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Development of a ROTEM-guided Transfusion Algorithm in Cardiothoracic Surgery Patients

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Final Scholarly Project: Development of a ROTEM-guided Transfusion Algorithm in Cardiothoracic Surgery Patients

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Abstract

Cardiothoracic surgical patients are at an increased risk for bleeding complications for various reasons, including induction of hypothermia, initiation of the coagulation cascade, degradation of the coagulation factors, mechanical destruction of platelets, and a systemic inflammatory response due to cardiopulmonary bypass (CPB). The American Society of Anesthesiologists recommends rotational thromboelastometry (ROTEM)-guided transfusion algorithms for perioperative blood management; however, there remains a heavy reliance on conventional coagulation laboratory values. Utilization of the following PICOT question will guide this project: In cardiothoracic surgical patients, how does the use of ROTEM versus traditional coagulation laboratory tests (PT, INR, aPTT, ACT, platelet count, and fibrinogen) affect blood product utilization, patient mortality, and overall cost peri-operatively and post-operatively? The literature review encompasses the highest level of current evidence to determine if there is a statistically significant difference in the number of blood products administered, mortality, and cost associated with utilizing ROTEM technology. The proposed project site would be a large urban hospital with an anticipated sample of 240 cardiothoracic cases over six months. Outcome data will be examined to help the project team explore and compare the impacts of a ROTEM-guided transfusion algorithm versus traditional coagulation laboratory tests. Overall, this project aims to develop a blood product management algorithm utilizing ROTEM technology to enhance the identification of coagulopathies, thereby limiting inappropriate blood product administration, lowering mortality rates, and providing a cost-effective method for coagulation management.

Keywords: cardiothoracic, anesthesia, rotational thromboelastometry (ROTEM)

Problem Identification

Introduction of the problem

Coagulopathies in cardiothoracic surgery patients are a leading cause of inappropriate blood transfusion, morbidity, and mortality (Bartoszko & Karkouti, 2020). Current practices to identify perioperative coagulopathies include standard laboratory tests: international normalized ratio (INR), prothrombin time (PT), activated partial thromboplastin time (aPTT), activated clotting time (ACT), fibrinogen, and platelet count (Cohen et al., 2020). These laboratory findings can provide valuable information in evaluating hemostasis; however, they can result in delays in care, a lack of an all-inclusive examination of a patient's coagulation, and lead to inappropriate transfusions (Cohen et al., 2020). ROTEM provides advanced laboratory data that supplies substantially more information than the traditional laboratory values with a quicker turn-around time (Cohen et al., 2020). In 2015, the American Society of Anesthesiologists (ASA) updated the practice guidelines for identifying perioperative coagulopathies, adding the use of ROTEM (The American Society of Anesthesiologists, 2015). Amid the updated guidelines, there remains a need for a specific analysis and structured algorithm to guide blood transfusion and effectively identify and manage coagulopathies in cardiothoracic surgical patients.

Background

Various events lead to coagulopathies in cardiothoracic surgery patients peri-operatively. Induction of hypothermia, initiation of the coagulation cascade, degradation of the coagulation factors, mechanical destruction of platelets, and a systemic inflammatory response due to cardiopulmonary bypass (CPB) are all causes of coagulopathies (Butterworth et al., 2022). Cardiothoracic surgery has numerous unavoidable aspects that promote coagulopathies;

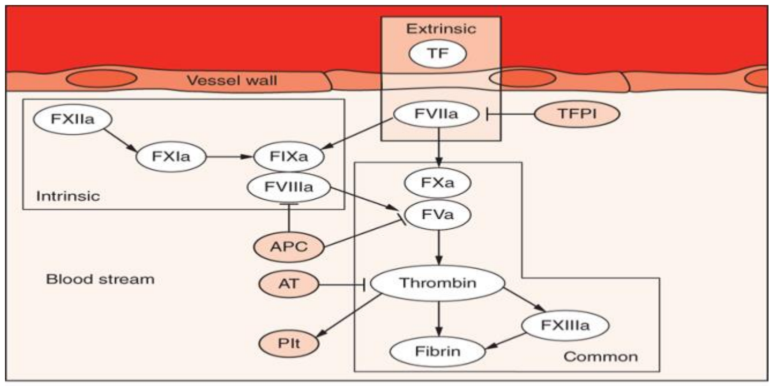
therefore, this project will focus on promptly identifying coagulopathies and forming a transfusion algorithm utilizing ROTEM.

Analysis of numerous laboratory tests aid in the detection of the underlying cause of a patient's abnormal bleeding. Discussion and comparison of the traditional laboratory tests and ROTEM are necessary to understand their significant benefits, disadvantages, and distinctions. The conventional coagulation laboratory tests include INR, PT, aPTT, ACT, fibrinogen, and platelet count. All of these laboratory tests analyze various aspects of the coagulation cascade.

The initial steps of the coagulation process (refer to Figure 1) rely on platelet adhesion, activation, and aggregation to form the primary platelet plug (Nagelhout, 2017). If the injury is too substantial for the primary platelet plug to provide hemostasis, the coagulation cascade initiates (Nagelhout, 2017). The external pathway is initiated due to exposure to damaged tissue, while exposure to collagen inside the vessel wall activates the intrinsic pathway (Levitzky, 2020). The extrinsic pathway involves clotting factors III (tissue factor) and VII (proconvertin), the most abundant of the clotting factors (Levitzky, 2020). Factors XII (Hageman), XI (Plasma thromboplastin antecedent), IX (Christmas), and VII (Antihemophiliac) all play a role in the intrinsic pathway (Nagelhout, 2017). The extrinsic and intrinsic pathways activate the final common pathway (Levitzky, 2020). The final common pathway begins with the activation of factor X (Stuart-Prower), which then initiates factors II (Prothrombin), I (Fibrinogen), V (Proaccelerin), and XIII (Fibrin Stabilizing), creating a stable secondary clot (Nagelhout, 2017). The traditional laboratory values utilized to evaluate the extrinsic and common pathways include PT and INR, while the aPTT and ACT assess the intrinsic and common pathways (Nagelhout, 2017). The fibrinogen laboratory test measures a patient’s fibrinogen level, which is necessary to evaluate the final common pathway (Nagelhout, 2017). Understanding the differences in the various coagulation pathways is essential to comprehending the importance of utilizing new innovative techniques.

Figure 1

Coagulation Cascade



Source: John D. Wasnick, Alina Nicoara: Cardiac Anesthesia and Transesophageal Echocardiography, Second Edition

The platelet count laboratory value quantifies the number of platelets in circulation; however, it fails to identify the functionality of those platelets (Cohen et al., 2020). The conventional laboratory values (PT, INR, aPTT, ACT) identify the initiation of clot formation but cannot account for the clot's strength (Cohen et al., 2020). Traditional laboratory values are unequipped to identify ineffective hemostasis due to their limited sensitivity (Nagelhout, 2017). Due to the limitations of the conventional coagulation laboratory values, ROTEM may further support the identification of various coagulation deficits.

Viscoelastic testing is an innovative technique for analyzing the coagulation process (Instrumentation Laboratory, n.d.). ROTEM is a laboratory test utilizing whole blood to provide an extensively detailed report, including initiation of the clot, speed of clot formation, and clot firmness and stability (Instrumentation Laboratory, n.d.). Various ROTEM assays (EXTEM, INTEM, FIBTEM, and HEPTEM) are available to assess distinct aspects of the clotting cascade (Instrumentation Laboratory, n.d.). EXTEM provides information regarding the extrinsic pathway (factors II, V, VII, and X), INTEM assesses the intrinsic pathway (factors II, V, VIII, IX, X, XI, XII, and heparin) FIBTEM, in conjunction with EXTEM, analyzes clot firmness, and HEPTEM evaluates the effects of unfractionated heparin on hemostasis (Instrumentation Laboratory, n.d.). ROTEM technology is ideal for the cardiothoracic surgery population because it identifies the root cause of a patient's coagulopathy and accurately guides transfusions.

The ROTEM system examines a blood sample throughout the continuum of the clotting process and utilizes numerous data points to determine which blood component is most appropriate for administration. Following the insertion of the blood sample into the ROTEM device for analysis, the initial reading will be Clotting Time (CT), indicating the first significant clot formation level (Calatzis et al., 2016). The CT value gives us insight into how quickly the patient is able to start forming a clot, which "facilitates the decision to substitute clotting factors [by administering fresh frozen plasma] (FFP) or anticoagulant antidotes such as protamine" (ROTEM basic interpretation guide, 2015, p.1). Clot Formation Time (CFT) is the time from CT to the point when the clot reaches the specified level of clot firmness (20mm) (ROTEM basic interpretation guide, 2015). The CFT provides information regarding platelet activation, fibrin, and factor XIII to identify issues with creating a stable clot (Calatzis et al., 2016). According to the value of the CFT, one can determine if the patient requires platelet concentration, FFP, cryoprecipitate (a high CFT) or if the patient is in a hypercoagulable state (a low CFT) (ROTEM basic interpretation guide, 2015).

Utilizing the starting point and the CT, an angle is measured to examine the amplitude created by the acceleration of clot formation; this is known as the alpha angle and is another value to infer clot stability (ROTEM basic interpretation guide, 2015). A small alpha angle typically correlates with hypofibrinogenemia or thrombocytopenia, while a large alpha angle can suggest a hypercoagulable state (ROTEM basic interpretation guide, 2015). The last two values are similar but taken at different time intervals. A10 examines clot firmness ten minutes after CT, while the Maximal Clot Firmness (MCF) evaluates clot firmness at the twenty-minute mark (ROTEM basic interpretation guide, 2015). Both A10 and MCF provide information to determine the need to administer platelet concentrate, FFP, or cryoprecipitate and aids in identifying a hypercoagulable state (ROTEM basic interpretation guide, 2015). The standard reference ranges for each measurement will be available as part of the ROTEM-guided transfusion algorithm guideline. All of the numerical values provided by the ROTEM analysis provide an encompassing and comprehensive evaluation of the patient's coagulation status.

The ASA recommends ROTEM-guided transfusion algorithms for perioperative blood management; however, there remains a heavy reliance on traditional coagulation laboratory values (The American Society of Anesthesiologists, 2015). ROTEM-guided algorithms are classified as A1-B level evidence, indicating a high level of evidence supporting the implementation of such algorithms (The American Society of Anesthesiologists, 2015). Although the evidence suggests ROTEM analysis is superior to traditional laboratory testing in identifying coagulopathies, there continues to be a gap in practice. There is a unique opportunity to intricately analyze current research and provide evidence-based practice guidelines for a ROTEM-guided blood management algorithm in cardiothoracic surgery at the local hospital level.

Significance of the problem related to Nurse Anesthesia

Cardiothoracic surgery, especially with the utilization of CPB, can lead to coagulopathies that amplify the requirement for blood transfusions, impair hemostasis, and increase the incidence of morbidity and mortality (Raphael et al., 2019). The ability of nurse anesthetists to rapidly identify and manage coagulopathies peri-operatively will significantly impact patient outcomes. ROTEM technology can decrease blood product usage, reduce transfusion complications, and provide a cost-effective alternative to traditional labs.

Population, Intervention, Comparison, Outcomes, and Time (PICOT) Question

The first step of an evidence-based practice project is to identify the clinical question. "Clinical questions are asked in PICOT format (i.e., *p*atient population, *i*ntervention or *i*ssue of interest, *c*omparison intervention or group, *o*utcome and *t*ime frame) to yield the most relevant and best evidence from a search of the existing literature" (Melnyk & Fineout-Overholt, 2018, p.47). Utilization of the following PICOT question will guide this project: In cardiothoracic surgical patients, how does the use of ROTEM versus traditional coagulation laboratory tests (PT, INR, aPTT, ACT, platelet count, and fibrinogen) affect blood product utilization, patient mortality, and overall cost peri-operatively and post-operatively?

Literature Review

A thorough and complete literature search was conducted utilizing the following databases and search terms. The literature search initially began using Otterbein University's Courtright Memorial Library's OneSearch to explore the topic broadly. To further investigate the viability of the PICO(T) question, the following databases were utilized: CINAHL Plus with full text, Cochran Database of Systematic Reviews, PubMed, and Science Direct. The following Boolean phrases and search terms were applied to the various database search engines: "ROTEM" OR "cardiac surgery" OR "blood transfusion" OR "mortality" OR "conventional coagulation tests." Inclusion criteria include publication within the last ten years, randomized control trials, meta-analyses, systematic reviews, studies including ROTEM, and studies utilizing the cardiac surgery population. Exclusion criteria include research in a foreign language and expert opinions. A literature review table (Appendix C) is available as a quick and organized reference of the literature utilized for this project.

Blood Transfusion

A review of various meta-analyses, randomized controlled trials, and health technology assessments provides consistent evidence to support the utilization of ROTEM to more accurately correct coagulopathies and minimize blood product usage (Görlinger et al., 2019). The review of 17 evidence-based research studies, including 235,779 surgical patients, determined a 39% decrease in transfusion rate with the implementation of a multimodal blood management protocol (Görlinger et al., 2019). Görlinger et al. (2019) analyzed two multi-center cohort studies; one study found the use of ROTEM directly correlates with a reduction in red blood cell (RBC) transfusion by 17%, while the other study discovered a 41% decrease in RBC, FFP, and platelet transfusions per admission. The evaluation of a meta-analysis including 8,332 patients reported "an odds ratio of 0.63 for patients receiving allogeneic blood products, 0.63 for RBC transfusion, 0.31 for plasma transfusion, [and] 0.62 for platelet transfusion" (Görlinger et al., 2019, p. 312); therefore, indicating a reduction in overall blood product utilization.

Haensig et al. (2019) studied 104 patients undergoing elective cardiac surgery and analyzed the utilization of a ROTEM-guided transfusion algorithm compared to a protocol using conventional coagulation laboratory values. According to this study, there was less bleeding post-operatively; however, requirements for RBC, FFP, and platelets were similar in both the control and experimental groups (Haensig et al., 2019). Haensig et al. (2019) determined that in patients with long CPB times, utilizing ROTEM may result in less bleeding and an overall decrease in cost and long-term mortality.

A stepped-wedge clustered RCT was conducted to determine if the implementation of a point-of-care (ROTEM) transfusion algorithm reduces blood product administration (Karkouti et al., 2016). Karkouti et al. (2016) studied 7,402 patients undergoing cardiac surgery with cardiopulmonary bypass across 12 hospitals. According to this study, "the intervention resulted in a 13% per patient reduction in units of red blood cells transfused, a 24% per patient reduction in doses of platelets transfused, but no change in units of plasma transfused. Overall, there was a 16% reduction in allogenic blood product transfusions." (Karkouti et al., 2016, p. 1157). The following RCT determined that using ROTEM to identify and manage coagulopathies more efficiently correlated with decreased blood product administration (Karkouti et al., 2016).

Karrar et al. (2022) examined 214 patients undergoing both elective and emergent proximal aortic surgery with deep hypothermic circulatory arrest to ascertain the practicality and applicability of a ROTEM-guided transfusion protocol compared to clinically-guided transfusion. Utilizing ROTEM to guide the administration of blood products resulted in a significant reduction in transfusion of RBCs (5 units in the control group vs. 2 units in the intervention group), platelet concentrate (2 pools of platelets in the control group vs. 1 pool in the intervention group), and plasma (1,980mL in the control group vs. 800mL in the intervention group) in elective surgery cases (Karrar et al., 2022). Results for the emergent surgery group were similar in the reduction of blood product usage in the intervention group (Karrar et al., 2022).

Forty patients undergoing on-pump cardiac surgery were studied to determine the correlation between traditional laboratory testing and ROTEM (Khalaf-Adeli et al., 2019). According to Khalaf-Adeli et al. (2019), there is an extended wait period for standard laboratory tests (40-60 minutes) compared to ROTEM (15-20 minutes). The results determined that "relying on traditional coagulation test results to decide whether [a] blood transfusion is necessary leads to the inappropriate transfusion, ultimately increasing the volume of transfusion, especially regarding the plasma products" (Khalaf-Adeli et al., 2019, p. 304). ROTEM is more effective and efficient than traditional laboratory tests in enhancing clinical decision-making and avoiding inappropriate blood product administration (Khalaf-Adeli et al., 2019).

A meta-analysis including 19 studies (15,320 participants) focusing on patients undergoing cardiac surgery with CPB analyzed the effects of a ROTEM or TEG transfusion algorithm on the quantity of blood loss and blood product transfusions (Li et al., 2019). A ROTEM or TEG-transfusion algorithm reduced blood loss volume by 132mL in comprehensive studies (Li et al., 2019). The relative risks (RR) in RCTs are as follows: for RBC transfusion 0.89, FFP transfusion 0.59, and platelet transfusion 0.81 (Li et al., 2019). This data is statistically significant in favor of using a ROTEM or TEG algorithm versus standard treatment regimens to markedly reduce blood loss and blood product administration (Li et al., 2019).

A meta-analysis of seven RCTs, including 1,035 patients, studied the applicability of viscoelastic (VE) hemostatic assays such as ROTEM in cardiac surgery patients (Meco et al., 2019). Exposure to allogeneic blood products was significantly reduced in patients treated with VE-guided transfusion algorithms in the experimental group (288/511) compared to those treated solely with clinician discretion in the control group (330/499) (Meco et al., 2019). RBC and platelet transfusions were decreased with the utilization of a VE algorithm with an odds ratio of 0.55 and 0.54, respectively (Meco et al., 2019). VE testing versus the control group revealed an estimated risk difference of 0.24 for FFP transfusion and an odds ratio of 0.31 for cryoprecipitate transfusion (Meco et al., 2019). The analysis of the current literature revealed a decrease in bleeding at 12 and 24 hours post-operatively due to the efficient identification of coagulopathies and more appropriate blood product administration (Meco et al., 2019).

To determine the effects of ROTEM and TEG-transfusion algorithms on the number of allogeneic blood transfusions, 11 RCTs were analyzed (Serraino & Murphy, 2019). The examination of various RCTs displayed a reduction in RBC, FFP, and platelet transfusions (RR 0.88, 0.68, and 0.78, respectively) (Serraino & Murphy, 2019). The literature analysis supports the use of ROTEM-guided transfusion algorithms to decrease blood product usage; however, Serraino & Murphy state that the current evidence is weak and future RCTs should include larger populations and limit bias (2019).

Ohio State University conducted an RCT of 68 patients undergoing liver transplant surgery to examine the benefits of a ROTEM-guided transfusion algorithm compared to traditional coagulation laboratory-guided transfusion on coagulation identification and management (Smart et al., 2017). The patients in the intervention group received significantly less FFP (4 units vs. 6.5 units), more cryoprecipitate (2 units vs. 1 unit), and a lower amount of blood transfused, including RBCs and salvaged blood (5.5 units vs. 8 units) (Smart et al., 2017). Overall, the utilization of a ROTEM-guided transfusion algorithm reduced allogeneic blood product administration (14.5 units vs. 17 units); however, this data was not statistically significant (Smart et al., 2017).

A meta-analysis reviewed 17 RCTs to identify the risks and benefits of ROTEM-guided transfusion compared with standard coagulation tests or clinical judgment to guide blood product administration (Wikkelsø et al., 2016). According to 10 studies, there was a reduction in the proportion of patients receiving RBC and platelet transfusions in the ROTEM group (619/251 per 1,000, respectively) compared to the comparison group (720/344 per 1,000, respectively)

(Wikkelsø et al., 2016). Eight studies evaluated FFP administration with the use of ROTEM (261 per 1,000) versus other treatment modalities (471 per 1,000) (Wikkelsø et al., 2016).

Mortality

A 2016 Cochrane meta-analysis reported a relative risk (RR) for mortality of 0.44 in trials utilizing ROTEM compared to a RR of 0.72 in TEG research studies (Görlinger et al., 2019). A large multi-center cohort study noted a reduction in hospital mortality with an odds ratio of 0.72 (Görlinger et al., 2019). Görlinger et al. (2019) performed a meta-analysis to evaluate the efficacy of a multimodal blood product management program and noted an 11% reduction in mortality (Görlinger et al., 2019).

A randomized control trial analyzed a ROTEM-guided transfusion algorithm versus blood product management based upon traditional coagulation laboratory values determining the 30-day mortality rate to be markedly reduced in the ROTEM group (Haensig et al., 2019). The 30-day mortality rate in the control group using traditional coagulation results was 8% (n=4) and 2% (n=1) in the ROTEM group (Haensig et al., 2019). At five years, the mortality rate was 12% (n=6) in the control group and 4% (n=2) in the ROTEM group (Haensig et al., 2019).

Fifteen RCTs, a total of 8,737 participants, were analyzed to determine the effects of ROTEM on mortality, blood loss, and blood transfusion (Serraino & Murphy, 2017). Seven trials studied the effects of ROTEM on mortality and found "mortality was lower in patients treated with TEG or ROTEM guided algorithms (12/350) [versus] controls (23/339)" (Serraino & Murphy, 2017, p.828). Although mortality was reduced in the intervention group, Serraino and Murphy found this data statistically insignificant (2019).

An analysis of eight studies, which included 717 patients, identified a reduction in mortality with a relative risk of 0.52 when using a ROTEM-guided transfusion protocol

(Wikkelsø et al., 2016). ROTEM or TEG-guided algorithms resulted in a significantly decreased mortality (3.9%) compared to the comparison groups (7.4%) (Wikkelsø et al., 2016). According to the data examined by Wikkelsø et al., there is substantial evidence to support the use of ROTEM or TEG algorithms in minimizing mortality rates of bleeding patients undergoing cardiac surgery (2016).

Cost

A multi-center cohort study found that due to a significant reduction in blood product utilization, there were estimated cost savings of $18,078,258 following the implementation of a ROTEM-guided blood management protocol (Görlinger et al., 2019). A health economic analysis executed an in-depth review of literature evaluating 755,733 patients and determined that utilization of ROTEM is an effective cost-saving blood product management technique (Görlinger et al., 2019). According to this health economic analysis, “the mean calculated blood product acquisition cost-savings were US $977,703 per 1000 patients and mean calculated [potentially preventable complications] PCC-related cost-savings $1,786,729 per 1000 patients” (Görlinger et al., 2019, p. 313). An RCT including 104 patients noted an average cost savings of 36% when using ROTEM compared to traditional coagulation laboratory values to guide blood product transfusions (Haensig et al., 2019).

A recent RCT provided information regarding the cost benefits of a ROTEM-guided transfusion algorithm compared with clinically-guided blood product administration (Karrar et al., 2022). According to Karrar et al. (2022, p.234), “a ROTEM-guided transfusion protocol potentially could save $5,421.04 per patient undergoing elective surgery and $578.12 per patient undergoing emergency surgery”. Although ROTEM costs approximately $346.45, the potential savings related to total allogenic transfusion products ($2,397.64) and overall hospital costs

($5,421.04) outweighs the cost of ROTEM; therefore, a cost-effective alternative to traditional clinically-guided transfusion practices (Karrar et al., 2022).

A 68-patient RCT studied the direct cost of allogeneic blood products, ROTEM, and conventional coagulation laboratory tests (Smart et al., 2017). The cost analysis includes individual blood product costs per unit: pRBCs, FFP, platelets, and cryoprecipitate ($206.28, $47.31, $489.97, and $335.33, respectively) (Smart et al., 2017). Examination of the total cost of all allogenic blood products for the ROTEM group ($123,067.01) and the control group ($103,786.09) identified a cost savings of approximately $19,000 (Smart et al., 2017). Smart et al. (2017) appraised each ROTEM assay and conventional coagulation test. The INTEM ($12.01), EXTEM ($12.01), FIBTEM ($24.92), and HEPTEM ($19.86) cost a total of $68.80 per patient, while conventional coagulation tests PT/INR ($6.73), PTT ($8.54), fibrinogen ($9.37), and CBC ($10.27) cost $34.91 per patient (Smart et al., 2017). Although there is an increased cost to utilize the ROTEM compared to conventional laboratory tests, the cost savings related to the reduction in blood product administration massively outweighs the laboratory costs (Smart et al., 2017). Although ROTEM cost $4,609.04 more than conventional laboratory testing, due to a reduction in intraoperative blood product administration accounting for $19,280.92 in savings, there was overall a net cost benefit of utilizing ROTEM resulting in a total cost savings of over $14,000.00 in this 68-patient study (Smart et al., 2017).

The literature review encompassed the highest level of current evidence to determine if there is a statistically significant difference in the number of blood products administered, mortality, and cost associated with utilizing ROTEM technology. The analysis of over 250,000 patients using ROTEM for blood product management identified a decrease in overall blood product administration compared to traditional management techniques. Multiple meta-analyses and RCTs discovered a direct correlation between using a ROTEM-guided transfusion algorithm and a reduction in mortality rates. Various evidence suggests using ROTEM is a cost-effective technique for assessing and treating coagulopathies compared to conventional coagulation laboratory testing in the cardiothoracic surgical population.

Project Objectives

The objectives for the development and implementation of a ROTEM-guided transfusion algorithm include:

- developing evidence-based practice guidelines for a ROTEM-guided transfusion algorithm in cardiothoracic surgical patients
- establishing a comprehensive plan for implementation of the ROTEM-guided transfusion algorithm utilizing the Johns Hopkins Evidence-Based Practice Model for Nurses and Healthcare Professionals
- determining methods by which the intervention will be monitored and measured
- developing a plan for continuous evaluation of the ROTEM-guided transfusion algorithm and use the Johns Hopkins Evidence-Based Practice Model to make necessary modifications and improvements if outcomes (blood product utilization, patient mortality, and overall cost) are less than desirable

Best Practice Model

The selection of a theoretical model is essential to developing an innovative scholarly project. Permission was received (Appendix A) to use the Johns Hopkins Evidence-Based Practice Model for Nurses and Healthcare Professionals (Appendix B) to guide this project. The selection of the Johns Hopkins Model is primarily due to the crucial aspect of continuous reflection throughout each phase of project development. The Johns Hopkins Model provides a structured outline starting with identifying a problem, steps to conducting an evidence-based practice literature review, implementation, and continuous reflection, evaluation, and modification (Dang et al., 2022). Although providing the same goals, "the recently revised model and tools draw attention to the value-added contribution of [evidence-based practice] as an interprofessional activity to enhance team collaboration and care coordination" (The Johns Hopkins University, 2022). Nurse anesthetists work in an environment where multidisciplinary care and communication are essential to providing safe, efficient, and effective patient care. When developing an evidence-based practice project, it is imperative to consider the interdisciplinary team members affected by the planned interventions. The following will discuss the model's systematic approach to an evidence-based practice project.

Inquiry and Practice Question, Evidence and Translation (PET)

Inquiry is the initial step involving problem identification, identifying current practices, and determining if a research project is necessary. The PET process marks the start of an evidence-based practice project. The practice question and project planning steps include developing a PICOT question, identifying stakeholders, and recruiting interprofessional team members (Dang et al., 2022). The next step in the PET process is performing a literature review of current evidence-based research (Dang et al., 2022). The evidence portion of the Johns Hopkins model involves thorough research analysis and synthesis to guide the development of evidence-based recommendations (Dang et al., 2022). The final step in the PET process is to create an action plan, implement the best evidence recommendations, evaluate the outcomes of the intervention and report the findings (Dang et al., 2022). For the purposes of this project, the ROTEM-guided transfusion algorithm will not be implemented in practice; therefore, a thorough discussion of how changes would be made if the outcomes were unfavorable is necessary.

Best Practices, Practice Improvements, and Reflection

The best practices sector is an extension of the translation portion of the model. The best practice is determined based on evidence-based research and implemented into current practice. The focus for practice improvements is typically following implementation; however, the Johns Hopkins model has intertwined reflection throughout project development, implementation, and evaluation, providing an opportunity to identify issues early, make improvements, and alter the project to optimize patient outcomes.

Method/Design

The Johns Hopkins Model will guide the methodology of this project. The initial step involves inquiring regarding current practices and determining the need for improvement in a critical clinical process. Due to the exponential risk for coagulopathies and the increased probability of bleeding in the cardiothoracic surgical population, an advanced technique is necessary to monitor, identify, and manage these coagulopathies. The following PICO(T) question will aid in the navigation of this project: In cardiothoracic surgical patients, how does the use of ROTEM versus traditional coagulation laboratory tests (PT, INR, aPTT, ACT, platelet count, and fibrinogen) affect blood product utilization, patient mortality, and overall cost peri-operatively and post-operatively? Following the development of a PICO(T) question, a thorough literature review was conducted to determine the current evidence-based practice recommendations regarding coagulopathy management in the cardiothoracic population. The highest level of current evidence-based practice research and literature was utilized to create a ROTEM-guided transfusion algorithm (Appendix D). The outcomes (blood product administration, mortality, and cost) will be evaluated utilizing quantitative measures to determine if using a ROTEM-guided transfusion algorithm compared to traditional laboratory testing decreases overall blood product administration, mortality, and cost. A reflection continuum will occur throughout the implementation and outcome evaluation process to identify process improvement opportunities.

Sample/Setting

The proposed setting for this project is a large urban hospital providing a significant magnitude of cardiothoracic surgical procedures. The number of patients will be determined based on the volume of cardiothoracic cases; however, the anticipated sample would include ten cardiothoracic surgical procedures weekly across six months for a total of 240 patients. A multidisciplinary approach will be utilized to implement the ROTEM algorithm. Cardiothoracic surgeons, anesthesiologists, and CRNAs will be involved in the intra-operative application of ROTEM-guided blood transfusion. Cardiothoracic surgeons, cardiothoracic nurse practitioners, and critical care nurses caring for these patients in the immediate post-operative period will carry out this algorithm 24 hours following surgical intervention.

Guideline Development

The ROTEM-guided transfusion algorithm guidelines (Appendix D) utilize the highest level of current evidence-based research, literature, and ROTEM resources to promote decreased blood product utilization, mortality, and cost. The initial step in this algorithm is to identify manageable influential factors, such as hypothermia, reversal of heparin, and acid-base imbalances, and remedy these factors to the best of one’s ability before beginning the ROTEM analysis. The algorithm provides the expected values for the various ROTEM assays and treatment interventions if the values fall outside the defined normal limits. Depending on the results of the individual ROTEM assays, the interventions include FFP, cryoprecipitate, platelet, aminocaproic acid, or protamine administration. If all clinical factors are alleviated and ROTEM results come back within defined normal limits, investigation of surgical bleeding should be considered. Overall, developing and implementing a ROTEM-guided transfusion algorithm will provide an effective, precise, and efficient method for directing blood product management.

Implementation Plan

The first step in implementation is introducing the concept to the key stakeholders, including the cardiothoracic surgical team (surgeons and nurse practitioners), the anesthesia team (anesthesiologists and CRNAs), the cardiovascular critical care nursing team (nursing leadership and staff nurses) as well as hospital leadership members. It is imperative to thoroughly discuss the project's goals in a direct, measurable, achievable, and relatable manner to gain buy-in from the major stakeholders. During this initial meeting, the roles and responsibilities of each member should be agreed upon to assist in defining expectations for project development and implementation. Intraoperatively, the anesthesia team will draw blood samples, run the ROTEM test, and appropriately treat the patients’ coagulation status based on the correct result interpretation. The ROTEM assays will be analyzed prior to cardiopulmonary bypass to determine baseline results and will be repeated post-bypass. Post-operatively the critical care nursing team and the cardiothoracic surgical team will collaborate to continue evaluating the patients’ coagulation status utilizing the ROTEM system. The frequency of ROTEM assays in the post-operative period will be determined by clinical presentation, including chest tube output, vital signs, Hemoglobin and Hematocrit values, and overall hemodynamic status. The critical care nurse’s responsibility would include drawing blood samples, running the ROTEM tests, and providing the results to the cardiothoracic surgeon or advanced practice provider. The cardiothoracic surgical team is responsible in the post-operative period for interpreting the ROTEM analyses and accurately ordering blood products in ordinance with the ROTEM algorithm. If blood product administration is necessary following the ROTEM analysis, the critical care nurse caring for the patient will administer the required products. The hospital data analyst will be involved in data collection and analysis to determine if the objectives and outcomes of the project are being met at each step of project implementation. Early identification of issues throughout the implementation phase is essential to make necessary modifications to reach the project's primary goals. Each member involved in the project's implementation plan will need a thorough understanding of their role, the project objectives, and the implementation plan because "key stakeholders are more likely to support the project when they have a clear understanding of the project goals" (Moran et al., 2019, p. 365). Open communication is vital in implementing a newly developed project; therefore, constructive criticism and feedback will be encouraged, and monthly meetings will be available to provide an environment for team members to express their thoughts and experiences throughout the implementation process.

Once all team members understand their role in the implementation process, the ROTEM training will begin. The first step of ROTEM education and training is an online education module allowing participants to work remotely. The goal of the online training is for team members to gain a general understanding of the ROTEM system, provide an initial introduction to ROTEM analysis, and begin developing an understanding of the interventions associated with each ROTEM result. Online training sessions will be available for one month. Once the online training program is completed, team members will have in-person hands-on training provided by a ROTEM representative. The hands-on training will allow the team members to practice running ROTEM tests and provide in-depth education on interpreting the ROTEM results and navigating the ROTEM-guided blood transfusion algorithm to manage coagulopathies accurately. A few members of each interdisciplinary team will be selected as superusers that will undergo more extensive training and will be available throughout the implementation process to assist in troubleshooting when questions arise. ROTEM-algorithm badge buddies will be provided to each team member during the hands-on training sessions as a resource guide to reference during clinical scenarios. Following the completion of the ROTEM education and training, implementation will begin.

The ROTEM-guided transfusion algorithm will be implemented in conjunction with traditional coagulation laboratory tests to provide a real-time comparison. Utilizing both methods for coagulation management allows an opportunity for team members to analyze the benefits of ROTEM compared to traditional laboratory testing, including time efficiency, reliability, and validity of the ROTEM system. Allowing team members to identify how the ROTEM algorithm alters and improves coagulation management in real patient scenarios will promote stakeholder support which is essential for the project's success. If outcomes are less than optimal, the project team members and key stakeholders will have a meeting to identify areas for improvement and discuss what changes can be made to enhance patient outcomes. Feedback from various points of view provides varying perspectives and ideas on modifying the newly developed guidelines or improving the implementation process to optimize results.

Outcome Analysis

A retrospective electronic medical record (EMR) review will take place before implementation to determine the baseline blood product administration, mortality rate, and cost to which the intervention group will be compared. The retrospective review will examine cardiothoracic surgery cases over the last six months to evaluate the methods by which coagulopathies were identified (traditional laboratory values or TEG), blood product administration throughout the intraoperative period, 12 hours and 24 hours post-operatively, the mortality rate of patients over the last six months and cost analysis to evaluate the overall cost associated with laboratory testing and blood product usage.

Three outcomes will be measured: the number of blood products administered, the mortality rate over six months, and the overall cost. This data will be evaluated utilizing the patients' electronic medical records, follow-up appointment data, and a cost analysis completed by the hospital data analyst at the end of the patient's hospital stay. The quality improvement team member and the hospital data analyst will work together to monitor the project objectives and provide statistical analysis of the measurable outcomes to evaluate the project's success.

Blood product administration will be evaluated in the intra-operative period, 12 hours post-operatively, and 24 hours post-operatively. The blood products which should be accounted for include packed red blood cells, fresh frozen plasma, platelets, and cryoprecipitate. A review of the patient's electronic medical record will provide the number of blood products administered at each time interval. The hospital data analyst will document the quantity of blood products in an excel spreadsheet. The mean, median, and mode will be calculated and compared to the data collected in the retrospective analysis. The data comparison will determine if the intervention decreases the number of blood products administered in the 24-hour post-operative period.

The mortality rate will be expressed by a percentage of patients who underwent cardiothoracic surgery and will be examined at 24 hours and six months post-operatively. If patient demise occurs within immediate 24 hours post-operatively, this information will come from the electronic medical record; however, later in the patient's recovery, this information will be collected from the cardiothoracic surgical follow-up data. The hospital data analyst will document mortality data points in an excel spreadsheet to examine the percentage of mortality at six months following surgery.

The overall cost analysis will involve an in-depth approach to determining the cost associated with blood product administration, traditional coagulation laboratory testing, ROTEM laboratory testing system and various assays, and inpatient mortality. All of these values are quantitative; however, the inpatient mortality cost has to do with insurance reimbursement, which may vary depending on the cause of death and type of insurance coverage. The hospital data analyst will document a pricing list in an excel spreadsheet for each patient, including traditional laboratory tests, blood products, and costs associated with patient mortality. The cost analysis will identify if a cost-benefit of using a ROTEM-guided transfusion algorithm compared to traditional coagulation laboratory testing exists.

After the completion of data collection and analysis of the retrospective EMR review and following the implementation of the ROTEM-guided transfusion algorithm, the hospital data analyst will run a t-test to "determine if there is a statistically significant difference in the mean values between two groups" (Moran et al., 2019, p. 292). The results of the t-test will identify if the ROTEM algorithm effectively reduces blood product administration, improves patient mortality rates, and decreases overall costs associated with the management of coagulopathies. Ultimately, the success of this project will be determined based on goal achievement, team members' acceptance of the newly implemented guidelines, and the effectiveness of the ROTEM algorithm in improving patient outcomes.

Limitations and Barriers

Moran et al. (2019) discuss various barriers to project implementation, including but not limited to lack of clarity, resistance to change, and lack of stakeholder support. One of the most significant potential barriers to this project implementation is a combination of resistance to change and lack of stakeholder support. All humans have different levels of comfort with change; however, ensuring that all stakeholders and team members clearly understand the overwhelming benefits of project success will help alleviate any hesitation when implementing new guidelines. Another potential limitation would include the cost of education and training all the necessary staff members. Although implementing a ROTEM-guided algorithm would potentially provide a cost-saving strategy for identifying and correcting coagulopathies in cardiothoracic surgical patients, the upfront cost could be a deterrent from initiating the project. Identifying all limitations and barriers before implementation is complex; therefore, "the key is to monitor the implementation process carefully, troubleshoot any identified issues early, and develop a mitigation plan" (Moran et al., 2019, p. 369). Problem-solving strategies are essential throughout the implementation process to ensure a smooth transition to the newly developed intervention.

Timeline

The proposed timeline begins with completing the ROTEM-guided transfusion algorithm guidelines and the implementation plan, which will be completed by May 2023. The first meeting with the project team and primary stakeholders will be held in June 2023 to thoroughly discuss the project and implementation plan. Once a consensus is met regarding how to roll out the project, the link to an online ROTEM training program will be sent out at the beginning of July 2023 to all staff members involved in the implementation process, including cardiothoracic surgeons, cardiothoracic advanced practice providers, CRNAs, anesthesiologists, and critical care staff nurses. These staff members will have one month to complete the online education portion of the ROTEM training program. Starting in August 2023, hands-on ROTEM training, led by a ROTEM representative, will be available every Monday from 4:30-6:30 pm to ensure all staff members involved in the implementation process can attend. Once all ROTEM education and training are complete, the ROTEM algorithm and testing will be instituted in cardiothoracic surgical cases. Data collection and analysis will occur weekly to maintain a strict schedule and confirm the intervention is providing the intended outcomes. Patient mortality data points will be examined at 24 hours and six months following their surgical date. Open communication between team members is imperative to project success; therefore, there will be various open lines of communication. An email chain will be available for day-to-day questions and concerns, and monthly meetings will be held to provide constructive feedback, discuss milestones, make adjustments as necessary, and verify the project's trajectory aligns with the project objectives.

Budget

The proposed budget (Appendix E) is an estimation accounting for ten cardiothoracic surgical procedures weekly across a six-month time frame (240 patients utilizing the ROTEM-guided transfusion algorithm). Although the budget includes the salaries for the anesthesia team, cardiothoracic surgical team, critical care nursing team, and healthcare data analyst, their wages would be paid by the theoretical hospital. ROTEM education and training would be counted toward continuing education hours for eligible team members. The salaries are included in this outline of expected expenditures to evaluate the overall cost analysis of implementing the ROTEM algorithm. The overall cost of the project consists of the ROTEM equipment and testing ($19,712.00), the traditional laboratory testing ($153,360.00), the ROTEM badge buddies for staff members ($100.00), and the ROTEM representative cost ($395.20) to provide the necessary ROTEM education and training for the various team members. It is important to note that these figures are estimates of what costs should be considered if this project were to be implemented into practice in the future.

Conclusion

Cardiothoracic surgery increases the risk for the development of coagulopathies leading to blood transfusions, higher mortality rates, and amplifies the associated cost. Current practice for blood product management in the cardiothoracic surgery population utilizes conventional coagulation laboratory tests. These traditional coagulation values provide a limited evaluation of a patient's overall coagulation status and can result in delays in care and treatment. ROTEM analysis is an innovative coagulation assessment tool enabling the provider to more precisely identify the root cause of the coagulopathy and manage the patient appropriately and effectively based on the results. Current evidence-based literature and research suggest a direct correlation between using a ROTEM-guided transfusion algorithm and minimizing blood product utilization, lowering mortality rates, and reducing overall cost. This project aims to develop a ROTEM algorithm to guide blood product management in the cardiothoracic surgical population and provide a thorough implementation plan, including a timeline and budget for future implementation. Following the development and implementation of the ROTEM-guided transfusion algorithm, the expected outcomes would include a reduction in blood product administration intraoperatively and at 12 hours and 24 hours post-operatively, a decrease in mortality rates both at 24 hours and six months post-operatively, and net cost savings per patient undergoing cardiothoracic surgery. Overall, using a ROTEM-guided transfusion algorithm in the cardiothoracic surgical population optimizes patient outcomes and should be utilized to enhance current practice.

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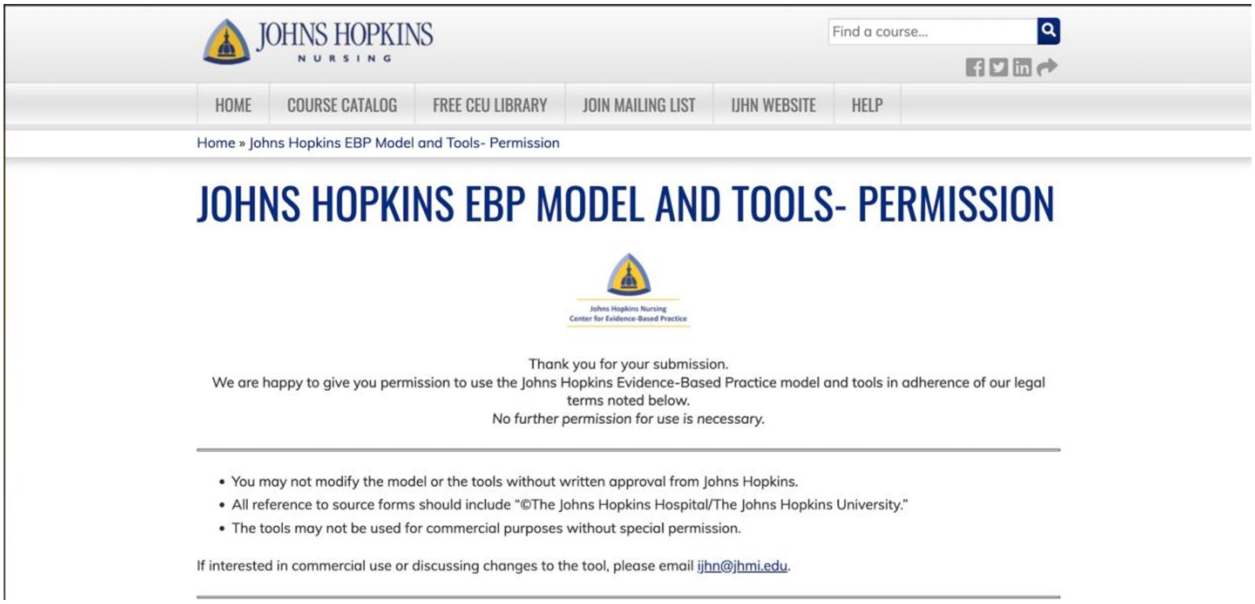
Appendix A

Permission to use the Johns Hopkins Model



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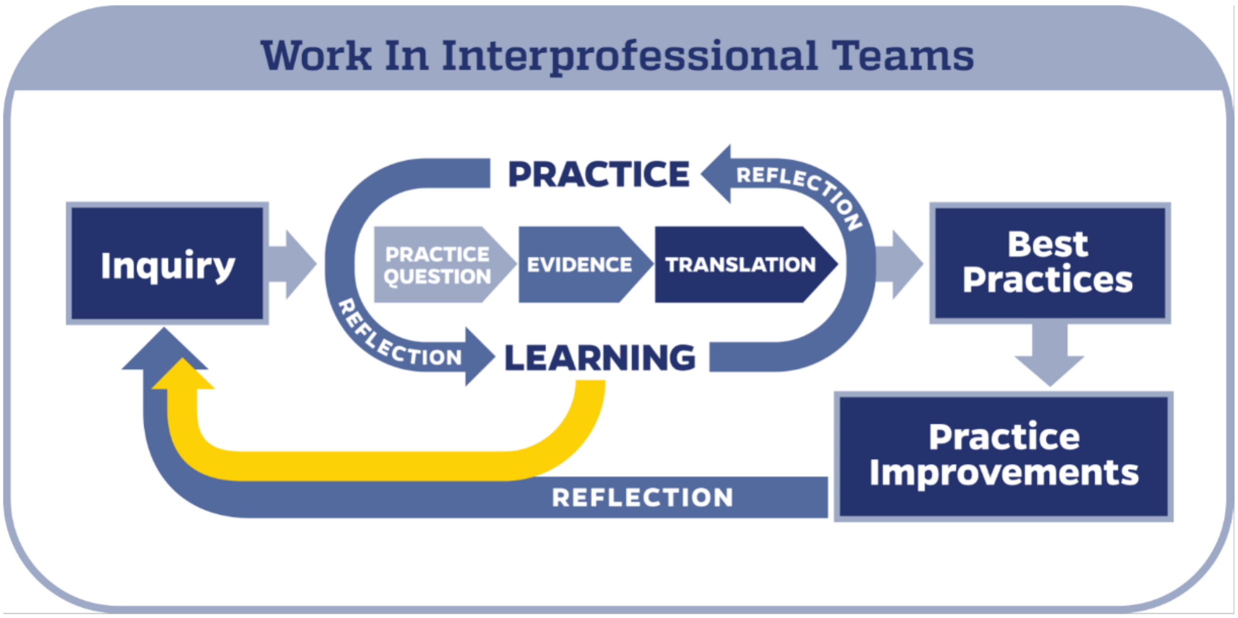
If interested in commercial use or discussing changes to the tool, please email ijhn@jhmi.edu.

Appendix B

Johns Hopkins Evidence-Based Practice Model for Nurses and Healthcare Professionals



Appendix C

Literature Review Table

Citation	Design/Method	Sample Size	Outcomes	Level of Evidence
Görlinger, K., Pérez-Ferrer, A., Dirkmann, D., Saner, F., Maegele, M., Calatayud, Á., & Kim, T.-Y. (2019). The role of evidence-based algorithms for rotational thromboelastometry-guided bleeding management. *Korean Journal of Anesthesiology*, *72*(4), 297–322. https://doi.org/10.4097/kja.19169	Literature Review	N/A	Transfusion requirement, patient outcomes (mortality), and health care costs	5
Haensig, M., Kempfert, J., Kempfert, P.-M., Girdauskas, E., Borger, M., & Lehmann, S. (2019). Thrombelastometry guided blood-component therapy after cardiac surgery: A randomized study. *BMC Anesthesiology*, *19*(1). https://doi.org/10.1186/s12871-019-0875-7	RCT	104 patients	Transfusion requirements, 24-h blood loss, re-thoracotomy rate, and cost analysis of blood and coagulation products	2
Karkouti, K., Callum, J., Wijeysundera, D. N., Rao, V., Crowther, M., Grocott, H. P., Pinto, R., Scales, D. C., Achen, B., Brar, S., Morrison, D., Wong, D., Bussières, J. S., de Waal, T., Harle, C., de Médicis, E., McAdams, †., Syed, S., Tran, D., & Waters, T. (2016). Point-of-care hemostatic testing in cardiac surgery. *Circulation*, *134*(16), 1152–1162. https://doi.org/10.1161/circulationaha.116.023956	RCT	7,402 patients	Blood product transfusion, major bleeding	2
Karrar, S., Reniers, T., Filius, A., Bunge, J. J., Bekkers, J. A., Hoeks, S. E., & Horst, M. (2022). Rotational thromboelastometry-guided transfusion protocol to reduce allogeneic blood transfusion in proximal aortic surgery with deep hypothermic circulatory arrest. *Journal of Cardiothoracic and Vascular Anesthesia*,	RCT	217 patients	Use of blood products, patient outcomes, coagulation factor concentrate, and costs	2

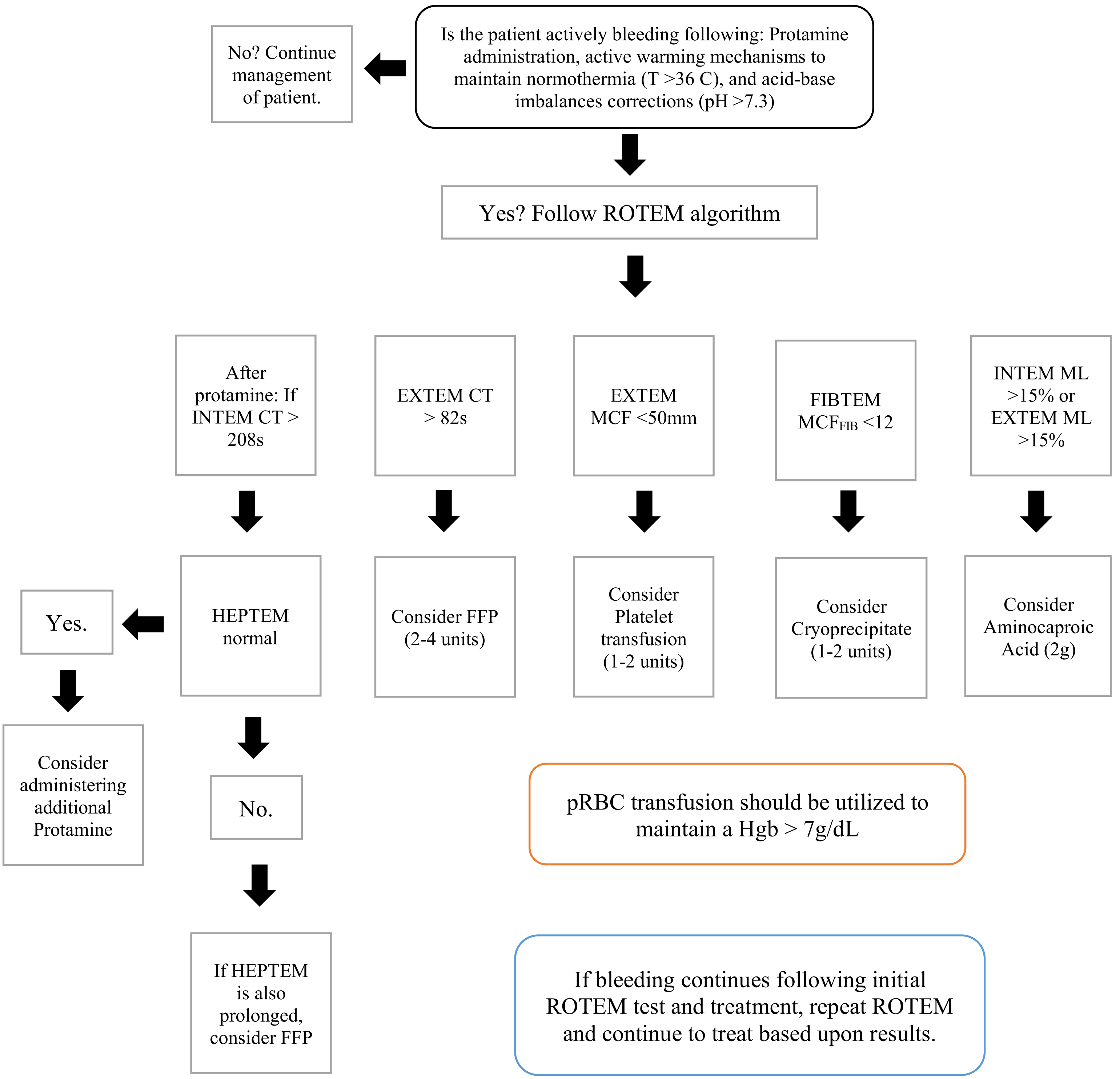
36(4), 1029–1039. https://doi.org/10.1053/j.jvca.2021.08.020				
Khalaf- Adeli, E., Alavi, M., Alizadeh-Ghavidel, A., & Pourfathollah, A. (2019). Comparison of standard coagulation testing with thromboelastometry tests in cardiac surgery. *Journal of Cardiovascular and Thoracic Research*, *11*(4), 300–304. https://doi.org/10.15171/jcvtr.2019.48	RCT	40 patients	ROTEM vs. traditional coagulation laboratory values	2
Li, C., Zhao, Q., Yang, K., Jiang, L., & Yu, J. (2019). Thromboelastography or rotational thromboelastometry for bleeding management in adults undergoing cardiac surgery: A systematic review with meta-analysis and trial sequential analysis. *Journal of Thoracic Disease*, *11*(4), 1170–1181. https://doi.org/10.21037/jtd.2019.04.39	Meta-Analysis	19 studies (15,320 participants)	Mortality, blood loss volume, and blood product transfusion	1
Meco, M., Montisci, A., Giustiniano, E., Greco, M., Pappalardo, F., Mammana, L., Panisi, P., Roscitano, C., Cirri, S., Donatelli, F., & Albano, G. (2020). Viscoelastic blood tests use in adult cardiac surgery: Meta-analysis, meta-regression, and trial sequential analysis. *Journal of Cardiothoracic and Vascular Anesthesia*, *34*(1), 119–127. https://doi.org/10.1053/j.jvca.2019.06.030	Meta-Analysis	7 RCTs (1,035 patients)	Blood product transfusion, post-operative bleeding, and need for redo surgery	1
Serraino, G., & Murphy, G. (2017). Routine use of viscoelastic blood tests for diagnosis and treatment of coagulopathic bleeding in cardiac surgery: Updated systematic review and meta-analysis. *British Journal of Anaesthesia*, *118*(6), 823–833. https://doi.org/10.1093/bja/aex100	Meta-Analysis	22 publications (15 RCTs, 8,738 participants)	30-day mortality, blood product transfusion, reoperation, acute kidney injury, stroke, myocardial infarction, ventilation time, ICU and hospital length of stay	1

Smart, L., Mumtaz, K., Scharpf, D., O'Bleness Gray, N., Traetow, D., Black, S., Michaels, A. J., Elkhammas, E., Kirkpatrick, R., & James Hanje, A. (2017). Rotational thromboelastometry or conventional coagulation tests in liver transplantation: Comparing blood loss, transfusions, and cost. *Annals of Hepatology*, *16*(6), 916–923. https://doi.org/10.5604/01.3001.0010.5283	RCT	68 patients	Intra-operative blood loss, blood product transfusion, and direct cost	2
Wikkelsø, A., Wetterslev, J., Møller, A., & Afshari, A. (2016). Thromboelastography (teg) or thromboelastometry (rotem) to monitor haemostatic treatment versus usual care in adults or children with bleeding. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.cd007871.pub3	Systematic Review	17 studies (1,493 participants)	Mortality, blood product transfusion, need for surgical reintervention, and excessive bleeding or massive transfusion	1

*RCT: Randomized Control Trial

Appendix D

ROTEM-guided Transfusion Algorithm Guideline



Appendix E

Table of Expected Expenditures

Expenditures	Cost
ROTEM Equipment:	
• ROTEM Viscoelastic Testing System	$800.00 x 4 systems = $3200
• Heptem	$19.86 x 240 tests = $4,766.40
• Fibtem	$24.92 x 240 tests = $5,980.80
• Extem	$12.01 x 240 tests = $2,882.40
• Intem	$12.01 x 240 tests = $2,882.40
	TOTAL ROTEM COST: $19,712.00
Traditional Laboratory Testing:	
• PT/INR	$30.00 x 240 tests = $7,200.00
• aPTT	$48.00 x 240 tests = $11,520.00
• Platelet Count:	$38.00 x 240 tests = $9,120.00
• CBC:	$24.00 x 240 tests = $5,760.00
• ACT:	$449.00 x 240 tests = $107,760.00
• Fibrinogen:	$50.00 x 240 tests = $12,000.00
	TOTAL TRADITIONAL LABORATORY COST: $153,360.00
Badge Buddies with ROTEM Algorithm:	$100.00 for printing and laminating
Indirect Expenses:	
• Anesthesiologist hourly rate	$159.22 x 5 hours of education x 23 staff members = $18,310.30
• CRNA hourly rate	$97.34 x 5 hours of education x 35 staff members = $17,034.50
• Critical Care RN hourly rate	$39.78 x 5 hours of education x 50 staff members = $9,945.00
• Cardiothoracic Nurse Practitioner hourly rate	$56.75 x 5 hours of education x 10 staff members = $2,837.50
• Cardiothoracic Surgeon hourly rate	$143.17 x 5 hours of education x 4 staff members = $2,863.40
• ROTEM representative hourly rate	$49.40 x 8 hours of hands-on training x 1 staff member = $395.20
• Healthcare Data Analyst	$26.71x 8 hours of data analysis weekly x 6 months = $5,128.32
	TOTAL PERSONALE COST: $56,514.22
	All wages are estimated based upon U.S. Bureau of Labor Statistics data