DEPARTMENT OF OPERATIONAL SUPPORT

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Guidelines

UN Haemovigilance System Framework for Data Collection Recording and Reporting

Approved By : Medical Director DHMOSH Signature _____ **Date** 30 April 2021
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UN Haemovigilance System Framework for Data Collection Recording and Reporting

A. PURPOSE

1. The United Nations (UN) is committed to providing a consistent level of high-quality medical care to all mission personnel, regardless of the country, situation or environment in which all UN Peace Keeping personnel, Military, Police, Civilian, Political or other Observers may require and receive medical treatment.

   Whether blood products are supplied by a vendor or collected by UN Missions as Whole Warm Blood Donation, which maybe the only option, the Haemovigilance System Framework will ensure the maximum protection of both donor and recipient of a whole blood donation, through a “Vein to Vein”, Haemovigilance System Framework and continuous corrective actions.

   Therefore, a key strategy for the usage of blood products within all UN Missions is an effective Haemovigilance System Framework (HSF), which meets internationally recognised standards for recording and reporting adverse events and implementation of corrective actions.

B. SCOPE AND APPLICABILITY

2. The scope of Haemovigilance has been expanded to include adverse events in blood donors, thus helping to improve safety for the donor as well as the patient.

   Haemovigilance should be fully integrated into the quality systems of all institutions involved with the blood and blood products supply chain, including donation, testing, processing, inventory management, shipment under temperature control, storage and distribution, and clinical transfusion, to ensure donor and patient safety at all levels.

   The UN Haemovigilance System Framework (HSF) addresses two distinct areas of work, one relating to Blood Products supplied by an internationally approved Vendor/Contractor and delivered to the UN Mission; and Blood Products, mainly in the form of whole blood, collected, tested and transfused by UN Missions in the field.

   This Haemovigilance System Framework comprises two Sections and four Annexes:

   Section I: Blood Products provided from authorised and approved vendor/contractors
   Section II: Blood Products collected from blood donors, tested, and transfused by UN Missions
   Annex I: Report Form – UN Haemovigilance System Framework
   Annex II: Scope of Work (SOW) with Contractor/Vendor
   Annex III: Algorithm – Flow of Haemovigilance Data
   Annex IV: Logical Framework Chart

C. GUIDELINE/PROCEDURE

3. This UN Haemovigilance System Framework for Data Collection Recording and Reporting adds and underlines the Policy of Clinical Use of blood in Field Situations. It is comprehensive and gives UN personnel on every level knowledge how to deal with all phases of the use of blood products.

C.1. Haemovigilance System Framework

4. Haemovigilance is learning from what went wrong in the past by accurate documentation of all steps in the “vein to vein” in blood transfusions and taking corrective measures to increase safety through continuous quality improvement of the transfusion chain.

5. Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up.

6. It includes the monitoring, reporting, investigation, and analysis of adverse events related to the donation, processing, and transfusion of blood, and taking actions to prevent their occurrence or recurrence.

7. The goal of Haemovigilance is continuous quality improvement of the transfusion chain through corrective and preventive actions to improve donor and patient safety, improve transfusion appropriateness, and reduce wastage. At its core, a Haemovigilance system resembles any continuous quality improvement cycle and shows the same elements and activities. As such, Haemovigilance should be embedded into every step of the transfusion chain, and into every organization that has responsibility for a part of that chain.

8. Haemorrhage, resulting from acts of violence is the main reason for death during a mission, whether on civilian duties or on the battlefield. The United Nations has prioritised an effective supply of essential Blood Products from an internationally sourced and accredited Blood Transfusion Service, as a vendor, for the provision of a regular and sustainable supply of Quality Assured Blood Products (QABP) to every mission in order to meet a recurrent requirement for the provision of blood and associated products to high risk UN Peace Keeping Operations (PKOs).

9. In austere settings, provision of Warm Whole Blood, from re grouped and tested, as well as first time voluntary blood donor on scene blood products, requires an adaptation of conventional supply blood chain strategies with availability of disposable Time Temperature Monitor labels and all other reagents and devices necessary.[Ref: United Nations Guidelines Vol I, II & III, see F. page 7].

10. The United Nations faces significant challenges in securing sustainable sources of blood products, recognising respective national government regulation on imports, maintaining the continuity of the blood cold chain, sustaining a supply of certain rarer blood groups and Rhesus types. Ensuring an effective Haemovigilance System Framework, whether in an established Hospital setting or in an austere military fields operation is a key strategic objective, whether blood products are sourced through a UN approved supply or blood is collected in a field situation, the UN Haemovigilance System will be used in each case to collect and analyse data, and implement all corrective actions necessary.

11. The implementation of a whole blood donation program will solve two other situations during high risk missions: Firstly, any shortage of blood products from the nearest Hospital Blood Bank, in the case of supply issues; secondly to mitigate for any mismatch between resources and needs during mass casualties’ incidents.

12. All investigations and analysis of adverse events must be accurately documented and recorded, and then expeditiously transmitted to designated senior authorities in UN Head Quarters and to the Vendor/ supplier of the Blood Product, which will include all data from the Blood Donor through to Transfusion of the Blood and disposal of unused or expired blood.

13. Corrective and rapid actions must be taken to address preventable and possible occurrence or recurrence of the causes leading to an adverse transfusion event, with the introduction procedures for improvement in safety and quality standards, as appropriate. All steps in the “Vein to Vein” transfusion chain must follow this UN Haemovigilance System Framework.

14. The Haemovigilance System Framework is for use by Distributors, Administrators, Clinicians, Nurses and Laboratory Scientists responsible for ordering, procurement, supply, transportation, and Clinical Use of Blood in Transfusion Medicine.

15. The Policy of Clinical Use of Blood in Field Situations recognises the requirements of UN Division of Healthcare Management and Occupational Safety and Health (DHMOSH) and UN Medical Support Section (MSS), for ensuring the safety, accessibility, and availability of blood and blood components for all patients transfused by UN Missions. Feedback and evaluation of use will ensure updating and improvement.

16. The Haemovigilance System Framework provides a comprehensive and wide range of practical criteria, which should be based on each specific environment, for assessing the suitability of blood donors to donate a safe and effective unit of blood or blood components, while at the same time recognising the importance of the skills and clinical acumen of the professional clinic staff in providing the necessary assessment needed.

17. There will be occasions when it will be necessary for either a UN Clinician/ Medical Officer in Charge, to provide clarification on an interpretation in recording of any adverse event, or if there is to be a deviation from the Haemovigilance System Framework. Due to a potential donor's medical condition, medication, or should the donor's status not be adequately described within the Guide.

18. There is space at the end of the Haemovigilance System Framework for individual additions and clarifications to be inserted. The Haemovigilance System Framework will be subject to continuous review, amendment and updating, which will ensure the effectiveness of the tool and all staff are required to provide continuous feedback with constructive suggestions and comments, while adhering to agreed timely and agreed data reporting schedules.

19. Detailed records of the "Vein to Vein" transfusion process must be submitted with a Haemovigilance System Framework report to Chief Medical Officer (CMO) for clinical and logistics review to be submitted to UN HQ.

20. The requirements expected from the Vendor/Contractor of the Blood Products to UN Missions, must at least meet EC Directive 2002/98 of The European Parliament and of the Council (Mother Directive) and three subsequent directives; "daughter Directives" (2004/33/EC, 2005/61/EC and 2005/62/EC), which constitute a common basis for provisions of quality and safety of blood in the European Union (EU), even if provided to a third party.

C.2. Haemovigilance in Clinical Transfusions

21. The UN Haemovigilance System Framework for UN Missions must form an important component of the recording and documentation of all steps taken when transfusing blood products, whether procured from an authorised contractor/vendor or collecting blood from walking donors, in austere conditions, should appoint a transfusion committee with the senior Clinician, as the Chairperson and a selected number of persons responsible for nursing, pharmacy/laboratory and logistics/supplies.

22. The UN Haemovigilance System Framework should address the detection, identification, documentation and reporting of adverse events occurring in the hospital, including the following:

- errors in the collection and testing of blood samples,
- errors in the identification of patients,
- inappropriate use of blood products (e.g. accidental over transfusion),
- incorrect blood product transfused,
- significant deviations from protocols,
- near misses,
- adverse reactions associated with the transfusion of blood products.

23. The system should include root cause analysis and corrective and preventive actions as part of a continuing improvement cycle.

24. The transfusion committee should maintain close links with the blood transfusion service that provides the blood products, so that investigation of adverse events can be efficient and timely measures can be initiated to prevent transfusion of related blood products.

25. Data from Haemovigilance should link to clinical audit programmes, so that recommendations arising from Haemovigilance reports can be incorporated into standards and guidelines, and compliance assessed and improved.

26. Networking between transfusion safety officers in different organizations should be encouraged. In all cases it is important that the transfusion safety officers have the time and financial resources available to fulfil their responsibilities.

27. The flow of Haemovigilance data is illustrated in Annex III and Figure 1 (page 37), showing the relationship between UN HQ, UN Mission, vendor and, as appropriate, any in country hospital blood bank, which may have been involved in the reasons for the adverse event or reaction.

28. Rigorous and transparent management of information, generated by the UN Haemovigilance System Framework, is a key strategy in implementing effective safety and quality standards in Clinical Use of Blood for transfusions for UN Peace Keepers in UN Missions, by implementing timely and effective corrective actions, in cases when adverse reactions or events are identified by the UN Haemovigilance System Framework.

29. An effective Haemovigilance System Framework will ensure improvements in processes in clinical transfusion practices, from donation of blood to transfusions of patients, which will prevent the effects of serious morbidity, and even mortality, as a complication of haemorrhage.

D. ROLES AND RESPONSIBILITIES

30. **CMO's Roles and Responsibilities** will ensure effective data records and traceability for the UN Haemovigilance System Framework.

31. **The CMO** will ensure that effective mechanisms are in place and implemented for data collection, validation and analysis, publication and dissemination of reports [including submission to Contractor/Vendor/Supplier of blood product utilisation and disposal], development of recommendations and monitoring implementation; these include, but are not exclusive of the following:

    - receiving adverse event reports from blood transfusion services and hospitals,
    - reviewing reports to ensure the quality of reporting,
    - identifying trends and investigating underlying causes,
    - providing guidance to address root causes and improve safety, and seeking expert advice, when necessary,
    - identifying improvements in the processes of the transfusion chain,
    - improving education in clinical use of blood and Haemovigilance,
    - producing a regular and timely Haemovigilance report, which are submitted to focal points in DHMOSH and MSS,
    - use of rapid using effective communications to communicated relevant alerts and early warning system to share information,

- implement a regular review, monitoring and evaluation of the effectiveness of the UN Mission System Framework Haemovigilance.
- confidentiality and anonymity for donors, patients and nonpunitive reporting,
- data security and compliance with applicable adherence to established UN Mission data protection,
- minimal impact of data collection on the working methods of the blood transfusion I or health care system,
- nonpunitive or judgmental advice and guidance on further investigation, management, reporting and follow-up, with implementation of corrective actions, of adverse events,
- expert analysis of events and trends and provision of clear recommendations for improvement.

32. Vendor, UNHQ, DHMOSH and MSS see Annex II.

E. ABBREVIATIONS, TERMS AND DEFINITIONS

33. This section contains a list of terms and their definitions for words and phrases that are required to understand this guideline.

Abbreviation	Definition
SAE	Serious Adverse Event.
AER	Adverse Event Reporting.
SAR	Serious Adverse Reaction.
HSF	Haemovigilance System Framework
UNHQ	United Nations Headquarters
DHMOSH	Division of Healthcare Management and Occupational Safety and Health
MSS	Medical Support service
CMO	Chief Medical Officer
PKO	Peacekeeping Operation
QABP	Quality Assured Blood Products
EU	European Union
WHO	World Health Organization

Terms	Definition
Serious Adverse Event (SAE)	Any undesirable or unintended occurrence associated with transfusion or donation. It includes all adverse reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents.
Adverse Event Reporting	Sending information on adverse events to the Haemovigilance system for further investigation, analysis, and feedback.
Serious Adverse Reaction (SAR)	Any unintended response in donor or patient associated with the collection or transfusion of blood or blood components.
Corrective Action	Action taken to eliminate the cause of a detected non- conformity or other undesirable situation.
Haemovigilance Report	Report of aggregated analysed data from the UN Haemovigilance System Framework.
Imputability	The probability that an identified probable cause was the actual cause of an adverse event after the investigation of the adverse transfusion event is completed.
Incident	Any untoward occurrence associated with an activity or process, such as the collection, testing, processing, storage and distribution of blood and blood components, or in the transfusion or administration.
Near Miss	An error or deviation from standard procedures or policies which, if undetected, could result in the determination of a wrong blood group or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognized before the transfusion took place.
Notification	Mandatory information on a notifiable event, which must be documented and sent to CMO for referral to DHMOSH.
Preventive Action	Action taken to eliminate the cause, or any recurrence of a potential nonconformity or other potential undesirable situation or set of processes or actions.

F. ACKNOWLEDGEMENT AND REFERENCES

34. Acknowledgement is given to the numerous relevant documents from other Internationally recognised sources (WHO; EU Parliament/Council [EC Directives]; ISBT National Blood Regulatory Bodies); Blood Services, Military and Civilian Guidelines and Protocols, which have all provided invaluable information for the preparation of the UN Haemovigilance System Framework.

35. The UN Haemovigilance System Framework, should be utilised with reference to the 3 UN Guidelines on the Clinical Use of Blood and UN Policy Document on Blood Use, prepared for UN Missions, and if required, approved internally recognised literature and reference materials.

36. Normative or superior references:

    UN Policy Clinical Use of Blood in Field Situations, DOS 2021.06, May 1st, 2021.

37. Related procedures or guidelines:

- United Nations Guidelines – Selection and Medical Assessment of Blood Donors in Emergencies (doc. I)
- United Nations Guidelines for the Selection of Blood Donors and Collection of Whole Blood (doc. II)
- United Nations Guidelines for Managing Blood Donations and Whole Blood transfusions (doc. III)

G. MONITORING AND COMPLIANCE

38. After release of this guideline respective medical officers are required to implement the Haemovigilance System framework, in particular the data collection recording and reporting.

39. UNHQ DHMOSH will monitor the implementation.

H. HISTORY

40. This is the first version of this guideline. It was first approved and issued on the 1st of June 2021. It will be reviewed periodically. First review will be not later than (NLT) 30th of September 2022. Since this guideline is a living document and is dependent on international medical, logistical, and legal regulations changes could be made at any time. UN personnel is requested to submit remarks or recommendations.

I. SECTIONS 1-2

SECTION 1 - HAEMOVIGILANCE SYSTEM FRAMEWORK WHERE BLOOD PRODUCTS ARE SOURCED FROM AN APPROVED VENDOR/CONTRACTOR

1.1 SCOPE OF REPORTING FOR UN HAEMOVIGILANCE SYSTEM FRAMEWORK

The scope of reporting shall be determined and agreed between the Vendor/Contractor and Customer (UN DHMOSH), in order for signing a contractual agreement to supply Blood Products, which must meet internationally recognized standards of quality and safety, from

point of donation, through collection, processing, testing/screening, dispatch, transportation and Haemovigilance System monitoring and reporting. The standards, recommendations and guidelines must meet to those of the World Health Organisation (WHO), European Union (EU) legislation on blood, and accepted recommendations of the International Society for Blood Transfusion (ISBT), conventionally referred to as the "vein to vein" quality and safety standards, in which data collection and reporting of all processes and procedures, from the blood donor to transfusion to a patient, and follow up, are effectively documented and monitored in a Haemovigilance System.

Data and records must be made available to all relevant parties, UN, and Vendor/Contractor, through a non-punitive reporting mechanism and corrective actions taken to avoid recurrence of any errors. The Haemovigilance System will include environmentally safe disposal of unused and expired blood and devices (blood bags, needles, and administration sets).

The agreed reporting and data collection records should consider Article 168 (as below) and use of the reporting Charts in Annex III as provided in Commission Directive 2005/61/EC of 30 September 2005: sections L 256/36 to L 256/40] (attached as HSF Annex I) and information provided in WHO's A guide to establishing a national Haemovigilance system. Ref: WHO.ISBN 978 92 4 154984 4 [ref: Annex I United Nations Haemovigilance System Framework Report]

The Vendor/Contractor's legal coverage of these definitions means that there is no mandated requirement to report events, which do not influence the quality and safety of the blood components and reactions in recipients that are not caused by a quality or safety defect in the blood components. Similarly, reactions in donors are not reportable under this legal framework.

According to Article 168 of the consolidated version of the Treaty on the Functioning of the European Union, the management of healthcare, i.e. the clinical use of blood and blood components, is not a competence for the European Union, and remains under the responsibility of the Member States.

Severe Adverse Events (SAE) occurring after the start of the medical act of transfusion are therefore not subject to mandatory reporting under the Blood Directive. Similarly:

Severe Adverse Reactions (SAR) not attributable to the quality and safety of the blood or blood component are not subject to mandatory reporting under EU legislation.

As a general principle, the Commission cannot require Member States to report more information than specified in the Blood Directives. The Commission is, however, aware that there are some areas where Member States would like to report additional data, and in these cases the Commission agrees to consider wider reporting submitted on a voluntary basis. For example, many Member States require, and consider good practice, the reporting of all SAR in blood donors, regardless of whether they have influenced the quality and safety of the blood components collected.

1.2 TABLE OF REPORTABLE SERIOUS ADVERSE REACTIONS

Directive 2005/61/EC categories	Reportable reactions
Immunological haemolysis due to ABO incompatibility	Acute haemolytic transfusion reaction (AHTR according to ISBT) due to ABO-incompatibility
Immunological haemolysis due to other allo-antibody	Acute haemolytic transfusion reaction (AHTR according to ISBT) due to irregular antibodies

	Delayed haemolytic transfusion reaction (DHTR according to ISBT) due to irregular antibodies
Non-immunological haemolysis	Acute haemolytic transfusion reaction (AHTR according to ISBT) due to physical, chemical, or biological (but non-immune) reasons (for example mechanical stress, temperature, osmotic pressure, pH, drugs etc.)
Transfusion transmitted bacterial Infection (T-t BI)	Sepsis due to T-t BI (according to SHOT/UK definition of transfusion transmitted infections)
Anaphylaxis / hypersensitivity	Severe allergic reaction (according to ISBT[iv])
Transfusion related acute lung injury (TRALI)	TRALI (according to ISBT[v])
Transfusion-transmitted viral infection – (TTI) (HBV, HCV, HIV-1/2, others)	T-t viral infection (according to SHOT/UK definition of transfusion transmitted infections)
Transfusion-transmitted parasitical infection (malaria, others)	T-t parasitical infection (according to SHOT definition of transfusion transmitted infections)
Transfusion-transmitted fungal infection	T-t fungal infection (according to SHOT definition of transfusion transmitted infections)
Post-transfusion purpura (PTP)	Post transfusion purpura (PTP according to ISBT)
Graft versus host disease	Transfusion associated graft versus host disease (TA-GVHD according to ISBT)
Other serious reactions (specify)	Febrile non-haemolytic transfusion reactions (FNHTR according to ISBT) Severe reaction due to transfusion associated circulatory overload (TACO according to ISBT) as well as cases occurring after 6 hours if clinically confirmed Severe reaction due to transfusion associated dyspnoea (TAD according to ISBT Definition) Transfusion-transmitted prion infection Others (including previously uncategorised complications of transfusions)

A. Acute haemolytic transfusion reaction (AHTR, ISBT definition)

AHTR has an onset within 24hrs of transfusion, with following findings:

Common clinical signs of AHTR:	**Common laboratory features of AHTR:**
□ Fever	□ Haemoglobinaemia
□ Chills/rigors	□ Haemoglobinuria
□ Facial flushing	□ Decreased serum haptoglobin
□ Chest pain	□ Unconjugated hyperbilirubinemia
□ Abdominal pain	□ Increased LDH an AST levels
□ Back/flank pain	□ Decreased haemoglobin levels
□ Nausea/vomiting	
□ Diarrhoea	
□ Hypotension	
□ Pallor	
□ Jaundice	
□ Oligoanuria	
□ Diffuse bleeding	
□ Dark urine	

Blood group serology usually shows abnormal results; however, an absence of immunological findings does not exclude AHTR, which may also be due to erythrocyte auto-antibodies in the recipient or to non-immunological factors like mechanical factors inducing haemolysis (malfunction of a pump, of a blood warmer, use of hypotonic solutions, etc.).

B. Delayed haemolytic transfusion reaction (DHTR) (ISBT definition)

DHTR usually manifests between 24 hours and 28 days after a transfusion.
Clinical or laboratory features of haemolysis are present.
Signs and symptoms are similar to AHTR but are usually less severe and may result in an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology is usually found to demonstrate abnormal results.

C. Allergic reaction (ISBT definition)

<u>An allergic reaction may present only with mucocutaneous signs and symptoms:</u>

□ Morbilliform rash with pruritus	□ Oedema of lips, tongue, and uvula
□ Urticaria (hives)	□ Periorbital pruritus, erythema, and oedema
□ Localized angioedema	□ Conjunctival oedema

An allergic reaction occurring during or within 4 hours of transfusion, usually presents no immediate risk to life of patient and responds rapidly to symptomatic treatment with anti-histamine or steroid medications and is classified as a ‘minor allergic reaction’ in Haemovigilance systems.

This type of allergic reaction is a Grade 1 - non-severe allergic reaction.

Allergic reactions can also involve respiratory and/or cardiovascular systems and present as an Anaphylactic Reaction, when, in addition to mucocutaneous system involvement there is airway compromise or severe hypotension or even associated symptoms of hypotonia and syncope requiring vasopressor treatment.

The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or soon after transfusion. The grading is according to severity: Grade 2 (severe), 3 (life-threatening) or 4 (death) depending on the course and outcome of the reaction.

Allergic reactions result from the interaction of an allergen and preformed antibodies, due to stimulation of mast cells; A Tryptase Test* can be used for the diagnosis of an allergic reaction.

IgA deficiency and/or anti-IgA in the recipient has been associated with severe allergic reactions. *(*Anaphylaxis is primarily diagnosed clinically, however, Tryptase test is an indicator of mast cell activation and may be used to confirm a diagnosis of anaphylaxis and together with a histamine test assists confirming anaphylaxis as the cause of person's acute symptoms).*

D. TRALI (ISBT definition incorporating corrections made in 2013)

In patients with no evidence of acute lung injury (ALI) prior to transfusion, the clinical diagnosis of 'TRALI' is recorded, when diagnosing post transfusion, with the following:

 Acute onset

 Hypoxemia: $PaO_2/Fi\ O_2$ < 300 mm Hg; or O_2saturation < 90% room air; or other clinical evidence

 Bilateral infiltrates on frontal chest radiograph

 No evidence of left atrial hypertension (i.e. circulatory overload)

 No temporal relationship to alternative risk factor for ALI during/within 6hrs of a transfusion.

Alternate risk factors for ALI

Direct Lung Injury		Indirect Lung Injury	
o Aspiration	o Lung contusion	o Severe sepsis	o Acute pancreatitis
o Pneumonia	o Near drowning	o Shock	o Cardiopulmonary bypass
o Toxic inhalation		o Multiple trauma	
		o Burn injury	o Drug overdose

E. Transfusion Transmitted Infection (TTI) (SHOT definition)

A Transfusion Transmitted Infection identified post transfusion, is reported should:

 Recipient develop an infection post-transfusion, with no evidence of the identified infection prior to transfusion and with no evidence of an alternative source of infection; and

 At least one component transfused from blood donor found positive with the infectious agent.

Ref: Annual Report 2006 'Serious Hazards of Transfusions (SHOT)' http://www.shotuk.org

F. PTP (ISBT definition)

PTP is reported if patient develops thrombocytopenia, 5-12days after a cellular blood component transfusion and develops antibodies against the Human Platelet Antigen (HPA) system.

G. TA-GVHD (ISBT definition)

TA-GVHD is a clinical syndrome characterised by symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia, and histological appearances on biopsy 1-6 weeks following transfusion with no other apparent cause and further supported by the presence of Chimerism.

H. FNHTR (ISBT definition)

FNHTR is diagnosed in the presence of one or more of following:

- fever (≥38ºC oral or equivalent and a change of ≥1ºC from pretransfusion value),
- chills or rigors (even in absence of a fever)

This *may be* accompanied by headache and nausea, during or within 4hrs following transfusion, without other causes such as haemolytic transfusion reaction, bacterial contamination or underlying condition. Usually, only the most serious cases of FNHTR; fever of ≥39ºC oral, or equivalent, with a change of ≥+2ºC from a pretransfusion value, with chills/rigors.

I. TACO (ISBT 2018 definition)

Patients classified with TACO (surveillance diagnosis) should exhibit at least one required criterion* with onset during, or within 12hrs, after transfusion, (a total of 3 or more criteria* Required Criteria).

A. Acute or worsening respiratory compromise and/or

B. Evidence of acute or worsening pulmonary oedema based on:

- clinical physical examination, and/or
- radiographic chest imaging and/or other non-invasive assessment of cardiac function.

C. Development of cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema

D. Evidence of fluid overload including: a positive fluid balance; with clinical improvement on diuresis

E. Supportive result of a relevant biomarker, e.g. an increase of B type natriuretic peptide levels (BNP or NT-pro BNP) above the age group-specific reference range and greater than 1.5 times the pretransfusion value (*A and/or B, and total of at least 3 criteria from points A - E).

J. TAD (ISBT definition)

TAD is characterized by respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, whereas TACO, or allergic reaction.

K. Others including previously uncategorized reported complications of transfusion; Signs and

Symptoms temporally related to transfusion and no other risk factor such as 'the red eye syndrome' associated with the use of leucodepletion filters, or possibly other new reactions, possibly related to psoralene or prion filters.

1.3 ADVERSE REACTION NOTIFICATION IN A RECIPIENT:

<u>Rapid</u> notification for a suspected adverse reaction in a recipient

Reporting establishment
Report identification
Reporting date (*year/month/day*)
Age and sex of recipient (ID…)
Date of transfusion (*year/month/day*)
Date of adverse reaction (*year/month/day*)

1.4 ADVERSE REACTION IN RELATION WITH BLOOD PRODUCT:

- Whole blood
- Red blood cells
- Platelets
- Plasma
- Other (*specify*)

ADVERSE REACTION DUE TO TRANSMISSION INFECTIOUS AGENT AND/OR IMMUNE RESPONSE

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to another allo-antibody
- Non-immunological haemolysis
- Anaphylaxis/hypersensitivity
- Transfusion-associated circulatory overload (TACO)
- Transfusion-related acute lung injury (TRALI) –(suspected or diagnosed)
- Transfusion-transmitted bacterial infection
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection, other (*specify*)
- Transfusion-transmitted parasitical infection (malaria)
- Transfusion-transmitted parasitical infection, other (*specify*)
- Post-transfusion purpura (PTP)
- Transfusion-associated – graft versus host disease (TA-GVHD)
- Other reaction(s) (*specify*)

L. Imputability level (NA, 0 to 3):

Severity level dependent on severity of Adverse Reaction:

Clinical outcome of the recipient (if known)

- Complete recovery
- Minor sequelae (*specify*):
- Serious sequelae (*specify*):
- Death (*give details explaining presumptive causation*)

1.5 VENDOR/CONTRACTOR BLOOD PRODUCTS UTILISATION RETURN FORM [EU Directive EXHIBIT III]

Mission / Destination Name: _____

Blood Unit Number	Date of Action	Action
		☐ Transfusion in UN patient
		☐ Returned to Customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)

SECTION 2 - WHOLE BLOOD COLLECTED AND TRANSFUSED BY UN MISSIONS IN FIELD-SITUATIONS

1.1 UN HAEMOVUGILANCE REPORT FOR UN MISSIONS

Blood Products collected, tested, by UN Mission Medical Teams in field situations:

All data collected from point of blood donor selection, education, collection (phlebotomy),
Screening (testing),
Storage, including Blood Cold Chain data,
Clinical Use of Blood and Components,
Disposal of used and/or unused expired blood and components,
Additional relevant and useful information for interpretation by DHMOSH.

COLLECTION AND USE OF BLOOD AND COMPONENTS

Donors active during the year

Regular and repeat blood donors* total number	
First time blood donors* total number	
On first visit donating blood or blood components, number	
On first visit giving blood samples for testing only, number	

First time donor: Someone who has never donated either blood or plasma

Repeat donor: Someone who has donated before but not within the last two years in the same blood establishment

Regular donor: Someone who donated blood or plasma within the last two years in the same blood establishment

Collection of blood and blood components

Whole blood, total **number** of donations	
voluntary non-remunerated, **per cent** of donations	
replacement donations,[1] **per cent** of donations	
autologous donations**,** planned pre-deposit, **number**	

[1] Replacement donations: Blood donation collected from donors recruited by patients to enable them to undergo therapy with blood transfusion

Comments to the data

Use of blood and blood components intended for transfusion

Please, indicate if the figures given relate to blood and blood components ☐ distributed to hospital blood banks, *or* ☐ transfused to patient directly	
Whole blood, *units[1], total number*	
Red cell units (red cells for transfusion; *excl*. autologous) units[2]	
Red cells/Whole Blood autologous, pre-deposit, units	
Plasma (plasma or **FFP** for transfusion), units[2]	
Platelets (adult therapeutic doses[3]), total number	
Platelets – recovered from whole blood unit[3]	
Cryoprecipitate, FVIII iu x 10^6	

[1] A unit of whole blood consists of approximately 450 or 500 ml of blood, collected in a suitable amount of anticoagulant solution.
[2] A unit of red cells or plasma is red cells or plasma recovered from one unit of whole blood or a comparable volume of red cells or plasma collected by apheresis.
[3] A platelet concentrate adult therapeutic dose usually consists of 200 – 450 x 10^9 platelets.

Comments to the data

SCREENING/TESTING BLOOD SAMPLES FOR WHOLE BLOOD DONATIONS

Screening for infectious agents, by serological testing methods

- Anti-HIV I/II
- HIV-Ag
- HBs-Ag
- Anti-HCV
- Syphilis[1]

Optional Screening for infectious agents, due to epidemiological evidence at location

- Malaria[2]
- Anti-HBc
- HCV-Ag
- Others[3]

[1] Treponemal Haemaglutination ASSAY (TPHA), RPR, or other screening tests.
[2] Specific to epidemiology and recommendations for Mission
[3] Please specify reasons, e.g. Chagas' disease, brucellosis, WNV, anti-CMV

CONFIRMATORY TESTING (if available)

Are repeatedly reactive screening test results subjected to confirmatory testing? ☐ Yes, always ☐ Yes, approximately _____ % of them ☐ No

Confirmed seropositive test results

Confirmed seropositive[1]	HIV 1/2	HBsAg	HCV	HTLV I/II	Syphilis
First time tested donors[2], number					
Repeat tested donors[3], number					

1 Confirmed seropositive: Repeatedly reactive (≥ 2 times reactive) in a screening test *plus* positive in at least one supplementary test based on another principle.
2 First time tested donor: Person who is tested for the first time (with or without donation) without report of prior serological testing in the blood establishment.
3 Repeat tested donor: Donor who has been subjected to previous serological testing in a given blood establishment.

Comments to the data

NUCLEIC ACID TESTING (NAT) - only if available at UN Mission

Screening for infectious agents, NAT (mini pools)			
Screening test performed	only 1st time donor	every donation	Comments
HIV NAT			
HBV NAT			
HCV NAT			
other NAT			please specify:

Size of mini pool(s)	**HIV:**	**HBV:**	**HCV:**
NAT only positive[4] test results, number			
First time donors			
Regular plus repeat donors			

4 NAT only positive:
Positive in a NAT assays for a specific virus (HIV, HCV, or HBV), not found seropositive for that virus in serological screening *plus* shown to be true positive by separate PCR or later serology.

SCREENING FOR BACTERIA IN PLATELET PREPARATIONS

% of platelet adult doses screened for the presence of bacteria	
Recovered platelet pools (adult doses)	
% of screened units confirmed positive by further testing	

GENERAL INFORMATION

UN MISSION COMMENTS

COMMENTS FOR UN HQ ON HAEMOVIGILANC REPORT SENT ON TIME?	☐ Yes	☐ No

RECOMMENDATIONS OR NEED FOR AMENDMENTS/UPDATE ON: UN Policy for Clinical Use of Blood	☐ Yes	☐ No
If yes, Report with Recommendations prepared	☐ Yes	☐ No

RECOMMENDATIONS OR NEED FOR AMENDMENTS/UPDATE ON: UN Guidelines for Clinical Use of Blood for Missions for the collection, testing, processing, storage and distribution of blood and blood components?	☐ Yes	☐ No

Comments to the information

QUALITY MANAGEMENT RELATED ISSUES

Quality system for Blood Transfusions implemented and maintained in UN Mission		☐Yes ☐ Planned ☐ No	
Percent of donations covered by	GMP	Local SoPs and instructions	Comments /observations

Is there an effective cold chain in place with constant temperature monitoring devices	Storage state: digital, or electronics		
	Bag Time Temperature		
* comments with detailed explanation:			

Are inspections performed at least twice each year?

☐ No ☐ Yes, by
☐ CMO appointed team
☐ UN HQ appointed expert consultant*:

* please, specify:

Education and Training

Are there Training Guidelines on blood transfusion medicine and an education and regular training programme in place for medical and administrative UN Mission staff? ☐ Yes ☐ No

System used for identification and labelling of donations and components		
Percent donations labelled according to	ISBT 128	Another system*
donation number		
component code		
* please, specify		

Comments to the information

UN HAEMOVIGILANCE SYSTEM FRAMEWORK REPORTS

UN Haemovigilance System Framework report: ☐ No ….☐ Yes – Prepared by UN Field Mission ☐ No…. ☐ Yes, - Prepared by Other than UN Field Mission * -* if "Yes", please give haemovigilance data, if available
*please, specify and provide **all** details with data attached:

Haemovigilance System Framework data Serious Adverse Reactions* observed in recipients of blood or blood components:		Serious Adverse Reactions* reported				
		Total + Unit ID number	with Causation/`Imputability level*			
			NA	0 - 1	2	3
Immunological or Haemolysis cause	ABO incompatibility					
	another allo-antibody					
Non-immunological haemolysis						
Post-Transfusion Purpura						
Anaphylaxis / hypersensitivity						
Transfusion Related Acute Lung Injury						
Graft Versus Host Disease						
Transfusion-associated viral infection	HBV					
	HCV					
	HIV-1/2					
	Other					
Transfusion-associated bacterial infection						
Transfusion-associated parasitic infection						

Circulatory overload					
Other serious reactions attach separate page as necessary					
Comments as necessary					

* When completing this table, use of the definitions of serious adverse reaction or serious adverse events using chart on causation/imputability must be used for interpretation.

DEFINITIONS USED IN HAEMOVIGILANCE SYSTEM FRAMEWORK

1. ***Serious adverse reaction (SAR)*** – an unintended response in a patient associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.
2. ***Serious adverse event (SAE)*** - Serious adverse events include all delivering defective products; repeatedly occurring adverse events, which give rise to the assumption of a faulty processing procedure or defective materials; critical events, also without the products being supplied; and without any serious reactions in the recipient.
3. ***Imputability/Causation*** - the likelihood that a serious adverse reaction/event in a recipient/product can be attributed to the blood or blood component transfused.

IMPUTABILITY/CAUSATION SCALE [0-3]

ASSESSMENT OF SERIOUS ADVERSE REACTIONS

Imputability scale		Explanation
N/A	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubts for attributing the adverse reaction to alternative causes.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.
Comments on the Haemovigilance System Framework Reports		

J. ANNEXES I-IV

ANNEX I

REPORTING FORM - UN HAEMOVIGILANCE SYSTEM FRAMEWORK

UN Haemovigilance System Framework report: ☐ No.….☐ Yes – Prepared by UN Field Mission ☐ No…. ☐ Yes, - Prepared by Other than UN Field Mission * -* if “Yes”, please give haemovigilance data, if available
*please, specify and provide **all** details with data attached:

Haemovigilance System Framework data Serious Adverse Reactions* observed in recipients of blood or blood components:		Serious Adverse Reactions* reported				
		Total + Unit ID number	with Causation/`Imputability level*			
			NA	0 - 1	2	3
Immunological or Haemolysis cause	ABO incompatibility					
	another allo-antibody					
Non-immunological haemolysis						
Post-Transfusion Purpura						
Anaphylaxis / hypersensitivity						
Transfusion Related Acute Lung Injury						
Graft Versus Host Disease						
Transfusion-associated viral infection	HBV					
	HCV					
	HIV-1/2					
	Other					
Transfusion-associated bacterial infection						

Transfusion-associated parasitic infection					
Circulatory overload					
Other serious reactions attach separate page as necessary					
Comments as necessary					

*When completing this table, use of the definitions of serious adverse reaction or serious adverse events using chart on causation/imputability must be used for interpretation.

DEFINITIONS USED IN HAEMOVIGILANCE SYSTEM FRAMEWORK

Serious adverse reaction (SAR) – an unintended response in a patient associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Serious adverse event (SAE) - Serious adverse events include all delivering defective products; repeatedly occurring adverse events, which give rise to the assumption of a faulty processing procedure or defective materials; critical events, also without the products being supplied; and without any serious reactions in the recipient.

Imputability/Causation - the likelihood that a serious adverse reaction/event in a recipient/product can be attributed to the blood or blood component transfused.

IMPUTABILITY/CAUSATION SCALE [0-3]

ASSESSMENT OF SERIOUS ADVERSE REACTIONS

Imputability scale		Explanation
N/A	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubts for attributing the adverse reaction to alternative causes.
0	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.
Comments on the Haemovigilance System Framework Reports		

ANNEX II

SCOPE OF WORK - WITH A CONTRACTOR/VENDOR FOR THE PROVISION OF BLOOD PRODUCTS TO UNITED NATIONS FIELD MISSIONS

INTRODUCTION

1. The United Nations (or the UN) peacekeeping and political missions (herein after referred to as "Field Missions"), which are widely distributed round the world have a recurring requirement for the supply of blood products, a critical lifesaving commodity in the healthcare delivery system. The local supply of this essential commodity in the countries where the Field Missions are located is mostly non-existent and where available, the quality cannot be ascertained due to the breakdown of national healthcare infrastructure due to war and other civil disobedience activities.

2. The UN may provide blood products to officials, employees, contractors, agents, representatives of the UN, to the UN's peacekeeping, humanitarian, or observer operations personnel (both civilian and military), to relatives and dependents of any of the foregoing, and, to patients treated under UN mandate, to whom the UN, during its operations may provide blood products in a humanitarian capacity (hereinafter referred to as the "Recipients"). In all of these situations, the blood and blood products shall be under the custody of the UN and shall be administered only by UN credentialed medical personnel.

3. The Contractor is required to meet at least the World Health Organization (WHO) standards, or European Union (EU) standards, or equivalent standards for the screening, collection and processing of blood products.

4. The blood quantities specified herein are only indicative and may change over the course of time depending on the operational requirements of the United Nations.

OBJECTIVES

5. This Scope of Work (SOW) outlines the requirements and technical specifications for the provision of blood products such as packed red blood cells (herein referred to as "blood products") to the UN field missions.

6. The Contractor shall deliver the Blood Products CPT (as defined in INCOTERMS 2010) to each mission specified airport in accordance with Annex C – List of Peacekeeping Missions.

7. Details of the Field Missions delivery destinations are included in this SOW for informational and labelling purposes for the Contractor.

REQUIRED BLOOD QUANTITIES

8. **Six (6) Monthly requirements:** An estimated quantity of units of packed red cells are required to be supplied to the Field Missions every 6 months. The total number of units per shipment of red cell requirements by ABO group and Rhesus type for each UN Field Mission is included in Exhibit I.

9. **Annual requirements**: Exhibit I also shows the total minimum requirement units every 12 months inclusive of the 10% allowance for contingency.

10. **Contingency Blood Requirements:** Occasionally, the Field Missions have additional, unforeseen, and urgent requirement for blood products, due to the nature of ongoing peacekeeping operations. Accordingly, the Contractor shall be prepared to provide contingency blood units, in the event of an emergency. The contingency requirement is estimated to be 10% of the total annual requirement for each Field Mission.

11. The **estimated quantities** of red cells that may be required by UN during the proposed duration of the Contract **is 22,290 units**. The UN does not guarantee to purchase any maximum or minimum quantities of the items listed in SOW.

DISCLAIMER ON UTILIZATION OF BLOOD PRODUCTS

12. The **requirements** for blood products are based on the working assumption that UN health facilities with blood transfusion capability shall hold a certain minimum number of blood units at any one time.

13. **Blood products** delivered to the Field Missions is for use within the field missions and is not for further distribution in country. Access to UN medical facilities is limited to UN military, and police personnel, UN international staff and any other person as authorized by the UN Field Mission Administration, such as UN contractors. Blood products may be provided to patients treated by UN medical personnel under UN mandate within the area and compound of the Mission. UN may not guarantee that all delivered blood units will be utilized. The UN shall submit to the vendor a quarterly blood return document indicating the destination of each unit of blood delivered to Field Missions. A sample blood return form is attached as Exhibit III to the SOW.

STANDARDS

14. **Standards and Good Practice Guidelines**: All blood products must meet the latest Good Practice Guidelines (GPG) for Blood Establishments prepared by the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM) and the Commission of the European Union (EU)[1]). The Contractor is required to supply blood products that meet the minimum standards as described in the following paragraphs. The Contractor shall maintain a quality system based on the principles of EU good manufacturing practice for blood establishments recommended by the EDQM[2].

15. **Quality and Safety Requirements for Blood:** All blood products must meet the latest EU standards for the collection, screening and processing of blood products referenced above and will inform the UN of any changes in these standards.

Blood Quality Measurements and Acceptable Results

Component	Required Quality Measurements	Acceptable Results for Quality Measurements
Red Cells	Volume	250ml ± 30ml - Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin	No less than 40g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf-life

The frequency of sampling for all measurements shall be determined using statistical process control.

[1] https://www.edqm.eu/en/good-practise-guidelines-blood-establishments

[2] https://www.edqm.eu/sites/default/files/medias/fichiers/Blood/good_practises_guidelines_for_blood_establsihmens-blood_guide_20th_may_2020.pdf

16. **Donors:** In line with the WHO blood donation guideline, the collection of blood shall only be from voluntary non-remunerated donors.

17. **Screening of donors and Donor traceability**: Parties or shall be able to identify the donor and have access to their medical history through a questionnaire and personal interview performed by a qualified healthcare professional. The Contractor shall take all necessary measures to ensure that blood collected, tested, processed, stored, released and/or distributed by the Contractor(s) can be traced from donor to recipient and vice versa.

18. **Seeking consent of donor**: The staff member responsible for the medical history of a donor must confirm that the donor has understood any comments provided, was given an opportunity to ask questions and was provided with satisfactory responses to any questions asked and given informed consent to proceed with the donation process.

19. **Blood processing and storage**: The Contractor shall comply with the quality system practices established in the EDQM GPG in all aspects of blood grouping, compatibility testing, component preparation and storage. Storage must be at refrigeration temperatures of between +2ºC to +6ºC.

20. **Bacterial control during collection**: The Contractor shall ensure that appropriate bacteriological control of the collection and manufacturing process is undertaken.

21. **Shelf-life**: At the point of handing over to the UN appointed Freight Forwarder, all blood shall have at least 90% of the original shelf-life from the initial time of collection. In the case of red blood cells, this translates to at least 28 days of shelf-life remaining at the time of delivery to UN Field Missions.

22. **Testing**: All screening tests on donated blood shall ensure the safety of transfused blood and shall be in line with the latest EU standards for the collection, screening and processing of blood products referenced above and shall at the minimum include the requirements mentioned below.

Blood Testing Requirements

Testing Type	**Screening Requirements**
Blood Group	ABO Group
	Rhesus D Type
Screening of Donors for Infectious Diseases as required by EU	Hepatitis B (HBs-Ag)
	Hepatitis C (Anti-HCV)
	HIV I & II antibody +HIVAg (Antigen)
	Syphilis (Anti-treponemal antibodies (RPHA/RPR Test)

23. **Epidemiological considerations**: In addition to the EU blood screening parameters contained in the Table above, donors must also be screen against Hepatitis A, Parvovirus B19 and TT Virus when there are evidences of the prevalence of the diseases amongst donors.

24. **Marking/Labelling of blood units:** The labelling of blood shall be in conformity with the International Standard for Blood and Transplant (ISBT) standard, ISBT 128. The Contractor shall provide evidence of compliance with ISBT standards including inter alia, certification from International Council for Commonality in Blood Banking Automation (ICCBBA) or equivalent accreditation.

DELIVERY OF BLOOD PRODUCTS TO THE UN

25. The Contractor shall deliver the blood products within the time established in the Delivery Schedule included in this document as Exhibit I to each UN mission specified airport.

26. The Contractor will organize the shipment by air of the required blood products from its blood bank location to the final delivery destination, the total shipping time shall not exceed 48 hours unless such deviation has been previously agreed by both parties.

27. The Contractor is to ensure that the Annex D details the shipping and arrival dates. The Contractor shall make the Delivery Schedule available to the United Nations at least one month before the commencement of any semi-annual period.

PRE-SHIPMENT ADVICE

29. The Contractor shall issue pre-shipment advice to receiving missions at least seven (7) days prior to the time of arrival of the goods at the port of entry to allow the UN in obtaining the custom clearances as necessary.

28. In the event that delivery of Blood Products to the Freight Forwarder cannot be completed on the scheduled date of pick-up, the Contractor shall notify the Freight Forwarder and the Mission Focal Points detailed in Annex D and the Point of Contact for UN Headquarters in the Logistics Division, Department of Operational Support ("LD/DOS"), allowing the Freight Forwarder sufficient time to modify its delivery logistics.

29. In the event that transport of Goods cannot be completed within forty-eight (48) hours, the Contractor shall seek inform the UN staff defined in Exhibit I of this document, to enable the UN to put in place mitigating measures prior to shipping the said blood products.

PACKAGING AND LABELLING INSTRUCTIONS FOR SHIPMENTS

30. The Contractor shall be responsible for packaging of the blood for delivery to each delivery location as established in Exhibit I - UN Field Mission Destinations. Each package shall come with a single use irreversible temperature logger to monitor the cold chain until its delivery in the Mission.

31. The Contractor represents and warrants that the packaging materials for the shipping and transport of the Goods are fit for their intended purposes (including, without limitation, to preserve the Cold Chain), and for purposes expressly made known to the Contractor by the UN.

32. Packaging of Blood Products shall be performed by the Contractor in a manner that will preserve the Cold Chain during a total packaging and shipping time (shipping by the Freight Forwarder) of a minimum of ninety-six (96) hours from time of activation of the temperature logger. Total Packaging and Shipping Time (96 hrs.) is inclusive of time of readiness of shipment (48 hrs.) and pick up and actual shipping and arrival in the mission (48 hrs.). The Contractor shall prepare the Blood Products for pick up in sealed storage containers.

33. For this Contract, cold chain shall be defined as storage within a temperature range of +2 ^{o}C to +6 ^{o}C (two to six degrees centigrade) and transportation within a temperature range +1^{o}C to +10^{o}C.

PLACING SUPPLY ORDERS

34. All activities pertaining to the issuance of Supply Orders to the Contractor shall be undertaken at the UN Secretariat in New York. Upon receipt of the approved delivery schedule and the applicable prices for the identified 6 (six) months period from the Contractor, the UN Secretariat shall issue to the Contractor a Supply Order based on individual mission requirement for the period. Supply Orders shall be issued on a biennial bases covering the period of January to June and July to December of the current year.

35. The UN will ensure each Supply Order is provided to Contractor in a timely manner. Such Supply Orders shall cover the Missions entire six-month requirements broken into lines representing monthly deliveries and shall include quantities, types of Blood Products, order numbers and any other instructions required. Each Supply Order shall, at a minimum, refer to the Contract number, indicate the quantities and types of Blood Products ordered, price, time of delivery, destination, and method of shipment.

36. The monthly or biweekly delivery dates incorporated into such Supply Order shall reflect the finalized Delivery Schedule issued by the Contractor to the UN and as agreed upon by each Mission.

TRANSPORTATION OF BLOOD PRODUCTS

37. The Contractor shall organize the shipment by air of the required blood products from its blood bank to the final UN field mission destinations.

38. All shipments must be accompanied by the necessary document for the purposes of custom clearances or national requirements for each mission as warranted.

39. The UN will cover all direct and indicted administration costs for transportation as part of the costs included in the contract.

NOTIFICATION OF UN FIELD MISSIONS OF NON-CONFORMING GOODS

40. The Contractor, through a written notice sent by electronic mail, shall promptly notify the individuals identified in Exhibit II of this document of any non-conforming Blood Products released for shipment. For notices to be effective, the Contractor acknowledges and agrees that notices have to be given to the personnel identified in Exhibit II of Annex A by electronic mail, immediately upon becoming aware of any facts, information or circumstances in respect of the Blood Products that may affect the quality of the Blood Products or of any other inconsistencies of the Blood Products with the specifications set forth in this Contract, in particular, Scope of Works.

41. The Contractor undertakes to give notices in the following order: first, by electronic mail, followed immediately by telephone. In providing such information, the Contractor shall identify, among other things, the Blood Products affected, the Supply Order number and the relevant unit number. The Contractor shall also provide the UN with any relevant facts, information, or circumstances in respect of the Blood Products that may affect the quality of the Blood Products or of any other inconsistencies of the Blood Products with the specifications.

42. The Contractor shall provide the UN and its designated Freight Forwarder with instructions on the handling of any blood products of which the Contractor has notified the UN in accordance with Section / Paragraph above. Any such instructions so given by the Contractor shall be clear and concise.

EXHIBIT I

Monthly Distribution to Field Missions by Blood Type/Total Blood Requirements/6 months

UN Field Mission	No. of blood units per shipment	Blood requirement by blood groups /shipments				Missions no. of shipments /6 months	Missions total no. of units / 6 months
	Requirements	O+	O-	A+	A-		
UN Support Office for AMISOM (UNSOS)	30	17	5	2	6	13	390
UN Mission in South Sudan (UNMISS)	25	16	9	0	0	13	325
African Union / UN Hybrid Operation in Darfur (UNAMID)	18	8	5	2	3	13	234
UN Interim Security Force for Abyei (UNISFA)	10	5	3	0	2	13	130
UN Organization Stabilization Mission in the Democratic Republic of the Congo (MONUSCO)	16	8	8	0	0	13	208
UN Multidimensional Integrated Stabilization Mission in Central African Republic (MINUSCA)	20	8	4	4	4	13	260
UN Multidimensional Integrated Stabilization	20	6	14	0	0	13	260

Mission in Mali (MINUSMA)							
UN Office in Nairobi (UNON)	10	0	5	2	3	7	70
UN Interim Force in Lebanon (UNIFIL)	6	3	2	1	0	6	36
UN Integrated Peace-Building Office in Guinea Bissau (UNIOGBIS)	5	1	2	1	1	6	30
UN Disengagements Observer Force (UNDOF)	6	3	3	0	0	6	36
Total units of blood per shipment	174						
Total units of blood for 6 months actual shipment							2,027
Contingency for 6 months (10% of 6 monthly requirement)							202
Total Requirement/6 months							2,229
Total Requirement/Year							4,458
Total Requirement/ 5 Years							22,290

EXHIBIT II

Communication and Haemovigilance Framework

United Nations Secretariat and Mission Contacts for Haemovigilance

Mission Focal Persons Responsible for Haemovigilance in the Missions:

The Chief Medical Officers (CMO) of the blood receiving Missions whose names and contact information are provided below, are responsible and accountable for Haemovigilance for their Missions. This role must be delegated to their subordinate Officers during their absence from the Mission with due notification to DHMOSH. Where a CMO is to be absent from the Mission for more than 3 months, the name and contact information for delegated Officer is to be communicated to the Contractor.

Entity	Name	Mobile Telephone	E-mail
UNAMID	Dr. Vincent Osabutey-Anikon	+249922410216	osabutey-anikonv@un.org
MONUSCO	Dr Tsegazeab Kassaye	+243997068715	tsegazeab@un.org
UNMISS	Dr Mohd Iqbal	+ 211912171999	mohd@un.org
UNSOS	Dr. Roberts Onebunne	+254790206704	onebunne@un.org
UNIOGBIS	Dr Jacob Tehem	+245966301055	tehem@un.org
UNISFA	Dr. Martin Konyango	+249 912143496 & +254 711983983	konyango@un.org
UNDOF	Dr Sachit Dhakal	+963958009318	undof-fmo@un.org
UNIFIL	Dr Binod K Sharma	+96170926968	sharmab@un.org
MINUSCA	Dr. Sophia Oteng	+23675980028	otengs@un.org
MINUSMA	Dr Samson Mathiu	+22394950174	mathiu@un.org

UN Headquarters Focal Person for Haemovigilance and Record keeping:

The DHMOSH Focal Person for Haemovigilance whose name and contact details are provided in the table below, shall provide guidance to the Mission CMO on all issues pertaining to clinical standards and procedures for Haemovigilance. In the meantime, before patient transfusion records are entered into the UN patient electronic data base, DHMOSH shall also be responsible for the transfer of transfusion records, collated at each Mission level to the Headquarters for compilation on a monthly basis and for transfer to the Contractor when required.

Entity	Name	Mobile Telephone	Email
DHMOSH	Col Dr Arne Mueller	+1718568-4081	arne.mueller@un.org

MISSION CONTACT FOR PRE-SHIPMENT ADVICE:

Mission contact persons for receipt of pre-shipment advices are responsible for prearrival customs clearance activities and ensuring that on arrival, blood consignments are received and transferred

to the CMO's office for inspection. Mission has the responsibility of reviewing the list of its Focal Persons to ensure no communication from the Contractor is lost, which might jeopardize early customs clearance and possible break in cold chain.

Mission	Name	Phone No.	Email Address
UNAMID	Walid Abu Shunnar	+249922410587	abushunnar1@un.org
	Dr. Kandarpa Jha	+249922410225	jhak@un.org
MONUSCO	Innocent Wibyula	+243977814966 +243896824056	wibyula@un.org
	Abid Gul	+243978044626	abid.gul@un.org
	Gilles Valere Lawe Monga	+243829000244	gilles.lawemonga@un.org
	Gemma Redolin Urbano	+256757708171	urbanog@un.org
	Dr. Tsegazeab Kassaye	+243997068715	tsegazeab@un.org
	Marc Daniel	+256757708020	daniel9@un.org
	MONUSCO-EBB-MOVCONTRA - FFICSHIPPING	+256757708094	monusco-ebb-movcontrafficshipping@un.org
UNMISS	Agada Agada	+211(0)912170333	agada@un.org
	Nadim Ansari,		Ansari5@un.org
	Dr Mohd Iqbal,	+ 211912171999	mohd@un.org
UNIOGBIS	Emmanuel Egunyork	+245966087445	egunyork@un.org>
UNISFA	Gilbert Konlak Demekong	+249 9040 95147	gilbert.konlakdemekong@un.org
	Isaac Donko	+249 9638 60332	donko@un.org
UNDOF	Bernard Lee	+963947777025 & +972543230521	lee43@un.org
	Anthony Feeney	+972546118221	feeneya@un.org
UNIFIL	91. Binod Kumar Sharma	+ 961 - 70926968	sharmab@un.org

Mission	Name	Phone No.	Email Address
	Elma Jocson	+ 961 - 81628444	jocson@un.org
	Nataliya Awada	+ 961 - 81628777	awadan@un.org
	Effendi Syukur	+961 - 76 678767	syukur@un.org
MINUSMA	Lassana Konde	+22394951073	kondel@un.org
	Chidi Udeaja	+22394951550	udeajac@un.org
MINUSCA	Ali Abdelkarim	+236 75981639	abdelkarim1@un.org
	Margaret Cardovillis	+236 75981826	mbugua4@un.org
UNSOS	Dr Mohamed Baby	+252612857462	babym@un.org
	Zipporah Wanjohi-Kwame	+254716431731	wanjohi-kwame@un.org
	Lindah Siangani	+254413506282	unsos-movconshippingunit@un.org
	Evans Mahiti	+254 722 711120; +254413506284	
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	Steve Maina	98. +254 733 847 959	99. steve.maina@ags-globalsolutions.com

Supply Orders, Payments, and Contract Administration:

Only the personnel herein determined may contact Vendor ® to provide Supply Orders and will be authorized to receive invoices, price lists changes and request for contract amendments.

UN Headquarters Focal Persons for Contract Management:

Activities	Name	Phone	E-mail
Review of delivery Schedule Review	Jolly Abu	+16468973822	abuj@un.org
Supply Orders	Marta Valeska Garcia Argenal	+1-212-963-8715	marta.garcia@un.org
Invoices and Payments	Jolly Abu	+16468973822	abuj@un.org
Price Changes and Contract Amendments	Marta Valeska Garcia Argenal	+1-212-963-8715	marta.garcia@un.org
Changes in medical Testing Standards, medical Issues with Quality and Safety	Col Dr Arne Mueller	+1718568-4081	arne.mueller@un.org

Contractor`s focal person for Contract / Haemovigilance:

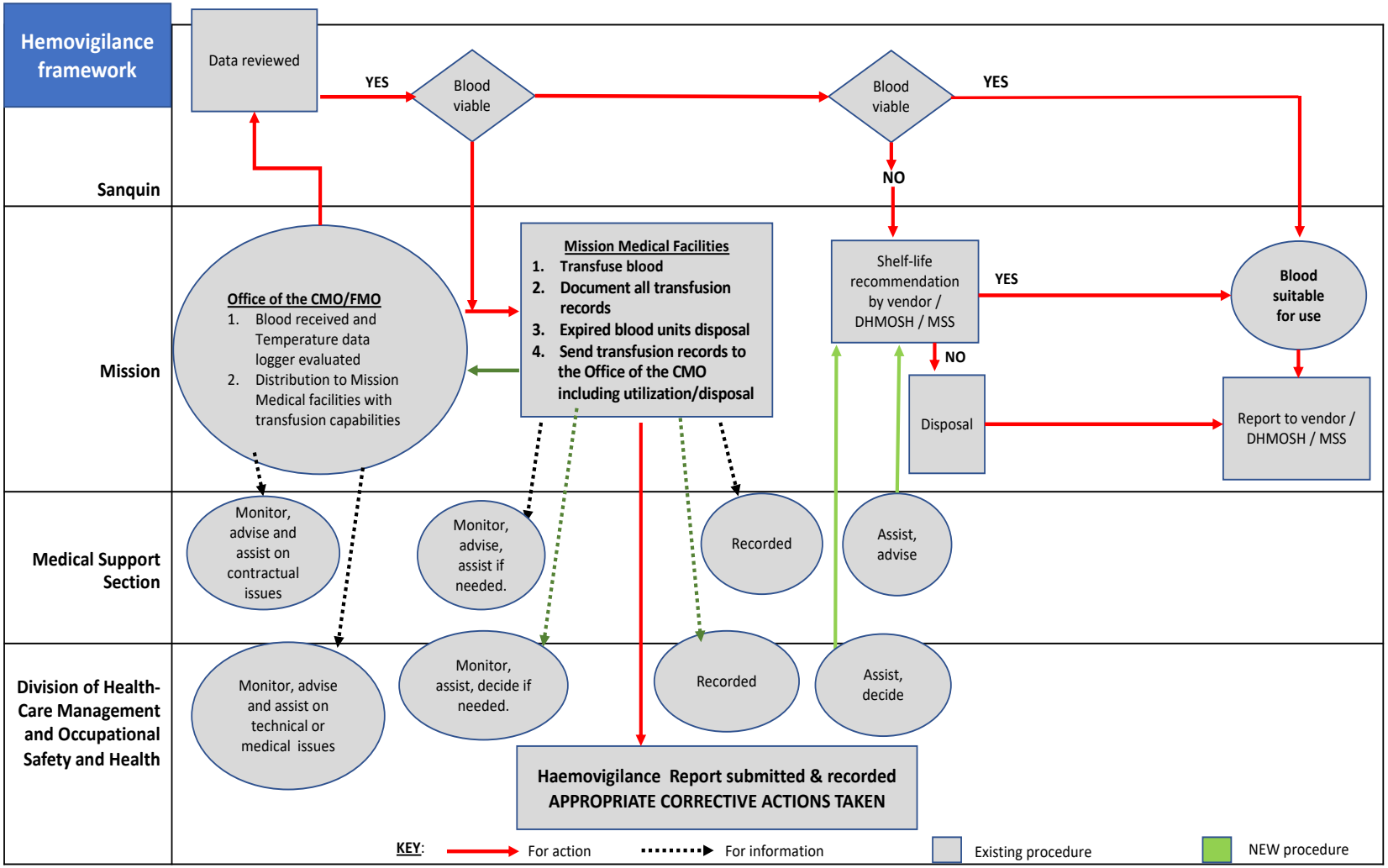
It is important that the Contractor and the UN blood receiving Missions establish an effective and reliable two way communication channel to ensure early notification of arrival dates for shipments, prompt notification of supply of defective blood and blood products, product recalls and remedial actions to be taken where defective blood has been transfused, communication of data on blood transfusion and traceability of recipients, changes in blood collection and transfusion procedures, changes in clinical standards where applicable etc. The Contractor shall also provide the UN with any relevant facts, information, or circumstances in respect of the Blood Products that may affect the quality of the Blood Products or of any other inconsistencies of the Blood Products with the specifications.

	Name	Phone	FAX	E-mail
Nonconforming and defective products				
Vendor Transfusion HCP responsible and for reporting of adverse reactions				
Vendor Quality Assurance				
Product recall				

Roles and responsibilities of the Contractor in UN Haemovigilance System Framework:

Responsibility	Vendor	UN Mission	Comments
Advanced notification of shipping no less than 7 days.	X		See Paragraph 27 to 29 above. In the event that delivery of Blood Products to the Freight Forwarder cannot be completed on the scheduled date of pick-up, the Contractor shall notify the Freight Forwarder and the Mission Focal Points detailed in Annex D and the Point of Contact for UN Headquarters in the Logistics Division, Department of Operational Support ("LD/DOS"), allowing the Freight Forwarder sufficient time to modify its delivery logistics
Collection, testing, in accordance with EU and Dutch regulations/guidelines	X		Agreement of LD/OSCM/DOS should be sought prior to any changes to the collection and testing process by the Contractor.
Nonconforming and defective products	X		Should be reported to the UN by telephone and followed by email for documentation purposes.
Managing of adverse reactions	X		Serious Adverse Reaction" shall mean an unintended response in Recipients of the Blood Products associated with the transfusion of the Blood Products that is fatal, life-threatening, disabling or incapacitating, or which results in, or prolongs, hospitalization or morbidity
Packaging and labelling in accordance with EU and Wibv (oa EIN)	X		Packaging materials for the shipping and transport of the Blood Products are suitable for their intended purposes (including, without limitation, to preserve the Cold Chain) under normal and timely transport conditions, up to delivery to the agreed locations
Delivery to transport/carrier	X		Ensuring timely delivery of consignments to its Freight Forwarder at the agreed location. When not possible to deliver, inform Freight Forwarder and the UN well in advance for appointment of alternative Freight Forwarder and or cancellation of predetermined shipping arrangements

Figure 1: Algorithm of the UN Haemovigilance System Framework



BLOOD TRANSFUSION RECORDING AND TRACEABILITY IN THE FIELD

Sequence of Activity	Description of integrated actions	Ownership of Activities	Outcome
Arrival of Blood in the Mission	1.Blood is received, and temperature data logger download and analyzed 2. Blood is inspected for completeness of quantity, adequate labelling, expiration and shelf-life and integrity of blood cells etc. consistent with JACIE standards. 3. Inspection is carried out within 12 hours and report is sent to Contractor at most within 24 hours with copy to the Clinical Governance Section of DHMOSH. 4. Document all reports for reference purposes.	CMO or delegated Medical personnel	Detailed temperature logger reports read-outs. CMO notifies the Contractor in writing of the UN's acceptance of the Blood Products
	5. Where blood is defective: • Advise Mission on disposal methodology. • Take necessary action to replace defective product or issue credit note. • Advise mission on remedial actions, clinical or otherwise to reverse any adverse reactions and possible harm to the transfused patient. 6. Where spike is observed on the temperature chat, advise the Mission on need to discard product or adjust shelf-life for best used time 7. Document all reports for reference purposes.	Contractor	Documentation of emails with advice provided to the Mission
Distribution of blood to UN medical facilities	8. Distribute blood to only Mission owned or contracted medical facilities with blood transfusion capabilities; including personnel and equipment. 9. Ensure that Mission owned or contracted medical facilities with blood transfusion capability are equipped with adequate blood storage capacity and capability for maintenance of +2^{o}C to +6^{o}C with back up UPS and digital temperature recording. **NOTE:** **if below +1^{o}C possibility of haemolysis**	CMO	N/A

Traceability	10. Ensure that blood is transfused only by UN certified medical personnel with the right professional certification to do so. 11. Ensure that blood transfusion is carried out in line with optimal clinical protocol/practice. 12. Subject to force majeure, Mission **must report any adverse reaction** to blood transfusion ASAP or at most within 24 hours to the Contractor, the CMO and DHMOSH shall take remedial action, where defective blood has already been transfused and record all details. **Note: Reporting should be non-punitive** 13. Maintain all records of transfused patients in their case files (hard copy and or electronic). 14. Dispose of all expired or defective/nonconforming blood products by incineration - if that is all that is available. 15. Collate, analyze and forward report of blood utilization including number and blood group transfused or discarded to the Office of the CMO for compilation. 16. CMO to collate, analyze and document a single report as described above for the entire Mission. 17. Forward report of transfused or discarded blood to the Contractor without disclosure of patient identity and clinical information. 18. Forward report of transfused patients not in EarthMed to the Clinical Governance Section of DHMOSH on quarterly bases. 19. DHMOSH to maintain electronic copy of blood transfused records for 30 years and hardcopy for 5 years for traceability purposes.	Joint responsibility of UN certified medical personnel/CMO/DHMOSH	Reports of Serious Adverse Reaction Records of transfused patients Blood utilization report
Disposal of expired or defective blood	20. All defective/nonconforming blood and blood products are to be disposed of by incineration - if that is all that is available. 21. All blood disposal exercises must be monitored, documented, and reported to the medical Officer in charge of the medical facility from where it was collected for compilation.		Blood utilization report

EXHIBIT III

Blood Return Form – Destination of Blood Products

Mission / Destination Name: _____

Blood Unit Number	Date of Action	Action
		☐ Transfusion in UN patient
		☐ Returned to Customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)
		☐ Transfusion in UN patient
		☐ Returned to customer
		☐ Expired and Discarded
		☐ Other (Specify)

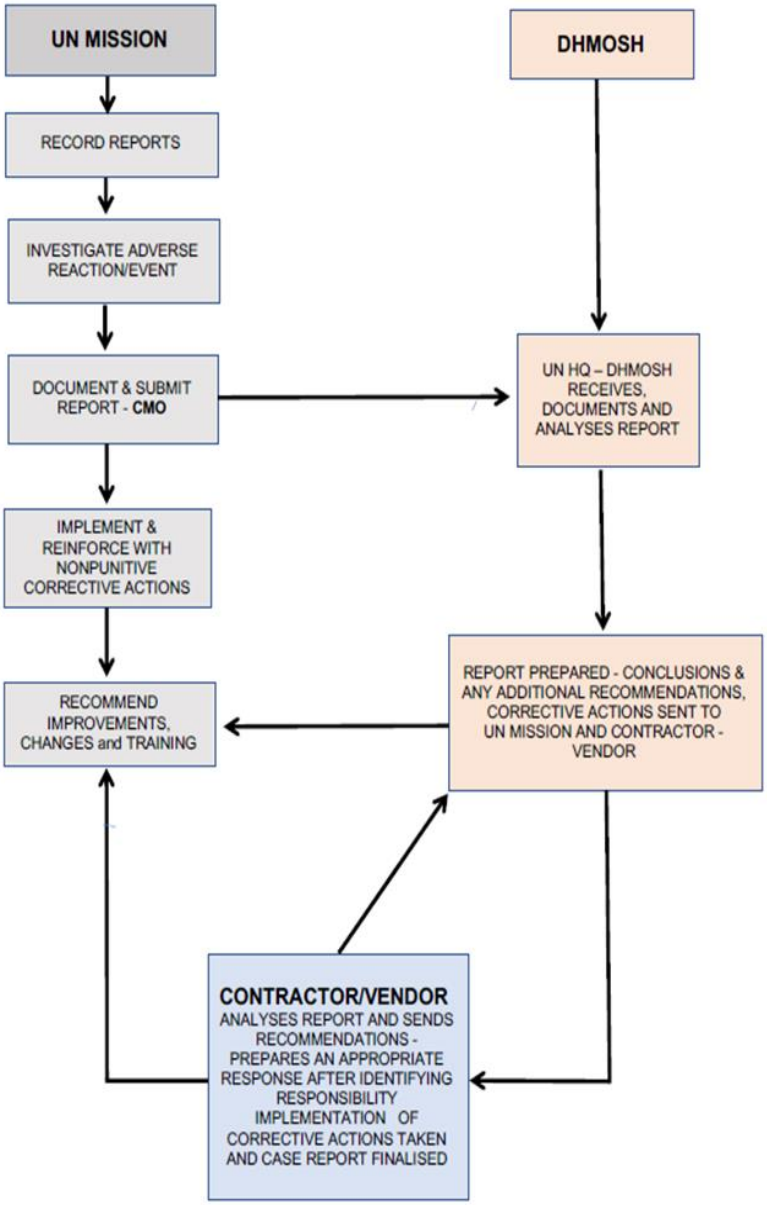
EXHIBIT IV

UN Field Mission Destinations of Blood Requirements for purpose of labelling

UN Field Mission	Delivery Airport	Final Delivery Destination
UN Support Office for AMISOM (UNSOS)	**Nairobi, Kenya**	**Mogadishu, Somalia**
UN Mission in South Sudan (UNMISS)	**Entebbe, Uganda**	**Juba, South Sudan**
African Union / UN Hybrid Operation in Darfur (UNAMID)	**Khartoum, Sudan**	**El Fasher, Darfur, Sudan**
UN Interim Security Force for Abyei (UNISFA)	**Entebbe, Uganda**	**Abyei, South Sudan**
UN Organization Stabilization Mission in the Democratic Republic of the Congo (MONUSCO)	**Entebbe, Uganda**	**Goma, Democratic Republic of the Congo**
UN Multidimensional Integrated Stabilization Mission in Central African Republic (MINUSCA)	**Bangui, Central African Republic**	**Bangui, Central African Republic**
UN Multidimensional Integrated Stabilization Mission in Mali (MINUSMA)	**Bamako, Mali**	**Bamako, Mali**
UN Office in Nairobi (UNON)	**Nairobi, Kenya**	**Nairobi, Kenya**
UN Interim Force in Lebanon (UNIFIL)	**Beirut, Lebanon**	**Beirut, Lebanon**
UN Integrated Peace-Building Office in Guinea Bissau (UNIOGBIS)	**Dakar, Senegal**	**Bissau, Guinea Bissau**
UN Disengagement Observer Force (UNDOF)	**Bierut, Lebanon**	**Bierut, Lebanon**

ANNEX III - FLOW OF HAEMOVIGILANCE DATA ALGORITHM

Figure 1. Flow of Haemovigilance Data



ANNEX IV – LOGICAL FRAMEWORK

LOGICAL FRAMEWORK			
Narrative Summary	**Verifiable Indicators**	**Means of Verification**	**Assumptions & Risks**
UN DHMSOH GOAL: To establish and maintain a UN Mission Haemovigilance System Framework (HSF)	Haemovigilance Systems in place for Blood and Components provided by Vendor/Contractor and UN Field Missions	Monitoring and recording of all steps in Blood Transfusion Practice	ata record sheets and electronic connections available in country field mission
Goal: Identification of Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR) in clinical blood transfusions leading to corrective actions.	Recordings of all blood delivered from Vendor/Contractor within Blood Cold Chain (BCC) parameters; receipt, storage, clinical indicators on need of transfusions, monitoring of transfusions pre, during and post transfusion. Recording of all steps of a Whole Warm Blood Donation in the fields ("Vein to Vein").	Haemovigilance reporting sheets accurately completed, submitted to CMO UN Mission, and transmitted to DHMOSH and MSS.	Availability of effective facilities for BCC transportation; storage in UN Mission; trained medical staff and reliable communication networks through phone and internet. No experience in Whole Warm Blood Donation.
Purpose: To develop and implement a robust and effective UN Mission HSF (Haemovigilance System Framework) for use by UN Missions in Field settings.	A Haemovigilance System Framework established and guidelines and protocols in place and known in UN Missions.	The Haemovigilance System Framework established, and guidelines and protocols known and used by UN Missions with timely reports reaching UN HQ DHMOSH and MSS.	Vendor/Contracts not established in time or Blood orders not dispatched/arriving in time. Training of Medical staff not completed.

Output: 1. UN Mission Haemovigilance System Framework (HSF) approved and implemented for use by al UN Missions.	Guidelines and Protocols in place in UN Missions following successful field evaluations and provision of required methods and communication protocols.	UN Mission Haemovigilance System Framework (HSF) data collection and reporting successfully implemented and documented by CMOs and transmitted to UN HQ DHMOSH and MSS.	Lack of facilities for communication of reports in field situations leading to delay or loss of data.

2. UN Mission Haemovigilance System Framework (HSF) guidelines and protocols known and used by UN Mission Medical Staff with evaluations and reports provided on time.	*Human resources* Establishment of HSF Committee at UN HQ DHMOSH and MSS and at each UN Mission where CMO identifies medical and technical staff for HSF Field Committee. *Blood Cold Chain facilities for storage, field transportation monitoring and disposal* Data Loggers, Time Temperature Monitors (TTMs), Blood Bag Teal time monitors available and used for BCC to ensure safety and quality of Blood & components. *Data records and Blood Stock Management Systems in place* Audits carried out and reports documented; stock checked, and disposal of used and expired blood products carried out;		

	Blood and Components delivered and meet orders from Vendor/Contractor Annual target assessments for blood provided and used are within target estimates, with minimal wastage or excess by each UN Mission *Field missions have laboratory services provide support from Hospital Blood Banks* Adequate facilities, reagents, devices, and BCC and Quality assurance scheme in place.		
3. UN Mission needs for blood and components are sufficient to meet expected and possibly unexpected needs.	Demand – supply versus expiry gap reduced annually with 80% of needs met in medium term +/-3yrs).	Planned orders and delivered Blood and Components lead to ensuring needs and significant reduction in expiries and destruction of blood.	Assumptions dependent on reasonably stable continuum of field situations; unforeseen escalations in conflict and austere conditions impact needs for blood.

4. UN MSS successfully negotiates a contract with an internationally recognised Vendor/Contractor for the supply of Blood and Blood Components, which is an accredited and financially sustainable organisation.	Evidence of the Vendor or Contract being internationally recognised and certified as an operationally swell managed organisation capable of providing Blood Products to the highest expected standards of quality and safety.	Internationally accredited and recognised by authorities such as EC/EU, CoE, WHO and by ISBT.	Inability to secure a Vendor Contract for the supply of Blood, Components and, if needed Plasma Derived Medicinal Products (PDMPs).

Activities		
Output 1: Implementation	**Output 2 Management Systems**	**Output 3 Meeting needs**
Establish UN Haemovigilance System Framework with practical and effective guidelines and protocols; appropriate documentation for recording and safely securing records long term; taking measures to carry out corrective actions from information provided by HSF which will ensure changes to ensure safety and quality of care to patients requiring transfusions from “Vein to Vein”.	Establish UNHQ DHMOSH Team responsible for providing medical support, assistance, and advice to UN Missions on Blood Transfusion practices. *Human resources:* Appoint clinically competent Medical Administrator at DHMOSH and MSS to assist, coordinate and collaborate with CMO in UN Missions. *Finance/Administration/Data IT:* Establish accounting/finance and data base IT system management for HSF information system. *Stock Management:* Establish IT computer system and monitor performance. *Training Medical Staff/Hospital support:* Ensure comprehensive training for UN Mission Medical staff in Clinic Blood Transfusion Practices.	Appoint and train relevant Medical Staff in UN Missions and relevant DHMSOH and MSS Support Teams to UN Missions. Establish targets for ordering and monitoring blood and component needs for each individual UN Mission dependent on field and operational demands and expectations. Output 4 Sustainability Establish an effective Data Capture System for information on Haemovigilance System Framework and response to ensure implementation of management change to improve quality and safety for Clinical Blood Transfusions.