STANDARDS-RELATED DOCUMENT

SRD-1 to AMedP-1.1

OPERATIONAL BLOOD SUPPLY MINIMUM STANDARDS AND TOOLKITS

EDITION A, VERSION 1

AUGUST 2026

NORTH ATLANTIC TREATY ORGANIZATION

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NORTH ATLANTIC TREATY ORGANIZATION (NATO)

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NATO LETTER OF PROMULGATION

6 August 2026

1. The enclosed Standards-Related Document, SRD-1 to AMedP-1.1, Edition A, Version 1, OPERATIONAL BLOOD SUPPLY MINIMUM STANDARDS AND TOOLKITS, which has been approved in conjunction with AMedP-1.1 by the nations in the MILITARY COMMITTEE MEDICAL STANDARDIZATION BOARD (MCMedSB), is promulgated herewith.

2. SRD-1 to AMedP-1.1, Edition A, Version 1, is effective upon receipt and supersedes AMedP-1.1-1, Edition A, Version 1, which shall be destroyed in accordance with the local procedure for the destruction of documents.

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4. This publication shall be handled in accordance with C-M(2002)60.

Thierry POULETTE
Major General, FRA (A)
Director, NATO Standardization Office

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CHAPTER 1 INTRODUCTION AND PRINCIPLES

1. This document supports STANAG 2939 (revision 2025) and outlines the NATO systems requirements for blood provision in operational settings, establishing a minimum standard to ensure interoperability, international collaboration among member nations and reduction of associated risk as low as reasonably practicable.

2. Blood supply and the systems in place to support its safe use are critical to sustaining life-saving medical interventions in deployed environments, and this document aims to harmonize approaches while respecting individual nations' adherence to their National standards.

3. The classification of blood supply systems outlined in STANAG 2939 is a foundational element, providing a structured framework to understand and manage blood supply in the operational context. Emphasis is placed on operational blood collection, addressing challenges such as maintaining supply chain integrity, ensuring blood safety, and mitigating environmental impacts.

4. Adaptability is a key focus, as operational settings often present unpredictable challenges, including supply chain disruptions, casualty surges, or environmental constraints. Associated risks, such as blood shortages or compromised safety standards, are identified, with strategies proposed to minimize their impact.

5. By defining shared terms and setting minimum operational standards, this document enables member nations to work cohesively, ensuring the timely provision of safe, effective blood and blood components in complex operational environments. The goal is to support military medical readiness, enhance coalition effectiveness, and support lifesaving intervention through robust and coordinated blood supply systems.

6. Non-conformance with the standards outlined in this document or associated STANAG 2939 must be recorded within nations' quality management systems and remain accessible according to their national regulations.

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CHAPTER 2 BLOOD SUPPLY RISK ASSESMENT

2.1 PURPOSE

The purpose of this chapter is to provide military medical planners and clinicians with an understanding of the risks associated with the use of blood and blood components in the deployed environment. It is to provide a reference to facilitate continuous review of clinical risks associated with blood provision and to act in an informed and controlled way to address risk, optimising donor and recipient safety.

2.2 SCOPE

This chapter relates to blood and blood components exclusively and does not include blood products regulated as pharmaceuticals[1].

2.3 CATEGORIES OF BLOOD

The following three categories define the systems from which blood and blood components are sourced.

a. **Category 1 blood**. Blood and blood components manufactured by NATO and PIAG[2] nations' licensed and/or registered blood establishments.

b. **Category 2 blood.** Blood and blood components collected in an area of operations by NATO and PIAG nations in compliance with the related document.

c. **Category 3 blood**. Blood and blood components **not** collected and processed by NATO or PIAG nations.

2.4 RISK PROFILE

1. In controlled and regulated hospital environments mature systems and specialised personnel are in place to lower risk associated with transfusion as low as reasonably practicable. This mitigation includes specialist laboratory oversight, component selection, disease screening, crossmatching, precise and accurate testing, assured transit and quality management systems designed for the management and assurance of blood. The absence of any of these systems increases the risk associated with blood transfusion.

[1] Some blood products may be classified as either pharmaceuticals or blood components depending on national regulations and can also change dependent on reconstitution / state (e.g. dried plasma). In such cases, national classification should be observed.

[2] PIAG - The Partner Interoperability Advocacy Group -PIAG- is an informal grouping of like minded nations established in 2015. The original seven signatories -Australia, Austria, Finland, Ireland, New Zealand, Sweden and Switzerland- represent their interests by advocating for interoperability between NATO. In the process of becoming NATO Allies, Finland and Sweden left PIAG in 2022, leaving the remaining five members -Australia, Austria, Ireland, New Zealand and Switzerland in charge.

2. Each category of blood listed in para 2.3 has a different risk profile which should be considered during planning. Considerations include: availability of trained laboratory staff; assurance frameworks; testing sensitivity; likelihood of transfusion transmitted disease; clinical effectiveness; population at risk; logistic constraints; and blood volume and availability.

3. A risk assessment of the blood supply is required during planning. Consideration of the population at risk, the recipient risk and the casualty estimates will assist in the identification of the most suitable blood source according to the acceptable level of risk.

2.5 RECIPIENT RISK IMPACT

1. Transfusion reactions are adverse events associated with the transfusion of blood and blood components. They range in severity from very mild to life-threatening and can occur during a transfusion, termed acute transfusion reactions, or days to weeks later, termed delayed transfusion reactions.

2. For a dynamic risk assessment, potential recipient adverse events should be classed according to impact as: very high (life-threatening), high (very severe reaction), medium (severe reaction), low (moderate reaction), or very low (mild reaction).

3. The risk of delaying or under transfusing a patient(s) should be balanced against the blood supply risk.

2.6 RECIPIENT ADVERSE EVENTS

Recipient adverse events may include the following.

a. **ABO incompatible transfusion** leading to acute haemolysis is a life-threatening and preventable transfusion risk. When ABO incompatible transfusion does occur, it is most often due to human factors and/or administrative error. All efforts should be made to ensure validated control systems are in place and available to mitigate ABO incompatibility in the deployed setting.

b. **Bacterial contamination** of blood and blood components can be life-threatening and can originate from either endogenous (from the donor) or exogenous (during collection and processing) routes. Processes should be in place to minimise contamination and reduce the likelihood of contaminated units being transfused.

c. **Blood transfusion after inappropriate transport or storage** can lead to severe and potentially life-threatening transfusion reactions. Blood and blood components must be transported and stored appropriately in systems validated for the specific purpose.

d. Other recipient adverse events to be considered include:

(1) **Haemolytic transfusion reactions** (non-ABO) can occur due to donor or recipient factors and may range from mild to severe reactions and should undergo investigation to confirm impact and origin.

(2) **Febrile non-haemolytic transfusion reactions**. A common and largely unavoidable adverse event and are more likely when using blood components that have not been leukoreduced. These reactions are generally mild and self-limiting.

(3) **Allergic reaction** are common adverse events and rarely may be life-threatening (anaphylactic). Consideration should be made to ensure regular monitoring of recipient to identify and treat anaphylactic reactions.

(4) **Transfusion associated circulatory overload** (TACO), is pulmonary oedema / respiratory compromise due to volume overload and develops within 12 hours of transfusion. It can occur after transfusion of relatively small volumes if there are patient risk factors.

(5) Other non-infectious adverse reactions such as transfusion related acute lung injury (TRALI) and transfusion associate graft versus host disease (TA-GvHD) are very rare, but can have severe clinical impact. The likelihood can be mitigated but not eliminated by an appropriately resourced clinical environment with established assurance systems in place.

(6) **Transfusion transmitted infection risk**. Transmission of infection by transfusion of contaminated blood or blood components can be reduced, but not eliminated by:

(a) Selecting donors with a low probability of infection (donor screening questionnaire and voluntary donation).

(b) Testing donors prior to donation (pre-screening personnel for EDP).

(c) Testing donor samples taken at time of donation.

(d) Meticulous cleaning of venepuncture site.

(e) Correct handling and storage of blood and blood components.

(f) Use of quality management systems to assure hemovigilance and traceability of blood or blood components transfused.

2.7 GENERATING A RISK PROFILE

1. In order to generate a risk profile, an assessment of impact of blood source to recipient against likelihood of an adverse event should be calculated and subsequently compared against a known risk appetite. An example of risk considerations aligned with impact and likelihood are outlined in Table 2.1 and Table 2.2.

2. Likelihood can be defined relative to delivery in a gold standard hospital environment. It should be interpreted according to absence of typical mitigation in the deployed setting. e.g. In a typical hospital setting with laboratory professionals crossmatching blood components the likelihood of an ABO incompatibility resulting in death would be very low. In a setting without adequate risk reduction the likelihood of ABO incompatibility will be increased.

Score	Impact	Criteria
5	Very High	life-threatening reaction, critical constraint on the quality of blood provision, limited component selection or availability.
4	High	Very severe reaction, significant constraint on the quality of blood provision, limited component selection or availability.
3	Medium	Severe reaction, major constraint on the quality of blood provision, volume or component selection.
2	Low	Moderate reaction, moderate constraint on the quality of blood provision, volume or component selection.
1	Very Low	Mild reaction, minimal constraint on the quality of blood provision, volume or component selection.

Table 2.1 - Risk impact scoring for blood planning criteria.

Score	Likelihood	Criteria
5	Very High	Almost certainly will occur
4	High	More likely to occur than not
3	Medium	Fairly likely to occur
2	Low	Unlikely to occur
1	Very Low	Extremely unlikely

Table 2.1 : Risk likelihood example scoring for blood planning.

3. An overall risk profile can then be calculated by multiplying the impact and likelihood scores. The higher the number the greater the risk. This can be compared against risk appetite and potential mitigation identified. An example is illustrated in Table 2.3.

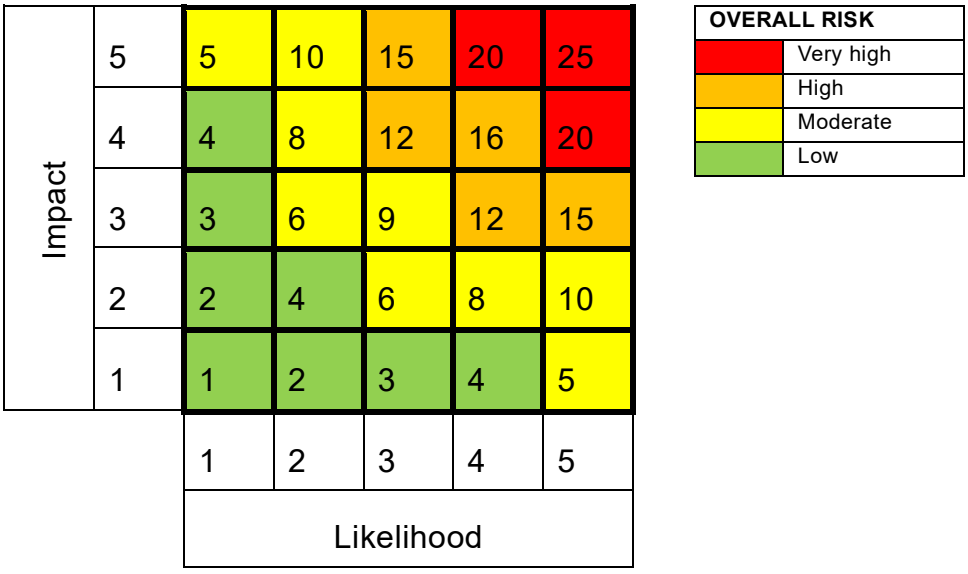

Table 2.2 - Example of matrix used to calculate overall risk from clinical impact and likelihood scores, to be weighed against risk appetite and potential mitigations.

2.8 RISK REDUCTION MEASURES

In order to select the most appropriate source of blood or to reduce risk, medical planners, competent medical authority and clinical users may identify actions, systems or personnel that may lower recipient risk. Risk reduction measures include, but are not limited to:

- use of validated systems that maintain and monitor temperature during transit and storage;
- use of universal blood and blood components, such as low titre O whole blood (LTOWB) and AB plasma;
- laboratory based testing with specialist laboratory personnel;
- use of pre-screened donors from an Emergency Donor Pool (EDP);
- systems to ensure hygiene during donor venepuncture;
- two-person administrative checks prior to transfusion;
- secure and robust logistic routes;
- ability to track individual components from point of donation to transfusion;

- supplementary specialist training; and
- digital systems to reduce opportunity for human error.

2.9 DONOR RISK ASSESSMENT

1. Risk to donor following blood collection applies to all blood categories and includes missed vein, hematoma (bruising), arterial or nerve puncture, vasovagal reactions, hypovolemia, allergic reactions, and infection.

2. Within the operational environment, planners and medical staff must consider the donor risk associated with category 2 blood.

3. In an optimised system, blood donation is a very low risk activity. However, poor donor care could result in additional casualties and reduce force effectiveness.

4. The occupational impact of donation should be considered. These may be:

- occupational regulations such as, fitness to fly following donation; and
- transiently impaired physiological reserve can occur.

2.10 CATEGORY 3 BLOOD SUPPLY RISK

Utilisation of Category 3 blood supply is likely to introduce **unknown risks** depending on source. As a result, consideration should be made for potential risks due to:

- increased frequency of unit contamination;
- differing volumes or quality of blood or blood components;
- inadequate storage leading to bacterial infection or degraded components;
- reduced ability to conform to standard hemovigilance procedures if donor identity cannot be readily traced;
- insecure or unvalidated transit routes or systems; and
- increased risk from directed and/or paid donation.

2.11 BALANCING TRANSFUSION, CONSENT AND CLINICAL RISK

1. Planners and clinicians should work together to support the trauma system with adequate blood supply, identifying and balancing risk in order to manage casualty volumes.

2. The risk associated with blood supply should be balanced against the indication for transfusion, including potential for harm due to withholding or restricting transfusion.

3. Consent for transfusion should be sought where possible.

4. All patients should be made aware transfusion has taken place during their treatment. If post transfusion surveillance and/or monitoring is required, clear details should be provided.

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CHAPTER 3 PLANNING CONSIDERATIONS FOR OPERATIONAL BLOOD SUPPLY

3.1 PURPOSE

This chapter is intended to provide guidance for efficient and effective blood supply on operations.

3.2 SCOPE

This chapter relates to blood and blood component supply. Critical adjuncts to transfusion such as tranexamic acid (TXA), Intravenous calcium and blood products regulated as pharmaceuticals must be considered alongside, supported by evidence based clinical guidelines.

3.3 GENERAL PLANNING CONSIDERATIONS FOR BLOOD SUPPLY ON OPERATIONS

1. Health logistic planners and the clinical team/staff are responsible to plan the blood supply in relation to risk of operation, logistical challenges, and donor pool, in short and long-term perspectives.

2. Careful consideration must be given to the source of blood used on Operations. Medical planners should consider the potential for military dependence on the civilian blood supply chain and the impact on civilian health services that this may cause.

3. The blood supply risk must be communicated to Commanders.

4. The Commander is responsible for risk management in relation to Military goal. The Commander must be clearly informed about casualty estimates and estimates of blood supply, including consequences of insufficient blood supply.

3.4 LOGISTIC PLANNING CONSIDERATIONS

For the purpose of planning blood supply for operations, the following principles will assist.

a. Blood planning is not limited to military infrastructure, assets and capabilities. Therefore, coordination with civilian blood supply networks is required.

b. Across the continuum of care, 20% of injured casualties will require transfusion at an average of 8 units of whole blood (WB) or whole blood

equivalent (WBE*[3]). This planning factor equates to 1.6 WB or WBE per injured casualty.

c. The distribution of blood across the continuum of care will depend on several factors, including evacuation time, medical treatment facility (MTF) capacity and casualty rate.

d. Supply and re-supply of blood and blood components into the area of operation will depend on modes and availability of transport, packing, rotation of assets, source of supply, and availability of temperature assured transports and storage.

e. Failure to fully satisfy demand for blood and blood components will impact survivability and operational effectiveness.

f. Table 3.1 contains a non-exhaustive list of a range of blood and blood components available. The storage times and conditions may differ from those illustrated. Components should be clearly labelled with storage conditions and shelf-life. Component manufacturers' storage advice should be followed.

[3] One whole blood equivalent (WBE) is composed of: 1 unit of Red Blood Cells, 1 unit of Plasma, 0.2 adult therapeutic dose of platelets, and 0.2 pools of Cryoprecipitate..

Product		Expiration	Storage Temp	Shipping Temp
Fresh Whole Blood (FWB)	CPD[1]	24 hours	1 – 25°C Avoid temperature extremes	1 – 25°C Avoid temperature extremes
	CPDA-1[1]			
Low-Titer O Whole Blood (LTOWB), Cold-Stored Whole Blood (CSWB)	CPD	21 days	1°C - 6°C	1°C - 10°C
	CPDA-1	35 days		
Red Blood Cells (RBC)	CPDA-1	35 days	1°C - 6°C	1°C - 10°C
	AS-5/SAGM	35-42 days		
	PAGGSM[1]	49 days		
Liquid Plasma (never frozen, LP)	CPD/ CPDA-1	5-40 days	1°C - 6°C	1°C - 10°C
Dried plasma		15-24 months	2-25°C	2-25°C
Fresh Frozen Plasma (FFP) / Plasma Frozen within 24-hrs (PF-24)		3 months-1 year 3 years	≤ -18°C ≤ -25°C	Remain Frozen
Cryoprecipitate (CRYO)		1 year		
Fresh Frozen Plasma (FFP)/ Deep frozen plasma		2-14 years	≤ -65°C	Remain Frozen (Dry ice)
Frozen RBC (FRBC)		10-30 years	≤ -65°C	Remain Frozen (Dry ice)
Deglycerolized (thawed) RBC		1-21 days	1°C - 6°C	1°C - 10°C
Cold-Stored Platelets (CSP)		14 days	1°C - 6°C	1°C - 10°C
Fresh platelets		4-7 days	20°C - 24°C	20°C - 24°C
Frozen platelets		1-6 years	≤ -65°C	Remain Frozen (Dry ice)

[1]CPD, CDPA-1, AS-5 defined: Citrate Phosphate Dextrose; Citrate Phosphate Dextrose Adenine; Additive Solution (Optisol),SAGM (saline, adenine, glucose, mannitol) PAGGSM (phosphate, adenine, glucose, guanosine, saline, mannitol)

Table 3.1 Non-exhaustive list of a range of blood and blood components.

3.5 DONOR PRINCIPLES

1. Collection of whole blood from pre-screened, approved donors should be prioritized.

2. Donor virus tests are valid for 12 months in the area of operations, if the health questionnaire doesn't imply any additional risk exposure. If available, rapid virus testing of donated units immediately prior to transfusion should be considered.

3. For universal pre-hospital use, WB blood group O donations are mandatory. Type specific blood donation can only be considered if blood type in recipient and donor can be definitively established.

4. Every effort should be made to ensure blood provision for patients as quickly and safely as possible.

5. Donations are voluntary, and donors can withdraw at any time without justification.

CHAPTER 4 BLOOD STORAGE AND TRANSPORT

4.1. PURPOSE

The purpose of this chapter is to outline the storage and transit conditions for blood and blood components and the areas within which blood is managed.

4.2. SCOPE

This chapter will cover the minimum requirements for the storage, transit and management of blood and blood components in order to preserve quality and functionality.

4.3. REFRIGERATED BLOOD AND BLOOD COMPONENT STORAGE

This section relates to the storage of blood and blood components in powered storage solutions.

1. Blood and blood components containing red blood cells (except for components prepared specifically for deep frozen storage), must be stored in validated storage systems at a core temperature of 1 - 6 °C. Storage duration is dependent on component type and specification.

2. Variation from the core temperature must be kept to a minimum during storage and distribution with removal from controlled temperatures restricted to short periods necessary for examining, labelling or issuing.

3. At ambient temperature, not exceeding 25°C, units can be out of controlled temperature for up to 4 hours, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue to allow core temperature to return to 1 - 6 °C. At higher ambient temperatures, time out of controlled temperature should be halved for each 5°C increment above 25°C.

4. At ambient temperature of less than 0°C, removal of units from storage should be avoided unless kept warm and used immediately. If units are exposed to temperatures of less than 0°C and haemolysis testing is available, units to be quarantined by placing in a secure refrigerator, tested, and if results within acceptable limits they can be released. If no haemolysis testing, units must be discarded due to the risk of haemolysis.

5. Internal temperature of storage equipment must be recorded as per national requirements and routinely monitored for deviation. There must be an alarm fitted to storage equipment with alternative power supply to alert users to temperature deviation or power failure. Appropriate actions on alarms should be defined.

6. Exceptionally, i.e. due to equipment failure, for temperature excursions where the core temperature has not exceeded 10°C or fallen below 1°C, components may be released for subsequent transfusion provided that:

- the component has been exposed to such a temperature change on one occasion only;
- the duration of the temperature change during storage has not exceeded 5 hours;
- a documented system is available to cover such eventualities; and
- adequate records of the incident are compiled and retained.

4.4. STORAGE OF FROZEN BLOOD COMPONENTS

1. **Frozen components**. Fresh Frozen Plasma should be stored in validated system at a core temperature of ≤ -25°C or below for a maximum of 36 months and transfused as soon as possible after thawing. If delay is unavoidable, the component should be used within 4 hours if maintained at 22°C±2°C or up to 120 hours if stored at 4°C±2°C.

2. **Cryopreserved** (deep frozen) components should be stored in a validated system at a core temperature of ≤ -65- - 90°C (typically -80°C) for a maximum of 48 months (platelets), 2 years (plasma) or 10 years (red cells and plasma).

3. **Thawed** components should be transfused as soon as possible after thawing (and subsequent deglycerolising in the case of red cells). If delay is unavoidable, the component should be used within 4 hours if maintained at 22°C±2°C (platelets), 24 hours to 21 days at 4°C (red cells), and up to 120 hours at 4°C (plasma). Timings are dependent on component specification quality control results.

4.5. BLOOD TRANSPORTATION

1. Transportation of blood and blood components must be under conditions that maintain integrity and quality at all stages. Transit systems should ensure that blood and blood components are transported as close to storage temperatures as possible.

2. Procedures for distribution should be validated to ensure the quality of blood and blood components throughout. All transportation and storage actions, including receipt and distribution, should be defined by written procedures and specifications. Packaging should maintain the integrity and temperature of blood and blood components during transportation.

3. A risk assessment should be performed to consider the impact of variables in the transportation process other than those conditions which are continuously controlled or monitored, e.g. delays during transportation, failure of cooling and/or monitoring devices, blood component susceptibility for quality reduction and any other relevant factors.

4. Due to the variable conditions expected during transportation, continuous monitoring and recording of any critical environmental conditions to which the blood component may be subjected should be performed, unless otherwise justified. Continuous monitoring is suggested during transit and storage to ensure shipped blood products remain at appropriate temperature and safe to administer. Deviation in surface temperature below 1°C must not occur and may only be up to 10°C for a single period no longer than 24 hours during transportation.

5. There should be a system to ensure stock rotation involving regular and frequent checks that the system is operating correctly. Blood and blood components beyond their expiry date or shelf-life should be separated from usable stock and quarantined until destroyed.

6. Records should be kept of the distribution of blood components between blood distribution hubs and final locations. These records should show the date of supply, unique component identifier and name of the blood component, the quantity received or supplied, name and address of the supplier or consignee.

4.6. GENERAL MANAGEMENT

1. General storage areas should be of sufficient capacity and provide for appropriately secure, segregated and orderly storage of different categories of blood and associated material i.e. Blood undergoing processing, returned or recalled, samples, reagents, packaging material or material in quarantine.

2. Blood should be physically separated from waste material at all times with access to all areas restricted to authorised persons.

3. Storage and processing areas should be designed or adapted to ensure appropriately validated conditions. In particular, they should be clean and dry and maintained within predefined ambient temperature limits.

4. Procedures for storage and distribution should be validated to ensure the quality of blood and blood components throughout. All transportation and storage actions, including receipt and distribution, should be defined by written procedures and specifications. Packaging should maintain the integrity and storage temperature of blood and blood components during distribution and transportation.

5. An alarm system should alert users in a timely manner to any excursion outside predefined limits. Provisions should be in place in the event of equipment failure or power failure in the main storage facility.

6. A risk assessment should be performed to consider the impact of variables in the transportation process other than those conditions which are continuously controlled or monitored, e.g. delays during transportation, failure of cooling and/or monitoring devices, blood component susceptibility for quality reduction and any other relevant factors.

7. Any event that may impact blood quality or integrity must be recorded and investigated.

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CHAPTER 5 CATEGORY 2 BLOOD SUPPLY – MINIMUM REQUIREMENTS FOR THE ROUTINE GENERATION OF AN EMERGENCY DONOR POOL

5.1. PURPOSE

This chapter is intended to provide guidance for personnel conducting and managing Emergency Donor Pool (EDP) screening sessions, in order to generate assured lists of donors that deployed military medical chains of command can be assured are of a minimum safe standard for category 2 blood, blood collected on operations.

5.2. SCOPE

1. This chapter outlines the minimum requirements for conducting an EDP screening session to generate an assured list of suitable donors that blood and blood components can be collected from on operations.

2. It will identify minimum test and donor information required to maximise interoperability and maintain both donor and patient safety, wherever possible, whilst adhering to the relevant regulatory standards for donor care and hemovigilance. It does not restrict participating nations from exceeding this minimum standard.

5.3. EMERGENCY DONOR POOL (EDP).

1. In order to reduce the risk of using blood collected on operations to as low as reasonably practicable, a list of pre-screened volunteer donors is used to select a suitable donor, this list is known as the EDP.

2. All EDP donors must consist of consenting adults who have voluntarily participated in a screening session and be informed of, and acknowledge the risk, testing requirements and responsibilities associated with the screening process and donor status.

3. Inclusion on EDP is valid for a period of up to 12 months from the date of screening.

4. **Emergency Blood Collection (EBC)** is the collection of blood from a donor in extremis for a known casualty. An EBC is conducted to provide a source of fresh whole blood (or blood components collected by apheresis, if available) for patients when blood or blood components are unavailable or have been exhausted.

5. EBC from members of an EDP, confer less clinical risk than non-pre-screened donors of transfusion reactions, disease transmission or harm to donor.

6. Individuals who are not part of an EDP and have not been pre-screened may be asked to donate fresh whole blood (FWB) in life-threatening situations where members of an EDP are not available. It is the responsibility of the attending clinician to select donor source based on risk to patient (see Chapter 1).

7. **Contingency blood collection** describes the process of collecting blood or blood components from donors with the intent of storage and subsequent issue.

5.4. EMERGENCY DONOR POOL SCREENING

1. The screening of EDP volunteers reduces the risk of unsafe blood being used in emergency situations and lowers the risk of harm to a donor. There are three screening methodologies employed to lower clinical risk as much as reasonably practicable:

- self-deferral;
- health questionnaire; and
- blood testing.

2. Volunteers may remove themselves from the process. They do not need to specify a reason for self-deferral and can do so at any time during the process without providing justification.

3. EDP screening sessions must include a donor questionnaire consisting of lifestyle and health related questions that may identify potential donor activities or exposures that increases risk or disease transmission to potential casualties or who may experience negative health consequences from donating blood.

4. The questionnaire is designed to defer potential donors whose blood may not be suitable for transfusion at the time of screening. Donor questionnaires should align with National blood establishment best practice where appropriate, as for donors for Category 1 blood.

5. The questions asked during a screening event are confidential, involving sexual practices, drug use and personal travel. It must be clear to all individuals involved that the screening process can be terminated, at the request of the volunteer (self-deferral), at any time.

6. Self-deferral criteria can be briefed collectively pre-screening to enable withdrawal without explanation or consequence.

7. Wherever practicable, separate spaces should be available for an EDP screening session.

a. A confidential area to allow for review of screening documents and promote honest medical in confidence discussion with potential donor.

b. A separate clinical phlebotomy area to allow clinical sample collection and labelling.
c. Processes should be in place to enable follow up of donors for whom issues are identified.

5.5. TESTING

1. Review of screening questionnaire and discussion is followed by the collection of a venous blood sample to determine ABO blood group, antibody status and for any transfusion transmitted infection (TTI). Sample labelling and integrity are critical in the generation of safe and reliable results. Test results are used to generate a list of eligible donors to form an EDP. The minimum testing requirements are as follows:

- ABO Group and Rh D status;
- HIV1 & 2;
- Hepatitis B;
- Hepatitis C; and
- for universal group O components, test Anti-A and Anti-B titre, if IgM>256 not be suitable as low titre donor.

2. Blood samples collected at a screening session must be transported to a laboratory via process that ensure sample viability and integrity. Use of accredited laboratories is preferential. The testing laboratory must have a quality management system in place. Potential Donors may be included in the pool if found to be negative for TTI.

3. Samples and associated documentation must be labelled with a unique identification number (e.g laboratory number or ISBT label) with the following four points of Identification legible in indelible ink:

- first and second name;
- date of birth;
- sex at birth; and
- identification number unique to the individual (e.g. Service number or social security number).

5.6. EMERGENCY DONOR POOL SCREENING SESSION

1. Screening sessions are intended to be coordinated and managed by suitably qualified and experienced personnel to ensure process integrity, donor safety and confidentiality.

2. To conduct a screening session, suitably qualified and educated medical personnel are essential. This training must be recorded, assured and updated every two years. The minimum requirements to generate an EDP are as follows.

a. A registered medical doctor must be available for clinical referral or to respond to a donor clinical event.

b. Personnel managing the EDP session and reviewing documentation must be able to coordinate groups of people effectively or be able to delegate appropriately. They must have had training that covers documentation, the

screening process and sample transit. This training must be recorded, assured and updated every two years minimum to ensure familiarity with amendments or updates.

3. Personnel involved with sample collection must be trained and certified competent in venepuncture.

5.7. EMERGENCY DONOR POOL DOCUMENTATION

1. The collection and retention of screening related documents is essential. This documentation is to be retained in accordance with medical in confidence policy for the minimum period required by national regulators.

2. Each EDP screening session must be given a unique number and referenced across associated documentation.

3. Documents may vary, but the EDP sessions leads must provide the following.

a. **Written donor Information leaflet** to ensure the volunteers attending a screening event are aware that screening is voluntary, and participants are able to withdraw their consent to participate at any time, with no explanation required, and without consequence. The information form must clearly state that the screening process is to identify potential donors. It should highlight the process and risks involved with participating.

b. **Personal data and samples statement**. The information form must state that individual participating in the screening event will have their personal information and blood collected for assessment, and the results of the blood tests will be disclosed to their military's medical team. If required, results may be disclosed to other entities (e.g. public health). An example of an information form can be seen at Annex A.

c. **Consent form** to provide documented evidence that individuals attending a screening event have been properly briefed, understand the process and risks involved and are participating voluntarily. An example of a consent form can be seen at Annex B.

d. **Suitability screening questionnaire** must be completed to determine potential risk factors related to lifestyle, health and travel. Questionnaires must be reviewed by a medical professional trained in interpretation.

5.8. EMERGENCY DONOR POOL GENERATION

1. Based on responses received to questionnaires and testing results, participants may be deferred (temporarily or permanently) from inclusion in an EDP. All participants should be allowed to provide blood samples for testing and must be informed of deferral via the medical chain of command.

2. Individuals responsible for the generation of an EDP list must be medical professionals registered with an accredited body and familiar with the process, documentation, result interpretation and experienced enough to interpret questionnaire responses and articulate risk of donor acceptance. They must have access to and be competent in the interpretation of geographical endemic diseases, temporary and permanent deferral criteria.

3. EDP reports may be generated for individuals or as a complete list of accepted donors. All reports must contain the following information.

   a. Date of Screening.

   b. Unique screening session number.

   c. Name: Last, First.

   d. Identification number unique to the individual e.g. service number or social security number.

   e. Date of Birth.

   f. ABO Group and RhD status.

   g. Deferral period if appropriate.

   h. Where tested for Anti-A and Anti-B titre, report should state ‘group O low titre’ (low titre threshold - IgM ≤256).

4. EDP reports must be forwarded to the associated medical authority in accordance with medical in confidence procedures. Where any additional testing is performed, this should be annotated on the report.

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CHAPTER 6 CATEGORY 2 BLOOD SUPPLY – MINIMUM REQUIREMENTS FOR ESTABLISHING AND CONDUCTING AN EMERGENCY BLOOD COLLECTION (EBC)

6.1 PURPOSE

This chapter outlines the minimal requirements for establishing and conducting an Emergency Blood Collection (EBC) in a military area of operations (AOO).

6.2 SCOPE

This chapter is intended for use by personnel involved in the setup and management of EBC in either a military medical treatment facility or in the pre-hospital environment.

6.3 EMERGENCY BLOOD COLLECTION - BACKGROUND

1. Emergency Blood collection is conducted to provide a source of Fresh Whole Blood (FWB) or blood components for named patients in extremis, when sources of cold-stored whole blood (CWB) or appropriate component therapy are unavailable or have been exhausted.

2. Blood drawn during an EBC is preferentially obtained from a group of pre-screened donors who form an Emergency Donor Pool (EDP) (See Chapter 3). Blood donated by non-EDP donors and transfused into patients increases the risk of adverse events including ABO mismatch and the transmission of transfusion transmitted infections (TTI) such as HIV or Hepatitis.

3. Patient safety is paramount and EBCs are inherently less safe than obtaining blood through licensed establishments. The risk of transfusing blood obtained through an EBC must be weighed against the patient's condition and should be evaluated by a trained and competent medical professional.

4. In situations where the ABO group of the recipient cannot be quickly or definitively established, blood should be drawn only from group O donors, preferably with low antibody titres (IgM ≤256).

5. In situations where the ABO group of both the donor and recipient can be definitively established, EBC collections of type specific FWB are appropriate to preserve utility of universal Group O donors.

6.4 EMERGENCY BLOOD COLLECTION - REQUIREMENTS

6.4.1. Personnel. To effectively conduct an EBC, trained and qualified medical personnel are essential. Training requirements are outlined in Chapter 8.

a. Minimum personnel required and their associated responsibilities are listed in Annex C.

b. Although there can be only one Trained Medical Authority, the number of Trained Medical Providers may vary substantially dependent upon the location of the event and personnel available.

c. The qualification levels and professions of both the Trained Medical Authority and the Trained Medical Providers may vary dependent upon the location of the event and the personnel available. It is recommended that the Trained Medical Authority is a physician, and the Trained Medical Providers are Nurses or Medical Technicians.

6.4.2. Facilities. EBCs can be performed in a wide variety of locations and facilities, from hospitals to austere battlefield settings. Patient, donor, and staff safety is of paramount importance, and this must be considered when selecting a location to conduct an EBC. Due to the wide variances in potential EBC locations, facility requirements must remain as recommendations to ensure unnecessary limitations are not imposed. Minimum recommended facility requirements can be found in Annex D:

6.4.3. Equipment. It is understood that specific brands or models of items will vary dependent on the host nation's facility. Equipment used must be in accordance with the form, fit, and function of the items listed. Minimum required equipment including example NATO Stock Numbers (NSN) is listed in Annex E.

6.4.4. Collection time. The maximum collection time to accept the donation should not exceed 15 minutes. Donations which exceed the maximum time period should be recorded and discarded.

6.4.5. Testing. Pre-transfusion point of care testing of FWB cannot be mandated due to the wide variety of circumstances under which an EBC may occur. However, if point of care testing is not performed, a mechanism is required to enable donor traceability and haemovigilance.

a. It is strongly recommended that, when possible and prior to the transfusion of the unit, point of care testing of donated units occur for, at a minimum, ABO group, HIV1+2, Hepatitis B, Hepatitis C.

b. Where practicable, samples of transfused blood should be aliquoted, frozen and sent for definitive TTI testing at a licensed testing facility.

c. Follow up testing of recipient should occur at intervals 1 month and 6 months.

6.4.6. Documentation: The collection and retention of transfusion related documents is imperative. The following documents must be completed and retained for a period of time consistent with the regulations of the lead nation conducting the EBC. These documents may vary according to the individual nations conducting EBC.

6.4.7. Consent Form: An appropriate consent form must inform the potential donor that their blood will be drawn for transfusion into a patient in extremis and is subject to TTI testing and results reporting. The risks to the donor of blood donation must be stated explicitly. A consent form may be completed prior to the activation of an EBC and may occur as far in advance as the initial event which created the EDP. An example consent form at Annex F.

6.4.8. Donor Questionnaire. A donor questionnaire must be completed prior to the collection of blood, with the intent of either accepting a potential donor, referring a potential donor for further screening, or deferring a potential donor from screening.

a. Donor questionnaires must seek to screen out individuals attempting to donate whose blood may not be suitable for transfusion. Minimum required questions for potential donors who are part of an EDP are listed in Annex G.

b. Minimum required questionnaire and risk evaluation for potential donors who are not part of an EDP and therefore have not been pre-screened are listed in Annex H.

c. The decision to defer or accept a potential donor with an answer of “Yes” to any of the listed questions except question one is the responsibility of the Trained Medical Authority. “Yes” answers must be investigated using the donor screening criteria of the lead nation conducting the EBC.

6.4.9 Blood Unit Tracking: A procedure must be in place to track a unit of blood from when it was drawn until after it has been transfused. Minimum required data for tracking purposes are listed in Annex 9.

6.4.10 Labelling: Labelling of blood bags and blood tubes should follow the International Society of Blood Transfusion (ISBT) format. If ISBT labels are not available, the blood bag should at minimum contain:

- unique donation number;
- product type;
- ABO Blood Type;
- date and time collected;
- date and time of expiry;
- details of additional testing: e.g. RhD status, viral testing; and
- Nation conducting collection.

6.4.11 Storage and Expiry: EBC can be stored at room temperature for up to 24 hours from the time of donation. If blood or blood components collected as part of an EBC are not utilised, and if infrastructure and systems in place for contingent blood collections, storage can be considered in line with Chapter 5.

6.4.12 Recipient Follow-up testing. TTI testing of transfusion recipients should occur at intervals not exceeding 1 month and 6 months and 1 year (if testing not performed at 6 months) following transfusion.

CHAPTER 7 CATEGORY 2 BLOOD SUPPLY – MINIMUM REQUIREMENTS FOR ESTABLISHING AND CONDUCTING A CONTINGENCY BLOOD COLLECTION (CBC)

7.1 PURPOSE

This chapter outlines the minimal requirements for establishing and conducting a Contingent Blood Collection (CBC) in a military area of operations (AOO). A CBC describes the process of collecting blood or blood components from donors with the intent of storage and subsequent issue. Whole blood is stored refrigerated, provided adequate blood storage infrastructure and assurance framework is available.

7.2 SCOPE

This chapter is intended for use by personnel involved in the setup and management of CBCs in a military medical treatment facility.

7.3 CONTINGENCY BLOOD COLLECTION - BACKGROUND

1. Blood and blood components collected with the intent to store can provide increased resilience of blood supply in situations where re-supply is neither possible or practical.

2. The time taken to generate blood and blood components by CBC should be considered when planning. CBC can be considered to mitigate the risk of delayed transfusion if a surge in casualty numbers is expected or interruption to routine supply occurs.

3. CBC collection may include donated whole blood or apheresed components.

4. Additional elements such as validated storage and governance systems are introduced to reduce risk as low as reasonably practicable.

5. The minimum screening, selection, donation and testing requirements outlined in chapter 5 and those relating to storage conditions outlined in chapter 4 apply to CBC.

   a. The risks to donor of CBC are similar to those for EBC.

   b. The risk to the recipient of CBC compared to EBC may be increased through protracted hold, number of donations being managed, and the number of donors being processed concurrently.

7.4 CONTINGENCY BLOOD COLLECTION - REQUIREMENTS

1. CBC is pre-planned and therefore every effort should be made for it to be carried out in a clinical area intended for the safe withdrawal of blood from donors. It should be appropriately equipped and staffed to address donors experiencing

adverse reactions or injuries associated with blood donation and sufficient to manage the anticipated volume and associated administration.

2. A collection location should be organised in such a way as to guarantee adequate interim storage, ensure the safety of both donors and workforce, to avoid errors in the collection procedure, administration, tracking of donations or confusion between donors, donated units, documentation and samples for testing.

3. The procedures employed must be documented and the environment that blood processed in secure, safe and clean in order to minimise the risk of interference or microbial contamination and maintain the integrity of donor data.

4. The procedure for blood collection should be designed to ensure that the identity of the donor is verified and recorded securely, and that the link between the donor and blood, blood components and blood samples is established clearly.

5. Donor identity must be confirmed immediately prior to venepuncture and a system of unique donation numbers. e.g. International Society of Blood Transfusion (ISBT) labels could be used to identify each donor records, samples and donation where available.

6. The procedure used for the labelling of records, blood bags, and laboratory samples with donation numbers should be documented and designed to avoid any risk of identification error and mix-up.

7. Significant effort and resource should be allocated to ensure traceability from donor to final recipient be maintained in as much detail as reasonably practicable. This data must be held securely for 30 years and accessible on request.

8. The maximum collection time to accept the donation should not exceed 15 minutes. Donations which exceed the maximum time period should be recorded and discarded.

9. The blood collection system should be checked immediately post donation for any defect.

7.5 HANDLING DONATED BLOOD

1. After blood collection, blood bags should be handled in a way that maintains the quality of the blood with storage and transport temperatures appropriate to the requirements for which the donated blood may be used.

2. Freshly collected blood should be placed in controlled and validated conditions as soon as possible after venepuncture. Freshly collected blood is to be stored at 4°C±2°C ideally within 8hrs but no more than 24hrs after collection and must not be exposed to ambient temperatures below 2oC or above 25oC during this transition period.

3. Storage conditions of blood collected by CBC should follow those in para. 4.3.

4. If donation and storage sites are not co-located donations and samples should be transported in accordance with procedures that ensure a constant approved temperature and secure confinement.

5. If samples for testing are transported independently of donations this should be in accordance with documented procedures and ensure a constant approved temperature and secure storage.

6. There should be validation data to demonstrate that the method of transport maintains the blood and samples within the specified temperature range throughout the period of transportation. Portable temperature loggers may be used to record the temperature during transportation of blood to the processing site for review on arrival.

7.6 DONATION TESTING

1. The absolute minimum testing requirement for CBC is assured ABO blood grouping. All efforts should be made to achieve the testing outlined below. Any deviation must be recorded and retained as previously described.

2. Testing of donations for blood group and infectious agents is a key factor in ensuring that the risk of disease transmission is minimised and that blood components are suitable for their intended purpose.

3. Category 2 blood drawn from donors who are not part of an established EDP and have therefore not been pre-screened will have blood samples drawn at the time of donation for ABO and transfusion transmitted infection (TTI) testing. Samples must be appropriately transported and stored to ensure viability until testing can occur.

4. Testing must be undertaken by suitably trained, experienced individuals competent in result sample management and result interpretation. All tests and equipment must be validated and have documented procedures in place prior to use. Testing equipment in use must reflect the volume of processing and minimise risk of data or transcription error.

5. Blood donations must have ABO group confirmed through a validated and assured process.

6. As a minimum blood donors should be tested at each donation for HIV-1/HIV-2, HBV and HCV. Additional testing may be indicated by screening documentation and undertaken, if available.

7. Where blood and blood components have had a single reactive screening test, the original sample should be retested in duplicate. Blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses HIV-1/-2, HCV or HBV should be excluded from use. They should be labelled as reactive and should be stored separately in a dedicated environment or destroyed. In the case of confirmed positive results, appropriate

donor management should take place, including the provision of information to the donor and follow-up procedures by the medical chain of command.

8. There should be a reliable process in place for transcribing, collating and interpreting results. The work record should identify the test(s) and methodologies employed so as to ensure that entries, such as the calculation of results, are available for review.

9. Laboratory test results which do not satisfy the specified acceptance criteria, should be clearly identified, to ensure that blood and blood components of that donation remain in quarantine.

10. The testing location must ensure that the expected standard of performance of the assays used is being achieved through the use of the appropriate Quality Control (QC) samples and the statistical monitoring of assay control and QC sample results.

11. Documented procedures must ensure that no donations, or components/products prepared from them, can be released for issue until all mandatory and any additional laboratory tests have been completed, documented and approved within a validated system of work.

7.7 DOCUMENTATION AND QUALITY MANAGEMENT SYSTEM

1. All documentation, test results and associated quality assessment data associated with a donation must be retained within a system that allows reach back of information and cross referencing. The system must allow the tracking of all units of blood from the point of donation to final location and fate inclusive of temperatures it has been exposed to throughout. This data must be held for a minimum of 30 years.

2. There must be a documented Quality Management System, suitably robust and supported that allows for the monitoring of data, the recall of units, incident investigation and quality improvement.

CHAPTER 8 CATEGORY 2 BLOOD SUPPLY – MINIMUM TRAINING CURRICULUM FOR PERSONNEL INVOLVED IN COLLECTING BLOOD IN OPERATIONS

8.1 PURPOSE

This chapter outlines the minimal training curriculum for personnel involved with Operational Blood Collection.

8.2 SCOPE

1. This chapter is intended as a minimum curriculum for personnel being trained in the collection of whole blood on Operations. It does not include training for supporting elements such as, laboratory testing, clinical management, apheresis component collections or quality assurance.

2. The coordination, management and collection of blood on operations is a complex process contributed to by multiple individuals not all of whom require a detailed understanding or competence of all aspects. For example, a combat medic collecting blood from a specified donor may not need to know the rationale of why that specified donor was selected, whereas the medical officer in charge of initiating the blood collection will.

3. All individuals involved must understand the part they play and how it contributes to overall assurance and safety.

4. Courses should be tailored to ensure adequate knowledge and competence is aligned to the role being performed.

5. It is suggested the training is delivered in modules and that nations decide what clinical employment group (CEG) are required to undertake each module.

8.3 BACKGROUND – WHOLE BLOOD COLLECTION

Whole blood collection on operations is a crucial capability that enables an additional layer of resilience of blood supply to support injured casualties. In order to be a safe and viable capability, a minimum training standard is required. This chapter outlines a suggested framework and nations can enhance training above this minimum standard as they deem appropriate.

8.4 FORMAT

All modules should include a theoretical knowledge element and a practical element. It is not possible to deliver adequate training through dependence on one element alone.

8.5 OBJECTIVES

Course objectives should include:

a. To be able to implement a whole blood collection session for the treatment of severely bleeding patients in an area of operations.

b. To be able to perform emergency blood collection from an Emergency Donor Pool or non-pre-screened donors.

8.6 MODULE FRAMEWORK

A modular framework should be used as follows.

a. Module 1 Blood collection.

b. Module 2 Donor selection.

c. Module 3 Donor consent and screening.

d. Module 3 Initiation of emergency blood collection.

8.7 CONTENT – THEORETICAL KNOWLEDGE

Theoretical knowledge should include the following subjects.

a. Rationale for the use of whole blood in the treatment of severely bleeding patients.

b. Constituents of blood and their function during bleeding to include:

   (1) Basics of immunohaematology, blood groups and antibodies.

   (2) Basic physiology and pathophysiology of blood clotting.

c. Use of blood transfusion for patients with severe bleeding to include:

   (1) Pathophysiology of haemorrhagic shock.

   (2) Monitoring bleeding patients.

   (3) Remote Damage Control Resuscitation (RDCR) principles.

d. Criteria for the collection of whole blood from the blood donors, including assessment of blood donors.

e. Practical aspects of implementation of Emergency Blood Collection (EBC) program, to include:

   (1) Establish and maintain an emergency donor pool.

   (2) Training of personnel.

   (3) Documentation, hemovigilance and regulatory aspects.

8.8 CONTENT - PRACTICAL

Practical content should include the following:

a. Rapid testing of blood type (ABO and RhD testing).

b. Familiarization with EBC equipment used in Nation(s).

c. Emergency collection of whole blood, to include donor care.

d. Autologous reinfusion of whole blood for training purposes can be considered to enhance fidelity of training, only if appropriate oversight and assurance measures in place.

8.9 ASSESSMENT AND REVALIDATION

1. A validated assessment to include theoretical and practical elements should be used to assure quality of training.

2. A EBC competency should be recorded and requires refresher training after 2 years.

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• ANNEX A. EXAMPLE DONOR SCREENING INFORMATION LEAFLET

An Emergency Donor Pool (EDP) is a list of **volunteer** blood donors that are available to donate fresh whole blood in urgent situations.

It is a Defence capability used on deployments only.

The EDP provides rapid access to blood donors when there is a clinical need.

To be part of an EDP you must complete a health screening questionnaire and have blood samples taken to confirm your blood group and to look for diseases that can be transmitted by blood transfusion.

NOTE - You cannot be on the EDP if:

You are HIV positive

You are HTLV positive

You are a Hepatitis B or C carrier

You have had an organ transplant or stroke

Health Screening Questionnaire

The EDP questionnaire covers your personal lifestyle, medical history and recent travel history.

All questions must be answered honestly and to the best of your ability.

Your responses will be reviewed by an EDP administrator with you present and additional questions may be asked.

Informed Consent

You will need to complete and sign the EDP questionnaire to confirm that you understand the process and consent to blood screening tests being undertaken. If you do not fully understand, then please ask.

This is a voluntary process and if you do not wish to continue you can remove consent at any time, even after the blood sample collection.

Blood tests

Blood samples will be taken and tested in accordance with Nation and NATO policy for:

Hepatitis B, C & E

Human T Lymphotrophic Virus (HTLV)

Human Immunodeficiency Virus (HIV)

Syphilis

Malaria

Other tests may be undertaken based on your responses.

All females will be tested for Human Leucocyte Antibodies (HLA)

EDP Inclusion

Trained clinical personnel will review your responses to the questionnaire, alongside the laboratory results, and decide whether you are eligible to be part of an EDP.

Responses to the questionnaire or positive test results may mean you will not be included in the EDP. You will be informed through your Medical Officer/Health Chain/Health Centre if this is the case.

Risks of Blood Donation / Phlebotomy

The blood donation process is not totally risk free and when donating whole blood the following may occur:

Fainting – 1 in 55

Bruising / Haemotoma – 1 in 200

Arterial bleed – 1 in 12,500

This is a voluntary process and if you do not wish to continue you can leave at any time.

Personal information

We are committed to protecting the confidentiality of donors and to meet our responsibilities under the Data Protection Act 2018.

A record of all completed questionnaires and results of any tests are retained securely for at least 30 years.

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• ANNEX B. EXAMPLE EMERGENCY DONOR PANEL CONSENT FORM

Consent for Donors Participating in Donor Screening Event

SN	Surname	Given name	DOB (yyyy-mm-dd)

Purpose

Emergency Donor Pools are comprised of informed, consenting individuals who have voluntarily participated in a screening event. These events involve the drawing of an individual's blood for ABO group, antibody, and transfusion transmitted infection (TTI) testing. A questionnaire consisting of lifestyle and health related questions is also completed, with the goal of creating a pool of eligible donors whose blood may be drawn as part of an Emergency Blood Collection (EBC).

Screening

As a participant for this Fresh Whole Blood Donor Suitability Screening Event, you will be asked a series of health and lifestyle-related questions to determine your eligibility to donate blood. These questions are asked to determine whether it is safe for you to donate blood AND for someone to receive your donation. Many of these questions are personal in nature and involve topics including sexual practices and history, drug use and travel history. If you do not wish to answer these questions, or are unable to do so truthfully, please do not participate in the Screening Event.

Testing and use of your blood samples

Prior to your acceptance as a pre-screened donor, your blood may be testing for the following:

Blood group (ABO and Rh)

Hepatitis B, C and E

Human Immunodeficiency Virus (HIV)

HTLV virus

Syphilis

West Nile virus

Chagas

Malaria

Collection, use, disclosure and retention of personal information

For the purposes of screening you as a volunteer donor, you will need to provide personal information such as your name, date of birth, contact information, service number and answers to health-related questions. Your personal information, including the test results from your blood samples, will be used to determine your eligibility to donate blood as of the date of screening and sample collection. If you are determined ineligible to donate, the Military Health Services Team will use your personal information to update its database of ineligible donors and track its members for follow up.

The Military Health Services Team may disclose your personal information as follows:

Your completed questionnaire will be retained in your medical record.

In the event that you are deferred from making a donation, the reason for this deferral and its duration will be noted in your medical record.

The Military Health Services Team will disclose any positive infectious disease results to public health authorities, as required by law.

The Military Health Services Team may disclose required personal information to other blood operators, foreign and domestic, to ensure the safety of the entire blood system.

The Military Health Services Team may disclose your personal information to others if authorized and required by law.

SN	Surname	Given name	DOB (yyyy-mm-dd)

Risks

There is a small risk of pain and bruising at the site where your blood has been collected, light headedness, fainting and, rarely, infection. If you have any concerns, please discuss them with your Health Care Provider.

Consent for collection of whole blood

I have read and understood the Information Sheet for individuals participating in a FWB Donor Suitability Screening Event.

I have been made aware of the responsibilities surrounding being a part of an Emergency Donor Pool.

I have had all my questions answered to my satisfaction.

I acknowledge and understand that I may withdraw or refuse consent at any time during the screening and collection process without explanation or consequence.

I understand that consent may be withdrawn anytime up until collection.

I consent to the use and disclosure of my personal information and the collection and testing of my blood as described in the Information Sheet for individuals participating in a FWB Donor Suitability Screening event.

I understand that the final determination of my eligibility to donate blood while deployed internationally is the sole responsibility of the Military Health Services Team.

Privacy notice statement

Personal information is collected under the authority of the National Defence Act and is protected pursuant to the provisions of the Privacy Act. Your information is required for the purpose of conducting a medical assessment as required for all blood donors. If you refuse to provide the information your medical suitability as a donor cannot be confirmed. The information collected is administered and disclosed in accordance with the Privacy Act and is retained in accordance with the Defence Subject Classification and Disposition System (DSCDS) Primary 6610.

HAVING READ AND FULLY UNDERSTOOD THIS CONSENT, THE INFORMATION SHEET FOR DONORS PARTICIPATING IN THE BLOOD PROGRAM AND THE PRIVACY NOTICE, **I consent to the collecting of my personal information through a questionnaire and taking**

Name:	
Date (yyyy-mm-dd):	Signature:
Military Health Services staff member name:	
Date (yyyy-mm-dd):	Signature:

samples of blood for testing. I further agree to answer questions asked of me during this event honestly and to the best of my ability.

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• ANNEX C. EMERGENCY BLOOD COLLECTION PERSONNEL REQUIREMENTS

Position (Required)	Responsible for:
Trained Medical Authority	The activation and stand up of the EBC as deemed necessary.
	The termination and stand down of the EBC.
	The overall conduct of the EBC.
	Final acceptance or deferral of donors.
Trained Medical Providers	The setup of materials and equipment.
	The verification of members of the EDP.
	The final screening of potential donors.
	The obtaining of consent from potential donors to collect blood.
	The collection of FWB.
	The labeling of blood bags and any samples collected.
	The appropriate documentation of blood collection and assurance of traceability.
	The care of donors pre, during and immediately post donation.
	The grouping of all blood units collected.
	The point of care testing of units collected for TTI.
	The aliquoting and shipping of samples for definitive testing.
	The releasing and tracking of all blood units collected.
Position	Responsible for:
Laboratory specialist (if available)	The grouping of all blood units collected.
	The point of care testing of units collected for TTI.
	The aliquoting and shipping of samples for definitive testing.
	The releasing and tracking of all blood units collected.

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• ANNEX D. EMERGENCY BLOOD COLLECTION FACILITY RECOMMENDATIONS

Facility Attribute	Rationale
Out of direct fire/fortified	Safety of patients, donors and staff.
Organized for flow of donors	Maintains the integrity of the screening and donation process, minimizes the possibility of clerical errors.
Private screening area	Allows for review of screening documents and promotes confidentiality.
Briefing/waiting area	Allows for donor briefings to be provided en masse and offers a comfortable space for potential donors to wait.
Phlebotomy area	Includes appropriate furniture for donors (phlebotomy chair, stretcher) and space for trained medical providers to function.
Laboratory area	To conduct grouping and point of care testing of blood units.

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• ANNEX E. SUGGESTED EMERGENCY BLOOD COLLECTION EQUIPMENT

Example NSN	Description	Qty/Donor
6508-99-260-8951	**Wipe disinfectant**	3
6510-21-907-7339	Sponge surgical absorbent gauze	5
6510-99-211-6996	Plaster self-adhesive	3
6510-99-161-4027	Adhesive tape*	4
6515-99-519-0465	Glove medical exam nitrile unpowdered non-sterile	4
6515-99-998-2299	Tourniquet iv/ phlebotomy latex free non-sterile*	1
6530-99-690-8727	**Blood collecting & transfusion set, donation volume 450 ml to 500 ml**	1
6515-99-001-9756	Scissors bandage 14.6cm lg (4.4cm cut)*	1
	Container, needle disposal, sharps, non-sterile, latex-free, w/needle unwinder*	1
	Marker*	1
	Unique donation number with blood bag label	1
6550-01-279-5285	ABO testing kit	1

Absolute minimum equipment required in **BOLD.** *equipment that can be utilised for more than one donation.

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• ANNEX F. SAMPLE DONOR CONSENT FORM

EMERGENCY BLOOD COLLECTION

An Emergency Blood Collection (EBC) has been activated to provide Fresh Whole Blood (FWB) for a critical clinical need.

You have been selected to be a donor because you were a previously a volunteer and have tested negative for all relevant screening tests and have agreed to be part of the Emergency Donor Panel.

To be a donor today you must:

Be a volunteer

Feel well

Complete a Health Screening Questionnaire

Consent for blood samples to be screened retrospectively

This is a voluntary process and if you do not wish to continue you can leave at any time.

Health Screening Questionnaire

The Health Screening questionnaire covers your personal lifestyle, medical history and recent travel history.

All questions must be answered honestly.

Informed Consent

You will need to complete and sign the Health Screening Questionnaire to confirm that you understand the process and consent to blood screening being undertaken.

If you do not fully understand, please ask.

Questionnaire Review

Trained personnel will review your responses and decide whether you can be a donor today.

Risks of Blood Donation

Donating Whole Blood is not totally risk free the following may occur:

Fainting – 1 in 55

Bruising / Haematoma – 1 in 200

Arterial bleed – 1 in 12,500

This is a voluntary process and if you do not wish to continue you can remove consent at any time, even after the bleeding process.

Blood tests

In addition to the whole blood donation blood samples may be taken and tested for:

- Hepatitis B, C & E
- Syphilis
- HTLV
- Malaria
- HIV

Personal information

We are committed to protecting the confidentiality of donors and to meet our responsibilities under the Data Protection Act

A record of all completed questionnaires and results of any tests securely for at least 30 years.

If you do not understand any part of the process, ask the EDP administrator.

Donor Declaration and Consent
To the best of my knowledge, I am not at risk of infection or of transmitting infections from my blood donation. I understand the nature of the donation process and the possible risks involved. I agree that my blood can be tested for HIV, Hepatitis B C & E, HTLV, Syphilis and any relevant discretionary tests. I understand that if my blood gives a positive result for any of these tests I will be informed via my senior medical officer and asked to attend for further confirmatory tests and advice. I agree to the Armed Forces and/or National Blood Service holding my personal details on their donor databases and processing this information as required for blood donation tracking.
Donor Signature **Date**

• ANNEX G. EMERGENCY BLOOD COLLECTION DONOR SCREENING QUESTIONNAIRE AND DEFERRAL CRITERIA

The following screening questionnaires and defer criteria should be used for all emergency blood collections. If EBC being performed on non-pre-screened donors, the additional questions listed in Annex H are required.

1	Do you wish to donate blood?	Yes	No
2	Do you feel well now?	Yes	No
3	Do you have an infection of any sort?	Yes	No
4	In the last 3 days have you had dental work?	Yes	No
Since being accepted on to the EDP have you engaged in <u>any</u> of the following activities:			
5	High risk sexual activity or sex in exchange for money or drugs	Yes	No
6	Have you taken illegal drugs with a needle (inc. steroids)		
7	Have you ever received a blood transfusion		
8	Had a tattoo in last 12 weeks?		
9	Donated blood in the last 8 weeks?		
Other			
10	In the last 7 days have you taken **any** medication*?	Yes	No
111	Are you breastfeeding or could you be pregnant (Females only)?	Yes	No

Medicine	Deferral Time	Comment
Containing Aspirin	Up to 5 days	Affects Platelet Function
Non-Steroidal anti-inflammatory (NSAID) (Diclofenac / Ibuprofen)	12 hrs	Affects Platelet Function
Steroids	7 days	If oral or injected ONLY

DONOR EVENT SINCE SCREENING	**ACTION**
No longer a volunteer	DEFER
Feels unwell	DEFER
High risk sexual activity	DEFER
Taken IV drugs – Received a transfusion	DEFER
Had a tattoo	DEFER
Has donated blood in the last 8 weeks	Hb TEST / DEFER
Had Aspirin/ Steroid/ NSAID medication in the last 7 days.	See deferral time
Pregnancy or breast feeding	DEFER

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- **ANNEX H. EMERGENCY BLOOD COLLECTION UNSCREENED DONOR ADDITIONAL SCREENING QUESTIONS**

If you are conducting an emergency blood collection (EBC) from previously non-pre-screened donors and there is no time to undertake pre-donation viral testing, then in addition to the pre-donation screening in ANNEX G you must also ask the following general lifestyle and health questions:

If the answer is yes to any question, then defer donation

1	Are you taking medication for blood pressure, stroke or heart, lung, kidney cancer or blood conditions?	Yes	No
2	Are living with Hepatitis B or C, HIV/ Aids or living with anyone with these conditions?		
3	Have you permanently been refused as a donor and told never to donate blood?		
4	In the last 6 months have you travelled to South America, Asia or Africa		

Note: The decision to defer or accept a potential donor with an answer of “Yes” to any of the listed questions is the responsibility of the Trained Medical Authority. “Yes” answers must be investigated by the Trained Medical Authority using the donor screening criteria of the lead nation conducting the EBC.

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• ANNEX I. MINIMUM REQUIRED TRACKING INFORMATION

	Donor Information
1	Name: Last, First
2	Service Number (if Military), ID Number (if Civilian)
3	Nationality
4	Date of Birth
5	ABO Blood Group and RhD type
6	ISBT label number or alternate unique number if used
7	Date and Time of Collection
8	Notes if blood was drawn from a donor not fulfilling predefined selection criteria
	Adverse donor reactions (if any)
	Recipient Information
1	Name: Last, First
2	Service Number (if Military), ID Number (if Civilian)
3	Nationality
4	Date of Birth
5	ABO Blood Group and RhD type
6	Date and Time of Transfusion
7	Adverse Reactions (if any)

SRD-1 to AMedP-1.1(A)(1)