

Paediatric Intensive Care Unit

Prevention and management of severe bleeding in patients on PICU following paediatric cardiac surgery and during ECMO.

Staff relevant to:	Medical and allied health professionals involved in the care of paediatric patients undergoing cardiac surgery or ECMO
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Contents

A guide to prevention and management of post-operative paediatric cardiac surgical bleeding flow chart 2

1. Introduction and Who Guideline applies to 3

2. Roles and Responsibilities 3

3. The rationale for the guideline algorithm 4

 3.1 Pre-operative assessment..... 4

 3.2 Immediate post by-pass management 5

 3.3 Definition of severe bleeding 5

4. Tests 5

5. Education and Training 9

6. Monitoring Compliance 9

7. Supporting References 9

8. Key Words 11

Contact & review details 11

Appendix 1 11

 Poster guide to the management of post-operative paediatric surgical bleeding..... 11

A guide to prevention and management of post-operative paediatric cardiac surgical bleeding algorithm

PATIENT BLEEDING POST PROTAMINE OR ON ECMO

Perform TEG, ROTEM, Platelet Function Tests and Check Hb.
Give Blood:FFP Ratio 1:1 to maintain haemodynamic stability.
Repeat appropriate tests every 30 minutes.

TEG
Kaolin Plain (K) &
Kaolin with Heparinase (KH)

Haemoglobin
(ABG) (Target
Hb100g/L)

Packed red
cells
10-20ml/kg

Heparinase
R time
Normal
Plain R time
extended

Heparinase
R time
>10
minutes

MA 40-47

MA <40

α Angle
<47

LY30
> 7.5%
with Cl
<1.0

1-2mg/kg
Protamine*
To reverse
excess heparin
(excluding
ECMO).
Repeat TEG
10mins

PCC
15-20 IU/kg
over 5-10
minutes

Platelets
10ml/kg

Platelets
20ml/kg

Cryo
5ml/kg

Tranexamic
Acid
5mg/kg/hour
for 10 hours

ONGOING BLEEDING despite 2 cycles of tests and interventions, EXCLUDE SURGICAL BLEEDING

Safety check if >20ml/kg RBC and >20ml/kg FFP given and still on-going significant blood loss with haemodynamic instability: **Activate Massive Transfusion Protocol**

TEG
Kaolin (K) &
Kaolin with Heparinase (KH)

If R – Heparinase time remains >10
mins and at least 20ml/kg has already
been given in total (as 10ml/kg doses)

Repeat dose of PCC 15-20 units/kg

ONGOING BLEEDING
EXCLUDE SURGICAL BLEEDING
CONSIDER APROTININ

(0.5-1ML/KG/HR OF SOLUTION 10,000 KIU/ml (max 50ml/hr)

AVOID CONCURRENT USE OF PCC & NOVOSEVEN

Risk of systemic thrombosis is very high if Novoseven is used in conjunction with PCC. If Novoseven must be used in exceptional circumstances, ensure a minimum of 2 hours interval after last dose of PCC

Continue to give
Blood:FFP Ratio 1:1

Repeat tests until normalised
and/or bleeding is controlled

1. Introduction and Who Guideline applies to:

Paediatric cardiac surgery is associated with an increased risk of perioperative bleeding. The underlying mechanisms are complex and involve disturbances in various physiologic systems including primary haemostasis, coagulation, and fibrinolysis.

The disturbance in primary haemostasis is related to the type and complexity of the operation. The highest risk of bleeding in cardiac surgery is found in young children undergoing complex surgery with a long cardiopulmonary bypass (CPB) time and deep hypothermia.

Coagulation is deranged by a number of factors, including the dilution of coagulation factors and platelets in the relatively large fluid volume of the pump prime, and activation of the coagulation system by the CPB circuit.

Fibrinolysis is also enhanced by CPB circuit and antifibrinolytic agents such as tranexamic acid, and in some cases aprotinin, are used to reduce bleeding and consequent transfusion requirement.

CPB circuit also induces acquired and reversible defects of platelet function whereby platelet count may be normal but function may be significantly impaired for several hours following the bypass surgery.

Allogeneic transfusion of packed red cells, platelets concentrates and plasma is often required, with the potential risk of transmitting infectious agents, and provoking adverse immunologic reactions. Recent studies suggest that peri-operative allogeneic blood transfusion may be associated with increased morbidity and mortality. Reduction of operative blood loss is important to avoid reoperation and to diminish postoperative anaemia that could lead to congestive heart failure, delayed wound healing, delayed mobilisation, and other complications.

An algorithm summarising the key actions and recommendations from this guideline is included on page 2 and link to poster version in Appendix 1. The rationale behind the algorithm is described in section 5.

This guideline is aimed at all medical and allied health professionals involved in the care of paediatric patients undergoing cardiac surgery or ECMO support. It is intended to provide a pathway that begins at pre-operative assessment and follows the patient journey through to admission to PICU after cardiac surgery. Management of CPB circuit and of bleeding during CPB is outwith the scope of these guidelines.

2. Roles and Responsibilities

UHL PICU/CICU Clinical Practice Group:

The PICU/CICU clinical practice group are responsible for this guideline.

CBU Managers/Medical leads/Heads of Nursing:

The CMG leads are responsible for ensuring that all staff responsible for paediatric patients undergoing cardiac surgery refer and adhere where possible to the guideline in the prevention and management of post-operative cardiac surgical bleeding, and bleeding on ECMO.

Ward/Department staff:

Ward and department staff are responsible for ensuring that any paediatric patients admitted or pre-assessed in their area are screened and managed according to this guideline.

3. The rationale for the guideline algorithm

[\(Please refer to page 2: Poster guide to the management of post-operative paediatric surgical bleeding\)](#)

The mechanisms underlying acquired coagulopathy following cardiac surgery are complex and multifold, including reduction in coagulation factors from dilutional effect, the effects of hypothermia, anticoagulation with heparin, increased fibrinolysis resulting from bypass circuit, and platelet dysfunction due to antiplatelet drugs as well as that induced by CPB circuit. The pathophysiology of such acquired coagulopathy remains poorly understood. However several studies have attempted to investigate the effects of cardiac surgery on coagulation. Coakley and colleagues demonstrated a reduction of 30–50% in coagulation factor levels, compared with 10% reductions in parameters relating to thrombin generation. Patients who lost >1000 mL blood had lower values for: platelet count, coagulation factors IX, X, XI, endogenous thrombin potential and initial rate of thrombin generation. Solomon and colleagues have shown more marked impairment of the fibrin function compared to thrombin generation following cardiopulmonary bypass, although there were no differences in fibrin formation or endogenous thrombin potential between patients receiving FFP, FFP and platelets, or no transfusion. This is in contrast to the increased thrombin generation seen during orthopaedic surgery (Green L, Lawrie AS, Patel S, et al). Ternstrom and colleagues demonstrated a 30% reduction in all coagulation factors at the end of surgery with the exception of factors VIII and IX, and reported an inverse correlation between plasma fibrinogen and factor XIII levels with the severity of post-operative bleeding.

Impairment of platelet function commonly occurs after cardiopulmonary bypass, and may result in substantial bleeding. Platelet dysfunction is often multifactorial and may result from prior use of anti-platelet drugs, the effect of heparin, hypothermia and mechanical functional impairment associated with the use of membrane oxygenators in the bypass circuit (Friedenberg, William R. et al).

Given the complex nature of acquired coagulopathy, the challenge is to promptly identify and define specific underlying cause(s) to enable targeted and timely therapeutic interventions with the aim of achieving rapid correction of deranged component(s) of coagulation, thereby preventing a downward spiral of coagulopathy as early as possible.

Point of care testing (Thromboelastography – TEG) is available within UHL Theatres and PICU for rapid diagnosis of the underlying cause of coagulopathy. Rapid laboratory tests of platelet function using Multiplate technology (available at Glenfield blood bank ext 13577) are planned from April 2018

3.1 Pre-operative assessment

Anticipate the patient who is at increased risk of perioperative bleeding (complex surgery, anticipated long CPB time, redo sternotomy) and consent accordingly

If the patient is on the following medications:

Aspirin stop for 7 days before surgery

Clopidogrel stop for 7 days before surgery

Warfarin stop for 48 hours and admit to convert to IV Heparin infusion

As part of pre op assessment the following tests should be performed:

All patients: Full Blood Count (FBC) and Coagulation screen

Patients on warfarin/heparin: Baseline TEG

3.2 Immediate post by-pass management

Intra-operative and immediate post bypass management and monitoring of heparin is not covered by this guideline. This guideline is intended to be from after cardiac bypass and 10 minutes after protamine has been given to reverse heparinisation. Once any bleeding is considered to be under control and there is no intention of putting the child back on bypass, the child will be transferred to PICU where this guideline will continue. A surgical cause for persistent bleeding must be considered and reconsidered at all times.

3.3 Definition of severe bleeding

Bleeding is considered to be severe post cardiac surgery or ECMO cannulation or procedure when drain/measured losses exceed:

4ml/kg/hr in the first hour

2ml/kg in the second hour

1ml/kg in subsequent hours

Or any bleeding below this threshold associated with haemodynamic instability

4. Tests

- **TEG**

Thromboelastography (TEG) is a rapid point of care test useful to monitor global haemostasis in paediatric patients undergoing cardiac surgery involving significant blood loss. TEG tests should be performed on induction (baseline), on re-warming, post bypass (10minutes post protamine) and if still bleeding on PICU.

For TEG analysis, 1ml of whole blood is collected in a labelled plain syringe, added to a kaolin vial, mixed and then added to the appropriate cup for analysis. The TEG test must be started within 4 minutes of sample collection to ensure accurate results.

Two types of TEG tests are available kaolin (K) and kaolin with heparinase (KH). The use of a plain cup and a heparin cup allows the distinction to be made as to whether heparin is the cause of bleeding. TEG parameters (R, MA & LY30) aid the clinician to decide appropriate timely intervention of blood components.

TEG should only be used in conjunction with the paediatric cardiac TEG algorithms (see below). It cannot provide information on platelet function or endothelial contribution to haemostasis including the activity of von Willebrand factor.

Please refer to the current PICU/CICU Paediatric Cardiac TEG Guideline –

[S:\3. PICU COMMITTEES & MEETINGS\1. PICU \(CPM\) CLINICAL PRACTICE GROUP\CPM archive\CPM 2015\CPM 9 Apr 2015\TEG guideline vs 4.pdf](#)

Poster guide to the management of post-operative paediatric surgical bleeding - [S:\3. PICU COMMITTEES & MEETINGS\1. PICU \(CPM\) CLINICAL PRACTICE GROUP\CPM 2020\9. CPM October\Paed Cardiac surgery poster Appendix1 April18.ppt](#)

- **Laboratory Tests**

Platelet count, PT, APTT and Fibrinogen levels are all sent as soon as the patient returns from theatre. It is important to note what clotting products have been given in theatre, prior to

these tests being taken, and in the interim between taking the blood tests and getting the results. Conversely in the presence of major bleeding as above, administration of blood products should not be delayed while awaiting results of laboratory tests

5. Blood products and therapeutic agents to reduce/control bleeding

- **Packed red cells**

In paediatric cardiac surgery longer blood storage is thought to be associated with suboptimal outcomes in high risk paediatric cardiac surgery. Ensure on request form that age and weight of the patient is stipulated.

Blood bank should issue packed red cells, where available and where the urgency of clinical need allows, as per the following protocol:

Patient aged ≤ 28 days: blood ≤ 7 days since collection

Patient aged 29 days up to and including 16th birthday: blood ≤ 14 days since collection

- **FFP**

Fresh frozen plasma (FFP) is prepared from whole blood or by plasmapheresis. FFP contains all coagulation factors including fibrinogen (2–5 mg/mL). It is most commonly used as first-line haemostatic therapy in haemorrhage because it provides replacement for multiple coagulation factor deficiencies.

The dose of FFP is usually based on patient weight (e.g. 10–15 ml/kg body weight) and should be sufficient to increase the coagulation factor levels to above the critical value (i.e. 30%) and control blood loss.

As this dose has not been validated in randomised controlled trials, a higher dose or repeated doses might be required to control blood loss.

- **PCC**

Prothrombin Complex Concentrates (PCC) contain coagulation factors II, VII, IX and X, and variable amounts of protein C and S and a small amount of heparin. PCC is not a substitute for FFP. FFP contains all coagulation factors including factor VIII, von Willebrand factor and Fibrinogen and anti-thrombin whereas PCC only provides Vitamin K dependent coagulations factors.

Where the use of PCC is indicated (bleeding post cardiac surgery and extended R heparinase time on TEG) the recommended dose is 15-20units/kg

It should be prepared and administered according to the UHL guidance 'PCC use in cardiac surgery' ([link to guidance](#))

It must be noted that use of PCC in this setting is associated with a significant risk of thrombosis such as stroke, MI or Venous thromboembolism. PCCs are contraindicated in patients who have had such thrombotic events within the previous 3 months.

Concurrent use of PCC and Novoseven is not recommended as this is associated with significantly higher risk of serious and life threatening thrombotic complications such as Stroke, MI and / or multi-organ failure.

PLEASE NOTE If Novoseven must be used in exceptional circumstances, ensure a minimum of 2 hours interval after last dose of PCC.

Please refer to the UHL guidance 'PCC use in Cardiac Surgery' [Prothrombin Complex Concentrate \(PCC\) UHL Guideline](#)

- **Cryoprecipitate**

Cryoprecipitate is the cryoglobulin fraction of FFP, the precipitated proteins that constitute cryoprecipitate are fibrinogen (140–300 mg/unit), factor VIII (70 IU/mL), von Willebrand factor, factor XIII and fibronectin.

Cryoprecipitate is most useful in massive haemorrhage as a rapid source of fibrinogen. It is also indicated in moderate bleeding when the fibrinogen is <1.0 g/L.

The prescribed dose of cryoprecipitate is generally 5 mL/kg body weight. The blood bank will issue appropriate volume as the nearest whole unit(s)..

- **Fibrinogen concentrate**

Fibrinogen concentrates are the treatment of choice for patients with inherited deficiencies of fibrinogen. For patients with clinical bleeding associated with afibrinogenemia or dysfibrinogenemia, replacement of fibrinogen to a level of 0.5–0.8 g/L is usually adequate to maintain haemostasis, although levels greater than 1 g/L have been recommended.

As the final substrate of coagulation and the ligand of the platelet GPIIb/IIIa receptors, fibrinogen plays a key role in clot formation. Severe hypofibrinogenemia due to dilutional or consumptive coagulopathy can cause uncontrollable generalised oozing in the surgical field. This type of bleeding can only be controlled by prompt and sufficient replacement of coagulation factors, particularly fibrinogen. Fibrinogen is often the first coagulation factor to drop below a critical value during massive bleeding and dilutional coagulopathy.

Although this 'critical value' of fibrinogen is not well defined in this setting, plasma level of > 2g/L is considered optimal, and levels below 1.0g/L constitutes severe hypofibrinogenemia. However, available evidence suggests that once severe hypofibrinogenemia and coagulopathy develops, fibrinogen levels need to be promptly to around 3-4 g/L to achieve prompt control of coagulopathic bleeding. Cryoprecipitate concentrates are routinely transfused in this setting, however the delay associated with the thawing, release from blood bank, and transfusion of multiple pools of cryoprecipitate can hamper prompt and sufficient supply of fibrinogen to reverse severe coagulopathic hypofibrinogenemia. In recent years, several reports describing the effectiveness and relative safety of fibrinogen concentrate to treat coagulopathic bleeding in cardiac surgery have been published; however evidence from large prospective RCTs is still awaited.

Fibrinogen concentrate may be used as an alternative to cryoprecipitate in patients with severe acquired coagulopathy following complex cardiac surgery. It is currently not available as a stock item at UHL. However, this can be requested via pharmacy at Glenfield at least 24 hours in advance on a named patient basis.

Plasma fibrinogen level should be determined by sending an urgent clotting sample (Citrate tube) to haematology lab.

Clinicians using fibrinogen concentrate in this setting need to be fully aware of the risk of major thrombotic events potentially associated with large doses of fibrinogen concentrates, particularly when this drug is being concurrently administered with Prothrombin Complex Concentrate (PCC).

- **Platelets**

Platelet transfusion is indicated for thrombocytopenia (<100 in the bleeding patient) or when there is platelet dysfunction. Platelet function tests are not currently available within UHL (anticipated April 2018) however some information can be gained from mA angle of the TEG (please refer to TEG Guideline. Much lower platelet levels are acceptable in the non-bleeding patient but that is not within the scope of this guideline.

Prescribed dosage

- < 20 Kg: 10-15 mls/kg
- > 20 Kg: 1 adult pack

(Blood bank will issue an appropriate volume to nearest whole unit. The prescribed dose may need to be adjusted to minimise wastage).

Compatibility testing will aim to provide ABO matched platelets although this is not essential - these will be Rh negative for paediatric females. Platelets are supplied either pooled (~310 mls - 4 donors per adult unit) or apheresis (~220 mls per adult unit - single donor). Neonatal packs contain approximately 55 mls (apheresis). Administration should occur over > 30 minutes but < 4 hours. Platelets should always be kept at room temperature.

- **Antifibrinolytic agents**

- Tranexamic acid: 5mg/kg/hr as infusion for 10hrs

Tranexamic acid is an anti-fibrinolytic drug that is used to minimise bleeding in patients undergoing surgery or with increased bleeding due to medical conditions. Fibrinolysis is a process of clot breakdown where fibrin is degraded by plasmin and is an integral part of haemostasis. Unwanted fibrinolysis can have an effect of prolonged bleeding episodes; inhibition of fibrinolysis can attenuate bleeding. TXA is a lysine analogue molecule that interacts at the lysine binding site of plasminogen and the heavy chain of plasmin and inhibits fibrin degradation.

- Aprotinin

Recommended dose: 0.5-1ml/kg/hr of solution equivalent to 10,000 KIU/ml (Kallikrein inactivator units) up to max dose 50ml/hr . Review bleeding 6 hourly and stop infusion if improvement. Continue for maximum of 12/24 hours. (Refer to UHL aprotinin IV monograph)

As debate still exists regarding the usefulness and potential side effects of aprotinin use for reduction of bleeding/blood product transfusion post paediatric cardiac surgery our protocol does not recommend the routine use of this product. The use of aprotinin in this context also remains unlicensed in children.

However, where the UHL protocol has been followed, deficits in coagulation tested accordingly and surgical cause for bleeding has been excluded, yet there is still significant bleeding it would be reasonable to consider (as a special circumstance) the administration of aprotinin in these patients (only under the joint direction of the PICU, ECMO and Cardiothoracic consultants)

Aprotinin can now only be given on a named patient basis and can only be requested by approved UHL consultant. For PICU/ECMO this is currently Mr Chris Harvey (ECMO director). So if aprotinin is needed, it can be requested from pharmacy (preferably by a consultant) and then there is an expectation to keep a paper record every time a vial is used which can be retrospectively added to the registry – patient demographics, dosing and any ADRs.

- Recombinant factor VIIa (Novo seven)

This guideline does not support concurrent use of novoseven with PCC and / or Fibrinogen concentrate in view of significant increase in serious and potentially fatal thrombotic complications.

5. Education and Training

Each department is responsible for ensuring that all staff are aware of the guideline for the prevention and management of post-operative cardiac surgical bleeding.

The PICU /CICU Clinical practice group will provide support and advice to staff within the department on the guideline and tests but will not be responsible for delivering the training.

6. Monitoring Compliance

No auditable standards identified.

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8. Key Words

Paediatric cardiac surgery, Perioperative bleeding, Thromboelastography (TEG), PlateletS, PT, APTT, Fibrinogen, Packed red cells, FFP, PCC, Cyroprecipitate, Antifibrinolytic agents, Tranexamic Acid, Aprotinin, Novoseven

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs. As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

Contact & review details	
Guideline Lead (Name and Title) Claire Westrope - Consultant PICU/ECMO	Executive Lead Chief Medical Officer
Details of Changes made during review: V2 January 2018 Paragraph "ROTEM" + "Platelet function tests" deleted – planned, but still not available in the hospital. Paragraph "Fibrinogen concentrate" changed - Point of care fibrinogen test using ROTEM to guide fibrinogen concentrate dose was deleted (Rotem not available). The information about Desmopressin was deleted Appendix 2 deleted. Poster flow chart placed at front of document for quick access	
V3 October 2020 No changes Format update only	
V4 January 2024 No changes	

Appendix 1

Please follow link below to access poster size version of: Poster guide to the management of post-operative paediatric surgical bleeding

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