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Policy

THE CLINICAL USE OF BLOOD IN FIELD SITUATIONS

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POLICY ON THE CLINICAL USE OF BLOOD IN FIELD SITUATIONS

A. PURPOSE

The purpose of this Policy on the Clinical Use of Blood in Field Situations (hereinafter the "Policy") is to establish a policy on the clinical use of blood and blood components in all United Nations field missions, for optimal patient care and management provided to UN personnel, including uniformed military and police personnel.

The document describes the requirements, necessary to ensure

- accessibility and availability of a safe and adequate provision of blood and blood components in all UN field missions,
- transfusion practices in UN field missions (field or hospital (UN clinic) settings),
- blood cold chain requirements,
- monitoring and Haemovigilance of blood donations and patient transfusions, which take place under the care and supervision of UN authorized staff in UN field missions.

All relevant United Nations personnel, at Headquarters and field missions, are required to have read and understood the scope and contents of this document, to implement the principles, and coordinate and integrate the actions stated herein.

B. SCOPE AND APPLICABILITY

1. The provisions of this Policy apply to all United Nations field missions administered by the Department of Peace Operations (DPO), Department of Political and Peacebuilding Affairs (DPPA) and Department of Operational Support (DOS). The Policy does not address resourcing implications necessary for implementation. Mission leadership has the primary responsibility of ensuring that identified personnel have access to and have read this Policy and that they have the necessary education and training for its effective implementation.

C. RATIONALE

- 2. United Nations field operations are deployed in many countries, with varying geographical environments, various languages, and ethnic population groups; comprising of multicultural populations; and in areas with limited infrastructure and capacities. This creates challenging operating environments that require United Nations missions having to provide the necessary logistics and capacity for ensuring effective treatment and management of medical emergencies, including those resulting from life-threatening haemorrhage.
- 3. This Policy aims to define minimum standards and actions required to provide for the timely provision of whole blood and, when possible blood components, to effectively treat and manage casualties occurring during missions, which adhere to internationally- and regionally-recognized medical and ethical standards of clinical medical practice, which are appropriate for implementing life-saving procedures in remote and austere situations.

Saving a life is the priority. The use of fresh whole blood (FWB), that may not have been screened for infectious agents, is a medical decision made after very careful consideration of risks and benefits. All decisions, actions and outcomes must be recorded, documented, and sent to the UN Medical Support Section (MSS), Logistics Division, Office of Supply Chain Management, DOS, and to the Division of Healthcare Management and Occupational Safety

and Health (DHMOSH), Office of Support Operations (OSO), DOS, as stated in the UN Haemovigilance System Framework.

D. PRINCIPLES

- D1. Principles of Damage Control Resuscitation
- 4. Clinical evidence suggests that the risk of death, or serious morbidity, can be avoided, or significantly mitigated, if resuscitation with appropriate clinical triage interventions is instituted early, or as soon as possible, after the onset of a life-threatening injury or illness.
- 5. The management of trauma-related massive haemorrhage relies on "Damage Control Resuscitation" (DCR). Damage Control Resuscitation is the early response and appropriate clinical intervention to identify the site of bleeding and, if possible, prevent further blood loss due to trauma or in non-trauma patients. The aim is to maintain vital functions through adequate oxygenation, maintaining blood volume and blood pressure, and stem further bleeding. The objective is to prevent the development of the lethal triad of hypothermia, disseminating intravascular coagulopathy (DIC) and acidosis.

Established optimal Chain of Rescue – the timings are stated as the 10-1-2 timelines:

10

1

2

Immediate life saving measures are applied by personnel trained in first aid. Bleeding and airway control for the most severely injured casualties is to be achieved **within 10 minutes** and a casualty alert message transmitted.

Advanced resuscitation / treatment is commenced by emergency medical personnel within 1 hour of injury / illness onset.

Where required damage control surgery (DCS) is commenced as soon as practicable, but **no later than 2 hours** after injury / illness onset.

The 10-1-2 timeline is cumulative in nature with a limit of 2 hours from the onset of injury/illness to possible DCS.

D2. Haemovigilance

- 6. 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. 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 the continuous quality improvement of the transfusion chain through corrective and preventive actions, to ensure donor and patient safety, improve transfusion appropriateness, and to reduce waste. A haemovigilance system resembles any continuous quality improvement cycle and incorporates the same elements and activities. Haemovigilance must be embedded into every step of the transfusion chain, from supplier, transportation, and every organization responsible for each part of the chain.

8. Detailed records of every transfusion must be submitted with a haemovigilance report to the Chief Medical Officer (CMO) for clinical and logistics review, to MSS and to DHMOSH.

<u>Ref:</u> WHO ISBN 978 92 4 154984 4 -available on the WHO website (<u>http://www.who.int</u>) Guide Haemovigilance

- D3. Collection of Blood in the Field and Definition of Walking Blood Bank Donation
- 9. Walking blood bank donation (WBBD), is, ideally, collected from pre-screened volunteers, in case of any future need for their blood, which is classified as fresh warm whole blood (FWWB). This blood is collected for use, only when stored whole blood (SWB), or blood components, are not available. SWB is provided from a licensed blood bank/service contracted by the United Nations to provide pre-screened SWB or blood components to the UN.
- 10. Walking Whole Blood Donors (WWBD) may be used to save lives within in-extremis emergency situations for Point of Injury (POI) transfusions and for support transfusions, during casualty evacuation and medical evacuation (CasEvac/MedEvac), when stored whole blood (SWB) supply is not available.
- D4. Blood Products [Whole Blood + Components + Plasma Derivatives]
- 11. In the context of UN peacekeeping missions, when there is a requirement to stock blood products, the different blood groups to stock must be defined by the Chief Medical Officer in accordance with the UN Haemovigilance System Framework.
- 12. Blood types '**O** positive' and '**O** negative' blood should be accessible at field hospitals wherever there is a reasonable risk of a need for Whole Blood for serious haemorrhage.
- 13. The quality and safety of all blood, blood components, or blood products, including devices, must be assured throughout the 'vein to vein' transfusion chain, which must be included into the UN Haemovigilance System. Definitions of Blood Products can be found in ANNEX B.
- D5. Logistical Support for Blood in Peacekeeping Missions
- 14. Blood and blood components will be collected from a safe voluntary unpaid donor population; processed tested, transport and stored ensuring an optimal blood cold chain process, which is coordinated by MSS as part of an effective Haemovigilance System.

When required, Plasma Derived Medicinal Products [PDMPs], which include Immunoglobulins and coagulation factor products, will be purchased from licensed internationally recognised sources, which must meet international standards of Good Manufacturing Process (GMP) and Quality Assurance (QA).

- 15. **Management of Blood Supply.** The logistics of blood supply is centrally managed by MSS and coordinated and managed by the Mission Chief Medical Officer, in coordination with the Force Medical Officer (FMO), Senior Medical Officer (SMO) or Commanding Officer of a Troop Contributing Country (TCC) Hospital, whose joint responsibility is to ensure that each mission has a safe, accessible and adequate stock of blood and blood components wherever needed in the mission's area of operation and designated Hospital, for CasEvac/MedEvac cases.
- 16. **Source of Blood and Blood Components.** The provision of all Blood Products is centrally managed and facilitated through established 'Global Systems Contracts' (GSCs). If a current GSC is unsuitable for meeting specific mission requirements, UN MSS will coordinate with the mission to establish alternate contracts, which will meet the same safety and quality standards. The establishment of local arrangements can only take place with the specific endorsement and approval of UNHQ (OSCM and DHMOSH).
- 17. Emergency Administration of non-United Nations-sourced Blood. During emergency events of inaccessibility or inadequacy of blood or blood products for resuscitating

patients, non-United Nations-sourced blood including freshly drawn whole blood from a walking blood bank could be an option to save lives. It is mandatory that these clinical decisions are overseen by a blood panel led by the CMO. The CMO is also required to establish an emergency blood support plan for such contingencies and make related records and documentation comprehensive and well archived.

18. Disposal of Blood. All unused blood products must be properly documented and disposed of in line with Department of Peace Operations (DPO) guidelines for "Managing Medical Waste" (see H. references and guidelines, b.). Destruction of the products may result in situations that can be environmentally challenging. Missions should adhere to UN applicable disposal procedures as well as instructions issued by the relevant supplier and applicable conditions in the relevant contract(s). In general, donating unused and near expired blood and blood products for transfusion by third parties is not allowed. In all cases where donation of blood is considered, Missions shall consult with DHMOSH and MSS.

E. PROCEDURES

- E1. Clinical Use of Blood and Components
- 19. Blood has a pivotal role in field missions, especially those assessed as high-risk. Everywhere else, the stockpiling of blood should be consistent with the intended clinical use. [ANNEX C]
- E2. Implementation of Procedures
- 20. This Policy is intended to serve UN field missions to ensure accessibility and availability of a safe and adequate provision of blood and blood components, for clinical blood transfusions, in a field or hospital setting, while ensuring an effective blood cold chain and monitoring of transfusions from the point of blood donation to patient transfusions, in the "vein to vein" approach, with a haemovigilance system, which takes place under the care and supervision of authorized UN medical staff.
- E3. Mission-Specific SOP for the Use of Blood and Blood Products
- 21. Mission-specific Standard Operating Procedures (SOPs) are a pre-requisite for the appropriate clinical use of blood and ensuring a Haemovigilance System Framework, which will ensure the Policy is utilised effectively for analysing situations and making a needs assessment, leading to decisions on making appropriate adjustments for any corrective action plan.
- E4. Risk Assessment
- 22. The stated requirements for blood and blood components have been assessed through a Health Risk Assessment (HRA). In any situation where the determined blood supply does not meet expected standards of care, additional actions and measures must be identified to mitigate all risks e.g. consulting the established mission blood panel. In case of uncertainty DHMOSH in close cooperation with MSS will elaborate a decision.
- E5. Training, Testing and Evaluation
- 23. Capacity building and training of staff (UN staff and TCC Level 1+ and Level 2/3) must be carried out on skills and knowledge in areas of donor selection, motivation, recruitment and, if possible, retention as potential future donors for a Walking Blood Donor Programme. Additional training on donor phlebotomy, care and safety of blood donors in collection procedures, knowledge of rapid testing of blood units for blood groups, Rhesus typing, screening for recognized transfusion transmissible infectious (TTIs) agents, blood cold chain, storage, distribution, administration, documentation, and Haemovigilance Systems should be carried out before deployment to any mission.

- 24. Regular evaluation of the capacities is a mandate and the responsibility for implementation by the CMO as part of the UN HQ Haemovigilance System, as part of UN Quality Assurance.
- E6. Reporting
- 25. A UN Haemovigilance System Framework is implemented to ensure that quality within all actions and activities in the access, availability, and safety is inherent in the appropriate clinical use of blood.
- 26. Accurate record keeping of the care and follow up of blood donors, ensuring notification and counselling of the identification and confirmation of any untoward findings, which may adversely affect the donor or donor contacts, including tracking and notification of recipients with regard to any harmful agents that may have been transmitted by transfused blood or components, which data is recorded in the UN Haemovigilance System Framework.
- 27. Haemovigilance System Framework records all the steps and actions in the "vein to vein" transfusion chain, from the blood donation to the transfused recipient, in the short and long term, including any 'look-back' tracing to supplier/vendor.

F. ROLES AND RESPONSIBILITIES

F1. United Nations Headquarters

28. Under-Secretary-General for Operational Support

Ensures that the United Nations Policy on the Clinical Use of Blood in Field Situations is established and enforced.

29. UNHQ Medical Support Section

Negotiates for an effective centralized UN system to contract purchase of blood, blood components, quality materials and devices, providing oversight for all logistics and management of blood and blood components in field operations.

30. UNHQ DHMOSH Medical Director

- a. Ensures that United Nations medical standards for the use of blood and blood components as well as plasma derived medicinal products (PDMPs) (Immunoglobulins, albumin, and coagulation products) are established and enforced.
- b. Ensures that all medical confidential information related for the use of blood and blood products is secured under United Nations medical governance, including donor and patient care, follow-up, counselling, and care.
- c. Provides policies, guidelines and recommendations on the appropriate clinical use of blood (CUB) for all UN field missions.

F2. Responsibilities in The Field

31. Chief Medical Officer (CMO)

Is responsible for ensuring availability, accessibility, and safety of an adequate supply of blood and components within a field mission; assisting in the preparation of mission SOPs; appointing a responsible individual for the daily management of the blood supply/stocks in the mission area and maintaining an effective Haemovigilance System Framework.

32. Force Medical Officer (FMO)

Assists the CMO in monitoring and auditing the protocols for the storage, management, and distribution of blood to field missions and TCC hospitals, and appropriate Clinical Use of Blood records and Haemovigilance System monitoring and audit reports.

33. Senior Medical Officer (SMO) or Commanding Officer of a Troop Contributing Country (TCC) Hospital

SMO is responsible for all aspects of CUB at each respective facility under their responsibility.

34. TCC or UN Medical Doctor

TCC/ UN Medical Doctor must understand and ensure effective implementation of this UN Policy, UN Guidelines, and any Standards of Policies (SOPs) relating the appropriate clinical use of blood.

G. TERMS AND DEFINITIONS

ABBREVIATIONS

The abbreviations and any definitions provided in this UN Policy are only for the purposes of this document. They neither reflect, nor imply a broader general meaning/definition beyond the scope and purpose of the contents of this document.

BCC CASEVAC CMO CUB DCR DCS DIC DoD DPO DHMOSH	Blood Cold Chain Casualty Evacuation Chief Medical Officer Clinical Use of Blood Damage Control Resuscitation Damage Control Surgery Disseminated Intravascular Coagulopathy Department of Defence Department of Peace Operations Division of Healthcare Management and Occupational and Safety Health
FFP	Fresh Frozen Plasma
FWB	Fresh Warm Blood
FWWB	Fresh Warm Whole Blood
FMO	Force Medical Officer
GMP	Good Manufacturing Process
GSC	Global System Contracts
HRA	Health Risk Assessment
LTOWB	Low Titre 0 Whole Blood
MEDEVAC	Medical Evacuation
MSS	Medical Supply Service
PLT	Platelet Concentrates
POI	Point of Injury/Illness
PRC	Packed Red Cells
RBC	Red Blood Cell Concentrates
RCC	Red Cell Concentrates
Rh	Rhesus
SAGM	Saline, Adenine, Glucose, Mannitol
SMO	Senior Medical Officer
SOP	Standard Operating Procedure
SWB	Stored Whole Blood [pretested blood bank blood]
TTD	Transfusion Transmitted Disease
TTI	Transfusion Transmitted Infection
ТХА	Tranexamic Acid
TCC	Troop Contributing Country
UN HQ	United Nations Head Quarters
WB	Whole Blood
WBBD	Walking Blood Bank Donation
WWB	Whole Warm Blood
WWBD	Walking Whole Blood Donors
WWBD	Whole Warm Blood Donation

H. REFERENCES AND GUIDELINES

The Policy on the Clinical Use of Blood in Field Situations should be read in conjunction with current conventional evidence-based documents, materials, and publications from internationally recognized authoritative bodies, institutions, and organizations.

- Manual on Policies and Procedures Concerning the Reimbursement and Control of Contingent-Owned Equipment of Troop/Police Contributors Participating in Peacekeeping Missions [COE Manual and information UN General Assembly (Link). [ANNEX D]
- b. Related Guidelines
 - UN Guidelines on Clinical Use of Blood Series [Nos: 1 3]
 - UN Haemovigilance Systems Framework & WHO Haemovigilance Guidelines
 - SOP for the Development of Waste Management Plans for UN Field Missions" (2018.30), 1 January 2019
 - UN General Assembly Secretary General A/75/121 (CoE-Manual), 31 August 2020
 - DPKO/DFS Medical Support Manual for UN Field Missions, 3rd Edition (2015)

I. MONITORING AND COMPLIANCE

The Department of Operational Support (DOS) provides technical supervision and is supported by the Division of Healthcare Management and Occupational Safety and Health (DHMOSH), which has the authority for oversight and monitoring of the compliance to this policy implementation, in their respective areas. The Directors of DHMOSH and MSS should ensure that heads of missions are properly informed of this policy.

J. CONTACT

All enquiries about this policy and requests for amendment should be sent to Division of Healthcare Management and Occupational Safety and Health/Office of Support Operations.

e-mail: <u>medicaldirector@un.org</u>

K. HISTORY

This is the first edition of the UN Policy on the Clinical Use of Blood in Field Situations and is scheduled for review three years from date of issue.

ANNEX A. HAEMOVIGILANCE

- 1. 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. 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.
- 2. Haemovigilance is necessary to identify and prevent the occurrence, or recurrence, of transfusion-related unwanted events, and to increase the safety, efficacy, and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. Haemovigilance systems may be established in many countries, however, it is recognized that there is a lack of effective haemovigilance in many resource-limited settings, and implementation in such settings remains an important and challenging problem.
- 3. The transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion. Learning from adverse events and identifying problems results in the introduction of measures to enhance the quality, safety, efficacy and cost-effectiveness of blood and blood products as well as of the donation and transfusion processes.
- 4. 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.
- 5. Detailed records of every transfusion must be submitted with a Haemovigilance report to CMO for clinical and logistics review to UN MSS and DHMOSH.

Refs: -WHO Guide Haemovigilance ISBN: 9789241549844- WHO website (http://www.who.int)

https://www.who.int/bloodsafety/haemovigilance/en/

- EC Directive 2002/98 The European Parliament and Council; and 2004/33/EC, 2005/61/EC; 2005/62/EC

CAUSALITY

The assignment of the causality should be assessed by the Senior Medical Officer (SMO) responsible for the overall care of patients, using the definitions in the table.

If there is any doubt about the causality, the SMO should clearly record every detail of the adverse event and reasons for the treatment and management provided and forward the completed detailed Haemovigilance Report, together with relevant Monitoring Charts and Laboratory Results to UN CMO.

In cases where there are discrepancies in individual opinions or views on causality, these must be clearly recorded for future analysis and clarification.

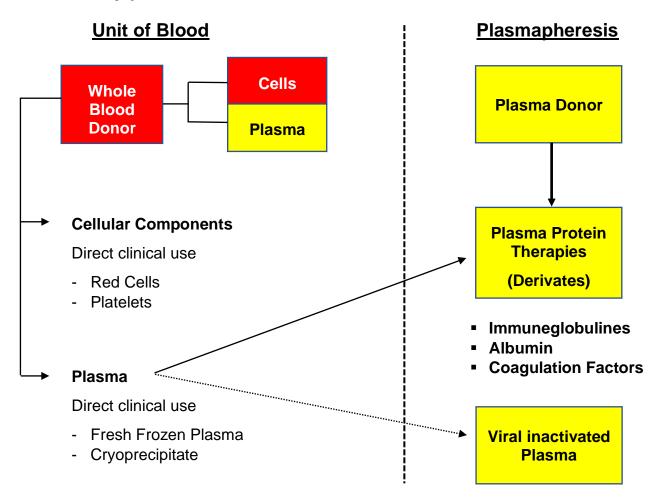
Relationship	Description	
Unrelated	There is no evidence of any causal relationship!	
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the event or transfusion) There is another reasonable explanation for the event (e.g. the patient's clinical condition other concomitant cause or treatment)	

Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs), within a reasonable time after administration of the transfusion or administration of medication. However, the influence of other factors may have contributed to the event (e.g. the extent of the trauma or haemorrhage and patient's existing clinical condition or and coexisting comorbidities).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not possible to assess	There is insufficient or incomplete evidence to make a clinical judgement of the causal relationship.

ANNEX B. WHOLE BLOOD AND BLOOD COMPONENTS

Definition of a Blood Product

-Any product that derives from Blood or Plasma / Serum-



- 1. Whole blood (WB) units may be separated into components, of Red Blood Cell concentrates (RBC), with an additive solution comprising Saline, Adenine, Glucose and Mannitol (SAGM), which improves red cell life and tissue level oxygen release; the separated plasma can be frozen at -20°C or colder and used as Fresh Frozen Plasma (FFP) or further processed using cry precipitation to concentrate Cryoglobulin Factor VIII (Anti-Haemophilic Globulin (AHG), in addition fresh plasma may be sent to a pharmaceutical fractionation facility for processing of Pharmaceutically Derived Medicinal Products (Immunoglobulins; Albumin and Coagulation Factors); Platelet Concentrates (PLTs) may be prepared, which require storage at +/- 22°C in a special agitator with a 7day life span.
- 2. Whole Blood [SWB and FWB] provides RBCs; FFPs; PLTs in a physiologic ratio to replace blood lost in Haemorrhage. If using individual blood components (RBCs, plasma and platelets) in recommended 1:1:1 ratio for Damage Control Resuscitation (DCR) it should be remembered that due to the dilution effect of the added anticoagulant in the blood collection bag (most of which is removed when preparing components) then SAGM added to RBCs the dilution effect reduces the haematocrit to +/- Hct 30%; and platelet count to +/-90,000/µL; and coagulation factors reduced to +/- 60% of "in vivo" expected concentrations in FWB.
- 3. FWB provides all components of RBCs; FFPs; PLTs, with minimal dilution effect from anticoagulant; especially if transfused within 24hrs and stored optimally.
- 4. UN Mission Medical Officers should be familiar with the terminology currently used in many resource limited countries when related to Blood and Blood Components:
 - a) 'Sedimentation Technique' Packed Red Cells (PRC) are derived from Whole Blood by removing excess plasma, by pressure on the blood bag and expression of a varying volume; of plasma consistent with maintaining adequate viscosity for flow for transfusion; the resulting components vary in red cell haematocrit in accordance with sedimentation time and amount of plasma removed
 - b) 'Centrifugation Technique' Packed Red Cells (PRC) produced in are produced in Blood Banks, which have refrigerated centrifuges to spin blood bags and then removal of plasma from the centrifuged whole blood bag; the components prepared can standardised by weight and quality due to cold chain being maintained; however the component will be dependent on the plasma volume removed as a reasonable volume must be retained or the Red Cell Concentrates (RCC) will have a high viscosity and poor flow through the transfusion administration filter set.
 - c) Red Cell Concentrates, from Whole Blood Collected in triple or quadruple blood bags with CPDA1 anticoagulant and an additive Solution with Saline, Adenine, Glucose and Mannitol (SAGM) in one satellite bag, are prepared by spinning the WBB with attached satellite bags in a calibrated Blood Refrigerated Centrifuge; the blood bag placed in a plasma expresser and all plasma, white cells and platelets removed (the latter in the "buffy layer" found between red cells and plasma); which can be expressed into one satellite bag for plasma and a bag for platelets; the SAGM Additive solution is then added to the RCCs, in the original collection bag; these RCC have a 45 day expiry potential.

WHO Manual on Management, Maintenance and Use of Blood Cold Chain Equipment

- 1. Transportation of Whole Blood (WB) or red blood cells should be maintained at a temperature of between +2°C to +6°C during BCC transportation to a Hospital Blood Bank.
- 2. WB and RBCs should be stored in a specifically manufactured Blood Bank Refrigerator at a constantly monitored and recorded +2°C to +6°C; Fresh Frozen Plasma (FFP) & Cryoprecipitate (AHG) should be stored at temperatures of 20°C or colder; Platelets once separated from WB are stored in a specifically manufactured Platelet Agitator at +22°C within a range of +20°C to +24°C [if platelets are stored in a blood refrigerator, their viability and activity diminish exponentially over time. Any deviating from the approved temperatures for more than 8 to 10hrs should be authorized by UN Chief Medical Officer or Specialist Clinician, on site, and written records justifying actions taken submitted as part of Haemovigilance. The blood cold chain (BCC) must always be maintained and electronically monitored and recorded. Ideally, all

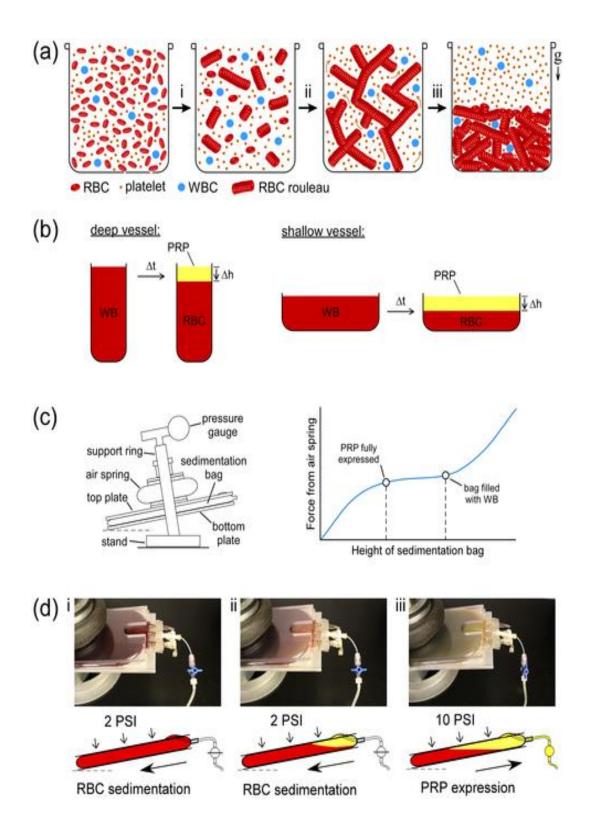
units of blood supplied to peacekeeping missions should come with an individual temperature monitor or indicator.

- 3. The upper limit of + 6°C (degrees Celsius) retains red cell viability and storage life and minimizes potential bacterial growth should there be any contamination in the unit.
- 4. The lower limit is the most critical, at +2°C (degrees Celsius), no lower, to ensure that the red cells do not freeze, which will result in haemolysis and the release of dangerous levels of intracellular Potassium (K+), which can rapidly lead to renal failure, cardiac arrest and death.
- 5. Blood Bank Refrigerators are specifically designed and purpose made, with trays for each blood unit to permit circulating cold air to contact each unit; with an internal circulating fan; a thick with cabin wall well insulated to retain temperature; a 24/7 temperature recording device as part of the device to measure actual product temperate (the probe should be in glycerol to mimic actual product temperature) and an air temperature probe, both recording separately, a double sided glass front door so that contents can be viewed without opening the door and losing cold air. The refrigerator must be connected to a back-up secondary power supply (generator) in case of electricity loss, and that of valuable life-saving product.
- Freezers for use in storing components [Cryoppt AHG and Fresh Frozen Plasma (FFP) at -20
 °C to -30 °C, or colder; these components can be stored in a good effective commercial freezer,
 as the frozen component has a wide frozen temperature range. (see WHO reference, as above).
- 7. Blood must be shipped in specific purpose made Blood Cold Chain Transport Boxes to maintain the blood cold-chain temperatures for the total duration of transportation; in a secure tamper proof locked and sealed insulated box; with appropriate cooling eutectic cold packs may be used for a shipping duration of 48 hours or more; an inbuilt temperature device and blood unit temperature loggers which ensure product temperatures.
 - Transport of pre-processed blood +20 °C to +24 °C Less than 6 hours
 - Transport of processed blood +2 °C to +10 °C Less than 24 hours
- 8. Red Blood Cells Concentrates (RBCs) with SAGM additive, have a shelf- life of 42 days from time of collection, provided temperature ranges are maintained; any variations will be subject to extent and time and an expert evaluation for a safe shelf life.
 - Storage of pre-processed or processed/tested blood +2 °C to +6 °C; +/- 35days
 - Red Cell Concentrates in CPDA + SAGM +2 °C to +6 °C; +/- 42 days
- 9. At least a 5day overlap should be implemented between expiry of current blood stocks and arrival of next consignment of Blood; usually a shipment and delivery at 28-day intervals; alternatively, arrangements made for 50% of the mission's blood requirements to be delivered every 14 days, which ensures an unbroken supply chain, due to unforeseen delays.
- 10. The Chief Medical Officer should assign a designated individual, who has received training in all aspects or ordering, tracking and receipt of shipments of blood to site of receipt, the responsibility of ensuring that blood is properly managed within the mission, then effectively checking the consignment BCC; record keeping and the storage of blood and distributing blood to designated mission field hospitals; finally submitting records for the Haemovigilance System.
- 11. Frozen Red Blood Cells, in Glycerol, are not recommended for use in field missions, or Peace Keeping Operations. The process of maintaining the frozen product, thawing and washing of the red cell unit is time-consuming (+/- 90minutes to have a unit ready for transfusion); difficult to prepare in emergency situations; requires specific technical skills, equipment and trained personnel for storage and processing, a challenge for a TCC medical facility. The solutions and equipment used for the thawing and cleaning significantly increases the cost of each unit.
- 12. Fresh Whole Blood (FWB), is collected on an emergency basis from suitable donors who are considered a "walking blood bank" (WBB). FWB is collected for immediate use or can be stored, unrefrigerated, for a maximum of 24 hours from collection, at less than 25°C temperature, after which time it must be destroyed. However, if refrigerated within 6 hours of collection, FWB, if refrigerated at a controlled temperature of 2°C 6°C, can be stored for at least 14days.

- 13. Mission Leadership should prioritise mission resources to meet all needs for treatment with whole blood/packed cells; and blood components at POI, or at a designated hospital.
- 14. Whole Blood (WB) has all required components and only requires refrigeration during transport or if stored. However, if whole blood has been separated into red cell concentrates, plasma or platelets components, in a blood bank facility, these components will require maintaining in a Blood Cold Chain System, appropriate for each component. Access and availability of safe blood and blood components require administration by medically competent personnel, who have the necessary skills and training for treating and managing field emergencies, which is an essential prerequisite in all deployed UN Missions. Current clinical data, comparing WB to transfused individual components, suggests that WB, used at POI, to treat haemorrhage, resulted in outcomes comparable to transfusions with component therapy comprising RBCs, Plasma and Platelets provided separately and FWB has a clear logistical advantage.
- 15. Clinical Use of Blood may be lifesaving and required in emergency settings due to acute haemorrhage and in some cases for non-trauma, medical reasons, such as complications of pregnancy or severe anaemia, such as due to complications of malarial infection. However, whether traumatic or non-trauma causes, massive haemorrhage remain the first cause of serious morbidity or death and transfusion is required as a medical emergency.
- 16. When bleeding is moderate and non-life-threatening, transfusion may be only required to prevent serious morbidity, depending on a patient's clinical condition.
- 17. Blood Transfusions, used correctly, can save life and prevent morbidity, however, the appropriate Clinical Use of Blood is dependent on education and training of all health care workers and the availability of adequate and accessible whole blood or blood components to treat blood loss or anaemia, which cannot be prevented or managed effectively by any other clinically recognized means, than blood transfusion.
- 18. Haemovigilance is necessary to identify and prevent the occurrence, or recurrence, of transfusion-related unwanted events, and to increase the safety, efficacy, and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. Haemovigilance systems may be established in many countries, however, it is recognized that there is a lack of effective Haemovigilance in many resource-limited settings, and implementation in such settings remains an important and challenging problem.
- 19. Transfusion of blood and blood products is a life-saving intervention. However, there are risks of adverse events associated with the donation of blood and its components, and with the transfusion of blood and blood products to patients. Adverse events include all reactions, incidents, near misses, errors, deviations from standard operating procedures and accidents associated with blood donation and transfusion. Learning from adverse events and identifying system problems can drive the introduction of measures to enhance the quality, safety, efficacy and cost-effectiveness of blood and blood products as well as of the donation and transfusion processes.
- 20. Blood units and components are transported and stored using constantly monitored Blood Cold Chain (BCC), within a quality system and meeting internationally recognized standards. Group O FWB, of unknown anti-A and anti-B titres, may be safer than attempting to X-match and blood group between donors and recipients, as risks of major mismatch are greater than transfusing very high titre group O, which titres are uncommon, to a non-group O recipient.
- 21. Low titre (anti A+B) Group O Whole Blood (LTOWB) units should ideally be included, in the supply of Group O whole blood, to UN Missions, in cases when ABO group specific blood is not available for immediate transfusion needs as a universal blood group donor.
- 23. Pre-registered volunteers as Walking Whole Blood Donors (WWBD) are pre-screened for: blood group, Rh type and screened for all recognized blood-borne pathogens. Group 0 should be screened for identification of all low titre A+B antibodies. Pre-screening should be repeated, at regular intervals, not exceeding 6months. Donated blood is collected with blood sample tubes, which, time permitting, must be re screened before transfusion and used as part of a Haemovigilance System.

- 24. Specimens from both donors and recipients are subject to comprehensive post-transfusion screening by a competent laboratory, a detailed record of the laboratory reports, patient's clinical records, reasons justifying the need for transfusion, monitoring charts and records of any adverse events and patient outcomes recorded and sent to UN HQ, to be summarized and included in a Haemovigilance System.
- 25. Pre-screened donors registered into the WBB Program are preferably composed of active duty, active reserve, active National Service, and other Department of Defence (DoD) beneficiaries.
- 26. FWB donors should be pre-screened, low titre O donors and those from blood groups A and B, who should be utilised for group-specific transfusions. FWB Donors who have not been fully pre-screened for Transfusion Transmitted diseases (TTDs) should be used when other donors are not available.
- 27. Transfusing FWB Group **O** with an unknown anti-A and anti-B titre, to a non-group O patient, is safer than attempting to accurately X-match blood groups between donors and recipients, in austere and difficult trauma situations, as high titres are rare, whereas the risk of haemolysis from a major mismatch is much greater.
- 28. **NOTE:** Patients of unknown blood group who receive group **O**, even if LTOWB should continue to receive LTOWB or group **O** RBC units for all further transfusions for at least 4 to 6 weeks as there will be continued presence of anti A & B circulation and this could cause an adverse reaction if RBC units from A or B were transfused.
- 29. FWB is reserved to treat a patient with life-threatening injuries, is clinically shocked or has evidence of a coagulopathy/bleeding (DIC), and SWB or relevant blood components are not available. FWB is not to be collected from pre-screened donors to maintain a routine inventory of SWB as it only utilised for emergency use only.
- 30. UN Clinics, TCC Level 2 and Level 3 Hospitals, authorised to provide support to UN Missions, for the UN WWBD strategy, are normally equipped with standard blood collection devices, materials and reagents and any other essential equipment as determined according to the risk assessment prepared by CMO and UN HQ; conforming to UN Quality Assurance Program and Haemovigilance System. This policy only applies to collection and processing of blood collected from WWBD at facilities authorised for the UN Walking Whole Blood Bank.

https://www.who.int/bloodsafety/Manual on Management,Maintenance and Use of Blood Cold Chain Equip ment.pdf



Ref.: Gifford SC, Strachan BC, Xia H, Vörös E, Torabian K, et al. (2018)

A portable system for processing donated whole blood into high quality components without centrifugation. **PLOS ONE 13(1):** e0190827. <u>https://doi.org/10.1371/journal.pone.0190827</u>

BLOOD ORDERING IN TIMES OF SHORTAGES

Principles to be followed when switching Blood Groups and Types due to Shortages

Group &Type	Principles to follow
	1. Use only O, Rh-negative if patient is sensitized to RhD.
O-negative	2. Use group O, D and Du -negative, C- and/or E-positive in preference to Rh(D)-positive.
	3. Avoid transfusing anything but O, Rh-negative to patients (ESPECIALLY FEMALES) under age 45.
	4. Restrict the use of O, Rh-positive blood for O, Rh-negative patients to
	acute emergency situations, and then use only if the patient either has a
	negative antibody screen or lacks Rh antibodies.
	5. If massive volumes of blood are required, and switching to Rh-positive
	is inevitable, avoid wasting O, Rh-neg blood by switching as early as
	possible. 1. Use only Rh-negative if patient is sensitized to RhD, i.e. Group-specific
	Rh-negative or O, Rh negative (as packed red cells, if possible).
A-negative	2. Use RhD & Du neg, C and/or E positive in preference to Rh(D) positive.
or	3. Avoid transfusing anything but Rh-negative blood to patients
B-negative	(ESPECIALLY FEMALES) under age 45.
	4. Restrict use of Rh-pos blood to acute emergency situations; then, use
	only if the patient has a negative antibody screen or lacks Rh antibodies.
	5. If massive volumes of blood are required, and switching to Rh-positive
	is inevitable, avoid wasting Rh-negative blood by switching as early as
	possible or from the start, & continue, in the case of males.
	 Conserve group O blood. Only group O can be given to a group O recipient.
	1. Use only Rh-negative if patient is sensitized to RhD.
	2. Use RhD and Du -negative, C and / or E-pos in preference to RhD.
	3. Group A blood may be used (as packed cells if possible) unless the
	patient has anti A1. The patient should, initially, be switched to group A,
then, secondarily, may be switched to group O unit.	
	Always do this before switching Rh types (see text).
AB-negative	4. Avoid transfusing anything but Rh-negative to patients
	ESPECIALLY FEMALES, who are, or will be able to become pregnant.
	5. Restrict the use of Rh-positive to acute emergency situations and then use only if the patient has a negative antibody screen or lacks Rh
	antibodies.
	6. If massive volumes of blood are required, and switching to Rh-positive
	is inevitable, avoid wasting Rh-negative by switching as early as possible.
	7. Conserve group O blood. Only group O can be given to a group O.
	1. A group O patient may receive only group O blood.
O-positive	2. Rh-negative may be used but this should be avoided, due to creating
A positivo	future supply problems.
A-positive or	1. Group O blood may be given (as packed red cells / plasma removed and replaced with additive solution – such as SAGM, when possible)
B-positive	2. Rh-negative may be used but this should be avoided due to supply
	problems.
	1. Group A blood may be used as packed red cells, if possible, as plasma
	with antibodies is removed (unless the patient is A_2B with anti- A_1). The
AB-positive	patient initially should be switched to group A, then alternatively, Group O.
	2. Conserve group O Blood as Only group O can be given to a group O.
	3. Rh-neg may be used but this should be avoided due to possible future
	supply problems.

ANNEX C. RECOMMENDATIONS

The following table provides DOS recommendations for blood stockpile requirements at different UN medical facilities in field missions, CMO and UN HQ addressed the issue of blood supply level in a **case-by-case approach**, relying of the risk assessment:

UN GENERAL ASSEMBLY [A/72/288] Seventy-second session Item 149 of the provisional agenda* Administrative and budgetary aspects of the financing of the United Nations peacekeeping operations; 4 th August 2017 TCC Level HOSPITAL 1; 2; & 3 Ref: UN GENERAL ASSEMBLY [A/72/288]. Link: http://undocs.org/a/72/288				
Medical Facility	Recommended Blood Stocks Level	Comments		
Forward Medical Team -AMET	Stored Whole Blood (SWB) [Warm Whole Blood (WWB) if stocks of SWB unavailable]	Massive haemorrhage due to trauma or a medical/clinical condition requires very URGENT and immediate response to control bleeding and replace blood loss with Whole Blood Transfusion, ensuring oxygenation and maintenance of normovolemia. Blood transfusions must be within the first hour after the injury. N Saline is used to establish a good intravenous line for Whole Blood Unit. [Colloids should not be used] TRANEXAMIC ACID (TXA) should be available and used as indicated under clinical supervision.		
TCC or UN Level	Stored Whole Blood (SWB)	Kits for collection WBB		
1 Clinic with damage control resuscitation (DCR) capacity	[Warm Whole Blood (WWB) if stocks of SWB unavailable] Red Cells Concentrates and Fresh Frozen Plasma Lyophilized Plasma if available Normal (Isotonic) Saline	Massive haemorrhage due to trauma or a medical/clinical condition requires very URGENT and immediate response to control bleeding and replace blood loss with Whole Blood Transfusion, ensuring oxygenation and maintenance of normovolemia. Blood transfusions must be within the first hour after the injury. N Saline is used to establish a good intravenous line for Whole Blood Unit. [Colloids should not be used]		

TCC or UN Level 2 hospital and Level 1 Clinic Recommended Stock Level: TOTAL: 10 UNITS SWB 5 units "Group O Rh pos" 5 units "Group O Rh pos" 5 units "Group O -Rh neg" Supplies for collecting 10 WBB TXA used under clinical supervision. Rapid Laboratory Test for Coagulopathy/DIC/Fibrinogen In Level 2 Hospital, transfusion of red cells is indicated in severe haemorrhagic shock as part of trauma life support and/or during damage control surgery (DCS) capacity TCC Level 3 and 4 Hospital UN approved Local Provincial, District or Referral Level Hospitals Locally available Blood and Blood Components which meet In Level 3 and 4 Hospitals, transfusion of red cells and components are indicated in severe haemorrhagic shock as part of trauma or severe bleeding due to clinical conditions for life support and/or during primary (definitive) Surgery. Wapproved Local Provincial, District or Referral Level Hospitals Locally available Blood and Blood Components which meet In Level 3 and 4 Hospitals, transfusion for life support and/or during primary (definitive) surgery. Referral Level Hospitals Cocmentrates (RCC) Fresh Frozen Plasma (FFP) Lyophilised Dried Plasma (LDP) Rapid Laboratory Test for Coagulopathy/DIC/Fibrinogen Platelet Concentrates Warm Fresh Whole Blood RECOMMENDED ADMINISTRATION RCC + FFP/LDP + PLATELETS Transfusion Ratio 1:1:1 Recommended Stock Level: Total: 20 UNITS comprising: 10 units "Group O Rh positive" 5 units "Group O Rh positive" 5 units "Group O Rh negative" Local availability and safety of a supply of blood and components must conform to UN Standards of safety and quality.			TXA should be available and used as indicated under clinical supervision.
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the UN Mission Medical Facility or a hospital blood bank and <u>clearly</u> marked:		No requirement for UN Missions to stock blood if UN Standards of safety and quality are met. If there are any concerns - arrangements must be made to provide blood and components to be held in in the UN Mission Medical Facility or a hospital blood	supply of blood and components must conform to UN Standards of
"For use by UN Mission"			

ANNEX D. TCC or UN LEVEL CLINIC / HOSPITALS (Level 1-3)

United Nations

A/75/121



Distr.: General 31 August 2020 Original: English

Seventy-fifth session

Item 154 of the annotated preliminary list* Administrative and budgetary aspects of the financing of the United Nations peacekeeping operations

Letter dated 31 August 2020 from the Secretary-General to the President of the General Assembly

Manual on Policies and Procedures concerning the Reimbursement and Control of Contingent-Owned Equipment of Troop/Police Contributors Participating in Peacekeeping Missions

- Appendix 1 page 78
 Chapter 3, annex C, appendix 1
 United Nations levels of medical support:
 <u>Basic-level</u> (first aid) requirements and standards.
- Appendix 4 page 85
 Chapter 3, annex C, appendix 4
 United Nations levels of medical support:
 <u>Level 1</u> (primary health and emergency care) requirements and standards.
- Appendix 5 page 87

Chapter 3, annex C, appendix 5 and appendix 5.1 United Nations levels of medical support: <u>Level 2</u> (basic field hospital) requirements and standards.

Appendix 4 page 95 Chapter 3, annex C, appendix 6 United Nations levels of medical support: Level 3 (advanced field hospital) requirements and standards.