Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Ospidéal Máithreachais na hOllscoile Corcaigh
Cork University Maternity Hospital

CUH
Ospidéal Ollscoile Chorcaí
Cork University Hospital

POLICY AND PROCEDURE & GUIDLINES ON THE TRANSFUSION MANAGEMENT OF MASSIVE LIFE-THREATENING HAEMORRHAGE IN CUH AND CUMH.

Reference Number: PPG-CUH-CUH-210	**Revision No:** 5	**Review Cycle:** 2 year
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Table of Contents

Policy Statement

It is the policy of the Cork University Hospital (CUH) and the Cork University Maternity Hospital (CUMH) that the transfusion of blood components to patients undergoing a massive life-threatening haemorrhage are managed according to this policy.

1 Purpose

The purpose of this policy is to outline the process and procedures of activating, participating and managing a Massive Transfusion Protocol (MTP) in line with current best practice guidelines as described in the in the National Clinical Practice Guideline 2022 (No.29) for the management of Unexpected Intraoperative Life Threatening Haemorrhage and also in the National Clinical Practice Guideline for the Prevention and Management of Primary Postpartum Haemorrhage 2022 (see Appendix).

Major life-threatening haemorrhage is a medical emergency requiring multidisciplinary care. Transfusion of blood products can be life-saving in conjunction with other interventions. It is important to note that massive transfusion is unlikely to achieve haemostasis by itself. An MTP acts as a bridge to definitive haemostatic interventions and to increase their chance of success through improved clotting function. (BSH 2022).

In obstetric patients, major blood loss can develop rapidly around the time of delivery and this is often under-estimated and may be concealed. Profound coagulopathy and DIC may develop rapidly in the absence of haemodynamic compromise. Close monitoring of all women in the peripartum period, and early recognition and rapid response, are critical (BSH 2022).

2 Definitions

<u>Massive Haemorrhage in a non-pregnant adult</u>
The definition of a massive haemorrhage differs between patient groups. In non-pregnant adults, life threatening haemorrhage is associated with clinical features including tachycardia (>110 beats per minute), hypotension (<90mmHg systolic blood pressure) or significant change in vital signs from baseline and suggests a sudden loss of at least 50% of blood volume (BSH 2022).

Other broad definitions include (and not limited to):

1. Loss equivalent to a person's total blood volume in a 24-hour period.
2. Loss equivalent to 50% of a person's total blood volume over a three-hour period.
3. Loss of blood volume at a rate of 150ml/minute.

Obstetric haemorrhage

A PPH is usually defined as an estimated blood loss of >1000 ml during a Caesarean section, or >500 ml after a vaginal birth. Blood loss may be revealed or concealed. Care providers should be vigilant for the signs and symptoms of hypovolaemia (tachycardia, hypotension, tachypnoea or altered consciousness) in those with ongoing bleeding. Severe PPH of >1500 ml remains a leading cause of early maternal death and morbidity, and obstetric management should consider prevention and management including uterotonics for uterine atony and surgery (BSH, 2022) (PMPPH 2022).

Maternal & Newborn - Clinical Management System (MN-CMS)
This is an electronic health record (EHR) for all women and babies in maternity services in Ireland. It is used to order, prescribe and record the administration of blood components/products in CUMH.

Personal Digital Assistants (PDAs)/Electronic BloodTracking System (EBTS)
The BloodTrack® Tx Personal Digital Assistants (PDAs) (also known as the Electronic BloodTracking System [EBTS] phase 3) are a national IT based solution designed to improve the safety of blood transfusion processes. The PDAs can be used to perform the pre-transfusion checks by ensuring that the details on the patient's wristband are identical to the demographics on the compatibility label(s).

3 Scope

All clinical staff involved in the transfusion process working in the CUH and CUMH.

3.1 Target Population

- This policy addresses the management of patients **above 16 years of age with** critical, life-threatening haemorrhage who require massive transfusion.

- Note: For guidance on the management of a **paediatric massive haemorrhage** refer to Appendix 12.3.

4 Legislation/Related Policies

- Unexpected Intraoperative Life Threatening Haemorrhage. National Clinical Practice Guideline No 29. National Clinical Effectiveness Committee (NCEC). 2022.
- National Clinical Practice Guideline. Prevention and Management of Primary Postpartum Haemorrhage. 2022 (PMPPH 2022) (ISWID-PPPG-C-COBS-009)
- EU Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 - Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (see Appendix)
- PPG-CUH-CUH-13: P&P on collection and administration of blood components / products in CUH and CUMH.

- PPG-CUH-CUH-36: P&P on Sampling and Labelling of Blood Transfusion Specimens in CUH and CUMH
- PPG-CUH-CUH-80: Policy and Procedure on providing blood transfusion information leaflet and Prescribing Blood Components/ Products in Cork University Hospital & Cork University Maternity Hospital
- PPG-CUH-CUH-242: P&P for the management of patients presenting with excessive anticoagulation (INR>5.0) while on Vitamin K antagonists e.g. warfarin at the Cork University Hospital Group.
- PPG-CUH-NUR-9: P&P on The Management of Patients on Oral Anticoagulant Therapy in CUH and CUMH
- PPG-CUH-CUH-42: P&P for the Prescribing, Ordering and Administration of Prothrombin Complex Concentrate (PCC).
- PPG-CUH-CUH- 267: The management of patients on Non Vitamin K antagonist Oral Anticoagulants (NOACs)
- PPG-CUH-CUH-209: P&P for Prescribing, ordering and the administration of Fibrinogen in CUH and CUMH
- LP-C-BTR-TRXNINV: Performing a Transfusion Reaction Investigation
- PPG-CUH-CUH-169 – P&P on the management of patients who refuse blood and blood components in CUH and CUMH

5 Glossary of Abbreviations

BT – Blood Transfusion
CUH – Cork University Hospital
CUMH – Cork University Maternity Hospital
MHP – Massive Haemorrhage Pack (Pathway / Protocol)
MTP - Massive Transfusion Protocol (Pathway / Pack)
POCT – Point of Care Testing
ABG – Arterial Blood Gas
VBG – Venous Blood Gas
ED – Emergency Department
OT – Operation Theatre
ICU – Intensive Care Unit
HDU – High Dependency Unit
RCC – Red Cell Concentrate
PPH – Primary Postpartum Haemorrhage
PLT – Platelets
P&P –Policy and Procedure
FIB – Fibrinogen Concentrate (1g)
PCC – Prothrombin Complex Concentrate
FBC – Full Blood Count
U&E – Urea and Electrolytes
DIC –Disseminated intravascular coagulation
PPiD – Positive patient identification
MN-CMS - The Maternal and Newborn Clinical Management System: An electronic health record (EHR) for all women and babies in maternity services in Ireland.

5.1 Roles and Responsibilities

It is recommended that all staff involved in the blood transfusion chain are familiar with these guidelines.

6 Procedure

6.1 ACTIVATION OF A MASSIVE TRANSFUSION PROTOCOL / PATHWAY

6.1.1 SENIOR CLINICIAN

An experienced clinician (registrar grade or above) should assume overall responsibility for the immediate management of the patient.

TASK:

The senior clinician states that they are activating the Massive Transfusion Protocol or the Life-Threatening Haemorrhage Protocol using recognized terminology such as:

- **MASSIVE TRANSFUSION PROTCOL / PATHWAY / PACK**
- **MASSIVE HAEMORRHAGE PROTOCOL / PATHWAY / PACK**
- **CODE RED (specifically for massive intra-operative haemorrhage)**
- **CODE RED OBSTETRICS (specifically for massive PPH).**

The senior clinician should identify an **EMERGENCY COORDINATOR.**

6.1.2 EMERGENCY COORDINATOR

A designated emergency coordinator (this may be a senior nurse or midwife or another doctor) should be identified by the senior clinician when the MTP is activated.

TASK:

The principle tasks of the emergency coordinator are to:

1. Mobilise resources
2. Direct and coordinate the various roles.
3. Identify a communication lead
4. Coordinate transfusion support (as guided by senior clinician)
5. Document all aspects of the massive haemorrhage management from time of initiation to stand down, including the status of blood product support.
6. In the event that the patient is moved from one area of clinical care to another (e.g. ED or Delivery Suite to ward or theatre or ICU) or there is transfer of care to another clinical service it is the responsibility of the coordinator to ensure there is clear communication around transfusion issues with the receiving team.

6.1.3 COMMUNICATION LEAD

A robust communication link between the blood transfusion (BT) laboratory and clinical area is essential. Closed loop communication is highly recommended to confirm instructions/information is understood (NCEC 29).

TASK:

1. The communication lead identifies themselves and provides a contact number / location.
2. The communication lead should state the following:

"MASSIVE TRANSFUSION PROTCOL ACTIVATED IN LOCATION xxxxx FOR PATIENT yyyyy"

3. The communication lead must keep the emergency coordinator informed of events and calls key personnel for assistance.

6.1.4 Key Personnel

KEY PERSONNEL	COMMUNICATION
Surgeon or Physician (CUH)	**Switch**
Obstetrician (CUMH)	**Switch**
Anaesthetist	**Switch**
Blood Transfusion (BT) Personnel	**EXT 22537 (08:00 – 20:00)** **BLEEP: 199 (20:00 – 08:00 & Weekends)**
Porter	Local communication / switch
Haematology Laboratory	EXT: 22541 BLEEP: 399
Biochemistry laboratory	EXT: 22528 BLEEP: 376
Haematologist	Switch
CUH Emergency Theatre 3 CUH Cardiac Theatre 1 CUH Hybrid Theatre CUMH Theatre 2 & 3	22245 34147 34055 20638 / 20537
ADON ADOM as required	Switch
General / Vascular surgeon	Switch
Interventional Radiology	22807

4. The communication lead organises pre-transfusion blood samples and transfusion support with Blood Transfusion personnel:

- Identifies if a Group and Hold sample has been sent. If a sample has not been sent arrange with the Emergency Coordinator to do so **immediately**.
- Discusses blood component options and availability with BT personnel.
- Theatre Specific: Informs BT if the emergency O RhD negative blood from the CUH theatre fridge or emergency Fibrinogen from the CUMH theatre has been used and is required to be replaced

6.1.5 Preparation Time For Blood Components

Time to Prepare Blood Components	
Blood Component	**Time to Prepare**
Emergency Uncrossmatched RCC	**Immediately available for collection**
Group Specific Uncrossmatched RCC	**Supplied as available – typically within 30 minutes**
Fully Crossmatched RCC	**60 minutes approx (may be longer if antibody screen positive)**
SD-Plasma	**45 minutes approx**
Platelets	**60 minutes approx.**
Fibrinogen Concentrate	**15 minutes ***
Prothrombin Complex Concentrate	**15 minutes**
* An emergency supply of Fibrinogen is available in the drug fridge in Anaesthetic ROOM 3 in CUMH for massive obstetric haemorrhage	
Caveat: All blood products will be supplied as available notwithstanding competing demands from other service users.	

5. The communication lead requests other laboratory investigations. Serial haemostatic tests including FBC, coagulation screen and fibrinogen from before and after resuscitation should be taken every 30-60 minutes depending on the severity of the haemorrhage. POCT should be used in conjunction with laboratory tests where available. The results of these tests will guide and ensure the appropriate use of blood components. Calcium must be monitored and replaced as appropriate. (NCEC29):

6.1.6 Essential Blood Tests:

- FBC
- Coagulation screen **including** Fibrinogen levels
- U&E
- Calcium
- Lactate

Resuscitative Aims	
Haemoglobin	7-9 g/dL
Haemoglobin (Obstetrics)	>8 g/dL
Platelets	>50 x 10^9/L
PT / APTT	< 1.5 x mean control
Fibrinogen level (non-obstetric)	>1.5 g/L
Fibrinogen level (Obstetrics)	>2 g/L
iCa++	>1 mmol/L

Important considerations:
Do not use haemoglobin alone as a transfusion trigger. Haemoglobin results should be interpreted in the context of haemodynamic status, organ perfusion and tissue oxygenation (BSH 2022).

NB: Do not delay transfusion of blood products whilst waiting for results. If life-threatening haemorrhage continues proceed to empiric blood management

6.2 BLOOD TRANSFUSION MANAGEMENT

6.2.1 INITIAL EMPIRIC BLOOD MANAGEMENT

On declaration of a life-threatening haemorrhage proceed as follows:

Product	Administration / Dose
RCC (INITIAL SUPPORT)	Transfuse **2** x emergency Group O Negative RCC (or patient specific RCC if available) while waiting for MHP.
FIBRINOGEN EARLY USE IN PPH (OBSTETRICS)	In a PPH give 4g Fibrinogen Concentrate
TRANEXAMIC ACID (TXA)	Where clinically indicated give a 1g bolus over 10 minutes. Can be continued at a dose of 1g 8 hourly until bleeding ceases.

6.2.2 Massive Haemorrhage Packs

On declaration of a MTP, blood transfusion personnel will immediately begin to prepare a MHP. Initial blood management as described above allows blood transfusion personnel time to prepare the MHP without delaying transfusion of the patient. Following initial blood management and other resuscitative efforts, if the patient continues to have life-threatening haemorrhage, proceed as follows:

Proceed to Collection of the Massive Haemorrhage Pack (MHP)
The MHP is prepared exclusively by Blood Transfusion personnel and is designed to give a RCC to plasma ratio of 1:1.

The first MHP is composed of the following

- **4 x RCC**
- **4 x SD-Plasma**
- **1 x Platelet** (for immediate collection or on standby)

CONTENTS OF MHP 1

4 x RCC (May be Group O or Group Specific)

4 x SD-PLASMA (May be Group AB or Group Specific)

1 x PLATELET: Transfuse one unit of platelets for every 4 RCC and 4 SD-PLASMA (Note: 1 unit of platelets is equivilant to a pool of 4 single platelet donations).

CONTENTS OF MHP 2

(As above except for addition of 4g of Fibrinogen Concentrate)

4G Fibrinogen Concentrate (for Obstetric Haemorrhage early transfusion with Fibrinogen Concentrate is required)

Further transfusion management following transfusion of the first MHP
Following transfusion of the first MHP, if possible, pause and review the situation, paying close attention to POCT and laboratory test results.

If massive haemorrhage continues, order additional MHPs (Pack 2,3 ,4 etc.) and transfuse empirically, always **guided by test results** . Remember to repeat monitoring of FBC and coagulation, including fibrinogen every 30-60 minutes until bleeding is controlled.

All subsequent MHPs (from Pack 2 onwards) will contain the following:

- **4 x RCC**
- **4 x SD-Plasma**
- **1 x Platelet**
- **4g Fibrinogen concentrate**

6.2.3 CALCIUM GLUCONATE

Calcium is necessary for optimal coagulation and cardiac function. Consider a bolus of 10% Calcium gluconate. Where possible administer calcium gluconate (or calcium chloride) via separate IV access to blood products due to risk of coagulation. (NCEC 29, PMPPH 2022).

6.3 Blood Component Details

6.3.1 Pre-Transfusion PPiD Checking

In a life-threatening haemorrhage, as a minimum two clinicians should perform the pre-transfusion checks to ensure the patient's details exactly match the details on the blood component.

If any discrepancies are found DO NOT PROCEED under any circumstances and immediately alert the BT staff.

6.3.2 PPiD Using Blood Track Devices (CUH)

BloodTrack devices can be used to ensure that the name on the tag attached to the blood component matches the details on the patient ID-band.

Note: BloodTrack devices are not suitable when transfusing emergency blood components pre-labelled with the generic emergency patient identifiers as the details on the tag will not match those of the intended patient.

6.3.3 Emergency Red cell Concentrate (RCC)

Locations of the Emergency Labelled RCC:

Blood Transfusion Laboratory Issue Fridge:
6 x Emergency O Negative RCC units are stored in the Blood Transfusion Laboratory Issue fridge for adult patients. One unit of emergency O Negative RCC, suitable for neonatal use, is also stored in the BT Issue fridge. These units

are pre-labelled with generic emergency patient identifiers and are available for immediate transfusion.

General Theatre Fridge CUH:
2 x Emergency O Negative RCC units suitable for adult use, pre-labelled with generic emergency patient identifiers, are available for immediate transfusion. It is essential to communicate with BT staff when these units are used so that BT staff can replace the transfused units.

Transport of Blood to Clinical Areas:
When more than one unit of RCC is required in a clinical area setting, the RCC must be transported to the clinical area in an Igloo box packed by a Medical Scientist from the Blood Transfusion Laboratory. Up to 6 units of RCC can be stored in an Igloo box for a maximum of 6 hours.

For clinical areas with satellite blood fridges (CUH General Theatre, Cardiac OT and Cardiac ICU), blood can be transported to these areas at room temperature but must be stored on arrival in these areas in the designated blood fridges.

Transfusing Emergency RCC:
The choice of red cells depends on the degree of urgency. Emergency O Negative RCC can be used initially with life threatening bleeding. These are a limited resource. Where possible group specific or crossmatched blood should be used.

Transfusion of large volumes of blood over a short time frame can be administered via a rapid infuser. When transfusing large volumes of RCC, blood should be pre-warmed to avoid hypothermia in the patient.

Transfusing Patients with Serological Complications:
The presence of red cell antibodies may potentially complicate the delivery and provision of RCC. In the event that a MTP is declared for a patient who has red cell antibodies, a Haematologist should be consulted in such a scenario.

Emergency Transfusion of Rhesus D Positive RCC:
For males and for females >60 years, it may be necessary to transfuse Rhesus D Positive RCC if stocks of Rh D Negative RCC are critically low. A Haematologist may need to be consulted in such a scenario.

6.3.4 Emergency SD-Plasma

Plasma should be transfused 1:1 with RCC as part of initial resuscitation until results from coagulation monitoring is available. Once bleeding is controlled guided by haemostatic test results i.e. Trigger PT/APTT >1.5 times normal, use standard dose 15ml/Kg (NCEC29).

Preparation time: SD-plasma requires thawing by BT personnel. This process typically takes a minimum of 45 minutes from the time of request.

Blood Group Considerations: In most MTPs where blood components are being transfused to a patient with an undetermined blood group, the BT lab will issue

group AB plasma until the patient's own blood group is known. In the event that group AB plasma is unavailable a suitable alternative blood group will be issued.

6.3.5 Emergency Platelets

Request platelets to be on standby where ongoing bleeding and platelet count is $<100 \times 10^9$L. Transfuse to keep $>50 \times 10^9$L and $>100 \times 10^9$L in the case of brain / critical site bleeding (NCEC 29). Early platelet transfusion should be considered for abruption and abnormal placentation (PMPPH 2022).

Preparation and Provision: As platelets are typically not kept as "stock" in CUH, a special delivery from the IBTS (St. Finbarr's campus) may need to be arranged by BT staff. Therefore, provision of platelets to the clinical area may take up to 1 hour from the time of request.

Blood Group Considerations: The universal blood group for platelet transfusion is **group AB Negative**, however, as this blood group is extremely rare in the Irish population it is typically not an option for transfusion. In most MTPs where blood components are being transfused to a patient with an undetermined blood group, the BT lab will issue group **A Negative** platelets until the patient's own blood group is known. In life threatening haemorrhage, if group specific platelets are not available, platelets of any group can be considered. The Haematology medical team are available for consultation if necessary.

6.3.6 Emergency Fibrinogen 1g Concentrate

A dose of 4g typically increases fibrinogen by 1g/L in an adult. In major obstetric haemorrhage consideration must be given to the early use of fibrinogen supplementation (aim to keep plasma fibrinogen level of >2g/L). 4g of Fibrinogen concentrate are available at all times in the in CUMH Theatre area and should be considered as part of the initial empirical blood management for the patient. It is important to inform the BT laboratory when a decision has been made to transfuse emergency Fibrinogen concentrate stored in CUMH theatre to enable replacement of the product.

Use of Fibrinogen Concentrate as part of the MHP:
Fibrinogen concentrate is not included in the first MHP (non-obstetric only). 4g of Fibrinogen concentrate is however included in all subsequent MHP's (i.e. Pack 2,3,4 etc).

6.3.7 Tranexamic Acid (TXA)

There is evidence to support TXA administration in trauma patients with significant haemorrhage, some patients with significant bleeding and women with PPH. TXA should be administered within 3 hours of trauma (1g IV over 10 mins and then 1g IV over 8 hours) (Relke et al 2021)

6.3.8 Factor VIIa

Use of Factor VIIa requires advice and authorisation by a consultant Haematologist.

6.3.9 Patients on anti-coagulation

Direct Oral Anticoagulants**:** The term Direct Oral Anticoagulant (DOAC) encompasses Rivaroxaban, Apixaban, Edoxaban and Dabigatran. If a patient is taking Rivaroxaban or Apixaban and has a life-threatening bleed, reversal with Andexanet Alpha may be appropriate (refer to HSE prescribing guideline for Andexanet Alpha).

If a patient is taking a DOAC but Andexanet is not indicated, please refer to section 7.7 of PPG-CUH-CUH- 267: The Management of Adult Patients on Direct Oral Anticoagulants (DOACs) in the Cork University Hospital Group.

Heparin: If a patient is taking unfractionated heparin or low molecular weight heparin, reversal with Protamine Sulphate may be appropriate (refer to the SPC for dosing instructions of Protamine Sulphate).

Vitamin K antagonists (warfarin): The use of Prothrombin Complex Concentrate (PCC) is recommended in the urgent reversal of the effect of Vitamin K antagonists. The maximum permitted dose for PCC is 3000iu (Refer to PPG-CUH-CUH-42: Policy and Procedure for the Prescribing, Ordering and Administration of Prothrombin Complex Concentrate (PCC) in Cork University Hospital and to PPG-CUH-CUH-242 Policy and Procedure for the management of patients presenting with excessive anticoagulation (INR>5.0) while on Vitamin K antagonists e.g. warfarin at the CUH and CUMH).

6.3.10 Thromboprophylaxis after major bleeding

Early mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) should be applied while the patient is immobile and has a bleeding risk. This should be combined with pharmacological and IPC thromboprophylaxis within 24hrs after bleeding has been controlled and until the patient is mobilized. (NCEC29)

6.3.11 Stand-down following control of the episode

The BT laboratory must be instructed to discontinue the MTP as soon as massive transfusion is no longer required to minimise product wastage. Notify BT personnel when:

- Bleeding is controlled and MHP's are no longer required
- Further resuscitation is deemed futile and transfusion ceased
- If the patient is being transferred to another facility and products are NOT required for transfer.

Stand-down review:
Following official stand-down of the MTP a full review of transfusion documentation should be conducted to ensure compliance with mandatory traceability requirements
Any wastage, avoidable or unavoidable, must be explained to BT or Haemovigilance staff and documented in the medical records.

7 Implementation Plan

- An email will be sent out via the CUH and CUMH email system alerting all users that this revised P&P has been approved.
- The policy and supporting evidence will be made available to all wards/units through Q-PULSE system.

8 Revision and Audit

Revision
This procedure will be reviewed on a 2 yearly basis or earlier if indicated.

Audit
Audits will be carried out by Haemovigilance personnel as per NCEC 29 guidelines and following the launch of this revised policy as per the blood transfusion laboratory audit schedule which is managed on the hospital Q-Pulse system.

9 References/Bibliography

Unexpected intraoperative Life Threatening Haemorrhage. National Clinical Guideline No. 29. National Clinical Effectiveness Committee (NCEC) 2022.

National Clinical Practice Guideline Prevention and Management of Primary Postpartum Haemorrhage. Institute of Obstetricians and Gynaecologists. 2022 (PMPPH 2022)

EU Directive 2002/98/EC of the European Parliament and of the Council of Europe 27/01/03 - Setting standards of quality & safety for the collection, testing, processing, storage & distribution of human blood components

HSE Prescribing Guideline for Andexanet-alfa.
https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/protocols/hse-prescribing-guideline-for-andexanet-alfa.pdf

Haematological management of major haemorrhage: A British Society for Haematology Guideline (BSH) SJ. Stanworth, K. Dowling et al. 2022

Tranexamic acid evidence and controversies: An illustrated review. Relke N, Chornenki NLJ, Sholzberg M. Res Pract Thromb Haemost. 2021 Jul 14;5 (5):e12546.

PPG-CUH-CUH- 267: The Management of Adult Patients on Direct Oral Anticoagulants (DOACs) in the Cork University Hospital Group.

Protamine Sulphate for Injection and Infusion:
https://www.medicines.ie/medicines/protamine-sulphate-leo-pharma-1400-anti-heparin-iu-ml-solution-for-injection-and-infusion-33466/spc

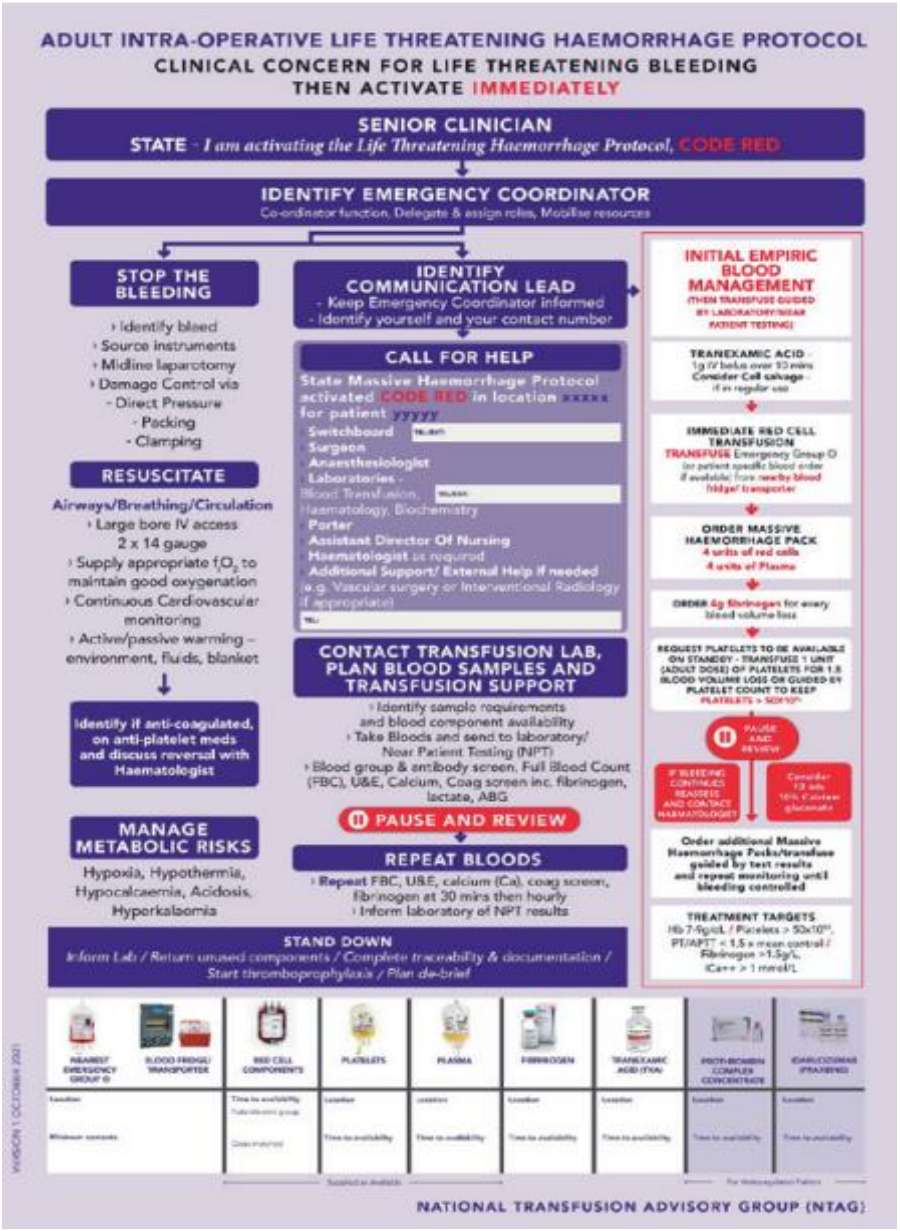
PPG-CUH-CUH-42: Policy and Procedure for the Prescribing, Ordering and Administration of Prothrombin Complex Concentrate (PCC) in Cork University Hospital.

PPG-CUH-CUH-242 Policy and Procedure for the management of patients presenting with excessive anticoagulation (INR>5.0) while on Vitamin K antagonists e.g. warfarin at the Cork University Hospital Group.

10 APPENDIX

10.1 Post Partum Life Threatening Haemorrhage Protocol Poster

10.2 Adult intra-operative life threatening haemorrhage protocol



10.3 EU Blood Directive

The EU Directive 2002/98/EC became law in Ireland on the 08.02.05 and has implications for hospital blood banks. Eight articles of the directive apply specifically to hospital Blood Transfusion laboratories and to all staff involved in blood transfusion process. The major implications refer to the total traceability of every blood product, quality systems for labelling laboratories and the training of personnel. Compliance with this legislation is policed by the HPRA (Health Products Regulatory Authority, formerly Irish Medicines Board), (IMB) under the IMB Act 1995 and in the event of non-directive compliance; the HPRA (IMB) has the authority to close a facility.

> Article 10 of the Directive makes specific reference refers to personnel: "personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely relevant and regularly undated training"

10.4 Cork University Hospital Protocol for Management of Massive Haemorrhage in Paediatrics

PAEDIATRIC MAJOR TRANSFUSION PROTOCOL (MTP)

Acute blood loss observed/estimated > 10mls/kg

↓

Contact the Consultant Paediatric, Surgical team on call and Consultant Haematologist

↓

Call transfusion laboratory (Tel: 22537 / Bleep: 199).
Establish if valid BT specimen in laboratory and that blood may be required urgently

↓

Secure intravenous access and take blood samples for:
- Blood Transfusion Group & X/match sample if required (correctly labelled),
- FBC, Clotting Screen (include Fibrinogen), Biochemistry, VBGs

↓

Give **tranexamic acid:**
- 15mg/kg. Note: Maximum 1g.
- Consider maintenance 2mg/kg/hr infusion

Commence **fluid resuscitation:**
- 10ml/kg warmed 0.9% NaCl

↓

Is blood required STAT?
(i.e. less than 10 minutes)?

→ **Yes** →

Request Emergency O Neg unit from BT Laboratory
- **Child <20kg: Request one unit of RBC**
- **Child > 20kg: Request two units of RBC**

↓ **No**

Request from BT Laboratory as described below based on body weight

Child < 10kg: 1 unit RBC + 1 unit SD Plasma	**Child 10-20kg: 2 units RBC + 2 units SD Plasma**
Child 20-40kg: 3 units RBC + 2 units SD Plasma	**Child > 40kg: 4 units RBC + 2 units SD Plasma**

Transfuse RBC and SD-Plasma:
Administer in 10mL/kg aliquots (in total 20ml/kg).
Prescribe all transfused components as mls/kg bodyweight.
Give RCC through blood warmer.
Reassess rate of blood loss and response to treatment and repeat as necessary.
Consider:
- **Platelets** (1 unit per 4 units of RBC transfused or 5mL/kg for every 10mL/kg RBC transfused)
- **Fibrinogen Concentrate 1 g** (if fibrinogen level <1.5g/L)
  If infant is **<10kg body weight**: give 100mg/kg of Fibrinogen Concentrate.

↓

Bleeding Controlled?

← **Yes**

→ **No** → (back to Bleeding Controlled?)

↓

- **Notify Blood Transfusion Laboratory to cease MTP**
- **Return all unused blood products to the lab. Ensure documentation complete**

Optimise:
- Oxygenation
- Cardiac Output
- Tissue Perfusion
- Metabolic State
- Watch ECG, O_2 saturation and BP

Monitor (every 30-60minutes):
- FBC
- PT / APTT / Fibrinogen
- Calcium and Magnesium
- VBG

If bleeding continues, aim for:
- Hb: > 8.0g/dL
- Platelets:
  - 50-100 x 10^9/L,
  - 100 if ICH / Life threatening bleeding
- PT/APTT: < 1.5 x normal
- Fibrinogen: > 1.5g/L
- Temperature: >35°C
- pH: > 7.2
- Base excess: < 6
- Lactate: < 1mmol/L
- Ca^{++}: >1.1mmol/L