply status. Regular assessments, family communication, responsible stewardship, and ethical resource allocation are essential, especially during times of blood shortages. This collaborative approach ensures judicious blood use while upholding ethical care and navigating the complexities of massive transfusion scenarios. Blood product availability may be improved by assuring blood conservation practices are observed for all transfusions. In addition, consider establishing cooperative blood drives with suppliers. ■

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