

Evaluation Tool for Assessing a Newly Implemented Massive Transfusion Protocol

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ABSTRACT

Exsanguination requires massive blood product replacement and termination of the bleeding source to prevent hemorrhagic shock and death. Massive transfusion protocols (MTPs) are algorithms that allow the health care team to quickly stabilize the bleeding patient and guide blood product administration. However, no national MTP guidelines or a standardized evaluation tool exist for collecting and reporting MTP-related data. The purpose of this article is to describe an original MTP evaluation tool, how it was used, barriers encountered, and a framework for reporting the MTP evaluation data. The evidence-based *Broxton MTP Evaluation Tool* was developed to evaluate the use of a newly implemented MTP via a retrospective review of electronic medical records (EMRs). Although the instrument itself worked well, barriers were encountered while reviewing the EMRs for the MTP evaluation. These barriers included no institutional entity was charged with tracking MTP activations, no searchable database was established to collect data concerning the MTP-activated patients, and no standard location in the EMR was designated for documenting the MTP activation. When devising protocols such as an MTP, a priori strategies should be developed for its implementation, documentation, and evaluation. Research is needed to determine best practices for evaluating an MTP to ensure positive patient outcomes with this protocol.

Key Words

Electronic medical record review, Massive transfusion protocol, Protocol evaluation tool

for reducing the mortality associated with exsanguination (Zink, Sambasivan, Holcomb, Chisholm, & Schreiber, 2009). Massive transfusion protocols (MTPs) are standardized algorithms that allow the health care team to quickly examine, diagnose, and stabilize the bleeding patient (Dente et al., 2009). Thus, exsanguination is prevented by following the prescribed treatment plan in the MTP. The MTP also includes a standardized recipe (formula) for blood product replacement, which research evidence has shown to significantly improve patient outcomes (Riskin et al., 2009). For example, Malone, Hess, and Fingerhut (2006) found that morbidity, mortality, and blood product utilization decreased by 50% when an MTP was implemented at a large medical center.

Many health care institutions have not yet developed and implemented an MTP despite the research evidence showing how they improve outcomes (Young, Cotton, & Goodnough, 2011). Consequently, each physician orders his or her own recipe for blood product replacement based on knowledge and experience. Furthermore, national standardized MTP guidelines have not yet been established that would produce a consensus regarding optimal treatment and provide a reliable recipe for blood product administration. This lack of national standards has resulted in a wide variety of MTPs by those health care institutions that have developed and implemented such a protocol. For example, Porteous (2015) described an MTP authorizing release of 5 units of packed red blood cells (PRBCs) and 1,000 ml of fresh frozen plasma (FFP) for immediate transfusion. Gehrie and Tormey (2014) reported the implementation of an MTP that allowed the transfusion of PRBCs and FFP at a 1:1 ratio, plus using laboratory data to consider transfusing platelets and cryoprecipitate after administering the first 4 units of PRBCs and FFP. Although these two studies presented a different MTP, they both demonstrated that early access to blood products, rather than the PRBC:FFP ratio, promoted positive patient outcomes.

As more health care institutions develop and implement an evidence-based MTP, a formal procedure is needed for evaluating its utilization and efficacy. Recently, a Level 1 trauma center implemented an evidence-based MTP to guide blood replacement therapy for patients experiencing a massive blood loss. After 1 year, an evaluation tool was designed and used to review the utilization and efficacy of the MTP. The purpose of this article is to describe the original MTP evaluation tool, how it was

Exsanguination is a disorder whereby a large acute blood loss produces hemorrhagic shock and death (Elmer, Wilcox, & Raja, 2013). Regardless of the underlying cause, blood product replacement and termination of the bleeding source are the priorities

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used, barriers encountered, and a framework for reporting the MTP evaluation data.

MTP EVALUATION TOOL

A review of the literature was conducted to identify an existing formal MTP evaluation tool; none were found. Therefore, measured variables from published research studies were used to create the *Broxton MTP Evaluation Tool* (Figure 1). The variables included in this newly developed MTP evaluation tool originated from common themes found in the MTP-associated research literature. For example, Dente et al. (2009) evaluated the effectiveness of a newly implemented MTP by measuring mortality rates at a Level 1 trauma center in two groups of subjects: MTP activated ($n = 72$) and non-MTP activated ($n = 84$) trauma patients. The subjects were young adults (mean age = 35 and 37 years; $p = .42$) and predominately male (84% and 82%; $p = .81$) in both the MTP and non-MTP activated groups, respectively. These investigators found that the MTP activated group had a significantly lower mortality rate than the non-MTP activated group at both the 24-hr (17% and 36%, respectively; $p = .008$) and

30-day (34% and 55%, respectively; $p = .04$) time points. These findings validated the usefulness of adding the 24-hr and 30-day mortality rates as variables in the *Broxton MTP Evaluation Tool* and evaluating MTP efficacy.

Hendrickson et al. (2012) evaluated how MTP implementation improved outcomes in pediatric trauma patients, who were designated as either MTP ($n = 53$) or pre-MTP ($n = 49$). The pre-MTP data were retrospectively collected from the electronic medical record (EMR), which were then compared with the MTP data prospectively collected over 15 months. These investigators measured hemoglobin (HGB), prothrombin time (PT), and partial thromboplastin time (PTT) at emergency department (ED) admission, which showed that 72% of the MTP and 80% of the non-MTP patients had at least one of these laboratory values outside the normal range. This finding demonstrates the importance of the HGB, PT, and PTT values as massive bleeding indicators that should be used as triggers for activating the MTP. For this reason, these laboratory values were incorporated into the *Broxton MTP Evaluation Tool*.

The most common variables measured in these two studies were age, gender, 24-hr mortality, PT, PTT, HGB, and administration of type and amount of blood products (PRBCs, FFP, and platelets). This measurement commonality for evaluating MTPs was a reason why these variables were included in the *Broxton MTP Evaluation Tool*. Other variables were also found useful for evaluating MTP implementation. For example, Nascimento et al. (2013) compared two MTPs to determine which protocol could be administered as a balanced strategy without causing cardiovascular overload or respiratory distress syndrome due to the administration of large quantities of blood products. By comparing one protocol guided by laboratory data and one using a fixed 1:1:1 ratio of PRBCs:FFP:platelets, these investigators also sought to determine the best MTP for preventing an unnecessary transfusion of blood products. After equally randomizing 78 patients into the two protocol groups, these investigators measured the injury severity score (ISS), Glasgow Coma Scale (GCS) score, and international normalized ratio (INR), along with the common variables previously mentioned. The results of this study found that the laboratory-guided protocol established an INR of less than 1.8 for triggering platelet transfusion. Thus, the INR variable was selected for inclusion in the *Broxton MTP Evaluation Tool*. However, the decision was made not to include the ISS and GCS scores in this tool due to their inconsistent use in the literature and the difficulty finding this information in the EMR.

The studies by Dente et al. (2009), Hendrickson et al. (2012), and Nascimento et al. (2013) collected not only the demographic data of age and gender but also the type of trauma (blunt or penetrating) sustained by the patient, as well as epoch data such as the number of ventilator

Subject Identifier Number:										
Patient Demographics					Mortality					
Age (years):					24-hour death:		Yes		No	
Gender: MALE FEMALE					30-day death:		Yes		No	
Bleeding Source										
Trauma			Surgical			Medical				
Blunt: Yes No										
Type: _____			Type: _____			Type: _____				
Penetrating: Yes No										
Type: _____										
Laboratory Data					Epoch Data					
Initial		24 hour								
PT					Hospital LOS _____					
PTT					ICU LOS _____					
INR					Days on Ventilator _____					
HGB										
HCT										
MTP Activation					Quantity of Products Used					
YES NO					# Units PRBCs: _____					
					# Units FFP: _____					
					# Units Platelets: _____					
≥ 4 units PRBCs given over 4 hours		Tranexamic Acid given			≥ 10 units PRBCs given over 24 hours		Uncross-matched PRBCs given			
Yes No		Yes No			Yes No		Yes No			

Figure 1. *Broxton MTP Evaluation Tool*. FFP = fresh frozen plasma; HCT = hematocrit; HGB = hemoglobin; ICU = intensive care unit; INR = international normalized ratio; LOS = length of stay; MTP = massive transfusion protocol; PRBCs = packed red blood cells; PT = prothrombin time; PTT = partial thromboplastin time.

days and length of stay in the intensive care unit and hospital. Therefore, these common variables from the literature were added to the *Broxton MTP Evaluation Tool* for the potential (future) analysis of patient outcomes and/or health care costs.

In addition to the variables previously discussed, Long, Heaney, Simms, McSwain, and Duchesne (2013) measured hematocrit (HCT) levels in 150 trauma patients during their 53-month retrospective evaluation of an MTP. Not only were these investigators the first ones to use HCT as an indicator of survival post-MTP activation but they also used this variable to divide their patients into four post-blood transfusion groups for data analysis: less than 21%, 21%–29%, 29.1%–39%, and more than 39%. The results showed that patients with a 21%–39% HCT post-blood transfusion had a 28%–35% survival rate after 25 days in the hospital compared with the 10% survival rate of those patients with either less than 21% or more than 39% HCT level. Hence, this study demonstrated the usefulness of measuring HCT levels when evaluating the efficacy of an MTP and why the HCT was included in the *Broxton MTP Evaluation Tool*.

Zink et al. (2009) retrospectively reviewed the medical records of 466 patients from 16 different Level 1 trauma centers to assess the efficacy transfusing blood at higher PRBC:FFP ratios than the typical 1:1 ratio used in the previously discussed studies. These investigators found an 80% 30-day survival rate in those patients who received blood transfusion at 1:1 PRBCs:FFP ratio, whereas only 50% had survived after receiving the 4:1 PRBCs:FFP ratio. Also, the 6-hr mortality rate was significantly lower in trauma patients receiving more than 1 unit of FFP for each unit of PRBCs (2% and 37%, respectively, $p < .001$) as well as more than 1 unit of platelets for each unit of PRBCs (3% and 23%, respectively; $p < .002$). These results emphasize the importance of documenting the amount of blood products given during a massive transfusion as well as tracking the type of blood product administered to the patient. Clinicians must be aware of not only the amount of blood but also the blood product ratio being transfused into the exsanguinating patient to enhance the survival rate. For these reasons, PRBC units, FFP units, and platelet units are variables in the *Broxton MTP Evaluation Tool*.

By adding variables found in the MTP-related literature to the *Broxton MTP Evaluation Tool*, this tool became clinically useful for acquiring consistent data while auditing an exsanguinating patient's EMR. However, three variables were also included in the *Broxton MTP Evaluation Tool* that were not discussed in the literature but had evidence-based clinical implications: (1) administration of tranexamic acid (TXA); (2) administering uncross-matched PRBCs; and (3) transfusing 4 units or more of PRBCs in 1 hr.

Tranexamic acid was the first unique variable added to the evaluation tool because it is an antifibrinolytic agent

that effectively terminates clot degradation. It is only used for the cessation of hemorrhage and exsanguination prevention (Dunn & Goa, 1999; Wafaisade et al., 2016). Therefore, if TXA was documented in the EMR, but the MTP was not activated, one can conclude that the practitioner prescribed TXA because of the patient's clinical presentation and assumption of imminent exsanguination. Also, the TXA administration data were useful for identifying a patient cohort who did not meet existing MTP criteria because TXA was pharmacologically effective. For example, a patient presented in the ED with signs of acute hemorrhage. Once the practitioner ordered and administered TXA, a different MTP algorithm was followed because the TXA's mechanism of action early in the exsanguination process stopped the patient's hemorrhaging. Thus, the need for TXA is an important indicator of the need for MTP activation and the reason why it was included as a variable on the evaluation instrument.

The second unique variable added to the *Broxton MTP Evaluation Tool* was the administration of uncross-matched PRBCs. Uncross-matched PRBCs are typically given only to patients needing immediate blood transfusions because of severe, uncontrollable active bleeding. Although early blood product transfusion does decrease mortality, transfusing uncross-matched blood is associated with a 64% increase in adverse transfusion reactions compared with cross-matched blood (Ball et al., 2011). For this reason, uncross-matched PRBCs are only given under dire clinical circumstances; stable patients are not prescribed uncross-matched blood. So as with TXA, the need for uncross-matched PRBCs is a crucial indicator of the need for MTP activation and the reason why it was included as a variable on the evaluation instrument.

Finally, collecting information concerning whether 4 units or more of PRBCs were administered in 1 hr was based on the authors' extensive clinical experience. If a patient needed this amount of blood in such a short time, these data anecdotally indicated the patient was massively bleeding. Clinically stable patients receive 1 unit of PRBCs over 3–4 hr, whereas unstable patients receive 1 unit of PRBCs over a few minutes (Carson et al., 2012–2016). Because the average unit of PRBCs has a volume of 300 ml, 4 units of PRBCs provide approximately 1,200 ml in 1 hr, which is a large volume of fluid to receive in a short amount of time. Hence, receiving 4 units or more of PRBCs in 1 hr denotes the occurrence of exsanguination. So as with TXA and uncross-matched PRBCs, the need for administering 4 units or more of PRBCs in 1 hr is an essential indicator of the need for MTP activation and the reason why it was included as a variable on the evaluation instrument.

Thus, the *Broxton MTP Evaluation Tool* contains relevant MTP variables found in the literature (demographic, mortality, bleeding source, laboratory and epoch data,

and quantity of blood products used) and/or justified by clinical expertise (administration of TXA, uncross-matched PRBCs, and/or ≥ 4 units of PRBCs in 1 hr). In hindsight, race may also be a beneficial variable to identify inequities in patient treatment. Therefore, future revisions of the *Broxton MTP Evaluation Tool* may include this variable.

IMPLEMENTATION

The *Broxton MTP Evaluation Tool* was utilized to determine the use and efficacy of an MTP during the first year of its implementation at a Level I trauma medical center. Approval by the institution's review board was obtained before beginning this project. A list of patients was acquired who were treated by the trauma physicians and had received any type of blood product from July 1, 2014 (3 months after the MTP was implemented), to June 30, 2015. Each qualifying EMR from this list was reviewed by the project manager and deidentified data collected with the *Broxton MTP Evaluation Tool* (Figure 1). The presence of massive bleeding was acknowledged if the EMR documentation indicated that the trauma patient received at least one of these four treatments: TXA, uncross-matched PRBCs, 4 units or more of PRBCs in 1 hr, and/or 10 units or more of PRBCs in 24 hr. By formally collecting data in this systematic manner, a holistic portrayal was obtained regarding how the MTP was used for treating trauma patients needing massive blood transfusions. A report of the findings was then presented to the trauma practitioners and administrators of the medical center.

BARRIERS

When the plan for evaluating the MTP was initially proposed, it appeared to be a straightforward assignment. However, several barriers were encountered while conducting this clinical improvement project. First, no institutional entity was charged with tracking MTP activations. Therefore, no database was available that listed those patients treated with the MTP. The only available database was one listing all patients who received any type of blood product within the given time frame. Although this database contained 10,000 patient names, it was not searchable using variables associated with MTP activation or congruent with MTP activation criteria. Hence, this database was rendered useless for this project.

The authors were eventually informed that the trauma department at this medical center maintained a database tracking all trauma patients in compliance with the Trauma Quality Improvement Program (TQIP) managed by the American College of Surgeons (ACS). The ACS established the TQIP and its associated registry in 2009 to improve the quality of trauma care (ACS, 2016). This organization currently collects trauma patient data from 650 participating hospitals in the United States. Once hospitals submit their TQIP data, the ACS provides recom-

mendations for improving their trauma patient care outcomes. Hence, the TQIP database for this medical center was the one used for this project. This medical center's TQIP database allowed trauma patients to be identified who were either (1) treated per the MTP activation or (2) met the MTP criteria but were not treated per the MTP (i.e., missed MTP activations) during the first year of the protocol's implementation.

A second major barrier was encountered upon discovering that the TQIP database could not be examined using MTP-related search terms per se. Therefore, a list was generated from the TQIP database identifying every trauma patient who received any type of blood product within the established time frame. Of the 108 trauma patients treated at the medical center within the first year of implementing the MTP, seven (6%) of these patients were 14 years or younger and had not sustained massive bleeding. Of the remaining trauma patients ($n = 101$) verified to be adults (≥ 18 years old), 43 (43%) of them did not experience massive bleeding with their injuries. Of the adult trauma patients who experienced massive bleeding ($n = 58$), 16 of them were treated per the MTP (i.e., the MTP was appropriately activated) whereas 42 patients were treated without the MTP (i.e., the MTP was not activated despite meeting the activation criteria).

The last barrier concerns inconsistent EMR documentation regarding who activated the MTP because no standardized specific location for these data had been established in the EMR. The EMR review revealed only circumstantial documentation about MTP activation in each chart. The MTP began with an activation order sent to the blood bank (Figure 2). However, no such order was found in any of the 101 EMRs reviewed for this project. When the MTP activation was documented by a practitioner, it was usually found in the history and physical portion of the EMR.

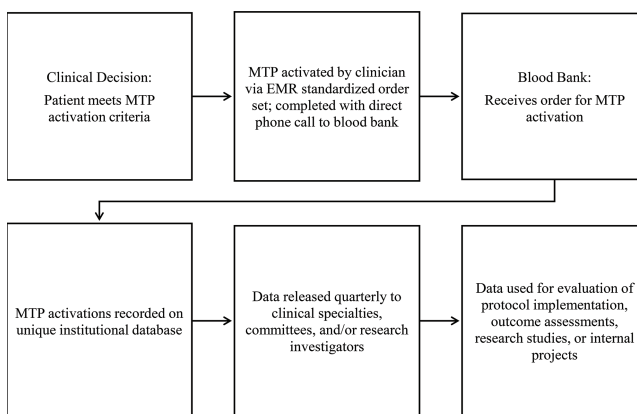


Figure 2. Proposed MTP data management plan. EMR = electronic medical record; MTP = massive transfusion protocol.

This project found that an accurate depiction of the MTP implementation process could not be clearly delineated because of a lack of consistent charting and tracking of MTP activations. This limited data access across varying patient populations resulted in opportunities for documentation improvement for several departments in this medical center. Therefore, one recommendation was to record blood product releases from the blood bank and MTP activations in one institutional database. Such a single database would allow diligent tracking and consistent documentation of MTP activations, while allowing future investigators access to the data of trauma and nontrauma patients who experienced massive bleeding. A limitation of this project was being only able to access the trauma patient population treated at this medical center. The number of nontrauma patients (e.g., surgical patients) who could benefit from the MTP activation is unknown. Although MTP-treated trauma populations have been thoroughly researched over the last decade, it is the comparable nontrauma populations that has been rarely investigated (McDaniel et al., 2013). Whether MTP activation for nontrauma patients reduces mortality and improves outcomes is unknown because little MTP data on this population has been published in the health care literature.

REPORTING EVALUATION DATA

When designing new evidence-based practice protocols such as the MTP, an evaluation instrument and data tracking method should be included in their development. Protocol implementation without a plan for evaluation reduces opportunities for future outcomes assessment and revision (Evans, Snooks, Howson, & Davies, 2013). Thus, a process was proposed for future MTP data management as illustrated in Figure 2. The first step when evaluating the MTP is making the clinical decision that the patient is experiencing a massive bleed. Second, the blood bank must be notified to begin the MTP algorithm for blood product release and other standardized treatments. Historically, MTP activation occurred via a telephone conversation only from the practitioner to the blood bank personnel or a written physician order for uncross-matched blood. This new management proposal standardizes the process with a standing order bundle located in the EMR, which once approved by the physician, triggers the MTP and its treatment algorithm. A practitioner would electronically activate the standing order bundle and direct dial the blood bank to confirm MTP activation. The responsible party charged with managing the MTP database would record the patient's demographic information, blood product release time, and type transfused, along with time the MTP activation process was completed. Not only would this process be compliant with the ACS TQIP Massive Transfusion in Trauma Guidelines (ACS, 2013) but it would

also allow the MTP database to be accessed for future patient outcome, cost analysis, measurement, and performance improvement projects. In addition, hospital data management systems should be revised to include reporting the release of large volumes of blood products for any individual patient (Camazine et al., 2015). This release time information would allow searching within the MTP database to determine whether trauma or nontrauma patients experienced massive bleeding and whether the MTP was appropriately activated. Finally, accessing this type of data also would aid in identifying barriers to MTP implementation and how well the protocol was being effectively used by practitioners.

CONCLUSION

When devising protocols such as an MTP, a priori strategies should be developed for its implementation, documentation, and evaluation. The evaluation process is a crucial component of creating standardized evidence-based protocols, policies, and/or guidelines. Research is needed to determine best practices for evaluating an MTP because little data exists regarding specific strategies and inclusion criteria necessary for assessing MTP-related patient outcomes. Also, future research should include all health care specialties who treat exsanguinating patients to ensure that every patient benefits from a well-established MTP.

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KEY POINTS

- The evidence-based *Broxton MTP Evaluation Tool* provides a formal method for assessing a newly implemented MTP.
- An MTP should be annually evaluated to ensure its efficient use and allow for appropriate protocol revisions to improve patient outcomes.
- A place for MTP activation should be established in the patient's medical record because consistent documentation is necessary for effectively evaluating patient outcomes.
- A unique database for MTP-related data should be maintained by a specific institutional administrator to improve data access for evaluating MTP implementation.

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