Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CUH
Ospidéal Ollscoile Chorcaí
Cork University Hospital

POLICY, PROCEDURE AND GUIDELINE FOR PREHOSPITAL TRANSFUSIONS CO-ORDINATED FROM CORK UNIVERSITY HOSPITAL

Reference Number: PPG-CUH-CUH-282	**Revision No:** 1	**Review Cycle:** 2years
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Approver (Lead): Dr M O'Connor	**Approval Date:** 13th June 2019	

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1 Policy Statement

The use of Red cells in the pre-hospital setting during hypovolaemic resuscitation with a move away from large volume intravenous crystalloids is becoming established practise internationally and has been shown to reduce mortality if given early in hypovolemic shock[1-4].

2 Purpose

The purpose of this procedure is to describe the use and management of red cell concentrate (RCC) for pre-hospital patients attended to by Emergency Medicine Doctors based out of Cork University Hospital (CUH) supported by the Blood Transfusion Laboratory, CUH.

3 Scope

This procedure applies to:

- Approved Emergency Medicine Doctors (appendix 18.1) working in the Cork University Hospital that are experienced in pre-Hospital medicine who may need to administer Blood or Blood components at the scene of an incident in a pre-hospital setting.
- Blood Transfusion Laboratory consultants and medical scientists at Cork University Hospital involved in the issuing of blood and blood components and blood stock management.
- Haemovigilance officers overseeing the haemovigilance and traceability activities at Cork University Hospital.

4 Glossary of Terms and Definitions

CUH	= Cork University Hospital
ED	= Emergency Department
EM	= Emergency Medicine
NAS	= National Ambulance Service
RCC	= Red Cell Concentrate
NHO	= National Haemovigilance Office

5 Legislation/Related Policies

- S.I. 360 of 2005, European Communities (Quality and Safety of Human Blood and Blood Components).
- ISO15189 (2012) Medical laboratories — Requirements for quality and competence.
- PPG-CUH-CUH-13: "P&P on the Administration of Blood Components to Patients in Cork University Hospital Group".
- PPG-CUH-CUH-36: "P&P on sampling and labelling of pre-transfusion specimens by medical staff in CUH Group".
- LP-C-BTR-IGLOO: "Transfer of Blood to External Sites using the Igloo Box".
- PPG-CUH-CUH-210: "Policy & Procedure on Transfusion Management of Massive Haemorrhage in Cork University Hospital Group".
- PPG-CUH-CUH-30: "Policy & Procedure on recognising, investigating and managing a suspected transfusion reaction in CUH Group".
- AML_BB_Minimum Requirements for Blood Bank Compliance with Article 14 and 15 of EU Dir. 2002/98/EC.
- FOR-CUH-CUH-7: "Blood Component Prescription & Transfusion Record".
- MP-C-BTR-HV_E&R: "Procedure for the management of reactions and events at Cork University Hospital and Cork University Maternity Hospital by Haemovigilance and Blood Transfusion Laboratory personnel"

6 Roles and Responsibilities

6.1 Responsibility for complying with the policy

Emergency Medicine (EM) Doctors providing pre-hospital care
Authorised EM doctors based in CUH are responsible for the prescription, pre-transfusion sampling, administration of RCC, relevant record keeping/documentation and traceability in accordance with this policy and associated training. Dr Eoin Fogarty Consultant in Emergency Medicine and Retrieval sits on the CUH transfusion committee. He will provide a monitoring, training and feedback function on blood transfused in ED and pre-hospital.

Medical Scientists
Medical scientists based in the Blood Transfusion Laboratory in CUH are responsible for issuing packed blood transport boxes as requested for pre-hospital care, validation of blood transport boxes, management of RCC and traceability in accordance with this policy and associated training.

Haemovigilance Officer(s)
Haemovigilance officers based in the Blood Transfusion Laboratory in CUH are responsible for ensuring full traceability of RCC and that good transfusion practice is applied with respect to pre-hospital transfusion.

6.2 Responsibility for ensuring compliance with the policy

Chief Medical Scientist

The Chief Medical Scientist in the Blood Transfusion Laboratory is responsible for ensuring all relevant scientists have been trained in the relevant procedures. They will also oversee that regular audits take place to ensure the requirements of ISO15189 and AML-BB are met.

Consultant Haematologist

The consultant haematologist will be responsible for providing clinical governance to ensure that the requirements of ISO15189 and AML-BB are met and to liaise with the EM Doctors (as required) in relation to the process.

Emergency Medicine Doctor

Dr Eoin Fogarty, Consultant in Emergency Medicine and Retrieval will be responsible for liaising with the Consultant Haematologist and overseeing that relevant EM doctors comply with the process. With the support of the Blood Transfusion Laboratory, the EM Doctor will ensure that regular audits are carried out and audit findings presented to the hospital transfusion committee as required.

Haemovigilance officer(s)

The haemovigilance officers are responsible for providing a series of workshops and training sessions to educate staff in this policy and procedure. They are also responsible for responding to any queries or questions staff may have with regard to this procedure (during routine hours). With the support of the Blood Transfusion Laboratory, the haemovigilance officers undertake regular audits of the implementation of this procedure and present audit findings to the hospital transfusion committee as required.

7 Procedure

- NAS informs Prehospital Doctor, as per current practise of unwell patient requiring Doctor to attend scene.
- Prehospital doctor requests blood from Dr Eoin Fogarty.
- Dr Eoin Fogarty determines if appropriate to carry O Rh D Negative RCC to scene / patient based on clinical information below (Appendix 18.2).
- Dr Eoin Fogarty rings Blood Bank – ext 22537 to order "3 Emergency O Rh D Neg RCC for transport to a pre-hospital setting/scene".
- Medical Scientists in the Laboratory records call on form LF-C-BTR-MASSIVE and prepare RCC as per procedure LP-C-BTR-IGLOO to be ready within 5-10 minutes.
- Dr Eoin Fogarty collects the packed Blood Transport container from the Blood Transfusion laboratory, CUH and places it in a securely fixed manner in the Marked Response vehicle (Appendix 18.3 and 18.4).
- RCC is to remain in the Blood Transport box in the Marked Response Vehicle until being used or returned to Blood Transfusion laboratory. On scene this vehicle is to be locked if not occupied.
- If blood to be used on scene:
    - Pre-transfusion Group and Hold sample to be taken (if possible) as per PPG-CUH-CUH-36 and transferred to CUH with patient.
    - Blood prescribed and administered using appropriate giving set as per PPG-CUH-CUH-13 and documented on FOR-CUH-CUH-7. *(Consent for treatment – verbal if appropriate / possible. Assumed to be Emergency Life Preserving time critical treatment; in such situations waiver applied unless known religious belief such as Jehovah's witness).*
    - Blood Transport box to be left open only for minimal time.
    - Empty RCC packs to be returned to hospital with the patient for safe disposal.
- Doctor stays with patient being transferred to CUH and on arrival ensures Blood Transport box (and pre-transfusion sample if available) is promptly returned to the Blood Transfusion Laboratory, CUH. EM Doctor is clinically responsible for the care of the patient and stays with the patient once a blood transfusion has been commenced.
- Unused blood is quarantined in laboratory until confirmed with EM Doctor if conditions specified in this procedure have been met. These are returned to stock or discarded as appropriate in the Blood Transfusion Laboratory in accordance with laboratory policy (see Section 14).
- This procedure is outlined in a process flow format in Appendix 18.7.

7.1 Patient Identification

For blood transfusion purposes, correct patient identification is of paramount importance. In order to circumvent any risk to the patient associated with the potential to misidentify a patient and streamline the process to enable transfusion practice to take place in the pre-hospital settings, patients will be assigned a pre-prepared set of unique proxy identifiers as outlined in Appendix 18.5 by the approved EM Doctor.

For pre-hospital stages, these identifiers will be used:

- On the patient's Wristband.
- On the patient's pre-transfusion Samples and Request Forms.
- On the Blood Prescription and Administration Forms.
- On Traceability documentation (e.g. 'Tag' on RCC units transfused)

Once the patient is admitted to Cork University Hospital, only when patient details have been ascertained and confirmed within the Emergency Department, the patient's actual identity will be updated in accordance with normal hospital procedures and merged in a controlled manner with the unique proxy identifiers which were assigned in the pre-hospital setting.

The Blood Transfusion Laboratory can only issue components labelled with the patient information provided on samples and requests forms.

7.2 Pre-Transfusion Sampling and Labelling

In the pre-hospital setting, the principles outlined in the CUH procedure PPG-CUH-CUH-36 apply (using the patient proxy identifiers as outlined in this document).

Pre-hospital assigned addressograph labels will be acceptable on pre-transfusion samples and request forms (as they are labelled at scene by patient's side by trained and approved EM Doctor).

While the importance of pre-transfusion samples is understood to facilitate blood transfusion laboratories provide blood component support to clinical areas, the unique nature and clinical picture in the pre-hospital setting, 3 likely scenarios exist:

- Pre-Transfusion Sample Obtainable
- Pre-Transfusion Sample Not Obtainable
- Pre-Transfusion Sample Obtainable ONLY after transfusion of RCC.

In the pre-hospital setting, the EM Doctor will attempt to obtain a pre-transfusion sample. If this is only possible after the administration of some emergency O Rh D Neg RCC, this **MUST** be communicated to the Blood Transfusion Laboratory.

7.3 Traceability of RCC

In order to achieve 100% traceability as per legal requirements, existing CUH procedures are utilised as described in PPG-CUH-CUH-13 where Prescription, patient details and RCC unit numbers are recorded on the Blood Component Prescription & Transfusion Record: FOR-CUH-CUH-7.

Compliance will be audited by Haemovigilance Officers in CUH.

7.4 Validation of Blood Transport Boxes (e.g. Eskys/Igloos)

Validation of Blood Transport boxes is overseen by the Blood Transfusion Laboratory, CUH in accordance with the procedure LP-C-BTR-IGLOO. Validation records are available in the Blood Transfusion Laboratory, CUH and show that the Blood Transport Boxes being used can maintain temperature between 2-6°C for 6 hours.

7.5 Serious Adverse Reactions and Events (SARs and SAEs)

It is acknowledged that transfusion-related reactions (SARs) are difficult to detect in the cohort of patients who may require blood in pre-hospital setting – therefore a high index of suspicion is required. These will be managed in accordance with CUH procedure PPG-CUH-CUH-30: "Policy & Procedure on recognising, investigating and managing a suspected transfusion reaction in CUH Group".

Serious incidents or adverse events pertaining to this procedure shall be immediately notified to the Chief Medical Scientist and Consultant Haematologist who will oversee that it is documented and managed in accordance with the Blood Transfusion Laboratory CUH procedure MP-C-BTR-HV_E&R "Procedure for the management of reactions and events at Cork University Hospital and Cork University Maternity Hospital by Haemovigilance and Blood Transfusion Laboratory personnel".

7.6 Blood Wastage Mitigation

Stringent cold-chain storage conditions (2-6°C) are required to maintain the integrity of blood components (i.e. red cells) and reduce wastage. The following should be considered to mitigate risk of blood wastage:

Blood Transport Boxes should:

- Only be opened by approved EM Doctor.
- Not be opened until at patient's side.
- Be opened to remove one unit at a time and closed immediately until next unit required to preserve remaining units.

7.7 Accepting Unused Blood to Stock

In the event that blood brought to the scene of an incident is not used, it is **ONLY** acceptable back into the Blood Transfusion Laboratory, CUH stock provided the following conditions have been met:

- The total time that the blood has been in the Blood Transport Box has not exceeded 6 hrs (Confirmed by Laboratory using Blood Track System).
- Physical check that the blood component shows no signs of leakage, unusual colour or haemolysis (Confirmed by receiving scientist).
- All issued units returned unused.
- If blood is used at scene, any unused Blood returned to the laboratory is quarantined and can only be accepted into stock once confirmed with approved EM Doctor that the unused blood remained in validated blood transport box at all times.

If these conditions have not been met it must be discarded by the Blood Transfusion Laboratory.

8 Implementation Plan

This procedure will be initially piloted for a 1-month period between June and July 2019 limited to Dr Eoin Fogarty. During this period, the procedure may only be activated between 08:00 hrs to 20:00hrs Monday to Friday.

Following review of an initial 1-month pilot by the Blood Transfusion Laboratory, Emergency Department and Medical Directorate of National Ambulance Service, if necessary this procedure may be piloted for an extended 5-month period between July and Dec 2019 involving approved EM doctors as defined in this document.

Subject to review of pilot phase(s) and agreement by all key stakeholders, the objective will be to have full implementation of the procedure (i.e. over 24/7/365).

This procedure will be made available to all relevant staff using Q-PULSE system and will be included in the regular haemovigilance education sessions as required.

9 Revision and Audit

This document has been developed and controlled in accordance the Blood Transfusion Laboratory's document control process MP-C-BTR-DOCCTRL and is available on Q-Pulse.

Dr Eoin Fogarty will oversee that the Resuscitation log – online in resuscitation room is to be completed on call cases / whether Red cells used or not. Monthly review of all cases will take place at Clinical review meetings in ED at CUH for clinical governance purposes.

Compliance with Haemovigilance and Traceability requirements will be audited by Haemovigilance Officers in CUH.

This Pre-hospital transfusion programme should be reviewed at quarterly Hospital Transfusion Committee meetings.

A suggested review and audit template is provided in Appendix 18.6.

10 References/Bibliography

1. Yazer MH et al, "Vox Sanguinis International Forum on the use of prehospital blood products and pharmaceuticals in the treatment of patients with traumatic haemorrhage." Vox Sang. 2018 Oct;113(7):701-706. Doi: 10.1111/vox.12678. Epub 2018 Aug 24.

2. https://nswhems.files.wordpress.com/2013/12/c-11-blood-management-vrs-2-april-2013.pdf

3. Shackelford SA, del Junco DJ, Powell-Dunford N, et al. Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan With Acute and 30-Day Survival. JAMA. 2017;318(16):1581–1591. doi:10.1001/jama.2017.15097

4. Jacob Chen, MD ,MILITARY MEDICINE, 182, 3/4:47, 2017 Prehospital Blood Transfusion During Aeromedical Evacuation of Trauma Patients in Israel: The IDF CSAR Experience.

11 Appendices

11.1 Approved Emergency Medicine Doctors with pre-hospital experience:

- Dr Eoin Fogarty
- Dr Conor Deasy
- Dr Jason Van Der Velde
- Dr Hugh Doran
- Dr Adrian Murphy
- Dr Karl Knapmann
- Dr. Darren McLoughlin

11.2 Guidelines to help EM Doctor determine appropriateness of carrying RCC O negative appropriate to scene / patient based on clinical information:

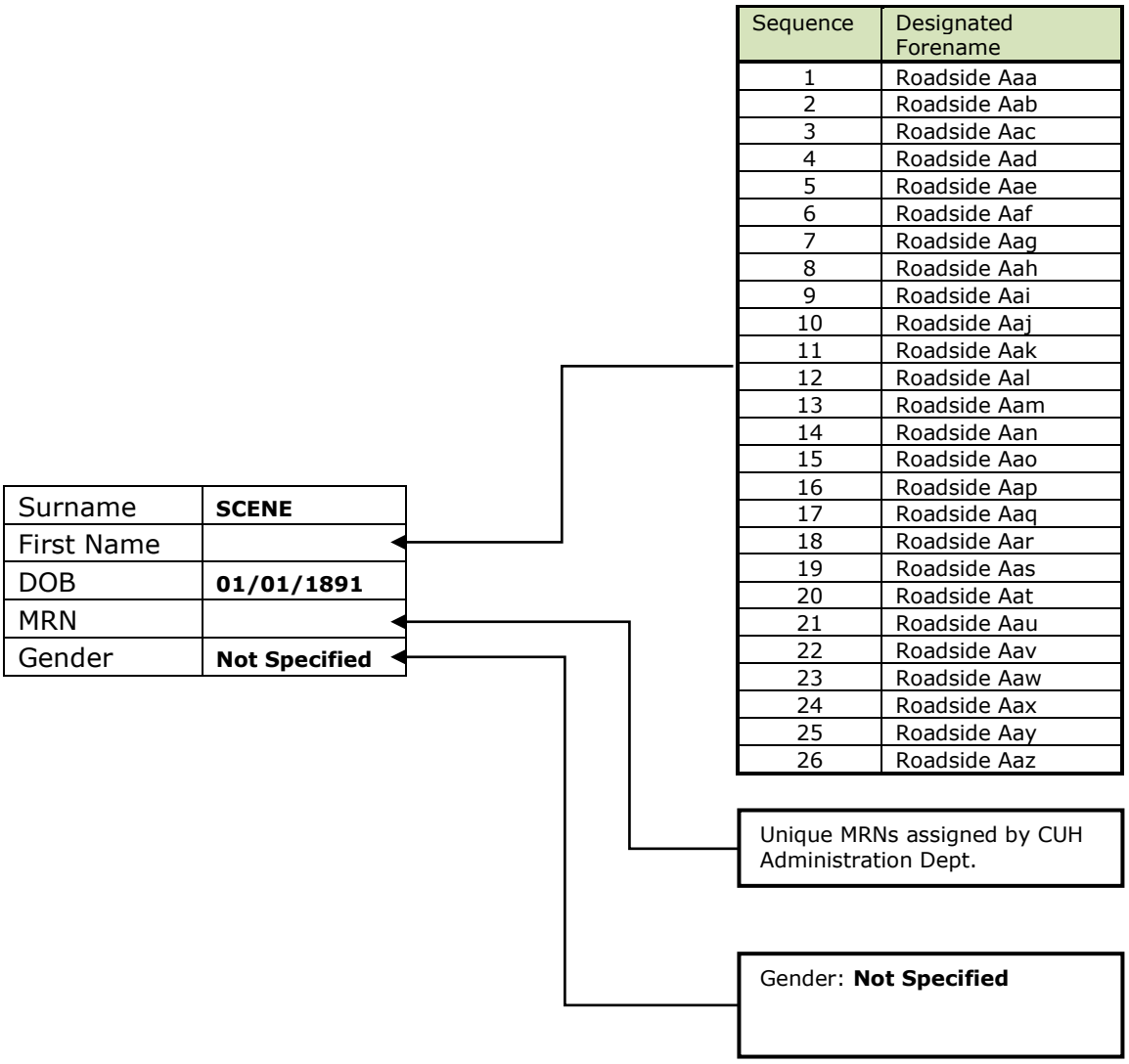
- Physiological signs of haemorrhagic shock:
  - Systolic blood pressure < 90mmHg.
  - Heart Rate ≥ 120/min.
  - Altered conscious state.
- Catastrophic, external haemorrhage.
- High index of suspicion for internal haemorrhage (mechanism, positive eFAST scan and clinical signs).
- Actual or anticipated 4 units red cells in <4hrs.
- Symptomatic anaemia.

11.3 Marked Response Vehicle

11.4 Blood Transport Box in Marked Response Vehicle

11.5 Proxy Patient Identification

- Standard Surname to indicate Pre-Hospital Sample ("Scene").
- Forenames "Roadside Aaa/ Aab" etc used in sequential order.
- MRNs are uniquely assigned by Administration CUH.
- Standard DOB (01/01/1891) to facilitate scanning of Blood through BloodTrack.
- Gender "Not Specified" on pre-printed labels.



11.6 Audit Criteria

Date of Pre-Hospital Transfusion:	
Patient Age:	
Patient Gender:	
Pre-hospital EM Doctor:	
Brief description of Incident/Injury:	

Time left CUH:	
Time at Scene:	
Time left Scene:	
Time at CUH:	

Indication(s) for Blood Products:	_____	
Blood ready for collection from CUH Lab? *If no, provide details.*	Yes ☐	No ☐
Pre-transfusion sample taken?	Yes ☐	No ☐
Accepted in Laboratory for Testing?	Yes ☐	No ☐

Pre-hospital Transfusion **at Scene**? *If Yes, provide Quantity of RCCs:*	Yes ☐	No ☐
Blood Warmer Used?	Yes ☐	No ☐
Pre-hospital Transfusion **during transfer** to CUH? *If Yes, provide Quantity of RCCs:*	Yes ☐	No ☐
Subsequent Transfusions **at CUH**? *If Yes, provide details:* Quantity of:	Yes ☐	No ☐
Tranexamic Acid Given?	Yes ☐	No ☐
Calcium Given?	Yes ☐	No ☐
Massive Haemorrhage policy activated in CUH?	Yes ☐	No ☐
Pre-hospital Blood Wasted?	Yes ☐	No ☐
Storage of Unused Pre-Hospital Blood Confirmed?	Yes ☐	No ☐
Pre-Hospital Blood returned to CUH Lab Stock?	Yes ☐	No ☐

Haemovigilance, Traceability & 24hr Review		
Prescription of Blood Products Correct?	Yes ☐	No ☐
Patient Observations Recorded?	Yes ☐	No ☐
100% Traceability of Blood Products?	Yes ☐	No ☐
Patient Information Leaflet provided?	Yes ☐	No ☐
Serious Adverse Event / Serious Adverse Reaction? *If yes, provide details.*	Yes ☐	No ☐
Any problems requesting tests (e.g. FBC, Bio, Radiology)	Yes ☐	No ☐
Patient Identified and merged with Proxy Identifiers?	Yes ☐	No ☐
Patient Outcome? *Provide Details:*		

RCCs:		*Fibrinogen:*	
Platelets:		*Octaplex:*	
Plasma:		*Other:*	

11.7 Process Flowchart