The Laboratory Services Reform Programme

ADVICE NOTE

Template Agreement for Rerouting of Red Cells and Platelets

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Clinical Practice Guidance Document Cover Sheet

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The Laboratory Services Reform Programme offers the following advice:

1.1 Advice for Laboratories

1. Moving blood components between hospitals ("re-routing") is managed between individual hospitals with local documentation. The National Transfusion Advisory Group wish to facilitate re-routing of blood products as necessary to minimise waste of product due to expiry before use. Re-routing of blood products requires a clear documented governance framework such as a Memorandum of Agreement between the institutions concerned. There have been requests from HPRA and INAB to standardise this documentation.

2. To facilitate this process please find a modifiable template MOU that hospitals may use to address the requirement for such governance and standardisation.

3. To use the template remove the 1st 4 pages of this document.

2 Background

The HSE issued a memo to Hospital Group CEO's relating to Re-routing Red Cells and Platelets between Hospitals. It states:

The IBTS supplies red cells and platelets to all hospitals when requested. Transfer of red cells and platelets between hospitals, as deemed necessary to ensure maximum utilisation and to minimise outdating, is through the re-routing programme. In the event of hospitals having red cells / platelets that are not required and / or nearing use by date they re-route these to other hospitals for patient use where appropriate. The objective is to improve red cell and platelet utilisation so as to ensure efficient and more effective use of red cells and platelets and to minimise outdating through a national re-routing programme.

1. Quality Management Specifications

Hospitals must comply at all times with the provisions of EC (Quality and Safety of Human Blood and Blood Components) Regulations 2005, SI 360/2005, including accreditation to ISO 15189 as assessed by the Irish National Accreditation Board (INAB). Each hospital is obliged to notify the other hospitals of any change to compliant status. It is recognised that all procedures and practices surrounding the receipt, storage and transportation of red cells and platelets are in accordance with ISO 15189 and AML-BB.

2. Obligation to Report Serious Adverse Events and Reactions

Hospitals are required to report in writing and without delay all serious adverse events (SAEs) and/or serious adverse reactions (SARs) to the National Haemovigilance Office (NHO) as per their standard procedures for red cells or platelets.

3. Traceability

Hospitals must ensure traceability of all red cells and platelets from the point of receipt by the hospital to their final fate or return to the IBTS for disposal. In the event of a product recall the IBTS will contact the hospital that requested the product from it. It is the responsibility of this hospital to contact any hospital to which they re-routed product and inform them of the recall issue. The IBTS will also notify all hospital of all recalls of red cells or platelets issued by the IBTS.

4. Transport of Red Cells and Platelets

All transport is provided by First Direct Medical and in accordance with Article 5 and Annex IV of Directive 2004/33/EC. The sending hospital must notify the receiving hospital in advance of transferring any red cells or platelets and complete a transport docket to accompany the units(s) sent. Each hospital must use their own hospital docket for re-routing blood products. This docket will indicate that the unit(s) was(were) under controlled storage, the unit number(s), group(s) and expiry date(s) and the staff member responsible for arranging the transport docket.

5. Transfer of Blood with a Patient via Ambulance

All red cell units transferred with a patient must be in a validated transport container and have a completed transport docket as above (see Section 4).

6. Charges

There is no charge to the receiving hospitals for red cells or platelets re-routed to them.

3 References

1. HSE Memo to Hospital Group CEOs 19-02-12

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HSE Clinical Lead for Laboratory Services Reform Programme.

MEMORANDUM OF AGREEMENT

In Conjunction with HSE Memo to Hospital Group CEOs 12/02/2019

This is an Agreement for

The Provision of Re-routing of Red Cell and Platelet Components (including Paedipacks)

Between

_____

And

_____

Signed on Behalf of _____

_____ Date _____

Signed on Behalf of _____

_____ Date _____

1. Duration

From _____ until terminated by either party.

2. Service Objectives

_____ and _____ hospitals agree to enter a Transfer Agreement for the re-routing of red cell and platelet components (previously supplied by the Irish Blood Transfusion Service (IBTS) to _____) to _____ for patient use.

This agreement to transfer red cell or platelet components with a limited residual shelf life and/or specified components designated for individual patients (e.g., HLA/HPA matched) is made with the objective of ensuring effective use of red cell and platelet component stock (especially Rh D negative) and to minimise outdating.

3. Services to be Covered

The main elements of the services to be covered by this agreement are:

- Provision of re-routing of red cell and platelet components between the agreed hospitals
- Cold storage facility management
- Compliance with haemovigilance requirements – Article 15 EU Directive 2002/98/EC
- Traceability services in compliance with Article 14 EU Directive 2002/98/EC

The supplying hospital will re-route red cell and platelet components in compliance with the Quality and Safety of Human Blood and Blood Components SI 360 of 2005. It is recognised that the requirements of the regulations are to be met by the supplying and receiving facilities and may be subject to inspection by the Health Products Regulatory Authority (HPRA) / Irish National Accreditation Board (INAB) to assess compliance with the regulations. For reference, the main applicable sections are:

- Article 10 Personnel
- Article 11(1) Quality system
- Article 12(1) Documentation
- Article 14 Traceability
- Article 15 Notifications of serious adverse events and reactions
- Article 22 Storage, transport and distribution conditions
- Article 24 Data protection and confidentiality

4. Quality Management Specification

Both hospital blood banks must operate in compliance with the Quality and Safety of Human Blood and Blood Components SI 360 of 2005 and be accredited to the ISO 15189 standards including Articles 14 and 15 by INAB.

Supplying hospital Reference No. _____

Receiving hospital Reference No. _____

Re-routing of Red Cell and Platelet Components

Under the agreement, the supplying hospital will re-route red cell and platelet components to the receiving hospital to ensure maximum utilisation of red cell and platelet components and to minimise outdating.

The supplying hospital undertakes to ensure that all red cell and platelet components supplied will be accompanied by appropriate documentation (e.g., Re-routing Blood and Blood Products to Another Hospital Form) and will be transported in a validated system by First Direct Medical (FDM) which ensures that the supplied red cell or platelet components remain within specification throughout the transport period and until they are transferred to controlled temperature storage at the receiving hospital. There is a service level agreement in place between FDM and the Health Services Executive (HSE).

The supplying and receiving hospitals will adhere to the quality system for hospital blood banks as required by the Quality and Safety of Human Blood and Blood Components SI 360 of 2005.

Responsibility of supplying and receiving hospitals is to ensure that:

- Timely contact is made by the supplying hospital with the receiving hospital when re-routing red cell and platelet components.
- The supplying hospital must notify the receiving hospital of non-conformances that have a potential impact on the quality and safety of the re-routed red cell and platelet components.
- Conformity between sites in relation to management of blood fridges/platelet agitators should include but is not limited to:
  - Review of temperature mapping reports - signed off by senior medical scientist (SMS) and quality officer (QO)
  - Blood fridges should have an adequate number of temperature monitoring probes to ensure that any fluctuations in temperature are captured in a timely manner.
  - Detailed review of continuous temperature monitoring system with alarms (e.g., Rees) providing readings/daily average data to enable detection of trends that may require investigation
  - All red cell/platelet/blood component storage equipment has preventative maintenance and temperature mapping performed annually.
- Equipment should be remapped if any of the following conditions arise:
  - If equipment is moved

  - If temperature set points are changed
  - If significant changes are made to the internal storage layout
  - If the load stored significantly increases or decreases
  - If the temperature controlling machinery of the unit has required unexpected maintenance. Note, as per the 'WHO Manual on the Management, Maintenance and Use of Blood Cold Chain Equipment', the temperature controlling machinery can be classed as the compressor, the condenser, the evaporator or cooling unit and the thermostat that controls the cycle.
- Standard operating procedures (SOPs) in place for the storage, distribution and transport of red cell and platelet components within the supplying and receiving hospitals.
- All sites must demonstrate adequate 'cold chain' procedures, supported by documentary evidence, which ensures that specified temperatures and storage conditions are satisfactorily maintained at all time.
- SOPs in place for environmental monitoring of blood bank fridges/agitators and areas where red cell and platelet components are placed.
- In the event of a product recall, the IBTS will contact the supplying hospital in relation to any red cell or platelet components issued to them. Each hospital should have a fully documented procedure covering responsibilities and actions to be taken in the event of a recall of blood products. This action will be initiated by the notified hospital blood bank with full co-operation from the other party. The notified hospital is responsible for the immediate response including identifying the status and location of the unit.
  - The notified hospital (supplying hospital) will inform the IBTS that the red cell or platelet components have been re-routed/rotated to the receiving hospital.
  - The notified hospital will also inform the hospital to which the product has been re-routed/rotated.
  - If the red cell or platelet components have not been transfused, they must be quarantined immediately and returned to the IBTS by the hospital holding that stock.
  - If the unit has been transfused the recall follow-up is the responsibility of the transfusing hospital.
- Comprehensive maintenance contracts for all red cell and platelet storage equipment and their temperature monitoring system must be maintained by all sites. These maintenance contracts will include a preventative maintenance schedule to include temperature mapping of the fridges on an annual basis or following major/significant repair.

5. Traceability

There must be full traceability for all red cell and platelet components transferred.

Complete records must be maintained of the distribution of all red cell and platelet components from the supplier to the receiving hospital and there must be a documented process in place to confirm the identity of the member

of staff who receives the supplied red cell or platelet components and when they were received (e.g., Re-routing Blood and Blood Products to Another Hospital Form).

At the time of re-routing the supplying hospital must record that the units have been re-routed. For re-routed red cell and platelet components that have been transfused in the receiving hospital, the receiving hospital will be responsible for recording the final fate of the units.

The receiving hospital will have responsibility for ensuring that re-routed/rotated red cell and platelet components are managed effectively.

6. Transport

Red cell and platelet components will be re-routed via the contracted temperature-controlled courier – currently FDM.

7. Mandatory Haemovigilance Reporting

Both sites must have SOPs for the notification of serious adverse events and reactions that satisfy the requirements of the Quality and Safety of Human Blood and Blood Components SI 360 of 2005.

In the event of a suspected transfusion reaction/adverse incident, the receiving hospital must report the event to the supplying hospital and investigate in accordance with local policy and SOPs. All serious adverse reactions and serious adverse events, as detailed by the National Haemovigilance Office (NHO), must be notified by the haemovigilance officer of the hospital site where this occurred to the NHO.

8. Compliance

Each hospital must ensure that the procedures and practices within their organisation satisfy the requirements of this agreement and are in compliance with EU Directive 2002/98/EC