## **Blood transfusion**

A manual for doctors, nurses and laboratory technicians

2010 EDITION

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## **Blood transfusion**

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## Foreword

This manual is intended for doctors, nurses, laboratory technicians and other health professionals involved in providing and administering blood in resource-limited health facilities.

We have tried to respond in the most practical way possible to the main questions and problems faced by health staff, using the recommendations of reference organizations such as the World Health Organization and the field experience of Médecins Sans Frontières. However, most countries have a blood transfusion policy and national recommendations should be taken into account when implementing blood transfusion activities.

In this manual, *blood* refers to *whole blood* and *packed red blood cells*. Other blood components such as platelet concentrates, fresh frozen plasma and cryoprecipitates, usually not available in the field, are not discussed.

The manual is divided into four chapters that cover risks related to transfusion and transfusion safety (Chapter 1), prescription and administration of blood (Chapter 2), blood donation and processing (Chapter 3) and implementation of blood transfusion activities (Chapter 4).

In addition, practical tools such as standard procedures for blood grouping and screening and examples of forms and registers are presented in the appendices and in the attached CD-ROM.

This manual addresses the minimum precautions required to ensure donor and recipient safety. Other techniques, such as detection of irregular antibodies, sensitive crossmatch procedures, determination of Rhesus and Kell phenotypes or leukofiltration, exist. Although rarely available in remote settings –thus not developed in this manual– these techniques should be used when available.

Despite all efforts, it is possible that certain errors may have been overlooked in this manual. Please inform the authors of any errors detected. The authors would be grateful for any comments to ensure that this manual continues to evolve and remains responsive to the reality of the field.

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## Abbreviations

Ab	Antibody	
AEB	Accidental Exposure to Blood	
Ag	Antigen	
BP	Blood Pressure	
BU	Blood Unit	
BT	Blood Transfusion	
DIC	Disseminated Intravascular Coagulation	
EDTA	Ethylen Diamine Tetraacetic Acid	
Hb	Haemoglobin	
NHFTR	Non-Haemolytic Febrile Transfusion Reaction	
PRBC	Packed Red Blood Cells	
QA	Quality Assurance	
RDT	Rapid Diagnostic Test	
RPR	Rapid Plasma Reagin (non treponemal syphilis test)	
RR	Respiratory Rate	
STI	Sexually Transmitted Infection	
TACO	Transfusion Associated Circulatory Overload	
TRALI	Transfusion-Related Acute Lung Injury	
TTI	Transfusion Transmissible Infection	
WHO	World Health Organisation	

CHAPTER 1

## **Blood transfusion safety**

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## 1. Introduction

Transfusion is an essential component of the management of life-threatening conditions such as decompensated anaemia or major haemorrhage.

Transfusion always carries risks for the recipient, related either to the transfused blood itself or to the patient's underlying condition. These risks are divided into 3 categories: immunological risks, infectious risks and other (non-immunological, non-infectious) risks.

In order to limit as much as possible the potential complications of transfusion, specific precautions have to be taken when collecting, processing and administrating blood:

- Donor selection is essential to reduce infectious risks.
- ABO Rh D grouping and compatibility testing are mandatory.
- Blood must be systematically screened for transfusion transmissible infections (TTIs). Screening for HIV 1 and 2, hepatitis B, hepatitis C and syphilis is mandatory, even in an emergency.
- Donors, blood units and recipients must be correctly identified and recorded.
- Patients must be closely monitored by trained staff during and after transfusion.

Despite these precautions, transfusion is still not totally risk-free; however, avoiding transfusion at any cost may be detrimental. Thus, it is the physician's responsibility to evaluate the risks and benefits of transfusion for each patient. Clear guidelines on indications help to prevent unnecessary transfusions. Transfusion, when clearly indicated, should be carried out without delay.

Transfusion safety is not limited to the above precautions. In addition, it must be ensured that:

- Transfusion is effective, e.g. the transfused blood has the required qualities to restore the patient's oxygen carrying capacity.
- Blood is used rationally to ensure that it will be available when and where needed. Unnecessary transfusions may cause a shortage of blood for patients in real need.
- Medical and cold chain equipment, consumable items and laboratory reagents of high quality are available to ensure that each step of the transfusion safety chain may be correctly implemented.
- All effective means to reduce or compensate blood loss (e.g. replacement fluids) are permanently available and used when indicated.

As transfusion of safe blood is a complex procedure, and blood a scarce resource, implementing all upstream measures (e.g. early management of anaemia, malaria, trauma or complicated pregnancies) that can reduce the need for transfusion is of critical importance.

## 2. Immunological risks

#### 2.1. Immediate immune reactions (< 24 b)

#### 2.1.1. Allergic reactions

About 2% of transfusions are complicated by mild allergic reactions. However, rare but severe anaphylactic reactions, may occur.

#### 2.1.2. Non-haemolytic febrile transfusion reaction (NHFTR)

Leukocytes in transfused blood may be targeted by the recipient's anti-HLA antibodies acquired through previous transfusions or pregnancy. Lysed leukocytes release pyrogens resulting in a febrile reaction<sup>1</sup>.

## 2.1.3. Acute haemolytic transfusion reaction (acute intravascular haemolysis)

Acute haemolytic reaction occurs when transfused red cells encounter naturally occurring antibodies in the recipient's blood. The antigen-antibody reaction triggers the lysis of transfused red cells, and possibly disseminated intravascular coagulopathy (DIC). The released haemoglobin can cause acute renal failure.

Ninety percent of immediate acute haemolytic reactions are caused by transfusion of ABO incompatible blood resulting from human error. The remaining ten percent are due to irregular antibodies from other blood groups (e.g. Lewis, P).

#### 2.1.4. Transfusion-related acute lung injury (TRALI)

TRALI is a rare<sup>2</sup> post-transfusion acute respiratory distress syndrome. TRALI is typically associated with plasma products such as fresh frozen plasma. However, it can occur in recipients of whole blood and packed red blood cells (PRBC) due to the residual plasma present in PRBC units.

#### 2.2. Delayed immune reactions

#### 2.2.1. Extravascular haemolysis

Extravascular haemolysis occurs when red cells are trapped and lysed in the spleen. The haemolysis is due to:

– Recipient's acquired antibodies to Rhesus, Kell, Duffy or Kidd.

In this case, transfused red cells are haemolysed.

or

 Hyperimmune anti-A or anti-B antibodies (haemolysins) from "dangerous group O donors".

In this case, recipient's red cells are haemolysed.

Extravascular haemolysis occurs 5 to 10 days after transfusion.

<sup>&</sup>lt;sup>1</sup> Leukofiltration, when available, reduces the frequency of NHFTR.

<sup>&</sup>lt;sup>2</sup> Estimated at 1:5000 transfusions, however the real incidence of TRALI is not established.

#### 2.2.2. Post-transfusion purpura

Anti-platelet alloantibodies developed by multiparous recipients destroy both the transfused platelets and the recipient's platelets.

Post-transfusion purpura develops within 5 to 12 days after transfusion. This condition rarely affects the patient's survival.

#### 2.2.3. Graft-versus-bost disease (GVHD)

GVHD can occur in newborns and in severely immune compromised patients. The T-lymphocytes of the transfused blood reject the recipient's tissues. GVHD is rare but fatal in half of all cases. The acute form (5 to 8 days post-transfusion) is always serious. The chronic form (3 to 4 weeks post-transfusion) may be reversible over a 4 to 6 week period. The risk of GVHD<sup>3</sup> increases with intra-family donation, especially in mother-to-child transfusion. For newborns and severely immune compromised patients, blood from a non-family donor or blood from a more distant relative than the mother (e.g. aunt or uncle) is preferred whenever possible in case of direct donation.

#### 2.2.4. Alloimmunization

As many different erythrocyte, leukocyte and platelet antigens exist, it is impossible to transfuse totally identical blood. Transfused blood inevitably introduces antigens that are foreign to the recipient. These antigens are called alloantigens. An alloantigen, introduced into a person who is lacking it, prompts an immune response including the production of specific antibodies to eliminate this alloantigen. This phenomenon is alloimmunization.

Alloimmunization against red cells refers to the development of specific blood group antibodies after the introduction of red cell antigens into a recipient who lacks these antigens. In transfusion practice, the most important alloantigens are those of ABO, Rhesus, Kell, Duffy and Kidd blood groups, as there are the most immunogenic.

Alloimmunization against leukocytes and platelets may also occur through the development of anti-HLA antibodies. This type of alloimmunization is quite common among multi-transfused patients and multiparous women.

The clinical significance of alloimmunization depends on the type and quantity of antigens introduced, the rate of their introduction, and the recipient's profile: sex (higher risk in women), immune status (higher risk in immune competent patients), and associated pathology (e.g. autoimmune disease).

Alloimmunization has consequences for the recipient's future transfusions and/or pregnancies.

<sup>&</sup>lt;sup>3</sup> Irradiating the blood is the only effective mean to prevent GVHD. Leukofiltration, when available, may reduce the severity of the reaction.

# 3. Blood groups and compatibility

A blood group is defined by the presence of an antigen on the red cell membrane. Persons who possess the same antigen belong to the same blood group.

Persons who do not express a given antigen may carry specific antibodies against the antigen. If the antigen is introduced by blood transfusion into such a recipient, then mild or severe haemolysis may occur. This defines blood incompatibility.

Patients to be transfused must only receive compatible blood, i.e. blood that will not carry the risk of haemolytic transfusion reactions.

Testing for compatibility in the two most important groups –ABO and Rhesus– is mandatory.

#### 3.1. ABO system

The ABO blood group is defined by the presence or absence of A and/or B antigens on the red cell surface. When either or both are absent from the red cell surface, the corresponding antibody(ies) is (are) present in plasma<sup>4</sup>.

Persons of group A	have A antigen on their red cell membranes and naturally occurring anti-B antibodies in their plasma.	
Persons of group B	have B antigen on their red cell membranes and naturally occurring anti-A antibodies in their plasma.	
Persons of group O	have neither A antigen nor B antigen on their red cell membranes and naturally occurring anti-A and anti-B antibodies in their plasma.	
Persons of group AB	have A and B antigens on their red cell membranes and no naturally occurring anti-A and anti-B antibodies in their plasma.	
	y reactions occur when the recipient's naturally occurring e transfused red cells that express the corresponding antigen.	
Persons of group A	may receive group A (identical) or group O (compatible) blood must <b>not</b> receive group B <b>nor</b> group AB (incompatible) blood.	
Persons of group B	may receive group B (identical) or group O (compatible) blood must <b>not</b> receive group A <b>nor</b> group AB (incompatible) blood.	
Persons of group O	may receive only group O (identical) blood must <b>not</b> receive group A <b>nor</b> group B <b>nor</b> group AB (incompatible) blood.	
Persons of group AB	may receive group AB (identical), or group A, or group B, or group O (compatible) blood.	

<sup>&</sup>lt;sup>4</sup> Except in children under 3 months of age (because they have not yet developed natural antibodies).

When ABO identical transfusion is not feasible, compatible blood with the fewest anti-A and/or anti-B antibodies should be transfused.

The administration of group O blood to a non-O recipient carries a risk of incompatibility between the antibodies of the transfused plasma<sup>5</sup> and the recipient's red cells. Transfusing O blood to non-O recipient must not be a routine practice and should be considered only when ABO identical blood is not available.

Thus, the rule is:

Recipient		Blood unit ABO group		
Recipient ABO group	1 <sup>st</sup> choice	2 <sup>nd</sup> choice	3 <sup>rd</sup> choice	4 <sup>th</sup> choice
0	0			
Α	Α	0		
В	В	0		
AB	AB	А	В	0

#### Transfuse only ABO compatible blood AND Favour ABO identical blood

#### 3.2. Rhesus system

The Rhesus system is the second most important system to consider when transfusing patients. It is made of 5 main antigens: RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e).

Antigen D is the most immunogenic antigen of the Rhesus system. The presence of antigen D defines Rhesus positive individuals. The absence of antigen D defines Rhesus negative individuals.

There are no naturally occurring Rhesus antibodies. These antibodies are always acquired through transfusion or during pregnancy and are developed by individuals who do not express the corresponding antigen (i.e. a Rh D negative patient may develop anti-D antibodies).

Incompatibility reactions occur when the recipient's acquired anti-D antibodies destroy the Rh D positive transfused red cells. Rhesus antibodies often cause mild and/or delayed haemolysis, but rarely immediate severe acute haemolytic reaction<sup>6</sup>.

The rule is:

#### Favour Rhesus D identical transfusion

<sup>&</sup>lt;sup>5</sup> Some O donors ("dangerous O donors") have acquired hyperimmune anti-A and/or anti-B antibodies, called haemolysins. These haemolysins, when highly concentrated, may induce haemolytic reaction after the transfusion of only one unit of ABO compatible, non identical blood.

When detection of anti-A and anti-B haemolysins is not routinely performed on all group O units and when these units are transfused to non-O recipients, it is advisable to transfuse PRBC, i.e. to minimise the amount of plasma transfused.

<sup>&</sup>lt;sup>6</sup> Rhesus antibodies can only be detected with laboratory screening and identification techniques that are complex to implement.

#### If Rhesus D identical blood is not available:

#### Rh D negative blood to Rh D positive recipient

Rh D negative blood may be transfused to Rh D positive recipient without immunological consequences, but only as second choice, since Rh D negative blood is rare and should be kept for Rh D negative recipients.

#### Rh D positive blood to Rh D negative recipient

Under exceptional circumstances (absolute emergency), Rh D positive blood may be transfused to an Rh D negative recipient:

- No immediate transfusion reaction is expected in Rh D negative men and women who have never been transfused or pregnant.
- Incompatibility reactions may occur if the recipient has developed acquired anti-D antibodies through previous transfusion or pregnancy. Since simple crossmatching cannot detect anti-D antibodies in the recipient, the risk of immediate transfusion reaction and ineffective transfusion is unpredictable.

Therefore, the decision to transfuse Rh D positive blood to Rh D negative patients must be a well-considered medical decision, taking into account not only the immediate risks but also the potential consequences:

- 1. The recipient has a high likelihood of developing anti-D antibodies: any future transfusions with Rh D positive blood may cause adverse events.
- 2. Rh D negative women are likely to experience obstetrical complications if they subsequently conceive Rh D positive children.

Recipient's Rhesus	Blood un	t Rhesus	
Recipient s Rilesus	1 <sup>st</sup> choice	2 <sup>nd</sup> choice	
Rh D positive	Rh D positive	Rh D negative	
Rh D negative	Rh D negative	See above	

Notes:

- It is useless and even counterproductive to administer anti-D immunoglobulin to prevent anti-D alloimmunization to an Rh D negative patient who has been transfused with Rh D positive blood. High doses of anti-D immunoglobulin would be required to achieve effective prevention, and these could even destroy the transfused Rh D positive red cells.
- Respecting Rh D compatibility rules does not exclude incompatibility reactions due to other Rhesus antigens. As is the case with anti-Rh D antibodies, anti-Rh C, anti-Rh c, anti-Rh E and anti-Rh e antibodies are acquired, and undetectable by simple crossmatch. However, alloimmunization caused by Rhesus C, c, E and e antigens is usually not of clinical significance, except in multi-transfused patients.

#### 3.3. Other group systems

Kell, Duffy and Kidd systems may be associated with severe transfusion reactions but cannot be tested in the field.

#### 3.3.1. Kell system

The Kell system consists of 2 main antigens: KEL 1 (K), KEL 2 (Cellano). The antigen KEL 1 is a rare, very immunogenic antigen. The presence of antigen KEL 1 defines Kell positive individuals. The absence of antigen KEL 1 defines Kell negative individuals. Kell antibodies are acquired and found among multi-transfused patients and multiparous women.

Anti-KEL 1 antibodies are responsible for haemolytic reactions, often mild and delayed. Since simple crossmatching cannot detect the recipient's anti-KEL 1 antibodies, the risk of transfusion reaction is unpredictable.

#### 3.3.2. Duffy and Kidd systems

The Duffy system consists of 2 main antigens: FY1 (Fya) and FY2 (Fyb). The Kidd system consists of 2 antigens: JK1 (Jka) and JK2 (Jkb). Anti-Duffy and anti-Kidd are rare, acquired antibodies found among multitransfused patients and multiparous women.

Anti-Duffy and anti-Kidd antibodies may be responsible for very severe haemolytic reactions. Since simple crossmatch procedures cannot detect these antibodies in the recipient, the risk of severe, but rare, transfusion reaction is unpredictable.

#### 3.4. Blood grouping and compatibility testing

#### 3.4.1. ABO and Rh D grouping

Determination of ABO and Rh D groups (see Appendix 15) is absolutely mandatory to ensure ABO and Rh D compatibility, but does not exclude incompatibility reactions related to other (non-tested) systems.

#### 3.4.2. Crossmatching

Crossmatching is a means to reduce immunological complications. It is a laboratory procedure that predicts if Ag-Ab conflict will occur during transfusion of a given blood unit. The technique consists in placing the recipient's plasma in contact with the red cells to be transfused.

A negative crossmatched blood unit means that there are no detectable antibodies in the recipient's plasma that may destroy the red cells to be transfused.

#### Simple crossmatch procedure - Tile method (Appendix 24)

It aims at detecting an incompatibility between the patient's plasma and red cells from the blood unit, due to agglutinating antibodies such as naturally occurring regular antibodies (anti-A, anti-B) and also some irregular antibodies (anti-Lewis a, anti-P).

#### Other crossmatch procedures

Women who have been pregnant and/or previously transfused patients should be targeted for more sensitive crossmatch procedures (at 37°C, in low ionic strength solution, test with antiglobulin) to detect non-agglutinating antibodies including anti-Rhesus, anti-K, anti-Duffy and anti-Kidd. These techniques may be available in some settings but, in general, are complex to implement.

The rule is:

#### Transfuse only negatively crossmatched blood units.

## 4. Infectious risks

Many pathogens present in donated blood can be transmitted to the recipient. In most cases, the recipient is infected by receiving blood from an infected donor. The donor selection process (history and clinical examination, see Chapter 3) and the routine screening of blood for infection markers can eliminate the vast majority of infected donations. However, despite these precautions, a residual risk of transfusing infected blood (e.g. human error, window period, test limitations, non-screened infections) persists.

#### 4.1. Bacterial infections

Bacterial infections may result from:

- transfusion of blood from an infected donor asymptomatic at the time of blood donation, or
- contamination of blood during collection (error in asepsis), or
- bacterial growth in the blood between collection and transfusion.

The severity of transfusion-acquired bacterial infection depends on the recipient's underlying condition, the type of bacteria, and the bacterial load.

#### 4.1.1. Septic complications

Bacteria found in blood units may be Gram-positive (e.g. *S. epidermidis*) and Gramnegative (e.g. *Klebsiella, Acinetobacter, P. aeruginosa, Y. enterolitica*: the last two are capable of multiplying between +2°C and +8°C). Gram negative bacteria are considered to cause the most severe septic complications, including septic shock.

To prevent septic complications, take measures to avoid contamination of blood during collection and to prevent bacterial proliferation<sup>7</sup>:

- Collect blood in a clean area, using an aseptic technique.
- Allow blood to sit for 2 to 4 hours between collection and refrigeration, if the temperature can be kept between +18°C and +24°C. This enables white blood cells to execute their bactericidal effect (see collection procedure, Appendix 10).
- Maintain and closely monitor the storage temperature of blood units.
- Start transfusion within 30 minutes of removing the blood unit from the cold chain.
- Administer each blood unit within 4 hours maximum.

#### 4.1.2. Syphilis

Blood must be routinely screened for syphilis (*Treponema pallidum*). The prevalence of syphilis among donors may be up to 15% in certain parts of Africa.

<sup>&</sup>lt;sup>7</sup> Additional methods to reduce bacterial contamination exist, such as diversion of the first 35 ml collected, or pre-storage leukocyte depletion filtration, but are rarely available in resource-limited settings.

#### 4.2. Viral infections

#### 4.2.1. HIV

Ninety percent of recipients transfused with HIV-positive blood are later found to be HIV infected, regardless of age, sex and type of component transfused. Therefore, screening blood for HIV is compulsory.

#### 4.2.2. Hepatitis B virus

The risk of hepatitis B virus (HBV) transmission is very high and varies according to the stage of infection in the donor. Screening donated blood for HBV surface Ag is mandatory.

In addition, it is recommended to offer hepatitis B vaccination to patients likely to receive repeated transfusions<sup>8</sup>.

#### 4.2.3. Hepatitis C virus

Hepatitis C virus (HCV) can cause severe liver disease in the long term. Screening donated blood for HCV must be routine practice.

#### 4.2.4. Other transfusion-transmissible viruses

Donated blood may also be screened for HTLV 1/2 (Human T- cell lymphotropic virus 1/2) and CMV (cytomegalovirus), depending on the context:

- In endemic areas, such as the Caribbean, blood is routinely screened for HTLV 1/2 by blood transfusion services, using ELISA tests. No rapid tests are currently available.
- While relatively harmless in immune competent patients, CMV is pathogenic in immune compromised patients. Transmission rarely occurs if the blood has been stored longer than 72 hours. In settings where CMV rapid tests are available, immune compromised CMV-negative patients should receive CMV-negative blood.

#### 4.3. Parasitic infections

In contrast to mandatory routine screening for HIV, hepatitis B and C and syphilis, screening for parasitic infections is performed according to the epidemiological context.

#### 4.3.1. Malaria

Plasmodium survives for at least 3 weeks in refrigerated blood. Therefore, the risk of acquiring malaria through transfusion of infected blood is high.

When malaria is highly prevalent, screening will detect many positive donors. On the other hand, routine exclusion of positive blood may lead to blood shortage. The decision to screen the donor's blood or to give an empirical antimalarial treatment to the recipient depends on the epidemiological situation in the area (see Chapter 3, Section 5).

<sup>&</sup>lt;sup>8</sup> Hepatitis B vaccination is also recommended for hospital staff at risk of blood exposure.

#### 4.3.2. Chagas' disease

In endemic areas (Central and South America), the prevalence of Chagas' disease can reach 30%. The likelihood of becoming infected through transfusion is 12 to 15% in low endemic areas, and can reach 48% in high endemic areas, e.g. Bolivia.

In endemic countries, blood transfusion services use gentian violet to inactivate trypanosomes within 24 hours. Screening tests should be used if available.

#### 4.3.3. African trypanosomiasis

The disease is endemic in certain parts of sub-Saharan Africa. Transmission by chronic asymptomatic carriers is possible, but rare. The CATT (Card Agglutination Test for Trypanosomiasis) detects antibodies against *T. b. gambiense* and should be used to screen blood in endemic areas.

#### 4.3.4. Visceral leishmaniasis (VL)

VL is endemic in 62 countries worldwide. However, the majority of cases occur in North- eastern India, Bangladesh, Nepal, Sudan, Ethiopia, and Brazil. In other countries, the disease is found in relatively small and localised foci or its prevalence is very low.

The risk of infection through transfusion is low and only a few cases of transfusionacquired VL have been reported in the literature.

However, since there is still a minimal risk, screening with the rK39 dipstick rapid test may be performed in endemic areas. Screening with the DAT test is not suitable in direct transfusion because of the time delay for the result (2 days).

Many other agents can be transmitted by transfusion but are not screened for, either because their importance in blood safety is only partially or totally unknown or because the necessary screening tests are not available or because the required testing technique is not feasible in many contexts.

## 5. Other risks

#### 5.1. Circulatory overload

Transfusion-associated circulatory overload (TACO) is cardiogenic pulmonary oedema due to high rates or volumes of transfusion.

Patients with cardiac or respiratory disease, elderly patients and children, are at a much higher risk of developing circulatory overload.

#### 5.2. Massive transfusion syndrome

Massive transfusion is defined as:

– The replacement of 50-100% of the total blood volume in 12-24 hours. or

- The transfusion of more than 4 units of PRBC within one hour in adults. or

– The transfusion of more than 20 ml/kg of PRBC within one hour in children.

Massive transfusion syndrome is a combination of:

- Hypothermia and hypoxemia
- Metabolic disorders: acidosis with hyperkalaemia due to potassium released by stored red cells<sup>9</sup>; hypocalcaemia due to the citrate contained in blood bags.
- Bleeding disorders due to dilution of recipient's coagulation factors and platelets, and lack of coagulation factors and platelets in stored, i.e. "non-fresh" blood.

In settings where calcium/potassium/coagulation/platelets monitoring is not feasible and specific blood components for treating massive transfusion syndrome (i.e. fresh frozen plasma and platelets) are not available, the only option to minimize the risk of massive transfusion syndrome is to use fresh whole blood, or at least, blood which has been collected within the past 2 days.

#### 5.3. Ineffective transfusion

Transfused red cells can be damaged during storage (storage lesions) or destroyed prematurely by antibodies not detectable at the time of transfusion, or by hypersplenism. In such cases, the benefice of transfusion may be less than, or shorter than, expected.

#### 5.4. Iron overload

In transfusion-dependent patients, repeated transfusion may cause an accumulation of iron in the body. This may lead to heart and liver failure.

For symptoms and management of transfusion-related complications, see Chapter 2, Section 5.

<sup>&</sup>lt;sup>9</sup> Plasma potassium concentration increases with duration of red blood cell storage.

CHAPTER 2

## **Blood transfusion** process

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## 1. Indications

#### 1.1. Severe anaemia

Anaemia is defined as Hb level lower than normal for age, sex and pregnancy state (see Appendix 1).

It results in a decrease in blood oxygen-carrying capacity. However, low Hb levels may be well tolerated<sup>10</sup>.

#### Decompensated anaemia

Transfusion is indicated when anaemia is decompensated, i.e. when the patient's oxygen carrying capacity is impaired to such an extent that vital organs, including brain, heart, and kidneys, are affected by tissue hypoxia.

Clinical signs of decompensation include: respiratory distress, tachycardia, altered consciousness, heart failure or coronary insufficiency or shock.

#### Transfusion thresholds (except for hereditary anaemia, see page 27)

The transfusion thresholds are the Hb values at which transfusion is indicated, even in the absence of clinical signs of decompensation. The WHO recommends the following thresholds:

Children	Transfusion is indicated if Hb < 4 g/dl	Transfusion is not indicated if Hb is <b>4</b> to <b>6 g/dl</b> unless there are signs of decompensation
Pregnant women < 36 weeks	Transfusion is indicated if Hb ≤ 5 g/dl	Transfusion is indicated if <b>Hb &lt; 7 g/dl</b> AND malaria, pneumonia or other serious bacterial infection or pre-existing heart disease
Pregnant women > 36 weeks	Transfusion is indicated if Hb ≤ 6 g/dl	Transfusion is indicated if <b>Hb &lt; 8 g/dl</b> AND malaria, pneumonia or other serious bacterial infection or pre-existing heart disease
Adults	Hb < 7 g/dl Consider transfusion in patients with severe malaria	

Adapted from the WHO, *Clinical use of blood*, 2005.

<sup>&</sup>lt;sup>10</sup> The clinical tolerance of anaemia is related to the speed at which it develops and to the patient's underlying condition. The more rapidly anaemia develops, the more likely the compensatory mechanisms to restore oxygen delivery will be overwhelmed, especially in patients with impaired cardiopulmonary function. Conversely, slow-onset chronic anaemia is usually well tolerated (except in patients with pre-existing cardiopulmonary disorders) since long-term compensatory mechanisms will have developed over weeks and months. However, many factors, such as fever, infection, haemorrhage or haemolysis can precipitate the decompensation of a well-tolerated anaemia.

In severe malaria, Hb level can drop by 2 g/dl each day. In children, the risk of death rises steeply below 4 g/dl.

The goal of red cells transfusion is not to normalize the Hb level but to relieve clinical symptoms of decompensation or prevent further decompensation in patients at high risk.

#### 1.2. Haemorrbage

Acute haemorrhage combines hypovolaemia and reduction in Hb in circulation.

Correction of hypovolaemia is the first priority. Crystalloids (0.9% sodium chloride or Ringer Lactate) are safer, cheaper and equally effective to colloids (Haemaccel®, Plasmion®, Gelofusin®). Blood should not be used to correct hypovolaemia.

Fluid replacement is usually sufficient to manage blood loss of Class I and II when combined with control of bleeding, oxygenation and other resuscitation methods.

The indication of transfusion is based primarily on clinical criteria. Transfusion is indicated if the patient remains haemodynamically unstable after initial adequate replacement with crystalloids. This happens when the blood loss is over 30-40% of the blood volume (i.e. blood loss of Class III and IV), or less if the patient's underlying condition prevents him compensating acute anaemia efficiently.

For assessment, classification of acute blood loss and indications for transfusion, see Appendix 3.

#### 1.3. Coagulation disorders

#### 1.3.1. Acquired disorders

Disseminated intravascular coagulation (DIC) is mainly seen in obstetrical complications (e.g. abruptio placenta, retained dead foetus), snake envenomation (viperids, crotalids) and severe infections (e.g. meningococcal and other bacterial septicaemia, malaria).

Management consists essentially of treating the primary cause of DIC and restoring platelets and coagulation factors by transfusion of *fresh whole blood*.

#### 1.3.2. Congenital disorders

Patients with congenital disorders of platelets or coagulation factors are at risk of severe bleeding during trauma, delivery or surgery and need specific blood components (e.g. cryoprecipitates, platelet concentrates) to correct their deficiency. They should be referred to a centre where these components are available.

In the event of haemorrhage, if referral is not feasible, transfusion of *fresh whole blood* may help to stop haemorrhage if the coagulation disorder is mild to moderate.

*Stored* (non-fresh) *blood* is not effective in correcting haemorrhage secondary to coagulation disorders.

#### 1.4. Special considerations

#### 1.4.1. Hereditary anaemia

#### Sickle cell disease

- Transfusion is indicated in:
- Severe anaemia: Hb < 5 g/dl or drop of 2 g/dl below the patient's baseline.
- Sequestration crisis with Hb < 6 g/dl (the objective is to reach 7-8 g/dl).
- Pregnant woman > 36 weeks with Hb < 8 g/dl.

#### Thalassaemia major

Thalassaemia major is a severe, transfusion-dependent anaemia.

The Hb target should be 10 to 12 g/dl.

Administration of iron chelating agents, such as deferoxamine, is essential for the treatment of chronic iron overload secondary to frequent transfusions.

Patients with thalassaemia intermedia usually do not require regular transfusions.

#### Glucose-6-Phosphate-Dehydrogenase (G6PD) deficiency

G6PD deficiency can cause acute or chronic haemolysis following severe viral and bacterial infections, ingestion of certain foods (e.g. fava beans) or exposure to various drugs (e.g. dapsone, nitrofurantoins, primaquine, sulfonamides, aspirin, chloroquine, quinine, chloramphenicol).

Transfusion is not required in most cases but is indicated in severe haemolysis.

#### 1.4.2. Severely malnourished children

In the absence of other explanations, a drop in Hb level within few days after admission suggests haemodilution (increase in plasma volume following oral or IV rehydration) and in itself is not an indication for transfusion.

According to the WHO, children with kwashiorkor may have redistribution of fluid leading to apparent low Hb, which does not require transfusion.

#### 1.4.3. Obstetrics

During delivery, normal blood loss is approximately 500 ml for vaginal delivery and 1000 ml for caesarean section delivery. If blood loss is not greater than normal and the Hb level was > 10 g/dl before delivery, blood transfusion is rarely necessary.

In the event of elective caesarean section, two blood units should be prepared and ready to be transfused<sup>11</sup> if the preoperative Hb level is < 8 g/dl.

#### 1.4.4. Surgery

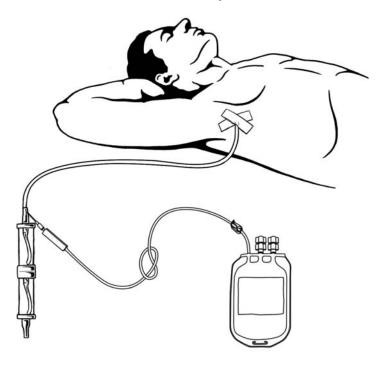
In healthy adults, the pre-operative Hb threshold depends on the patient's clinical tolerance of anaemia. However, be prepared for transfusion if Hb < 7 g/dl in a healthy adult undergoing major surgery or surgery with expected significant blood  $loss^{11}$ .

<sup>&</sup>lt;sup>11</sup> Have blood unit(s) ready for immediate use (compatible and crossmatched) but do not perform preventive transfusion.

In adults with low cardiac reserve (e.g. heart failure, coronary disease) or in elderly patients, an Hb threshold of 8-9 g/dl is usually recommended.

Notes:

- When a patient is referred to a surgical facility for elective surgery, it can be arranged that a compatible and negatively crossmatched donor selected from his entourage accompanies him in case the patient requires a transfusion.
- Recovery of shed blood may be an alternative to transfusion with donor<sup>12</sup>:
  - From sterile surgical sites: this requires experienced staff, adequate material (including a Cell Saver<sup>13</sup>) and carries a risk of infectious complications. It should be limited to life-threatening emergencies.
  - From a closed large haemothorax: requires experienced staff and adequate material. It can be done if the patient presents within 2 hours. The blood is collected from the chest tube in a blood bag, by inserting the needle of the collecting set in the rubber connector of the Heimlich valve, patient side (see Figure 1), and then transfused immediately.



**Figure 1** Blood salvage during haemothorax drainage

<sup>&</sup>lt;sup>12</sup> Autologous transfusion (transfusion with the recipient's own blood) is another alternative to blood transfusion with donor. Blood is collected from the patient prior to planned surgery and stored until used (pre-deposit autologous transfusion) or collected from the patient immediately before surgery and replaced by crystalloid/colloid solutions then restored to the patient at the end of surgery (acute normovolaemic haemodilution). Autologous transfusion has several limitations: not all patients are eligible; blood stored may not be sufficient to replace blood loss, thus, blood from a donor may still be needed; pre-deposit autologous transfusion of transfusion services (e.g. an adequate time period must be available to collect the blood units required); safety and efficacy of acute normovolemic haemodilution are controversial. In practice, these options are not commonly used.

<sup>&</sup>lt;sup>13</sup> Machine used intra-operatively to collect, wash, and filter blood so it can be given back to the patient.

#### 1.4.5. Severe burns

Burns initially do not bleed. In the absence of concomitant problems, such as trauma or profound pre-existing anaemia, burns alone do not call for a blood transfusion.

However, surgical interventions on burns, such as excision-grafting, may cause copious bleeding and therefore require preparation for possible transfusion.

## 2. Prescription

Only a physician is allowed to prescribe a blood transfusion. The physician is responsible for the following steps:

### 2.1. Request the patient's Hb level and determine the transfusion indication

Decision to transfuse is based on several parameters:

- Clinical tolerance of anaemia
- Coexistence of other pathologies (cardiovascular disease, pulmonary disease, etc.)
- Severity and speed of blood loss or of red cell destruction
- Haemoglobin level<sup>14</sup> (Appendix 14)

When transfusion is indicated, it should be carried out without delay.

## 2.2. Inform the patient of the need for transfusion and obtain verbal consent

Once the decision to transfuse has been taken, the patient or his legal representative has to be informed of the benefits/risks of transfusion.

The patient (and, for children, the legal representative) must give verbal consent for transfusion.

If the patient is unable to give consent (e.g. patient unconscious or incapable), the transfusion can be administered in the absence of consent if the physician considers it is in the best interest of the patient. In this event, the patient must be informed later on that he was transfused.

An adult, who is able to give informed consent, may refuse transfusion. In such cases, it is important to understand the reason for the refusal, to attempt to convince him to accept the treatment, and in case of continued refusal, to inform him of the consequences of his decision. Any transfusion refusal should be recorded in the patient's file.

However, emergency cases and cases involving children pose significant problems. The physician may challenge a patient or parent's refusal and balance the risk of over-riding this refusal with his duty to assist a person in danger. However, such cases remain exceptional.

#### 2.3. Request the patient's blood group determination

Even if the patient knows his blood group, blood group must be determined. See Appendix 15.

<sup>&</sup>lt;sup>14</sup> Recommended equipments for Hb measurement include manual haemoglobin photometers (e.g. HemoCue Hb 201+® or HemoCue Hb 301®) or automated haematology analyzers.

The patient's blood group can be determined once or twice. This decision depends on the likelihood of human errors during the blood grouping process (i.e. the risk of misidentification of patients, mislabelling of blood samples and misinterpretation of results).

In situations where the risk of errors is high (e.g. lack of training among staff, several patients to be grouped and transfused simultaneously, division of tasks between ward staff and laboratory staff), it is recommended to determine the patient's blood group twice, on two different samples. The second determination may allow detection of ABO Rh D discrepancies through comparison of the two results. If results are discordant, the patient's identity must be verified and a new EDTA tube must be drawn for further blood group determination.

When the risk of errors is limited, i.e. when *one patient* is to be transfused at a time and the blood grouping is performed on *capillary blood at bedside*, it is acceptable to perform a single determination. In this situation, the physician must validate the result.

*Note*: an EDTA tube is necessary for crossmatching (see page 34 and Appendix 24) and is drawn at this step of the process. All blood samples must be labelled with the patient's identity.

### 2.4. In the event of direct donation, ask for identification of a compatible blood donor

See Chapter 3.

## 2.5. Prescribe the blood product, the volume needed, the transfusion rate, indicate the urgency of transfusion

#### Choice of blood product

In most cases, the choice is limited to whole blood and packed red blood cells.

#### Packed red blood cells (PRBC)

PRBC are preferred:

- For patients with severe anaemia without hypovolaemia.
- For patients at risk of circulatory overload, i.e. those with cardiac or respiratory disease, elderly patients, and children.
- In the event of transfusion with non-ABO identical blood (see Chapter 1, Section 3).

If PRBC are not available, partial red cell concentrates (sedimented red cells) can be prepared from whole blood (Appendix 11).

#### Whole blood

*Stored whole blood* (i.e. kept refrigerated) is the most commonly used component. In stored blood, red blood cells keep their quality (oxygen carrying capacity, deformability) but platelets irreversibly self-aggregate at temperature below 16°C and coagulation factors are inactivated within 72 hours when stored at 4°C. When it is necessary to provide platelets and/or clotting factors, and if specific components are not available:

- Massive haemorrhages in surgical (including obstetrical) and trauma patients: if the volume of blood transfused within 12 hours reaches 50% of the total blood volume, stop to transfuse stored whole blood and administer *fresh whole blood* (blood freshly collected, for less than 4 hours, that has never been refrigerated).
- DIC: transfuse directly *fresh* whole blood.

#### Volume to be transfused

#### Adults

In a normal-size adult, one unit of whole blood or PRBC increases the Hb level by 1 to 2 g/dl.

Whole blood		
V (in ml) = (desired Hb – actual Hb)	<b>x patient's weight</b> (in kg) <b>x 6</b>	
PRBC		
V (in ml) = (desired Hb – actual Hb)	<b>x patient's weight</b> (in kg) <b>x 3</b>	

Calculation	Number of units to be transfused		
Whole blood			
Hb desired = 7 g/dl Patient's Hb = 4 g/dl Patient's weight = 60 kg Volume in $ml = (7 - 4) x 60 x 6 = 1080 ml$	2 units of 450 ml of whole blood		
PRBC			
Hb desired = 7 g/dl Patient's Hb = 4 g/dl Patient's weight = 60 kg Volume in $ml = (7 - 4) x 60 x 3 = 540 ml$	If centrifuged PRBC are available: 2 units of 300 ml of PRBC Where centrifuged PRBC are not available: Partially concentrated (sedimented) red cells from a 450 ml bag of whole blood correspond to a volume of 225 ml of red cells. In this example, administer: 2 units of sedimented red cells See Appendix 11		

#### Children

The volume to be administered is:

- In non-severely malnourished children:
   20 ml/kg of whole blood or 10 ml/kg of PRBC
- In severely malnourished children: 10 ml/kg of whole blood or 5-7 ml/kg of PRBC

See Appendices 6.1 and 6.2.

As the risk of circulatory overload is high, favour PRBC in order to reduce the volume to be transfused.

Close monitoring during and after the transfusion is critical as an increase in blood volume can precipitate or aggravate heart failure.

*Note*: routine administration of furosemide prior to transfusion in order to prevent cardiac failure or pulmonary oedema is not recommended. The decision to administer furosemide (0.5 to 1 mg/kg [maximum 20 mg] by slow IV injection) should be made on a case-by-case basis, according to the patient's clinical condition.

#### **Transfusion** rate

Transfusion should be completed within 3 to 4 hours maximum to limit bacterial proliferation at room temperature.

In the event of haemorrhagic shock, insert the blood unit into an inflatable cuff or a pressure cuff to increase the flow rate.

High infusion rates increase the risk of circulatory overload in patients with cardiac or respiratory disease, elderly patients, and children, especially severely malnourished children.

In children, the recommended transfusion rate is 5 ml/kg/hour (Appendices 6.1 and 6.2).

#### Urgency of transfusion

In urgent cases, blood is needed within 1 hour or less<sup>15</sup>.

In life-threatening emergencies, when the patient's blood group is unknown, the blood bank is allowed to issue O Rh D negative blood.

#### 2.6. Record all relevant information in the patient's chart

Record the reason for transfusion and the patient's Hb level and blood group. Record the prescription information: product, volume, rate, urgency, etc. Record that verbal consent has been obtained.

#### 2.7. Fill in a blood request form

The blood request form should provide all required information (Appendix 27). It is issued to the blood blank/laboratory in duplicate, along with the EDTA tube for crossmatching (and if relevant, 2<sup>nd</sup> blood group determination).

<sup>&</sup>lt;sup>15</sup> The minimum time required for a direct blood donation, including donor selection, blood collection, blood grouping, TTI screening and crossmatching is approximately 60 minutes when performed by experienced staff.

## 3. Delivery of blood units

The lab technician or the person in charge of delivering blood is responsible for the following steps:

## 3.1. Check the blood bank register for availability of ABO Rb D identical blood

Recipient	Blood unit ABO group			
Recipient ABO group	1 <sup>st</sup> choice	2 <sup>nd</sup> choice	3 <sup>rd</sup> choice	4 <sup>th</sup> choice
0	0			
Α	Α	0		
В	В	О		
AB	AB	А	В	0

If unavailable, check the availability of compatible blood.

Desirient's Dhasus	Blood unit Rhesus		
Recipient's Rhesus	1 <sup>st</sup> choice	2 <sup>nd</sup> choice	
Rh D positive	Rh D positive	Rh D negative	
Rh D negative	Rh D negative	See Chapter 1, Section 3	

For more information, refer to Chapter 1, Section 3.

#### 3.2. Inspect the blood unit

Inspect the blood unit for any abnormality. The blood unit and tubing should be intact with no visible leaks. The red cells should be dark red and the plasma bright yellow. Do not deliver units with visible clots, black, brown or purplish red cells, pink or pale plasma.

#### 3.3. Crossmatch the selected blood unit with the patient's plasma

For procedure, see Appendix 24.

Only negatively crossmatched units may be delivered.

Information on crossmatch (date, blood unit number, patient identification, result) should be recorded in a separate workbench register.

*Note*: crossmatch should not be omitted in direct donation.

#### 3.4. Deliver the blood unit in a vaccine carrier

The blood unit is provided together with:

- The delivery form (i.e. copy of the blood request form completed with information on the blood unit). See Appendix 27.
- A card for the bedside verification for ABO compatibility (Appendix 16).

## 4. Administration

The nurse is responsible for the following steps:

#### 4.1. Take delivery of, and inspect, the blood unit

The blood unit should be delivered in a vaccine carrier. If it is brought out of cold chain, check the time it was issued from the laboratory on the delivery form. Return the blood unit to the laboratory/blood bank if it has been out of cold chain for more than 30 minutes.

Inspect the blood unit for any abnormality. The blood bag and tubing should be intact with no visible leaks. The red cells should be dark red and the plasma bright yellow.

Return the blood unit to the laboratory if clots are visible; red cells are black, brown or purplish; plasma is pink or too pale, or if any other abnormality is observed.

Check the expiry date of the blood unit.

*Note*: if blood is not transfused within 30 minutes, it must be kept in the vaccine carrier or stored in a refrigerator.

### 4.2. Check the identity of the patient and match it with the prescription and the blood unit

A common cause of transfusion accidents is the transfusion of a blood unit that was intended for another patient.

In order to prevent these accidents, **at the bedside**:

Check the patient's identity. Ask the patient (or a family member if the patient is a child or is unconscious) to identify her/himself (first name, last name, age or date of birth). A double identity check (i.e. by 2 different persons) is recommended.

Patients who are unconscious or undergoing surgery and children should be identifiable, e.g. wearing a wristband with their name, surname and date of birth or medical file number.

- Compare the patient's identity with the prescription and the blood delivery form in order to ensure that the right patient gets the right blood.
- Check that the blood group indicated on the blood unit and on the delivery form is the same and corresponds to the patient's blood group.
- Check that the number of the blood unit corresponds to the number on the delivery form.

#### 4.3. Perform the bedside verification of ABO compatibility

Even if blood grouping has been performed on both the patient and the blood unit, ABO incompatibility accidents may still occur. These accidents are due to human

error, including blood specimens drawn from the wrong patient, blood units given to the wrong patient or labelling errors on tubes/blood units.

The bedside verification of ABO compatibility is performed just before transfusion (i.e. before installing the blood giving set on the blood unit). It is intended to verify one last time, at the patient's bedside, that the recipient's blood and the blood to be transfused are ABO compatible. See Appendix 16.

Keep the bedside testing card in the patient's file.

#### 4.4. Prepare a monitoring form and assess the patient's vital signs

See Appendix 7.

#### 4.5. Carry out the transfusion

For procedure, see Appendix 4.

 $\mathbf{X}$  Have basic resuscitation drugs and material at hand in case of adverse reactions.

*Note*: if venous cannulation is impossible, the intraosseous route can be used (see Appendix 5). This procedure is performed by the physician.

#### 4.6. Monitor the patient

The patient's condition and vital signs must be closely monitored throughout transfusion and thereafter in order to respond immediately in the event of adverse reactions.

During the first 15 minutes:

Stay with the patient in order to detect warning signs: fever, chills, flushed feeling, urticaria, pruritus, breathing difficulties, anxiety, pain or haemodynamic instability.

Assess the patient's condition and vital signs:

- 5 minutes after the start of transfusion.
- Every 15 minutes during the first hour.
- Every 30 minutes until the end of the transfusion; every 15 minutes in severely malnourished children.
- When the transfusion is completed and up to 4 to 6 hours thereafter.

The patient should be instructed to alert the nurse of any discomfort, malaise or unusual sensations. In an unconscious patient, the first manifestation of a transfusion reaction may be hypotension or haematuria or diffuse bleeding.

Alert the physician in case of warning signs, or if the patient's general condition changes (e.g. altered consciousness, agitation), or if vital signs are outside the normal range.

All information must be recorded on the monitoring form. Keep the monitoring form in the patient file.

Age		tory rate ns/min)	Pulse (beats/min)		Systolic blood pressure (mmHg)	
	Normal range	Alert threshold <sup>16</sup>	Normal range	Alert threshold	Normal range	Alert threshold
<1 month	30-60	> 60	120-160	> 160	> 60	≤ 60
2-11 months	30-40	> 50	80-120	> 140	70-90	
1-5 years	25-30	> 40	80-120	> 120	80-100	< 70
5-12 years	20-25	> 30	60-120	> 120	90-110	
> 12 years	12-18	> 20	60-100	> 100	100-120	< 80
Adult	12-20	> 25	60-100	> 100	110-130	< 60-80

#### Vital signs: normal values and alert thresholds

#### Urine output

If a urinary catheter has been inserted, urine output should be measured hourly. It should be:

> 30-60 ml/hour in adults

> 0.5 ml/kg/hour in children

> 1 ml/kg/hour in neonates

If there is no indication to insert a urinary catheter, check that the patient is voiding normally throughout the transfusion and for up to 6 hours afterwards. In case of doubt, notify the physician.

In the event of macroscopic haematuria, notify the physician. It can be related to the transfusion but may also be unrelated to the transfusion, i.e. due to the patient's underlying condition (e.g. acute haemolysis, malaria).

#### 4.7. Once the transfusion is completed

- Reassess the patient's condition and vital signs.
- Continue an infusion at a very low rate to keep the vein open.
- Inform the physician that transfusion has been completed and report the time on the monitoring form.
- Administer malaria and syphilis treatment if indicated (see Chapter 3, Section 5).

Checking post-transfusion Hb is not essential if clinical signs and symptoms of decompensated anaemia have been alleviated by transfusion.

<sup>&</sup>lt;sup>16</sup> Respiratory rate in malnourished children may be 5 breaths/minute lower than in healthy children.

## 5. Management of transfusionrelated complications

#### 5.1. Immediate complications (< 24 b)

5.1.1. Possible causes of signs/symptoms

Signs and symptoms	Most common causes	Less common causes
Fever with or without chills	<ul> <li>Patient's pre-existing infection</li> <li>Febrile non-haemolytic reaction</li> </ul>	<ul> <li>Acute haemolytic reaction</li> <li>Septic transfusion reaction</li> <li>Transfusion-related acute lung injury (TRALI)</li> </ul>
Urticaria, pruritus	<ul> <li>Allergic reaction</li> </ul>	
Hypotension or shock	<ul> <li>Patient's underlying condition (e.g. haemorrhage)</li> <li>Anaphylactic reaction</li> </ul>	<ul><li>Acute haemolytic reaction</li><li>Septic transfusion reaction</li><li>TRALI</li></ul>
Dyspnoea	<ul> <li>Patient's underlying condition</li> <li>Transfusion-associated circulatory overload (TACO)</li> </ul>	<ul><li>Anaphylactic reaction</li><li>TRALI</li></ul>
Pain	<ul> <li>Patient's underlying condition (e.g. trauma)</li> </ul>	<ul> <li>Acute haemolytic reaction (pain at venepuncture site, along the IV line; chest, back or flank pain)</li> <li>Anaphylactic reaction (abdominal cramping)</li> <li>TACO (chest pain)</li> </ul>
Haemoglobinuria	<ul> <li>Patient's underlying condition (haemolytic anaemia)</li> <li>Acute haemolytic reaction</li> </ul>	

#### 5.1.2. Initial management

During the early stage of a reaction, it may be difficult to determine the cause. In any case:

- Stop the transfusion but <u>keep the IV line open</u> with 0.9% sodium chloride.
- Notify the physician immediately.

- Recheck that the right blood is being transfused to the right patient, i.e. check the blood unit label and the patient's identity. If there is a discrepancy:
  - Check that other blood unit(s) administered in the same ward have been given to the right patient(s)<sup>17</sup>. If necessary, stop the transfusions temporarily until verifications are completed.
  - Notify the laboratory/blood bank.
- Assess the vital signs. If clearly needed, insert a urinary catheter.
- Look for bleeding at the venepuncture site.
- Draw a blood sample into an EDTA tube and a urine sample for further investigation (see paragraph 5.3).
- Do not throw away the blood unit; return it to the laboratory for investigation.

#### 5.1.3. Specific management

#### **ALLERGIC REACTIONS**

Within a few minutes and up to 3 hours after the start of transfusion:

#### Minor allergic reaction

#### Signs and symptoms

- Urticaria (usually associated with pruritus), with no other symptoms

#### Management

- Temporarily stop the transfusion.
- Administer H1-antihistamine (e.g. **promethazine** PO: children 2-5 years: 5 to 15 mg; children 5-10 years: 10 to 25 mg; children over 10 years and adults: 25 to 50 mg).
- It is possible to restart the transfusion if the patient is stable and no other symptoms are present after 30 minutes. This decision should be made by the physician.

#### Anaphylactic reaction

#### Signs and symptoms

- Breathing difficulties (dyspnoea, wheeze, fatigue, confusion, cyanosis) and/or airway obstruction (hoarse voice, pharyngeal/laryngeal oedema, stridor, bronchospasm) with, depending on the severity of the reaction, hypotension or circulatory collapse, tachycardia or bradycardia, altered consciousness.
- Nausea and abdominal cramping may be present.
- Skin and mucosal changes (erythema and/or urticaria and/or angioedema) are present in over 80% of anaphylactic reactions.

#### Management

- Stop the transfusion.
- High flow oxygen administration.
- IV fluid challenge: crystalloids, 20-30 ml/kg until normal haemodynamic parameters are obtained.

<sup>&</sup>lt;sup>17</sup> Check patient's identity, blood request/delivery form, concordance between the patient's blood group and the blood unit group and bedside verification of ABO compatibility card.

- Epinephrine IV:

Use a diluted solution (1:10 000 = 0.1 mg/ml) of epinephrine: add 1 mg of epinephrine (1 ampoule of 1:1000) to 9 ml of 0.9% of sodium chloride.

Children: 0.1 ml/kg (0.01 mg/kg) administered over several minutes

Adults: 1 ml (0.1 mg) every minute until BP, pulse and respiratory function have stabilized

If there is no response, start epinephrine infusion:

Add 1 mg (1 ampoule of 1:1000) of epinephrine to 1 litre of 0.9% sodium chloride to obtain a solution containing 1 microgram per millilitre.

Start the infusion at 5 ml/kg/hour, using a paediatric infusion set (approximately 0.1 microgram/kg/minute).

For example, 0.1 microgram/kg/min for a 60 kg patient: 0.1 (microgram) x 60 (kg) = 6 micrograms/min = 6 ml/minKnowing that 1 ml = 20 drops, 6 ml/min x 20 (drops) = 120 drops per minute Adjust the rate according to the clinical response.

A nurse or doctor must remain at the bedside as long as the epinephrine infusion is running.

No other drug should be added to the infusion.

No other infusions should be administered into the same vein.

- Inhaled bronchodilators: 2-10 puffs of **salbutamol** if bronchospasm does not respond rapidly to epinephrine.
- Corticosteroids have little place in the immediate management but are usually indicated to reduce the severity of the manifestations of the systemic inflammatory reaction and to prevent further deterioration.

**hydrocortisone hemisuccinate** slow IV or IM, every 6 hours for 24 hours or longer if necessary:

Children under 1 year: 25 mg/injection

Children 1-5 years: 50 mg/injection Children 6-12 years: 100 mg/injection

Adults: 200 mg/injection

Adults: 200 mg/injection

#### NON HAEMOLYTIC FEBRILE TRANSFUSION REACTION (NHFTR)

NHFTR is a common reaction in patients previously transfused and in women who have been pregnant.

#### Signs and symptoms

Within 4 hours after the start of transfusion:

– Chills followed by fever  $\geq 38^{\circ}$ C or a change of  $\geq 1^{\circ}$ C from pretransfusion value.

#### Notes:

- Always check pre-transfusion temperature as fever can be due to a pre-existing infection.
- Fever may also be the initial symptom of a more severe reaction such as haemolytic reaction or sepsis or TRALI.

#### Management

- Temporarily stop the transfusion.
- Administer paracetamol.

 Carefully restart the transfusion if no other symptoms are present. This decision should be made by the physician. If fever rises (≥ 39°C) or if the patient develops other symptoms, stop transfusion and look for another diagnosis.

#### ACUTE HAEMOLYTIC TRANSFUSION REACTION

#### Signs and symptoms

Within minutes of starting the transfusion:

- Anxiety, agitation, flushing, pain at venepuncture site and along the IV line, chest or flank pain.
- Fever, chills, tachycardia, hypotension, haemoglobinuria (dark urine) and uncontrolled bleeding due to DIC.
- Oliguria is common and is followed by acute renal failure.
- In an unconscious or anaesthetized patient, hypotension and uncontrolled diffuse bleeding might be the only signs of acute haemolytic reaction.

#### Management

- Stop the transfusion.
- Maintain the BP and renal flow (0.5-1 ml/kg/hour) in order to prevent renal failure using crystalloids at 20-30 ml/kg bolus.
- Reassess the patient and adjust according to clinical evolution.
- It might be necessary to induce diuresis, using **furosemide** IV at a dose of 0.5 mg/kg.
- If the patient improves but still requires blood, restart a transfusion with a new blood unit from another donor. There is no increased risk of a second haemolytic reaction provided that ABO compatible blood is transfused.
- If the patient does not improve (i.e. hypotension and oliguria still present), start an epinephrine infusion.

#### SEPTIC TRANSFUSION REACTION

#### Signs and symptoms

Within 4 hours of transfusion:

High fever ( $\geq$  39°C) or change of  $\geq$  2°C from pretransfusion value or hypothermia (< 36°C), rigors, tachycardia, drop or rise of  $\geq$  30 mmHg in systolic BP, nausea, vomiting.

In severe sepsis/septic shock: profound hypotension, mottled skin, altered consciousness, oligo-anuria.

#### Management

- Stop the transfusion.
- Perform blood cultures if available.
- Administer immediately broad-spectrum antibiotic therapy: ciprofloxacin PO or IV + gentamicin IV or IM or ampicillin IV + gentamicin IV or IM

According to severity:

- Oxygen administration
- Vigorous IV fluid resuscitation
- Epinephrine infusion as needed

*Note*: in the event of septic transfusion reaction during or after transfusion of a 100 ml unit (penta bag), all remaining 100 ml units prepared from the same 450 ml bag must be discarded.

#### TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

#### Signs and symptoms

During or within 6 hours after transfusion:

- Respiratory distress (dyspnoea, tachypnoea) and cough.
- Hypertension or normal BP, tachycardia, raised jugular venous pressure and peripheral oedema (e.g. puffy eyes, swollen hands).

#### Management

- Stop the transfusion.
- Sit the patient in an upright position.
- Administer oxygen.
- Administer furosemide by slow IV: Children: 0.5 to 1 mg/kg. Repeat after 2 hours if necessary. Do not exceed 6 mg/kg/24 hours. Adults: 40 mg. Closely monitor the patient and repeat as needed.

#### TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

#### Signs and symptoms

During or within 6 hours after transfusion:

- Rapid onset of dyspnoea leading to acute respiratory distress with hypoxemia.

- Cough, hypotension or normal BP.
- Fever and chills are reported, but may be absent.

#### Management

Treatment is that for respiratory distress syndrome from any cause: oxygen; mechanical ventilation often required. Symptoms may resolve in 24-48 hours.

#### Notes:

It can be difficult to distinguish between anaphylactic reactions, TACO and TRALI.

In anaphylactic reactions, respiratory difficulties are usually associated with mucocutaneous signs and symptoms (urticaria, pruritus, angioedema).

The risk of TACO is increased in children (especially malnourished children), the elderly and patients with pre-existing cardiopulmonary disease.

All other possible causes of respiratory distress must be ruled out before rendering a diagnosis of TRALI.

	TACO	TRALI
Temperature	Unchanged	Fever may be present
BP	Hypertension or normal BP	Hypotension or normal BP
Pulse	Tachycardia	Normal or tachycardia
Neck veins	Distension may be present	Unchanged
Chest X-ray	Normal heart size or enlarged heart Vascular congestion Perihilar oedema, Kerley's lines; pleural effusion	Normal heart size No vascular congestion Diffuse opacity; perihilar nodules and infiltration of the lower lung fields
Response to diuretics	Significant response	No effect Deterioration in hypotensive patients

Differential diagnosis between TACO and TRALI

#### 5.2. Delayed complications (> 24 b)

- Extravascular haemolysis: jaundice and anaemia, often preceded by a febrile reaction. This reaction is usually mild and self-limited. The treatment is symptomatic.
- Graft-versus-host disease: rare but can be fatal; treatment is supportive; there is no specific treatment.
- Iron overload in transfusion-dependent patients: chelating agents (e.g. deferoxamine).

#### 5.3. Investigating an immediate transfusion reaction

- According to the clinical presentation of the transfusion reaction:
  - Repeat the blood group (ABO Rh D) on patient's blood and on the blood unit.
  - Repeat the crossmatch.
  - Check for plasmatic haemoglobinaemia (pink plasma indicating free Hb in the patient's plasma).
  - Check for haemoglobinuria with a urine dipstick.

Plasmatic haemoglobinaemia and haemoglobinuria are suggestive of acute haemolytic reactions.

- Perform a chest X-ray.
- Perform blood cultures.
- Complete a transfusion reaction form (Appendix 8).
- Report all transfusion reactions to the Blood Transfusion Committee.

CHAPTER 3

## **Blood donation process**

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## 1. Ethical aspects

#### 1.1. Protection of donor's bealth

The donor's health should not be put at risk by donating blood. The objective of the questionnaire and physical examination are to detect potential problems that may contra-indicate a blood donation, either because of the donor's clinical status or medical history. Contra-indications should be respected.

Blood should not be taken too often during a given period (max. of 3 donations per year for women and 4 for men), nor in excessive volumes on a single occasion (maximum of 500 ml).

Hepatitis B vaccination should be offered to regular donors.

#### 1.2. Protection of recipient's bealth

The safety of transfusion for the recipient depends partly on the reliability of information provided by the donor in the questionnaire. The donor should be informed that, in the interest of the recipient, he may be excluded as a donor for reasons such as taking certain medications or having an infection that can be transmitted through transfusion.

#### 1.3. Informed consent of voluntary donors

Blood should be obtained from voluntary donors. No one must be forced to donate blood.

Donors must be informed that, and agree to:

- They might be excluded at any stage of the selection process for various reasons, e.g. medical history, high risk exposure to transfusion-transmissible infections, positive or doubtful screening tests, incompatibility with the recipient in the event of direct donation.
- Their blood will be screened to ensure that it is negative for at least HIV, hepatitis B and C and syphilis (and other tests when indicated).
- Their blood will not necessarily be used for their relative in case of replacement donation but for another patient, according to needs.

In general, verbal consent is sufficient. Written consent is required in some countries.

#### 1.4. Non-remunerated blood donation

The International Society of Blood Transfusion, the International Federation of the Red Cross and Red Crescent Societies and the WHO recommend that blood services should be based on non-remunerated blood donation, as remuneration carries the following risks:

- Remuneration of blood favours excessive blood donation, especially in low-income populations.
- Remunerated donors are not likely to respond truthfully to the questionnaire in order to avoid exclusion from donation.
- Studies show higher TTI prevalence rates among remunerated donors compared to non-remunerated donors.

However, in certain countries, the national policy is to remunerate donors or to provide them with incentives. In such contexts, it is essential to ensure that the remuneration/incentive system does not lead to abuse (e.g. excessive donation, collection from donors in bad physical condition) and that recruited donors are still low risk donors.

#### 1.5. Anonymous blood donation

The identity of the donor should not be disclosed to the recipient and vice versa. However, in the event of direct donation, the donor may be non-anonymous if he is recruited for the immediate needs of a patient in his close circle of acquaintances.

#### 1.6. Confidentiality

Personal information disclosed by the donor and tests results are confidential.

Donor's name, occupation, address or phone number may be recorded in a blood donor register for tracing purposes if required. This register must be kept in a safe place, under lock and key.

Donors' identifying information should neither be recorded in the blood donation register nor in the blood bank register (Appendices 25 and 26).

When feasible, in order to improve confidentiality, the person who collects the blood should not be the same one who tests it.

#### 1.7. Disclosure of results

The primary objective of routinely screening donor blood for TTIs is to provide safe blood to the recipient, not to diagnose these infections in the donor.

However, if donors are not informed of unexpected positive results, the opportunity to treat disease and/or prevent its transmission is lost.

Disclosure of results is a sensitive issue that must be considered when implementing blood transfusion activities. Check National Blood Policy on this topic.

Disclosure of positive results pose different problems according to which test is being considered:

Informing the donor of positive results for syphilis or malaria does not raise major issues: a single positive test is sufficient to offer treatment, these diseases are readily curable and the treatment is usually widely available.

With respect to HIV, the testing algorithm for selecting HIV negative blood differs from that used for diagnosing HIV infection in an individual:

- When diagnosing HIV infection in an individual, a first positive or doubtful HIV test is always followed by subsequent test(s) to confirm *seropositivity*. The individual makes an informed choice to learn about his or her HIV status, is aware of potential consequences, and a positive diagnosis is disclosed only when successive tests are clearly positive.

- In blood transfusion, a single HIV positive or doubtful screening test result is sufficient to exclude a donor or blood unit. When the result of the first test is clearly negative, a second test is performed on the blood unit only. The second test is intended to confirm that the blood to be transfused is *seronegative*.

The donor accepts that blood will be screened for the safety of the recipient and is aware that HIV diagnosis is not available through this screening process, as the test result that excludes the donor/blood unit cannot be interpreted as reliable evidence of infection.

Thus, donors who give blood in order to learn their HIV status should be referred to a Voluntary Counselling and Testing centre (VCT), intended to provide appropriate diagnosis, support and treatment, if needed.

When the national policy is to notify the donor of abnormal results, ensure that an appropriate process for notification and follow-up is in place, i.e.: the donor gives consent for disclosure before donation and understands that more tests may be necessary; a reliable diagnosis using appropriate algorithm can be offered; the diagnosis of HIV infection is disclosed only when the outcome of the testing process is unequivocal; confidentiality is ensured at all steps; and pre- and post-test counselling, and adequate treatment (if needed) are available.

## 2. Types of blood donation

The type of donation varies according to transfusion needs, capacity to store blood and the willingness of the population to donate blood.

#### 2.1. Voluntary donation

Blood is collected from voluntary donors who present to the donation centre or mobile collection sites on their own initiative, and who may become regular donors. A blood donor card can be issued for regular donors, with information on the blood group, donation dates and haemoglobin levels.

Collected blood is grouped, screened for TTIs, stored in a blood refrigerator, and supplied to wards or to external health facilities according to needs.

This type of donation is usually implemented by organised blood transfusion services (BTS) that supply blood to central/peripheral health facilities.

Hospitals that are not supplied by a BTS, or are insufficiently supplied, can recruit voluntary donors to establish their own blood bank.

Organisation of routine voluntary donor recruitment is appropriate when transfusion activity occurs on a regular basis. This system can only be implemented if the structure is able to store blood. Recruitment –and retention– of donors requires ongoing promotion of blood donation in the population.

#### 2.2. Direct donation

Where there is no blood bank, blood from a voluntary donor is collected for a particular patient in immediate need.

Blood is collected only if the donor's group is compatible with the recipient group and the donor's blood screens negative for TTIs.

Once the donor is approved, blood is collected and transfused to the patient.

Direct donation is typically the method used in small structures where blood transfusions are not regularly performed and where there is no external or internal blood supply service.

#### 2.3. Replacement donation

Relatives of patients transfused with blood issued from a blood bank are asked if they themselves would like to accept to donate blood. Bear in mind that:

- No one must be forced to donate blood.
- If families feel under pressure to donate blood, they may seek "professional donors". This is strongly discouraged.

Replacement donation can only be implemented in structures with blood storage capacity.

#### 2.4. "Walking blood bank"

Blood is collected from a pool of pre-identified, low risk, voluntary donors. Donors are called on demand, either because they have a rare blood group (e.g. O Rh D negative) or when there is a sudden increase in the need for blood.

A "walking blood bank" can be a temporary solution until a permanent service, i.e. a blood bank, is available. It can also operate in addition to a conventional blood bank.

Recruitment and retention of on-demand donors requires promotion of blood donation in the population.

## 3. Donor selection

See also Appendix 9.

The aims of donor selection are to provide blood as safe as possible for the recipient (e.g. by selecting donor at low risk of TTI) and to ensure that blood donation does not harm the donor's health.

"Professional" donors must not be recruited as they have a higher risk of being affected by HIV infection, hepatitis or syphilis.

The risk of TTIs is considered higher in donations from friends or relatives as, under family pressure to donate, potential donors may give false information during the selection process. However, this may be the only available option.

Voluntary non-remunerated donors are the safest group of donors. In some countries with high HIV prevalence, national programs favour high school adolescents (> 15 years old) as regular donors as they are the group with the lowest risk of TTI.

Recruitment of donors from the health staff is not recommended:

- It is particularly difficult to ensure the confidentiality of sensitive information, e.g. reasons for exclusion or tests results.
- The risk of stigmatisation of those who do not want or are unable to donate blood is high.
- It is difficult to ensure that the staff will not be solicited regularly.
- Direct donation by a member of the health staff, since it is not anonymous, may be prejudicial in the event of complication/death after transfusion. The recipient's family may well sue the donor, even if the complication is not attributable to transfused blood.

If a member of the staff wants to be a blood donor, he should be directed to another structure, which has no relation to the structure where he is employed. In this way, confidentiality of information and donor anonymity may be guaranteed.

#### 3.1. Pre-selection process

The pre-selection process aims at protecting the donor. Pre-selection criteria include age, weight, time since last donation, Hb level, and for women, pregnancy and lactation. Refer to the relative and absolute contraindications for blood donation on the following page.

#### 3.2. Pre-donation questionnaire

The questionnaire may help identify high-risk donors, thus minimizing the risk of collecting infected blood. It is estimated that 25% of potential donors are excluded on the basis of their history.

The interview should take place in an area where privacy is assured. The donor's name should not be recorded on the questionnaire. Answers are confidential.

The staff must ensure that the donor understands the questions and why they are asked.

The questionnaire should not be skipped in an emergency situation or due to a concern that the potential donor will change his mind if questioned on his personal history.

Questions regarding high-risk exposure (e.g. unprotected casual sex, multiple partners, IV drug use) should be asked with a non-judgemental attitude.

At any moment, the donor can self-exclude if he does not wish to answer.

The reason for exclusion should be given if the donor requests it.

The questionnaire can be adapted at the discretion of the blood transfusion committee. If questions regarding high-risk exposure are not explicitly asked, the donor should be informed about those "high risk situations" that contra-indicate blood donation, and should be able to self-exclude.

#### 3.3. Physical examination

All donors should be in good physical condition. The physical examination is brief:

- Measure temperature, pulse and blood pressure.
- Look for:
  - jaundice (conjunctiva)
  - cervical, axillary and inguinal lymph nodes
  - skin rash
  - oral thrush

The physical examination can be performed by a nurse provided that s/he has been specifically trained for this task. The potential donor must be referred to the physician in the event of abnormality on clinical examination.

*Note*: in the event of mobile blood collection, the pre-selection criteria are the same (including Hb level) and the questionnaire is still required but can be simplified.

#### 3.4. Contraindications for blood donation

		ABSOLUTE	RELATIVE
PRE-SELECTION	Age	< 15 years and > 65 years	
	Weight	< 45 kg	If 45 to 50 kg, collect a smaller volume (150 or 250 ml)
	Pregnancy	During pregnancy and up to 6 months after delivery or miscarriage	
	Breastfeeding	Exclusive breastfeeding	Mixed feeding: collect blood if child is > 1 year
	Last blood donation <sup>18</sup>	< 2 months	If < 3 months, collect a smaller volume (150 or 250 ml)
	Hb level	< 11 g/dl <sup>19</sup>	If < 12.5 g/dl, collect a smaller volume (150 or 250 ml)

<sup>&</sup>lt;sup>18</sup> Men: max. 4 blood donations/year if Hb > 13.5 g/dl; women: max. 3 blood donations/year if Hb > 12.5 g/dl.

<sup>&</sup>lt;sup>19</sup> Supplement with ferrous sulfate + folic acid.

		ABSOLUTE	RELATIVE
	Occupation	Sex workers	Military, drivers, itinerant workers
	Chronic illness	HIV, hepatitis, active TB, blood disease, epilepsy, insulin dependent diabetes, cancer	Refer to the physician if other chronic illnesses (e.g. pulmonary, cardiac).
	Current treatment		Antibiotics, anticoagulants, cardiovascular drugs (ß-blockers, anti-arrhythmics, etc.), insulin Live attenuated vaccines (e.g. yellow fever, oral polio) within the last 2 weeks. Refer to the physician.
	History of		
X	<ul> <li>Dental procedure</li> </ul>	< 3 days	
HISTORY	<ul> <li>Recent fever</li> </ul>		Refer to the physician if fever within the 3 last weeks.
H	- Confirmed malaria	Within the 3 last weeks	Positive malaria test <sup>20</sup>
	– Jaundice	Unexplained jaundice, regardless of when it occurred	If the cause is known, refer to the physician.
	History of STI <sup>21</sup>	< 4 months	> 4 months
	Blood transfusion, surgery or endoscopy	< 6 months	
	High risk exposure	In the last 4 months: unprotected casual sex (not with regular partner), multiple partners, rape In the last 6 months: IV drug use, scarification, tattoo, piercing	
	Temperature	> 37.5°C axillary <sup>22</sup>	
	Pulse	< 50 or > 100 or irregular	
SIGNS	Systolic BP	< 100 or > 180 mmHg	
	Conjunctiva	Jaundice	
	Others		Swollen lymph nodes, oral thrush, skin rash: refer to the physician.

 <sup>&</sup>lt;sup>20</sup> Refer to malaria screening, Section 5.
 <sup>21</sup> A previous STI such as chlamydial infection, gonorrhoea or syphilis is a marker for high-risk exposure to HIV and hepatitis.
 <sup>22</sup> Screen for malaria in an endemic area. Whatever the cause of the fever, exclude the donor or postpone the standard donor don

donation and refer to the physician.

## 4. Pre- or post-donation screening

**In direct donation**, screening for TTIs is always performed *before* blood collection as the blood cannot be collected if the result is positive.

**In mobile blood collection sessions**, due to organisational constraints, screening is always performed *after* blood donation, in the laboratory.

**For voluntary and replacement donations**, the screening strategy should be carefully considered before setting up blood transfusion activities as each strategy has advantages and disadvantages.

	Advantages	Disadvantages
Screening the <b>donor</b> before donation	Safer for staff handling blood (e.g. collection, grouping, disposal). In the laboratory, no risk of confusion between infected and safe blood units. Less waste (blood, bags, etc.) and less waste to dispose of. Enables prompt treatment of the donor if the blood is positive for syphilis or malaria (see pages 58-59).	Confidentiality harder to achieve. Risk of stigmatisation in case of exclusion after screening.
Screening the <b>donated blood</b> after donation	Confidentiality easier to achieve. Donors are less likely to use blood donation as a means of obtaining their HIV status.	Risk of handling infected blood. In the laboratory, risk of confusion between infected and safe blood units. Unnecessary blood donations and wastage of supplies. More waste and waste to dispose of. Missed opportunity to treat the donor for syphilis or malaria.

The prevalence of TTIs, especially HIV infection and hepatitis B and C, must be taken into account: e.g. in high HIV infection prevalence area, the tendency will be to screen before blood collection.

When numerous donors come to donate blood and time does not allow them to be screened one by one before donation, screening is usually performed after donation.

Screening the donor before donation brings up the issue of the reason for exclusion (see *Disclosure of results*, page 48).

#### If screening is performed before donation:

- Draw a blood sample in an EDTA tube.
- Perform the first HIV test<sup>23</sup>, and the test for hepatitis B, C and syphilis on the EDTA tube.
- Exclude the donor if any of the tests is positive or doubtful<sup>24</sup>.
- If all tests are clearly negative:
  - Collect the blood.
  - Then,
  - Perform the 2<sup>nd</sup> HIV test<sup>25</sup> on the blood unit, using the blood in the distal segment of the bag tubing.

#### If screening is performed after donation:

- Collect the blood unit.
- At the end of collection, fill an EDTA tube.
- Perform the first HIV test and the test for hepatitis B, C and syphilis using the EDTA tube<sup>26</sup>.
- Exclude the blood unit if any of the tests is positive or doubtful<sup>24</sup>.
- If all tests are clearly negative, perform the <sup>2<sup>nd</sup></sup> HIV test on the blood unit, using the blood in the distal segment of the bag tubing.

In both cases:

If the second HIV test is clearly negative: the blood unit is validated.

If the second HIV test is positive or doubtful: the blood unit is excluded.

Blood units with any positive test result must be disposed of (see Chapter 4, Section 6). Validated blood units must be clearly labelled including blood unit number, date of collection and date of expiry, group ABO Rh D (see Figure 2, page 61).

To perform blood collection, see Appendix 10.

<sup>&</sup>lt;sup>23</sup> First HIV test: HIV 1/2 Determine<sup>®</sup> is currently the most sensitive test available and recommended for blood safety

<sup>&</sup>lt;sup>24</sup> For syphilis, see also Chapter 3, section 5, page 58.

<sup>&</sup>lt;sup>25</sup> Second HIV test: Uni-Gold®.

<sup>&</sup>lt;sup>26</sup> In the event of high workload, batch testing may save time but the risk of clerical errors is higher.

## 5. Blood grouping and TTI screening

#### 5.1. Donor's blood grouping

For safety reasons, the blood grouping should be performed twice:

- First time: on donor's blood, before or after donation.
- Second time: on the blood unit, using the distal segment of the tubing.

The tile method is recommended since it is less prone to handling errors than the tube method. See Appendix 15.

When blood units are supplied from an external source, the group of the blood unit must be checked using blood from the distal segment of the blood bag tubing, unless the external source has been validated by a competent medical professional (see Chapter 4, page 67).

#### 5.2. TTI screening

Donated blood must be routinely screened for HIV, hepatitis B, hepatitis C and syphilis.

Other screening tests (e.g. malaria, Chagas' disease) are performed according to the epidemiological context (see Chapter 1).

Screening tests have to combine high sensitivity in order to detect infected blood and high specificity to avoid rejecting false positive blood. Tests must be stable under field conditions (e.g. transport, temperature, humidity) and results must be rapidly available.

Tests may be performed on each sample as a full battery (concurrent testing), or sequentially according to epidemiology of infections in the area, e.g. in high HIV prevalence area, hepatitis B screening may be done only on HIV negative blood.

Performing the full battery of tests is preferred as it provides more complete and accurate information about the positivity rate of each infection among donors/donations. Sequential testing is more cost effective and less time consuming but the positivity rates are not representative of the donor population, as they are based on different denominators.

See Appendices 17 to 23.

#### 5.2.1. HIV

The objective of screening blood for HIV is to provide safe blood for the recipient, not to diagnose HIV infection in the donor. Therefore, the algorithms for blood safety screening differ from the ones used for HIV infection diagnosis.

The WHO considers the use of one highly sensitive and specific HIV-1 and HIV-2 test sufficient to ensure transfusion safety regarding HIV transmission.

However, to improve screening reliability, it is prudent to perform 2 different tests on 2 different blood samples because rapid tests have inherent limitations and because human errors (e.g. in handling or storing tests, labelling tubes, bags and test devices) may result in inaccurate results.

The two HIV screening results must be clearly negative. In the event of doubtful or positive result at the first test, the donor or the blood unit must be excluded.

Nevertheless, negative HIV screening does not prevent HIV transmission through transfusion if the donor has been infected within the previous 3 weeks, which is the average window period for detection of HIV antibodies using rapid tests. Thus, predonation questionnaire and physical examination are essential to select low risk donors.

#### 5.2.2. Hepatitis B and C

In the event of doubtful or positive result, the donor or the blood unit must be excluded.

The average window period for hepatitis B surface antigen (HBs Ag) is 30 days (range 7 to 63 days) and 82 days (range 54 to 192 days) for HCV antibody using rapid tests.

#### 5.2.3. Syphilis

The screening should be performed using a rapid Treponema-specific test (e.g. Syphilis 3.0 SD Bioline®). RPR is no longer recommended as it is insufficiently sensitive and specific.

Syphilis positive blood should not be transfused: it can be infected by *Treponema pallidum*<sup>27</sup> and syphilis positive donors are at higher risk of having acquired other STIs, including HIV infection.

However, under exceptional circumstances (blood shortage, life-threatening emergency), the use of syphilis positive blood can be justified provided the recipient is simultaneously treated for syphilis.

If the <b>donor's test</b> is positive	If the <b>blood unit</b> is positive
(screening before donation)	(screening after donation)
<ul> <li>Collect blood only in case of emergency and when no other donor is available.</li> <li>Treat the donor AND the recipient for syphilis<sup>28</sup>.</li> </ul>	and store it separately in the refrigerator

<sup>27</sup> A positive syphilis test does not indicate whether the donor has been infected recently or in the past, nor whether he is still infectious. The test can remain positive even after successful treatment.

<sup>&</sup>lt;sup>28</sup> First choice treatment is benzathine benzylpenicillin IM: 2.4 MIU as a single dose. Doxycycline PO: 200 mg/day in 2 divided doses for 14 days is an alternative if benzathine benzylpenicillin is not available or in penicillin allergic patients.

<sup>&</sup>lt;sup>29</sup> *T. pallidum* is sensitive to cold. Infectivity declines when blood is refrigerated (2 to 8°C) and blood is no longer infectious after a period of 120 hours (5 days).

#### 5.2.4. Malaria

#### In low endemic areas or areas of seasonal transmission

Malaria screening should be performed, using a rapid diagnostic test. Despite a negative test, malaria can still be transmitted when the donor's parasitaemia is too low to be detected. Thus, during donor selection, donors with fever or history of fever or recent malaria infection should be excluded.

Donors with a positive malaria test should receive a full, effective antimalarial treatment.

Blood should not be collected, unless transfusion is needed urgently and no other donor is available.

Transfusion of malaria positive blood to pregnant women and children < 5 years is strongly discouraged unless there is no alternative.

Treat all recipients of malaria positive blood with a full, effective antimalarial treatment.

#### In highly endemic areas with stable transmission

The decision to screen for malaria or not should take into consideration the prevalence of the disease, the capacity of the laboratory to perform routine screening, and national recommendations.

Depending on the context, 2 options are possible:

- *Option 1*: malaria screening is omitted and an effective antimalarial treatment is routinely administered to all recipients.
- Option 2: screening is routinely performed but positive blood is not necessarily excluded. It can be drawn then labelled as malaria-positive and stored separately. When the blood is transfused, the recipient receives concomitantly an effective antimalarial treatment. However, transfusion of malaria positive blood in pregnant women and children under 5 is strongly discouraged unless there is no other alternative.

## 6. Registration and labelling

#### 6.1. Blood donor register

Donor's name, occupation, address, phone number may be kept in a blood donor register. This register must be kept in a safe place, under lock and key.

The blood donor register is the only document where the link between the donation number and the donor's identifying information can be found. This link allows tracing of donors and is established when:

- There is a pool of regular donors (including donors called on demand).
- The policy of the health structure is to be able to trace blood donors, e.g. when a serious transfusion complication is to be investigated or in the event of abnormal screening test results.

The results of TTI screening must not be reported in the blood donor register.

#### 6.2. Blood donation register

Information pertaining to the donation (date of donation, donation number, blood grouping and TTI screening results) should be recorded in a blood donation register (see Appendix 25).

The blood donation (i.e. the blood unit) is only identified by a number. Donor's name, age, address or any other identifying information is not recorded in the donation register.

In the event of mobile blood collection, ensure a different donation number series is assigned to the blood drive in order to avoid mix-ups with blood collected at the hospital.

#### 6.3. Blood bank register

A blood bank register is needed to track utilisation of blood units. It combines information on the blood unit and on the recipient.

The register, divided in 4 sections (for each blood group), is used to facilitate the search for the needed blood unit. When transfusion activity is high, one register per blood group can be used.

Each blood unit, once validated for transfusion, should be entered in the register with the following information: blood unit number, date of collection, blood group ABO Rh D, volume and expiry date.

Once the blood unit is issued, information on the recipient is entered in the register (name, age, sex, blood group and Hb level, reason for transfusion, ward, bed and patient file number) as well as the disposition of the blood unit (transfused, returned, discarded, expired). See Appendix 26.

If a blood unit is returned without being transfused, it can be reissued for another patient, provided it has been maintained in the cold chain.

#### 6.4. Blood unit labelling

Before collection, the empty blood bag is labelled with the donation number, blood collection date and expiry date, using a permanent marker.

The blood group is added after the second blood group determination.

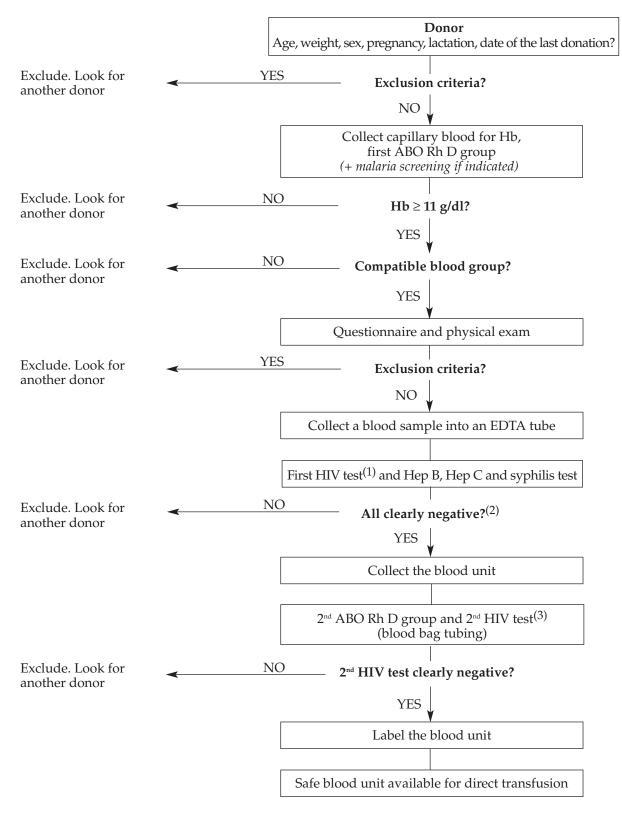
Blood units screening positive for malaria or syphilis must be clearly identified.



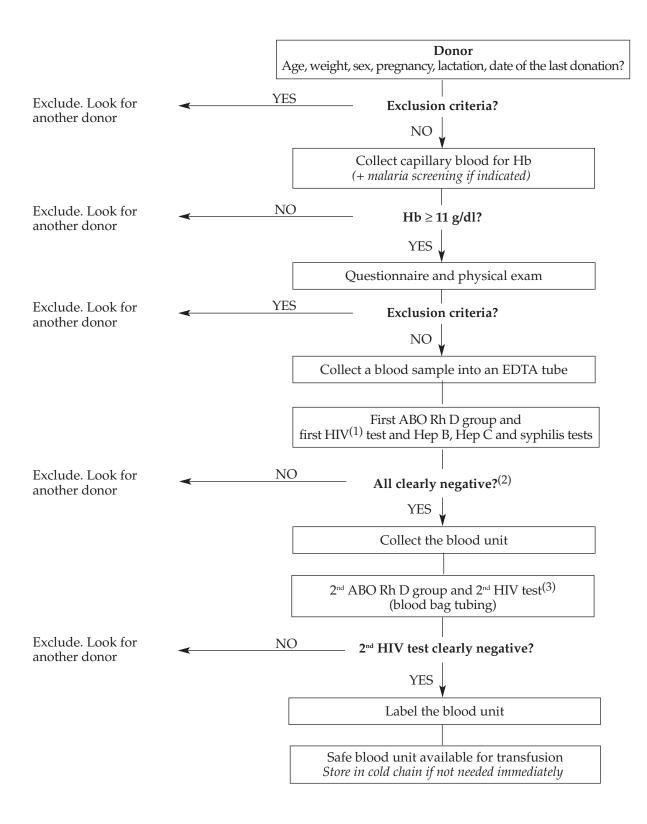
**Figure 2** *Information to be recorded on each blood unit* 

## 7. Flow charts

#### **Direct donation**



- (1) HIV 1/2 Determine<sup>®</sup>.
- <sup>(2)</sup> Refer to Chapter 3, section 5 in the event of positive syphilis or malaria screening.
- (3) Uni-Gold® or another validated brand.



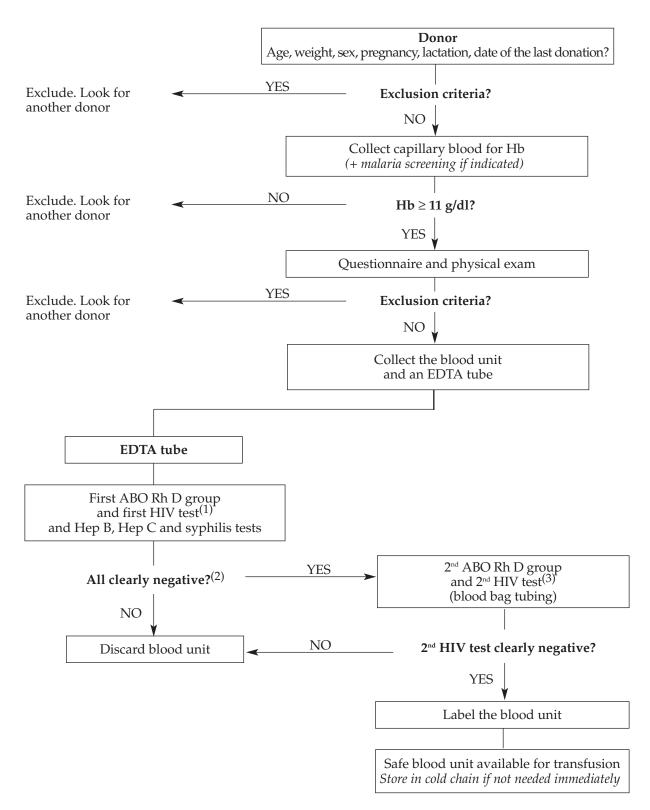
#### Voluntary donation and replacement donation

If screening is performed **BEFORE** donation

(1) HIV 1/2 Determine<sup>®</sup>.

<sup>(2)</sup> Refer to Chapter 3, section 5 in the event of positive syphilis or malaria screening.

(3) Uni-Gold® or another validated brand.



#### Voluntary donation and replacement donation

If screening is performed AFTER donation

(1) HIV 1/2 Determine<sup>®</sup>.

<sup>(2)</sup> Refer to Chapter 3, section 5 in the event of positive syphilis or malaria screening.

(3) Uni-Gold® or another validated brand.

*Note*: in case of high workload, batch testing on EDTA tubes is possible. However, the 2<sup>nd</sup> HIV test and the 2<sup>nd</sup> blood group must be performed one by one using the blood bag tubing.

CHAPTER 4

## Implementing and managing transfusion activities

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## 1. Implementing blood transfusion activities

#### 1.1. Initial assessment

#### 1.1.1. Assess the need for blood

Health facilities with low transfusion activity usually perform direct transfusion and do not have stocks of blood. In facilities where transfusion activity is high or regular, setting up a blood bank ensures a constant supply of blood.

Estimate the number of blood units needed per week or per month according to the current or expected activity. The need for blood is high in malaria endemic areas and in hospitals with obstetrical and surgical activities<sup>30</sup>.

#### 1.1.2. Assess external sources of blood

External sources include national blood transfusion services (NBTS) or other hospitals.

The capacity of an external source to supply safe blood must be assessed by a competent medical professional. Below is a list of questions/criteria to be considered:

- How are donors recruited, selected and retained?
- Are tests results disclosed to donors and, if so, how?<sup>31</sup>
- Are equipment, consumable items and reagents procured from validated sources?
- What tests and methods are used for blood grouping, red cell antibodies screening and TTI screening? Is the process automated? Are results double-checked? How are the results of the tests performed on each donation gathered? How quality controls are performed? Who is in charge of overall laboratory supervision?
- What is the positivity rate for each TTI in donated blood? What is the prevalence rate in the adult population?
- How many blood units can be supplied, and in what time frame?
- How are unsafe/untested blood units separated from safe blood units?
- Is the cold chain efficient and monitored? During storage? Transportation?
- To what institution is this structure accountable for activity data and performance indicators?

If the medical professional cannot come to a decision alone, a laboratory advisor should be mandated to perform the assessment.

<sup>&</sup>lt;sup>30</sup> According to the International Committee of the Red Cross, in a war context, an average of 45 blood units are needed for every 100 war wounded.

<sup>&</sup>lt;sup>31</sup> Blood transfusion services that report HIV results directly to the donor may attract high-risk donors looking for an individual diagnosis (see page 48).

#### 1.1.3. Determine the feasibility

- Assess the availability of qualified medical staff (physicians, nurses, laboratory technicians) and their competencies in transfusion.
- Assess the logistical capacity (power supply, space, cold chain equipment and waste management).
- Determine needs in terms of staff recruitment and training, and equipment.

Evaluate advantages/disadvantages and cost effectiveness of setting up a blood bank, based on this assessment. Alternatively, it may be more appropriate to set up an effective system for patient referral.

#### 1.2. Setting up a blood transfusion activity

### *1.2.1. Obtain authorisation from the health authorities and/or the NBTS*

#### 1.2.2. Establish a blood transfusion committee

This committee is responsible for the implementation of good transfusion practices. It includes the hospital director, the head nurse, physicians prescribing transfusions, the laboratory/blood bank supervisor and the pharmacist. See Section 3 for job descriptions.

#### 1.2.3. Where necessary, meet the religious or other local leaders

Inform them on the necessity to recruit donors and try to obtain their collaboration.

#### 1.2.4. Order equipment according to needs

The transfusion module (Appendix 29) gives an overview of the basic medical and laboratory equipment required.

For cold chain equipment, see Section 2.

#### 1.2.5. Organise the blood bank premises and waste management

See Section 5 and 6.

## *1.2.6. Train staff and ensure job descriptions are available for each position*

Train staff on: donor recruitment and selection, screening procedures, transfusion indications and procedures, cold chain maintenance, stock management, waste management, etc.

For the list of responsibilities, see Section 3. Each staff member must understand his/her role and responsibilities.

#### 1.2.7. Ensure procedures are written and adapted to the context

#### 1.2.8. Implement a data collection system

Data analysis helps in evaluating the adequacy and quality of the blood transfusion activity. Data are usually collected on a monthly basis. An example of data collection form, to be adapted to the context, is set out in Appendix 28.

# 2. Storage, transportation and stock management of blood units

Safe storage and transportation of blood units is an integral component of blood safety.

#### 2.1. Cold chain

#### 2.1.1. Equipment

#### Refrigerators

- Blood should be stored in a refrigerator with the 3 following specifications<sup>32</sup>:
  - Electricity-powered.
  - External thermometer display for continuous monitoring of temperature.
  - Alarm system (visual or audible), which alerts when temperature limits are reached.

This refrigerator should be used exclusively for the storage of blood. The number/size of refrigerators depends of the estimated number of units to be stored.

Gas-powered and petrol-powered refrigerators should not be used: they do not perform as well as electricity-powered refrigerators and require constant attention and maintenance to ensure correct and stable temperatures.

Domestic refrigerators are not designed for blood storage. They have no external thermometer display, poor insulation and poor temperature regulation (risk of blood freezing and rapid rise in temperature in the event of power failure).

 Reagents and tests should be stored in a separate refrigerator (e.g. Vestfrost MK204<sup>®</sup> or Sibir V170<sup>®</sup>).

#### Cold boxes and vaccine carriers

- Cold boxes (e.g. Electrolux RCW®) are necessary:
  - for transportation of blood from an external source or mobile collection sites to the blood bank;
  - for temporary storage of blood, in the event of refrigerator dysfunction or during refrigerator defrosting.
- Vaccine carriers (e.g. Gio'Style®) are necessary for transportation of blood from the blood bank to the wards.

#### Freezer and ice packs

A freezer (e.g. Vestfrost MF®) is necessary for ice pack production.

<sup>&</sup>lt;sup>32</sup> These are the standard recommendations for facilities with high transfusion activity. When the stock of blood is < 15 blood units, it is acceptable to store blood in a refrigerator without an alarm system, as long as it is electricity-powered and equipped with external temperature display.</p>

#### **Temperature-monitoring devices**

Every refrigerator and cold box must contain 2 temperature-monitoring devices:

- A thermometer: a mini-maxi thermometer is recommended. It records the minimum and maximum temperature (temperature range –50°C to +50°C) reached since the last reset.
- A freezing indicator device (e.g. Freeze-tag®): this device indicates that a drop in temperature to  $0^{\circ} \pm 0.3^{\circ}$ C for more than one hour has occurred inside the refrigerator/cold box (Appendix 33).

#### 2.1.2. Power supply

The electricity can be supplied by a local provider or by a generator provided that it is stable, continuously available and adequate to requirements. Power cuts/breakdowns should be anticipated and backup power supply must be available (i.e. batteries). The blood bank supervisor and the logistics officer are responsible for implementing the back-up procedure.

#### 2.1.3. Cold chain maintenance

The logistics officer ensures the maintenance of cold chain apparatus: checking and maintenance of the refrigerator gaskets, monthly checking of the alarm system, thermostats, changing of batteries and cleaning of the condenser (every 6 months), etc.

The blood bank supervisor ensures that the refrigerators are clean and free of ice.

#### 2.2. Storage conditions

#### 2.2.1. Storage temperature

Blood must be stored in the cold chain within 2 to 4 hours maximum of collection. In a blood bank, blood units are directly stored in the refrigerator. During mobile collection sessions, blood units are placed in a cold-box at 2-6°C until they can be stored in the refrigerator.

Once stored in the refrigerator, blood is not removed until it is transfused.

The optimal temperature to keep the red cells functional and to inhibit bacterial growth is 2°C to 6°C. However, an upper limit of 8°C is permissible.

Blood must never be frozen as freezing causes red cell haemolysis.

#### In refrigerators

To reduce the possibility of the temperature falling below 2°C, it is safer to set the thermostat at 4°C.

Avoid repetitive opening and closing of the refrigerator. To ensure cold air circulation, avoid overfilling the refrigerator.

#### In cold boxes

Ensure that the blood units are not in direct contact with ice packs. Use pieces of corrugated cardboard or bubble wrap to prevent contact between blood units and icepacks.

Discard any blood unit that has been:

- Out of the cold chain for more than 30 minutes. Re-cooling blood that has reached room temperature may stop bacterial growth but it does not prevent the release of endotoxins.
- Stored in cold chain at a temperature  $> 8^{\circ}$ C.
- Exposed to freezing temperature (freezing indicator device on ALARM).

#### 2.2.2. Temperature monitoring

A single individual should be identified and trained to monitor temperature. A second person should be identified to replace the person in charge in case of absence.

The logistics officer must be informed immediately in the event of cooling system dysfunction.

Depending on the cause/duration of the cold chain failure and refrigerator holdover time<sup>33</sup>, the blood bank supervisor makes the decision to transfer blood to another refrigerator or, failing that, to cold boxes.

Temperature of refrigerators must be checked and recorded on the monitoring sheet (Appendix 32) twice daily, 7 days per week.

Mini-maxi thermometers must be reset after each reading.

The monitoring is the same if blood is temporarily stored in cold boxes during refrigerator breakdown or defrosting periods.

*Note*: temperature devices inside cold boxes must be checked when a blood delivery is received.

#### 2.3. Transportation of blood units

#### From blood bank to wards

Blood units must be transported in a vaccine carrier if the ambient temperature is  $> 25^{\circ}$ C or if the blood might not be transfused immediately.

#### From mobile collection

Blood units are placed and transported in a cold box at 2 to 6°C until they can be stored in the refrigerator.

#### 2.4. Stock management

#### 2.4.1. Blood shelf life

The blood shelf life depends on the preservative solution used (e.g. CPDA<sub>1</sub>, SAGM, CPD)<sup>34</sup>. Check manufacturer's information. Usually:

- CPDA<sub>1</sub>: whole blood and PRBC can be stored for 35 days
- SAGM: PRBC can be stored for 42 days
- CPD: whole blood and PRBC can be stored for 28 days

<sup>&</sup>lt;sup>33</sup> Holdover time is the period of time a refrigerator is able to maintain internal temperature below 8°C at a given external temperature (usually 43°C) when power has been interrupted. Check manufacturer's information.

<sup>&</sup>lt;sup>34</sup> CPDA = Citrate Phosphate Dextrose Adenine; SAGM = Saline-Adenine-Glucose-Mannitol; CPD = Citrate Phosphate Dextrose

#### 2.4.2. Storage of blood units

The tested blood units should be stored in the refrigerator:

- By blood group (ABO and Rh D) and expiry date; e.g. all A Rh D-pos. units are placed together in a basket with the unit expiring first in the front of the basket.
- In an upright position, tubing down, in order to be able to transfuse partially concentrated red cells (Appendix 11).

*Note*: if untested blood units need to be stored, place them in a specifically identified basket in the refrigerator.

#### 2.4.3. Stock follow-up

A blood bank register is used to record entries and deliveries of blood units (Appendix 26). The register must be used to issue the most appropriate blood unit according to the patient's group, the patient's specific needs and the expiry date.

A blackboard or a notebook is used to update the stock of blood units daily (theoretical stock).

An actual count should be done once a week (physical stock).

A minimum level of stock should be determined according to the transfusion activity and the distribution of blood groups in the population. Group O blood should always be available in the stock.

Blood collection or ordering must be anticipated to maintain the blood stock.

When a large number of blood units require disposal, identify the underlying causes (e.g. problems in stock management, frequent cold chain rupture, screening after donation in an area with high prevalence of TTIs, change in blood requirements) and find solutions to address these issues.

#### 2.5. Blood units received from external sources

#### Check the delivery form

The delivery form should indicate the time the blood units were taken out of the refrigerator as well as the details of the blood units supplied: type of product (whole blood, PRBC), group, volume, unit number, collection and expiry dates.

Check if the delivery form corresponds to the initial order and to the units actually supplied.

#### Check the transportation conditions

Check the time elapsed in transportation, and the temperature devices inside the cold box:

- The temperature is between 2° and 8°C.
- The freezing indicator device does not display ALARM.
- The blood units have not been put in direct contact with the ice packs.

If there is no thermometer in the cold box, place one between 2 blood units. If the temperature is  $> 8^{\circ}$ C, discard or return the blood units and notify the supplier and the person in charge of transportation in order to obtain replacement blood units.

#### For each blood unit:

- Check that the information is complete and readable, including blood group, collection and expiry dates.
- Check that the tubing length is adequate (at least 50 cm), that the knots in the tubing are correctly tightened and that there is no leakage.
- Check the appearance of red cells and plasma: red cells should be dark red, plasma should be bright yellow and no clots should be seen. On visual observation, the proportion of red cells in a unit of whole blood, if fully sedimented, should be at least 1/3 of the blood bag contents<sup>35</sup>.

Discard the unit (or return to NBTS) if clots are visible, if red cells are purple, brown or black, if plasma is pink or pale yellow or if the proportion of red cells seems too low.

- Check that the blood bags are well filled and in doubt, weigh the blood units. The expected weight of a filled bag of whole blood is approximately:
  - 180 to 215 g for 150 ml bags
  - 295 to 350 g for 250 ml bags
  - 515 to 610 g for 450 ml bags

This estimation is given as an indication. Check with the NBTS or the manufacturer.

 Repeat the blood grouping and TTI screening on segments of the bag tubing unless the external source of the blood supply has been assessed by a competent medical professional and is considered to be reliable.

<sup>&</sup>lt;sup>35</sup> It is not possible to open the blood unit to check the Hb level as the system must be kept closed. Haematocrit can be visually estimated, by measuring the height of the sedimented red cells relative to the height of the total blood volume. Proportion of sedimented red cells in a unit of whole blood should be at least 33%.

# 3. Staff responsibilities

Position	Tasks and responsibilities
<b>Chief Medical Officer</b> (Medical Coordinator /Hospital Director)	<ul> <li>Obtain authorisation from the Ministry of Health to set up blood transfusion activities.</li> <li>Assess the quality/capacity of external sources of blood, with the collaboration of a laboratory advisor, if necessary.</li> <li>Organise training sessions with the head nurse, physicians and laboratory technicians.</li> <li>Ensure that written, updated and context adapted procedures are available and followed.</li> <li>Oversee the blood transfusion activity including analysis of quality indicators.</li> </ul>
Blood Transfusion Committee	<ul> <li>Ensure the implementation of good transfusion practice, safety of blood transfusion and Quality Assurance:</li> <li>Elaborate policies and procedures (donor recruitment and selection, indications, blood administration, patient information, etc.), and advise regarding their implementation.</li> <li>Monitor reliability of blood supply.</li> <li>Ensure appropriate use of blood.</li> <li>Perform critical analysis of data (every 3 to 6 months).</li> <li>Review transfusion reactions (including deaths).</li> <li>Review and analyse errors associated with transfusion.</li> <li>Identify the needs (e.g. improvement, development) and provide assistance, as required.</li> <li>Facilitate training of all staff involved in the process of blood transfusion.</li> </ul>
Physician/Anaesthetist	<ul> <li>Assess the patient and evaluate the risks/benefits of transfusion.</li> <li>Answer patient's questions; respond to concerns related to transfusion.</li> <li>Obtain informed consent.</li> <li>Prescribe the transfusion.</li> <li>Fill in and sign the blood request form.</li> <li>Manage adverse reactions.</li> <li>Fill in the transfusion reaction form in the event of adverse reaction.</li> <li>Supervise the staff in charge of donor selection.</li> <li><i>Can perform Hb and blood grouping.</i></li> <li><i>Can participate in donor recruitment.</i></li> </ul>
Ward nurse	<ul> <li>Draw blood samples.</li> <li>Perform Hb and blood grouping, if no laboratory technicians are available.</li> <li>Check patient's identity and concordance with the blood unit to be transfused.</li> <li>Perform the bedside verification of ABO compatibility prior to transfusion.</li> <li>Carry out the transfusion.</li> <li>Monitor the patient before, during and after transfusion and fill in the monitoring sheet.</li> <li>Notify the physician in the event of adverse reactions and fill in the transfusion reaction form.</li> </ul>

Position	Tasks and responsibilities
Trained nurse for donor care	<ul> <li>Recruit donors and promote blood donation.</li> <li>Select donors (questionnaire, physical exam, tests); refer donors to physician in the event of abnormality on physical examination.</li> <li>Respond to donors' concerns.</li> <li>Perform blood collection.</li> <li>Take care of the donor during and after collection.</li> </ul>
Laboratory technician /Blood bank supervisor	<ul> <li>Measure Hb and perform blood grouping, TTI screening and crossmatching.</li> <li>Issue compatible, safe blood units.</li> <li>Fill in and sign the delivery form.</li> <li>Manage the blood stock and complete the registers.</li> <li>Order, receive and check blood units from external sources.</li> <li>Ensure proper storage of blood units.</li> <li>Check that the cold chain is functioning correctly (including temperature monitoring).</li> <li>Notify the logistics officer in the event of cold chain problems.</li> <li>Fill in the registers.</li> <li>Fill in data collection forms (supervisor).</li> </ul>
Pharmacist	<ul> <li>Manage the stock of material and tests/reagents.</li> <li>If blood is stored in the pharmacy, monitor the cold chain.</li> <li>These responsibilities can be shared with the laboratory technician, according to the human resources available and division of tasks.</li> <li>Organise and supervise the blood waste management.</li> </ul>
Logistics officer	<ul> <li>Plan the layout of the laboratory/blood bank premises with the transfusion committee.</li> <li>Supervise the construction and organisation of the premises.</li> <li>Set up and maintain the cold chain, including power backup.</li> <li>Implement the tools for safe blood waste management.</li> <li>Organise transportation (blood drives/blood units from external sources).</li> </ul>

# 4. Quality Assurance in blood transfusion

The Quality Assurance system is based on four pillars:

#### 4.1. Staff

Staff should be:

- Qualified.
- Trained in the application of standard procedures.
- Aware their tasks and responsibilities.
- Supervised.

#### 4.2. Procedures

Procedures are:

- Appropriate to the context and the equipment available.
- Known, understood and applied by the staff.
- Updated at least once a year.

#### 4.3. Premises and equipment

- The premises are functional and suitable for the activity.
- The equipment comes from a validated source, is checked and maintained regularly.
- The reagents/kits and blood bags come from a validated source. They are stored according the manufacturer's recommendations.
- The laboratory equipment is calibrated at installation and at regular intervals.

#### 4.4. Documentation

The documentation includes:

- The organization and description of the transfusion process (procedures, flow charts, etc.).
- The staff safety policy (hepatitis B vaccination for staff exposed to blood, procedure in the event of accidental exposure to blood, etc.).
- Reference and training documents.
- Equipment and reagents/kits package inserts.
- Registers.
- Workbench registers (tests performed, reagent quality control, etc.).

- Blank forms (order/delivery forms, pre-donation questionnaire, monitoring and transfusion reaction forms, stock cards, etc.).
- Archived documents (forms and registers, results, quality controls, activity report, etc.).

Regular critical analysis should be performed on the data collected from registers/ documents by the blood transfusion committee.

#### 4.5. Follow-up and methods for improving practices

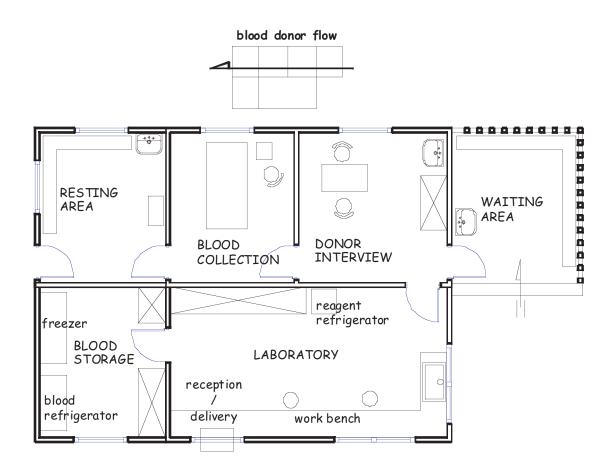
The Quality Assurance process aims to improve practices with the active participation of the staff involved.

Problems and errors must be discussed and analysed by the blood transfusion committee, in order to take corrective action rapidly.

# 5. Physical layout of premises

A blood bank should include:

- A waiting area for blood donors.
- A consultation room for interviewing and examining donors. Confidentiality should be ensured.
- A blood collection room. This room should be ventilated.
- A recovery area where the donor is cared for after blood collection.
- A laboratory room.
- A storage room with cold chain equipment. The room should be air conditioned or at least ventilated. Allow for enough space (50-60 cm) behind the refrigerator(s) for air circulation.



**Figure 3** Blood bank layout

# 6. Waste management

Blood units (and material in contact with blood such as bags or tubes) are infectious wastes, even with negative TTI screening.

In order to minimise the risk of accidental exposure to blood, the staff in charge of waste management (i.e. laboratory technicians, cleaners) should be adequately protected (i.e. gloves, goggles, protective clothes) when handling and disposing of blood.

Disposal of large volumes of infected or expired or damaged blood units is complex. Every effort should be made to minimize the volume of blood requiring disposal. Blood units that cannot be discarded immediately or transported to another facility for disposal should be removed from the refrigerator and place under lock and key in a clearly labelled box.

#### Empty blood bags

Empty blood bags may be incinerated or buried in a cement pit.

#### Unused blood units and tubes containing blood

#### Incineration

Blood units and sample tubes must be incinerated without being emptied beforehand.

This technique requires a powerful incinerator, since the blood, like any liquid, will extinguish a fire that is not strong enough. The incinerator must be preheated. Blood units must be incinerated one by one. Fuel should be added as required.

#### Burying

Blood units and sample tubes are discarded in a cement pit, without being emptied beforehand. The pit is filled with cement when it is full. This method requires space.

Alternatively, unused blood units may be emptied in an organic pit then disposed, as for empty blood bags (see above). The bag should be cut with scissors to avoid spills. Bags should not be pierced.

#### Sample tubes

Blood from sample tubes can be poured down the drain of the laboratory sink and flushed down with a 1% active chlorine solution. The empty tubes should then be disposed as contaminated medical waste.

*Note*: this method should not be used for unused blood units.

If large quantities of blood units must be destroyed, call for technical advice.

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### 1 - Normal haemoglobin values and thresholds defining anaemia (WHO)

	Normal	Anaemia		
	haemoglobin values (g/dl)	Haemoglobin (g/dl)	Haematocrit <sup>1</sup> (%)	
Newborns	13.5 to 18.5	< 13.5	< 34	
Children 2-6 months	9.5 to 13.5	< 9.5	< 28	
Children 6 months-6 years	11 to 14	< 11	< 33	
Children 6-12 years	11.5 to 15.5	< 11.5	< 34	
Men	13 to 17	< 13	< 39	
Women	12 to 15	< 12	< 36	
Pregnant women				
1 <sup>st</sup> and 3 <sup>rd</sup> trimester	11 to 14	< 11	< 33	
2 <sup>nd</sup> trimester	10.5 to 14	< 10.5	< 31	

Adapted from the WHO, Clinical use of blood, 2005

<sup>&</sup>lt;sup>1</sup> The haematocrit (%) is approximately equal to 3 times the Hb concentration (g/dl) when red cells are normal i.e. normochromic (normal mean corpuscular Hb concentration) and normocytic (normal mean corpuscular volume).

## 2 - Transfusion thresholds

Children (including severely malnourished children)

Hb < 4 g/dl  $\rightarrow$  Transfusion is indicated.

- Hb 4 to 6 g/dl  $\rightarrow$  Transfusion is indicated if clinical signs of decompensation.
- Hb > 6 g/dl  $\rightarrow$  Transfusion is not advisable unless there is a specific indication.

i legnant women	Pregnant	women
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$Hb \le 5 \text{ to } 6 \text{ g/dl}$	→ Transfusion is indicated.	
Hb < 7 to 8 g/dl	→ Transfusion is indicated if clinical signs of decompensation or associated malaria, pneumonia or severe bacterial infection, pre-existing heart disease.	
Hb < 8 g/dl	→ Have two blood units ready for immediate use (compatible and crossmatched) in the event of planned caesarean section.	

Adults	
Hb < 7 g/dl	<ul> <li>→ Consider transfusion in patients with severe malaria.</li> <li>→ In healthy patient<sup>1</sup> undergoing major surgery or surgery with expected significant blood loss, have blood unit(s) ready for immediate use (compatible and crossmatched) if necessary but do not administer preventive transfusion.</li> </ul>

<sup>&</sup>lt;sup>1</sup> Transfusion threshold is usually 8-9 g Hb/dl for elderly patients and patients with low cardiac reserve undergoing surgery.

### 3 - Acute haemorrhage: assessment, classification and indication of transfusion

#### 1. Normal blood volume

Neonates:85 to 90 ml/kg of body weightChildren:80 ml/kg of body weightAdults:70 ml/kg of body weight

#### 2. Hypovolaemia in adults

Hypovolaemic class	Class I	Class II	Class III	Class IV
Blood loss (ml)	< 750	750-1500	1500-2000	> 2000
Blood loss (% of blood volume)	< 15%	15%-30%	30%-40%	> 40%
<b>Pulse</b> (beats/min)	Normal	100-120	>120 Weak	> 140 Very weak
Systolic BP	Normal	Normal	Low	Very low
Capillary refill	Normal	Prolonged	Very prolonged	Absent
Mental state	Alert	Anxious	Confused	Coma/ Unconsciousness
<b>Respiratory rate</b> (breaths/min)	Normal	20-30	30-40	> 40 or slow sighing respiration
<b>Urine output</b> (ml/hour)	> 30	20-30	5-20	< 5
Replacement fluids	Crystalloids	Crystalloids or colloids Blood likely to be required		Crystalloids/ Colloids AND Blood required

Adapted from the WHO and the American College of Surgeons

Fractures		Internal injuries	
Humerus	0.5 litre	Ectopic pregnancy	0.5-2 litres
Tibia	1 litre	Haemothorax	1-1.5 litre
Femur	1.5 litre	Spleen	2-3 litres
Pelvis	2-4 litres	Retro peritoneal	2-3 litres

#### Standard estimated blood loss in adults

#### 3. Hypovolaemia in children

Hypovolaemic class	Class I	Class II	Class III	Class IV
<b>Blood loss</b> (% of blood volume)	< 15%	15%-25%	25%-40%	> 40%
<b>Pulse</b> (beats/min)	Increased	> 150	> 150	Increased or bradycardia
Systolic BP	Normal	Reduced	Very reduced	Not recordable
Capillary refill	Normal	Prolonged	Very prolonged	Absent
Mental state	Alert	Irritable	Lethargic	Comatose
<b>Respiratory rate</b> (breaths/min)	Normal	20-30	30-40	> 45 or slow sighing respiration
<b>Urine output</b> (ml/kg/hour)	< 1	< 1	<1 <1	
Replacement fluids	Crystalloids	Crystalloids	Crystalloids AND Blood likely to be required	Crystalloids AND Blood required

Source: Clinical use of blood, WHO, 2005

# 4 - Carrying out transfusions

**1.** If the blood unit has come from the refrigerator, leave it at room temperature for 10 min prior to transfusion. Cold blood administered at very high rates (i.e. > 100 ml/min) can cause cardiac arrest.

However, blood should never be warmed in hot water as this could lead to haemolysis. Keeping the patient warm is more important than warming the blood unit.



Have basic resuscitation drugs and equipment on hand in the event of adverse reactions.

- 2. Prepare a monitoring form and place the supplies needed on a tray (blood giving set, non-sterile gloves and compresses, antiseptic, tourniquet, IV catheter, adhesive tape).
- **3.** Measure and record pre-transfusion vital signs on the monitoring form: temperature, pulse, blood pressure and respiratory rate.
- **4.** Wash hands, or disinfect them with an alcohol-based solution. Wear gloves. Insert the IV catheter, check that it is correctly placed and fixed. Connect the blood giving set to the bag, with the flow regulator closed. Squeeze the drip chamber to fill it.

Prime the tubing, then re-close the flow regulator.

Connect the giving set to the catheter, using an antiseptic-soaked compress.

Do not add any medication to the blood unit.

5. Set the transfusion rate according to the volume and the duration prescribed. For most blood giving sets, 1 ml of blood = 15 drops.

> *Example of calculation of transfusion rate in drops/minute* for 250 ml of blood over 3 hours

Calculate the number of drops to be transfused	250 (ml) x 15 (drops) = 3750 drops	
Calculate the transfusion time in minutes	3 (hours) x 60 (minutes) = $180$ minutes	
Divide the number of drops by the number of minutes	3750 ÷ 180 = 21 drops per minute	

Tables with transfusion rates in drops/minute in children can be found in Appendices 6.1 and 6.2.

- 6. Safely dispose of waste. Remove gloves. Wash hands, or disinfect them with an alcohol-based solution.
- 7. Complete the monitoring form: transfusion start time, flow rate, anticipated end time, etc.

*Note*: if the blood flow slows down or stops, move the needle around gently. If this fails: clamp the blood giving set, remove it from the catheter (but do not disconnect it from the bag) then insert a second blood giving set to the second outlet of the bag, prime it then connect it to the catheter.

## 5 - Intraosseous transfusion

#### Indications

Placement of an intraosseous needle is indicated when intravenous cannulation is unsuccessful (i.e. after three failed attempts at inserting IV). In experienced hands, intraosseous access can be established within 1 minute. Although principally advocated for use in young children, it has been successfully used in older children where the iliac crest may also be used.

#### **Contra-indications**

- Fracture of the bone used as an access site, including femoral fracture on the ipsilateral side
- Östeomyelitis

#### Equipment

- Sterile gloves
- Sterile compresses
- Antiseptic solution (10% polyvidone iodine)
- Local anaesthetic (and syringe, needle) if necessary
- Sterile 0.9% sodium chloride
- Adhesive tape
- 5 ml syringe
- 10 ml syringe
- Sterile intraosseous needle. There are different needle sizes (14, 16 and 18G). The 14 and 16G are usually used for children > 18 months. However any size can be used for all ages.

#### Intraosseous needle placement

#### Site

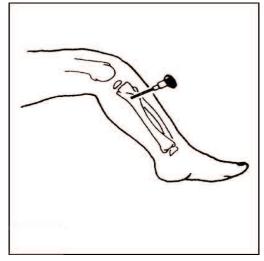
The best site to use is the flat anteromedial aspect of the tibia. The anterior aspect of the femur and the superior iliac crest can also be used. The tibia is preferred since the anteromedial aspect of the bone lies just under the skin and can easily be identified.

#### Procedure

The procedure must be performed under sterile conditions.

- 1. Flex the knee and put a suitable support such as a sandbag behind the knee. Position the leg with slight external rotation.
- 2. Palpate the tibial tuberosity. The site for cannulation lies 1-3 cm below this tuberosity on the anteromedial surface of the tibia.
- 3. Wear sterile gloves.
- 4. Disinfect the skin and allow drying.
- 5. If the child is conscious, inject a small amount of local anaesthetic in the skin and continue to infiltrate down to the periostium. If the child is unconscious it is not necessary to use local anaesthesia.
- 6. Immobilise the limb with the non-dominant hand, usually at the level of the knee. Avoid putting the hand behind the site of insertion to avoid accidentally injury (this hand is no longer sterile).
- 7. With the sterile hand, insert the intraosseous needle at 90 degrees to the skin (perpendicular) and slightly caudal (towards the foot) to avoid the epyphysial growth plate.

- 8. Advance the needle using a drilling motion until a 'give' is felt (this occurs when the needle penetrates the cortex of the bone). Stop inserting further.
- 9. Remove the inner trocar. Confirm correct position by aspirating bone marrow using the 5 ml syringe. If aspiration is unsuccessful, the needle may be blocked with marrow. To unblock the needle, slowly inject 0.9% sodium chloride, using the 10 ml syringe. Check that the limb does not swell up and that there is no increase in resistance. If the test is unsuccessful remove the needle and try the other tibia.
- 10. Secure the needle with sterile gauze and tape.



**Figure 4** *Insertion of intraosseous needle in the left tibia* 

Criteria for proper needle placement:

- The needle remains upright without support. Because infants have softer bones, the needle will not stand as firmly upright as in older children.
- There is no resistance (transfused blood flows freely through the needle).
- There is no subcutaneous extravasation (no swelling of the subcutaneous tissue).

#### Complications

- Tibial fracture especially in neonates
- Compartment syndrome
- Osteomyelitis, cellulitis, skin necrosis. When an aseptic technique is used, the incidence of osteomyelitis is < 1%.</li>

#### **Blood** administration

Connect the blood giving set to the intra-osseous needle; secure the tubing with adhesive tape.

Blood can be transfused under gentle pressure (by inflating a blood-pressure cuff around the blood bag).

The intraosseous needle should be removed as soon as transfusion is completed.

#### Removal of intraosseous needle

The needle should be removed using an aseptic technique.

- 1. Gently rotate the needle and withdraw smoothly.
- 2. Cover the puncture site with sterile compresses and apply direct pressure for several minutes.
- 3. Remove compresses and cover the site with a sterile dry dressing.

# 6.1 - Transfusion rate - Infants and children

ů ů				0 0			
	WHOLE BLOOD			PRBC			
Weight in kg	Volume (ml)*	Rate (drops/min)	Duration	Volume (ml)*	Rate (drops/min)	Duration	
3	60	4	4 hours	30	4	2 hours	
4	80	5	4 hours	40	5	2 hours	
5	100	6	4 hours	50	6	2 hours	
6	120	7	4 hours	60	7	2 hours	
7	140	9	4 hours	70	9	2 hours	
8	160	10	4 hours	80	10	2 hours	
9	180	11	4 hours	90	11	2 hours	
10	200	12	4 hours	100	12	2 hours	
11	220	14	4 hours	110	14	2 hours	
12	240	15	4 hours	120	15	2 hours	

Whole blood: 20 ml/kg at 5 ml/kg/hour **PRBC**: 10 ml/kg at 5 ml/kg/hour

\* 1 ml of blood = 15 drops

Blood units usually contain a volume greater than the prescribed volume. For example, for a child weighing 6 kg, who must receive 120 ml of whole blood, the blood bank will issue a 150 ml or 250 ml whole blood unit.

To ensure that the prescribed volume is administered, at the hourly rate of 5 ml/kg/hour, the duration of administration must be respected as it determines the volume transfused.

For example, in order to administer 120 ml of whole blood in a child weighing 6 kg, the transfusion must be set at 7 drops/min over 4 hours. At the end of 4 hours, the transfusion must be stopped (as 120 ml have been given), and the remaining blood must be discarded.

PRBC:

5 to 7 ml/kg at 5 ml/kg/hour

# 6.2 - Transfusion rate - Severely malnourished children

Whole blood:

10 ml/kg at 5 ml/kg/hour

		0 0		0	0	
XA7 + 1 /	W	HOLE BLOO	D	PRBC		
Weight in kg	Volume (ml)*	Rate (drops/min)	Duration	Volume (ml)*	Rate (drops/min)	Duration
3	30	4	2 hours	15 to 20	4	70 minutes
4	40	5	2 hours	20 to 30	5	70 minutes
5	50	6	2 hours	25 to 35	6	70 minutes
6	60	7	2 hours	30 to 40	7	70 minutes
7	70	9	2 hours	35 to 50	9	70 minutes
8	80	10	2 hours	40 to 55	10	70 minutes
9	90	11	2 hours	45 to 60	11	70 minutes
10	100	12	2 hours	50 to 70	12	70 minutes
11	110	14	2 hours	55 to 75	14	70 minutes
12	120	15	2 hours	60 to 85	15	70 minutes

\* 1 ml of blood = 15 drops

Blood units usually contain a volume greater than the prescribed volume. For example, for a severely malnourished child weighing 3 kg who must receive 15 to 20 ml of PRBC, the blood bank will usually issue a 100 ml unit of sedimented red cells<sup>1</sup>.

To ensure that the prescribed volume is administered, at the hourly rate of 5 ml/kg/hour, the duration of administration must be respected as it determines the volume transfused.

For example, in order to administer 20 ml of PRBC in a child weighing 3 kg, the transfusion must be set at 4 drops/min over 70 minutes. At the end of 70 minutes, the transfusion must be stopped (as 20 ml have been given), and the remaining blood must be discarded.

<sup>&</sup>lt;sup>1</sup> Sedimented red cells units are whole blood units that have been stored upright, with the giving set outlet at the bottom (see Appendix 11) in order to be able to transfuse concentrated red cells when centrifuged red cells are not available.

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# 7 - Transfusion monitoring form

Date:			Ward:
Patient	Name: Age: Blood group:		Bed No: Sex: Weight:
<b>Transfusio</b> Prescribing Nurse in c	g physician:		Blood unit number: Whole blood  PRBC
Duration of	blood to be administered: of transfusion: on start time:	ml	Rate (drops/min): Anticipated end time:
Monitorin	ıg		

	Time	T°	Pulse	BP	RR	Urine output	General condition
Before transfusion							
5 min							
15 min							
30 min							
45 min							
1 hr							
1 hr 30							
2 hr							
2 hr 30							
3 hr							
3 hr 30							
4 hr							
4-6 hr after the end of the transfusion							

Time transfusion stopped:

Volume administered:

#### **Problems encountered**

Time	Symptoms	Treatment	Evolution

#### Signature of the nurse in charge:

# 8 - Transfusion reaction form

Patient name:				Age:		S	ex:
Ward:	Be	d No.:		Patien	t's file No.:	E	Date :
	Α	В	AB	0		Positive	Negative
Patient blood group:					Rh D		
	А	В	AB	О		Positive	Negative
Blood unit group:					Rh D		
Blood unit No.:							

Indication for transfusion:								
Time the reaction occurred after the transfusion started: Volume transfused: ml								
Signs and symptoms:								
Type of transfusion reaction:								

Physician name and signature

Nurse name and signature

## 9 - Example of pre-donation form

#### **Pre-selection process**

#### 1) Questionnaire

Questions	Donor's answers	Comments
What is your age?		Exclude if < 15 or > 65 years.
What is your weight?		Exclude if < 45 kg.
Are you feeling well today?		If unwell, do not continue, and refer to the doctor.
When was the last time you donated blood?		Min. 8 weeks between 2 donations (time needed to replenish iron stores). Collect 150-250 ml max. if last donation > 8 weeks but < 12 weeks. Max. 4 times/year for men and 3 times/year for women.
For female donors		
Are you pregnant?		Exclude if pregnant.
Did you give birth or have a miscarriage in the last 6 months?		Exclude if birth or miscarriage < 6 months.
Are you currently breastfeeding? Is the child exclusively breastfed?		Exclude if exclusive breastfeeding. If not exclusively breastfeeding: collect only if the child is > 1 year.

#### 2) Hb level measurement

(+ blood group + malaria testing in endemic areas if direct donation)

#### Questionnaire

Questions	Donor's answers	Comments
What is your occupation?		High-risk occupation: sex workers, drivers, military personnel and any person with itinerant activity. See contra-indications, Chapter 3.
Are you suffering from a chronic illness (epilepsy, diabetes, cancer, heart, kidney, blood disease)?		See contra-indications, Chapter 3.
Are you taking any medical treatment?		See contra-indications, Chapter 3.
In the past, have you suffered from jaundice?		See contra-indications, Chapter 3.
Have you had any dental procedure in the past 3 days?		If yes, exclude temporarily (3 days after the procedure).
In the past 3 weeks: Have you had fever? Have you had malaria? Have you travelled to an area where there is malaria?		If yes, perform malaria test. See malaria screening, Chapter 3.
In the past month: Have you received any vaccine(s)?		Exclude temporarily (2 weeks) after immunisation with live vaccines.
In the past 3 months: Have you suffered from night sweats, weight loss, persistent fever or diarrhoea, swollen glands?		Exclude: risk of HIV infection, TB, chronic illness.
In the past 4 months: Have you engaged in unprotected casual sex? Have you had more than one partner?		See contra-indications, Chapter 3. Unprotected casual sex includes forced sexual intercourse (rape).
In the past 4 months: Have you been treated for STI (syphilis, gonorrhoea, chlamydia, genital ulcer or herpes)?		See contra-indications, Chapter 3.
In the past 6 months: Have you been hospitalised? Did you have surgery or endoscopy?		See contra-indications, Chapter 3.
In the past 6 months: Have you received a blood transfusion?		Exclude for 6 months after transfusion.
In the past 6 months: Have you shared used needles or syringes? Have you had scarification, tattoos or piercing (ears, body)?		If yes, exclude.

Date:

Do you wish to give blood regularly?

Can we contact you in future?

#### Physical examination

Criteria	Results	Comments
Weight (if unknown)		Exclude if < 45 kg.
Temperature		Exclude if T° > 37.5°C axillary and test for malaria in endemic area.
Pulse		Exclude if pulse < 50/min or > 100/min or irregular.
Systolic BP		Exclude if systolic BP < 100 or > 180 mmHg.
Signs suggesting an acute or chronic infection including HIV infection or hepatitis: yellow conjunctiva (jaundice), enlarged lymph nodes, skin rash, oral thrush, etc.		AND Refer the donor to the physician if any abnormality observed on physical exami- nation.

Donor excluded		Permanently Temporarily		 / _/
Donor selected		1 5		Day Month Year
Maximum volume t	o collect		ml	
Snack <sup>1</sup>				

 $<sup>\</sup>overline{1}$  A snack is given to the donor prior to blood collection.

## **10 - Blood collection procedure**

Collecting blood carries a risk of bacterial contamination and thus, a risk of secondary infection in the patient transfused with the contaminated blood. The procedure must be done with strict aseptic technique, using a sterile closed system and a single venepuncture.

One bag = One needle = One puncture

#### Equipment

- Blood bag (Appendix 30)
- Dressing tray
- Non-sterile, single use gloves
- Protective glasses
- Non-sterile compresses
- Antiseptic solution (10% polyvidone iodine)
- Tourniquet
- Adhesive tape
- Scissors
- EDTA tube
- Blood weighing scale
- Support for the scale (e.g. stool, small table)
- Sheet to place under donor's arm
- Sharps container
- 0.5% chlorine solution (or another disinfectant)

#### Procedure

- 1. Explain the procedure to the donor.
- 2. Inspect the arms: the skin should be free of scars and lesions. The puncture site must be clean. If necessary, ask the donor to wash his forearms with water and soap, especially the antecubital fossa.
- 3. Place the donor in a semi-sitting or lying position.
- 4. Wash your hands or disinfect them with an alcohol-based solution.
- 5. Prepare the supplies and place the scale at a level lower than the donor's arm to use gravity during the blood collection.
- 6. Prepare the blood bag:
  - Choose the bag size according to the volume of blood to be drawn, taking into account the donor's age, weight, Hb level and the available stocks and further needs. For direct donation, collect only what the patient needs, e.g. a 150 ml bag if the volume of blood prescribed is 100 ml.

A maximum of 8-10 ml/kg of blood can be drawn. The amount should be limited to: 500 ml in an adult > 50 kg

250 ml if the donor's age is between 15 and 18 or if the donor's weight is between 45 and 50 kg

- Remove the blood bag from its packaging.
- Close the clamp on the bag tubing (5 cm from the bag).
- Make one loose knot at the far end of the tubing, 10 cm from the needle (Figure 5).
- Label the blood bag with the donation number, date of the blood collection and expiry date.

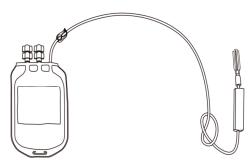


Figure 5

- 7. With the empty blood bag on it, adjust the scale to 0, so that the scale displays only the weight of the blood collected.
- 8. Prepare the venepuncture site:
  - Put a clean sheet under the donor's arm, to protect the armrest/the bed from blood spills.
  - Put on the tourniquet and locate a good vein in the antecubital fossa.
  - Wear gloves and protective glasses.
  - Disinfect the puncture site and let it dry without wiping. Repeat the procedure.
  - After the skin has been disinfected, the vein should not be palpated again.
- 9. Collect blood (the duration for the collection should not exceed 15 minutes):
  - Perform the puncture.
  - Open the clamp. When the blood is flowing in the tubing, secure the needle and the tubing with adhesive tape.
  - As soon as a few ml of blood are in the bag, start mixing the blood with the anticoagulant by gently tilting the bag, off the scale. Repeat the manoeuvre every minute until the bag is filled. Check regularly the weight of the blood bag. Stop the collection when the correct weight (volume) is reached (± 10%).

Blood bag size (in ml)	Minimum-maximum volume to be collected (in ml)	Weight of collected blood (in g) alone (no bag, no anticoagulant)	<b>Expected minimum-</b> <b>maximum final weight<sup>1</sup> (in g)</b> <i>including bag and anticoagulant</i>
150	135-165	140-175	180-215
250	225-275	235-290	295-350
450	405-495	425-520	515-610

Weight	of a	hlood	unit	(whole	hlood)
VVEIQIII	0j u	01000	инн	(whole	<i>01000i</i> )

<sup>&</sup>lt;sup>1</sup> Blood density = 1.05 g/ml

- Release the tourniquet.
- Close the clamp prior to removing the needle otherwise air will be introduced into the bag and may contaminate the blood.
- Ask the donor to press firmly on the puncture site with a compress, keeping the arm straight.
- Immediately slide the protective device over the needle.

10. Collect sample and seal the bag (Figure 6):

- Tighten the knot close to the needle.
- Cut the bag tubing close to the knot, at the patient end. When cutting the tubing, beware of blood spills. Position a compress to absorb the blood when cutting the tubing.
- Open the EDTA tube and collect the blood from the cut off piece of tubing.



Figure 6

- Discard the needle in the sharps container.
- Close the EDTA tube and label it with the donation number and date.
- Make 4 tight knots in the tubing at intervals of 10-15 cm, creating blood segments to be used for further testing (Figure 7).

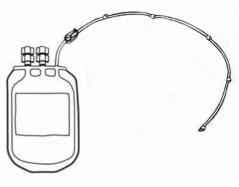


Figure 7

- Disinfect the armrest using a 0.5% chlorine solution and dispose of waste.
- Disinfect the scissors using a 0.5% chlorine solution and rinse thoroughly with running water to avoid cross-contamination of the following donation.
- Remove and discard the gloves; wash your hands or disinfect them with an alcohol-based solution.
- Send the EDTA tube to the laboratory in order to perform the tests as soon as possible.

- 11. Donor care
  - Tape a dry compress over the puncture site after checking that it has stopped bleeding.
  - The donor should remain in a sitting position for 5 minutes before slowly getting up. He should then be kept under observation and rest for 10 minutes. Encourage him to drink (500 ml); recommend him to avoid strenuous activity for a few hours.
- 12. Blood storage
  - If the blood unit will not be transfused within 4 hours, let it cool down (in a temperate cold box, an air conditioned room or by using a wet cloth) to a temperature between 18-24°C for 2 to 4 hours. This allows the bactericidal activity of the white blood cells to take place.
  - Blood must be stored in a refrigerator between 2-6°C within 2 to 4 hours of collection.

#### Possible incidents during or after collection

- *The blood flow is slow or the blood flow stops:* 

- Ensure the blood bag is lower than the venepuncture site.
- Ask the donor to pump his fist in order to increase the flow.
- Loosen and retighten the tourniquet in order to improve the flow.
- Move the needle around gently.
- *The blood flow stops before the minimum volume is reached:*

The unit cannot be used for transfusion. Discard the bag. Each blood bag contains a specific amount of anticoagulant solution for a determined quantity of blood and should be filled appropriately to ensure the correct ratio blood/anticoagulant.

If the donor agrees, attempt another collection on the other arm using a new bag. The blood bag size for the second collection should be chosen taking into account the volume already withdrawn from the donor, in order not to exceed the maximum amount per donation (e.g. if 150 ml were withdrawn during the first attempt, use a bag of 250 ml for a second blood collection when the donor is eligible for 450 ml collection).

*– In the event of vasovagal reaction:* 

Vasovagal reaction occurs during or after collection in up to 5% of blood donors. It is frequently triggered by anxiety or can happen when the donor gets up too quickly.

The donor feels unwell. Other symptoms include light-headedness, profuse sweating, pallor, blurred vision, transient alteration of consciousness.

In case of loss of consciousness, stop the blood collection. Position the donor on his back with the feet elevated. Once he has recovered, ensure he is properly hydrated.

*– In the event of accidental exposure to blood:* 

Follow the recommendations for post-exposure prophylaxis.

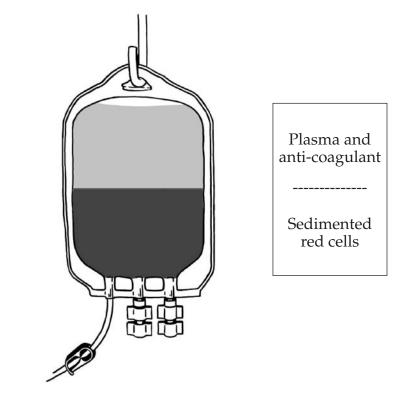
# 11 - Preparation of partially concentrated red cells from whole blood

Red cell concentrates are preferred for:

- Patients with anaemia and no hypovolemia
- Patients at risk of developing fluid overload
- Patients transfused with non-ABO identical blood

Packed red blood cells (PRBC) prepared by centrifugation are sometimes provided by national/regional blood banks but are unlikely to be available in many settings. Partially concentrated red cells can be prepared by storing the blood unit in the refrigerator, in an upright position, placing the giving set outlet at the bottom, for a minimum of 6 hours. This allows the red cells to sediment. The longer the sedimentation time the more distinct the separation between red cells and plasma. The sedimented red cells must not be disturbed during transportation and transfusion. Care must be taken to stop the transfusion when the plasma reaches the bottom of the blood unit or when the volume prescribed has been administered.

In 450 ml whole blood unit, sedimented red cells occupy a volume of  $\pm$  225 ml. In 250 ml whole blood unit, sedimented red cells occupy a volume of  $\pm$  125 ml. In 150 ml whole blood unit, sedimented red cells occupy a volume of  $\pm$  75 ml. In 100 ml whole blood unit, sedimented red cells occupy a volume of  $\pm$  50 ml.



**Figure 8** *Red cell concentrate prepared by sedimentation* 

## 12 - Preparation of paediatric blood units from penta bag system

The penta bag system is a closed system made of one primary 450 ml bag, containing anticoagulant-preservative solution, and four 100 ml satellite bags attached to the primary bag, which do not contain anticoagulant.

This system is used to divide the blood collected in the primary bag into 4 units of less than 150 ml, for paediatric use.

Satellite bags can only be prepared once the grouping and TTI screening have been performed on the donor or on the primary bag.

#### Equipment

- Hook or a stand to hang the system
- Scissors
- Compresses
- Non-sterile, single use gloves
- Protective glasses
- Fine-tip permanent marker
- Blood weighing scale

#### Procedure

- 1. Wear gloves and protective glasses.
- 2. Label the four satellite bags. Write on each bag:
  - The blood unit number of the 450 ml bag, plus an index number for each unit: (1) on bag 1, (2) on bag 2, (3) on bag 3, (4) on bag 4.
  - The collection and expiry date.
  - The ABO Rh D group.
- 3. Fill the four satellite bags:
  - Mix thoroughly the blood by gently tilting the 450 ml bag.
  - Open the 4 clamps and position them as close as possible to the 450 ml bag.
  - Hang the 450 ml bag high enough to let the 4 bags hang down.
  - Break the device, by firmly folding the tube, to let the blood flow through (Picture 1).
  - The four satellite bags will fill up simultaneously and equally, until the primary bag is empty. If not, check that the devices have been correctly broken. Once the 4 bags have been filled, each one contains 100 to 125 ml of blood depending on the volume contained in the primary bag (between 405 and 495 ml).

4. Fill the tubing with blood:

- Press gently on bag N°1 to evacuate the air from the tubing and fill it with blood (Picture 2).
- Close the clamp.
- Repeat for the bag N°2, N°3 and N°4.
- Once the 4 clamps are closed, unhook the system from the stand.

- 5. Close each bag and separate them:
  - For each bag, tie a knot in the tubing below and close to the clamp and tighten securely. Cut the tubing between the knot and the clamp while protecting from spills with a compress.
  - Tie two more knots in the tubing.
- 6. Waste management:
  - Clean the scissors with 0.5% chlorine, and rinse thoroughly under running water.
  - Safely dispose of the empty 450 ml-bag.
- 7. Enter the four 100 ml-units in the blood bank/register.



**Picture 1** *Break the device* 



**Picture 2** *Fill the tubing with blood* 



**Picture 3** *Paediatric bags filled, closed and labelled* 

#### Notes:

- To obtain volumes < 100-125 ml (e.g. 50 ml or 75 ml), satellites bags can also be filled one by one by closing the 3 other clamps. In this case, place the empty satellite bag on the scale and adjust the scale to 0, so that the scale displays only the weight of the blood collected. Fill the bag until the desired weight (volume) is reached, i.e. 80 g for a bag of 75 ml and 50 g for a bag of 50 ml. Indicate the weight of the bag on the label.</p>
- All the remaining units prepared from the same primary 450 ml bag must be discarded if:
  - An abnormality is detected in one satellite unit.
  - A septic transfusion reaction occurs during or after transfusion of one satellite unit.

# 13 - Drawing and use of capillary blood

#### Equipment

- Sterile disposable lancets
- Antiseptic solution
- Non-sterile compresses
- Non-sterile, single use gloves

#### Procedure

- 1. Wash your hands or disinfect them with an alcohol-based solution and wear gloves.
- 2. Choose a puncture site: sides of middle or ring finger, ear lobe or sides of the heel in neonates.
- 3. Massage gently around the puncture site to improve blood flow.
- 4. Disinfect the puncture site and let it dry.
- 5. Prick the site with a lancet at a right angle to the skin.
- 6. Wipe away the first drop of blood with a dry compress.
- 7. Use the drops of blood that follow for testing.

#### Testing device filling

To fill:

– A plastic loop

Touch the surface of the drop of blood to fill the interior circle of the loop. Make sure that the loop is not overloaded. The drop should be slightly convex.

- A pipette tip
   Press down the pipette plunger and apply the pipette tip to the blood. Release gently the pipette plunger in order to avoid aspirating air.
- A disposable dropper
   Press the dropper bulb and apply the dropper tip to the blood. Release gently the dropper bulb in order to avoid aspirating air.
- A disposable capillary tube
   Let the blood fill by capillary action, until the blood has reached the mark.
- A cuvette HemoCue®
   Introduce the pointed end of the cuvette into the centre of the drop of blood. Let the blood fill by capillary action in one continuous process.

### 14 - Haemoglobin measurement using HemoCue 301®

Hemocue 301<sup>®</sup> is a hand-held analyser allowing quantitative determination of Hb from capillary or venous blood samples.



HemoCue301®

Cuvette HemoCue301®

#### Equipment

- HemoCue 301® analyser
- Cuvettes HemoCue 301®
- Non-sterile, single use gloves
- Non-sterile compresses

*Note*: cuvettes 201 (in red top container) and 301 (in white top container) look similar, but are not interchangeable. It is not possible to insert cuvettes 201 in the HemoCue 301®, and vice versa.

#### Sample

- Capillary blood, for immediate testing (Appendix 13).

#### Procedure

- Switch on the analyser. It will automatically perform an auto-test with calibration.

<ul> <li>Introduce the pointed end of the cuvette into the centre of the drop of blood.</li> <li>Let the cuvette fill (10 microlitres of blood) by capillary action in one continuous process. It must be filled <b>completely</b> and uniformly.</li> </ul>	Rets
Wipe off excess blood on the outside of the cuvette with a compress, without removing blood from inside the cuvette.	A B
Ensure that no air bubbles are present in the cuvette.	the second se
<ul> <li>Pull the cuvette holder to the loading position.</li> <li>Insert the cuvette in the cuvette holder.</li> <li>Gently push the cuvette holder. It will close automatically.</li> </ul>	

- A filled cuvette must be analysed within 40 seconds of filling.

- Result is displayed within 30 seconds.
- Remove the cuvette and dispose of it in a sharps container.
- Push the cuvette holder back.

*Note*: if the test is performed on whole blood collected in an EDTA tube, mix the blood by tilting the tube several times in order to homogenize the blood sample. Apply one drop of blood on a glass slide then fill the cuvette.

#### Common causes of error

- Insufficient filling of the cuvette.
- Presence of air bubbles.
- Non-uniform filling of the cuvette due to presence of rouleaux or agglutination.

In these situations, repeat the test with another cuvette.

#### Cleaning of cuvette holder and optical unit

The cuvette holder should be cleaned at the end of each working day.

The optical unit should be cleaned at least once a month or after 50 tests or when the analyser shows an error message.

Follow the manufacturer's instructions.

#### Storage

Hemocue 301® and disposable cuvettes 301® are designed to operate between 10°C and 40°C.

When stored between 10°C and 40°C, cuvettes can be used until the expiry date.

When stored between 40°C and 50°C, they must be used within 6 weeks.

After opening the cuvettes container, cuvettes should be used within 3 months.

## 15 - ABO and Rh D grouping procedure (direct tile method)

Direct grouping determines the presence of antigens on the red cell membrane using commercial monoclonal antisera, which have agglutinating properties at room temperature.

#### Equipment and reagents

- Smooth ceramic white tile (approx. 15 x 30 cm)
- Applicators (wood or plastic mixing sticks, round bottomed tube, needle cap or similar item)
- Permanent marker
- Reagents vials:
  - Antisera:

Anti-A	Blue	
Anti-B	Yellow	
Anti-AB	Colourless	
Anti-D	Colourless	

• **Rh negative control** (the reagent must be from the same manufacturer as the anti-Rh D antiserum).

The labels of the vials are prone to becoming unstuck due to condensation. It is advisable to secure the labels by wrapping the vials with clear adhesive tape, as anti-AB, anti-Rh D and control reagent are colourless, and could easily get mixed up. Keep the set of 5 grouping vials currently in use in a designated stand.

#### Sample

Blood grouping of a donor or a patient:

- Capillary blood, for immediate testing
- Whole blood in EDTA tube

*Checking the blood group of a blood unit:* Blood from the distal segment of the bag tubing

#### Procedure

- 1. Allow the reagents to reach room temperature.
- 2. Ensure the tile is dry.
- 3. With the marker, divide the tile into 6 columns:
  - In the first column, note the sample identification:
    - for donor or patient blood grouping: initials and date of birth
    - for blood group verification on a blood unit: blood unit number
  - In the 5 remaining columns, note in the following order: anti-A, anti-B, anti-AB, anti Rh D, negative control.

- 4. Deposit 1 drop of each reagent in its respective labelled area of the tile.
- 5. Deposit 1 small drop of whole blood beside each reagent drop.
- 6. Mix the 2 drops in circles of 3 cm diameter with an applicator. Wipe the applicator between each test zone (or use a new one or use a fresh side of the applicator).
- 7. Rock the tile gently, in a tri-directional movement, for 2 minutes while observing the reactions. They may develop at different rates and to different extents. Be careful that the mixtures do not run into each other.

#### **Results and interpretation**

The interpretation of ABO Rh D grouping is possible only if the control reagent (Rh neg. control) is clearly negative.

Agglutinates form progressively, and leave the background free of red cells. When the mixture remains homogeneously coloured, no agglutination is present.

The presence of agglutination means that the antigen is present on the red cell surface.

If the reaction is not obvious, repeat the procedure using less blood (fewer red cells) and/or more reagent.

Anti-A	Anti-B	Anti-AB	Anti-D	Rh neg. control	Interpretation
+	_	+	+	_	A Rhesus positive
+	_	+	_	_	A Rhesus negative
_	+	+	+	_	B Rhesus positive
_	+	+	_	_	B Rhesus negative
+	+	+	+	_	AB Rhesus positive
+	+	+	_	_	AB Rhesus negative
_	_	_	+	_	O Rhesus positive
_	_	_	_	_	O Rhesus negative
+ or –	+ or –	+ or –	+ or –	+	No interpretation possible

Interpretation chart – Direct ABO Rh D blood grouping

+ : Presence of agglutination

-: Absence of agglutination

## Reporting the result

- A, B, O must be written in capital letters.
- Rh D group must be written in letters: pos. or neg.
- Report the ABO Rh D group in the registers.
- Report the ABO Rh D group in the patient's file or the blood group request form or the blood request form, or the blood bag label (using a permanent marker).

#### Common causes of error

- Sample haemolysed or clotted
- Cross-contamination of reagents by swapping caps
- Cross-contamination of the reaction zones during mixing

#### Major causes of interpretation difficulties

#### Weak agglutination:

- Repeat the test using less blood (fewer red cells) and/or more reagent.
- Agglutination may be incomplete if the patient was recently transfused with non-ABO identical blood.

#### *Positive reaction with the Rh negative control reagent:*

- This can happen in the following circumstances:
  - Rouleaux (piles of red cells) can be confused with agglutinates.
  - Autoagglutination of red cells is encountered in some pathologic conditions.
- If the reaction with the Rh negative control is not clearly negative, wash the red cells with normal saline:
  - Add NS to a few drops of whole blood in a new plastic tube, mix, centrifuge (1000 g, 2 min), discard the supernatant.
  - Perform a second washing and use the washed red cells to repeat the entire procedure.
- If the reaction with washed red cells is still positive, the grouping procedure is not validated. Thus:
  - When grouping a donor: do not use the blood unit as the blood group cannot be determined.
  - When grouping a patient: consider the patient as an O Rh neg. recipient.

# **16.1 - Bedside verification of ABO compatibility using Eldoncard® 2551**

The bedside verification of ABO compatibility aims at preventing ABO incompatibility accidents resulting from mislabelling of tubes/blood unit or misidentification of patients. The ABO group of both recipient and blood unit are checked.

The control is performed:

- By the nurse or doctor who carries out the transfusion
- At the patient's bedside
- Immediately before starting transfusion
- Using the recipient's capillary blood and blood from the tubing segment of the blood unit

## Equipment

- A card with 4 circles covered with a drop of desiccated blood grouping reagent: 2 circles with anti-A (green) and 2 circles with anti-B (pink) reagents
- 4 plastic sticks for mixing
- 1 piece of transparent adhesive
- 1 lancet
- 1 vial of 5 ml of non sterile normal saline solution

Anti-A	Anti-B	Anti-A	O Anti-B
RECIPIENT - Name - Nombre	EMPFÄNGER - RECIBIDO	DR DONOR - SPEND	ER - DONADOR
Born - Geboren - Na	cimiento	Born - Geboren - Nacimiento	
ABO	Date - Datum - Fecha	Signature - Unterschrift - Firma	ABO
	LOT 09371 X	2011-09 A	ő

## Procedure

- 1. In the zone RECIPIENT (left side, yellow), note the recipient's identification (full name, date of birth or patient file number).
- 2. In the zone DONOR, note the blood unit number (in the box "Name").
- 3. Note date and time and operator's name.
- 4. Apply 1 drop of normal saline solution on each drop of dessicated reagent.
- 5. Apply 1 small drop of the recipient's capillary blood on the RECIPIENT anti-A and anti-B circles.
- 6. Cut the extremity of the segment of the blood unit tubing and apply 1 small drop of blood on the DONOR anti-A and anti-B circles. Avoid applying clots.
- 7. In each circle, mix the blood and the reagent, using a new stick for each circle.
- 8. Tilt the card with a tri-directional movement for 1 minute and read.
- Note the interpretation and sign: If the blood issued is ABO identical: check that reactions are identical. If the blood issued is ABO compatible: check that reactions show that the blood is compatible with de recipient.

Any reaction that shows agglutination with the blood unit and no agglutination with the patient's blood contra-indicate categorically the transfusion.

In case of doubt, do not start the transfusion and call the physician in charge.

10. Once the card is dry, apply the adhesive. The card must be kept in the patient's file.

#### Storage

Eldoncard® 2551 should be stored below 37°C.

*Note*: this control does not replace a blood grouping and is not a cross-match procedure.

# **16.2 - Bedside verification of ABO compatibility using Serafol® ABO**

The bedside verification of ABO compatibility aims at preventing ABO incompatibility accidents resulting from mislabelling of tubes/blood unit or misidentification of patients. The ABO group of both recipient and blood unit are checked.

The control is performed:

- By the nurse or doctor who carries out the transfusion
- At the patient's bedside
- Immediately before starting transfusion
- Using the recipient's capillary blood and blood from the tubing segment of the blood unit

#### Equipment

- A card with 6 zones:
  - 4 circles containing a drop of desiccated blood grouping reagent: 2 circles with anti-A (blue) and 2 circles with anti-B (yellow) reagents
  - 2 squares (BLOOD) to deposit blood: 1 for the recipient's blood and 1 for the blood unit
- 4 plastic sticks for mixing
- 1 piece of transparent adhesive
- 1 Îancet
- 1 vial of 5 ml of non sterile normal saline solution



## Procedure

- 1. Note on the upper part of the card the recipient's identification (full name, date of birth or patient file number), the date and time and operator's name.
- 2. Note on the lower part of the card the blood unit number in the box "Unit No.".
- 3. Apply 1 drop of normal saline solution on each drop of dessicated reagent.
- 4. Apply 1 drop of the recipient's capillary blood on the upper square.
- 5. Cut the extremity of the segment of the blood unit tubing and apply 1 drop of blood on the on the lower square. Avoid applying clots.
- 6. With a stick, transfer the recipient's blood to the upper anti-A circle; mix the blood and the reagent.
- 7. With a new stick, transfer the recipient's blood to the upper anti-B circle; mix.
- 8. Repeat the same procedure with the blood from the blood unit, on the lower anti-A and Anti-B circles, using a new stick for each circle.
- 9. Tilt the card with a tri-directional movement for 1 minute and read.
- 10. Note the interpretation and sign:If the blood issued is ABO identical: check that reactions are identical.If the blood issued is ABO compatible: check that reactions show that the blood is compatible with de recipient.

Any reaction that shows agglutination with the blood unit and no agglutination with the patient's blood contra-indicate categorically the transfusion.

In case of doubt, do not start the transfusion and call the physician in charge.

11. Once the card is dry, apply the adhesive. The card must be kept in the patient's file.

## Storage

Serafol® ABO should be stored below 25°C.

*Note*: this control does not replace a blood grouping and is not a cross-match procedure.

# 17 - General recommendations when using rapid diagnostic tests (RDT)

#### Samples

RDT are sensitive tests. It is therefore crucial to avoid cross-contamination of samples:

- All material that comes in contact with samples is single use, including sample tubes, pipette tips, gloves, etc. Recycled supplies must not be used to perform RDT.
- Blood sample tubes should be kept closed: when testing samples, uncap only one tube at a time, and recap it before opening the next one.
- Take care that any blood on the underside of the sample tube cap does not contaminate materials (strips, pipette tips, etc.), workbench, or hands.

## Kits

When a new kit is opened:

- Write the date of opening on the package; check the kit for completeness and inspect each component to make sure that it does not show visible defects.
- Record the batch number, the expiry date and the date of opening in the workbench register.

*Note*: for Determine<sup>®</sup> kits (HIV 1/2 and HBs Ag), the batch number of the kit is not the same as the batch number of the strips.

A kit should no longer be used when one of the components runs out (usually strips or devices). Remaining reagents must be thrown away. Do not mix reagents from different lots.

#### Pouches containing strips/devices/reagents

- When a pouch includes a desiccant, the desiccant should remain there.
- Close tightly opened pouches, to protect contents from humidity and light.

#### Reagents

- When opening a bottle or reconstituting a reagent: write the date of opening or reconstitution on the bottle.
- Finish one reagent bottle before opening another one.
- If reagents are stored refrigerated, let them reach room temperature before use.

## Test bandling

- Open the individual protection of the strip/device just before performing the test.
- Do not touch the membranes with the fingers, even gloved, or with the reagent dropper, to avoid contaminating them.

- The dropper bottles or transfer pipettes should be held vertically, 2 cm away from the membrane, to deposit full drops, and thus an adequate amount of reagent or sample.
- Follow the recommended reading times, using a timer.
- Read the strips/devices on a horizontal surface, well illuminated with natural or artificial direct light.

#### Internal quality controls

#### Strips or devices internal control

Strips or devices include an internal control (control bar or dot) that attests to the migration of the reagents and the sample (in the case of lateral flow membranes), the addition of the sample (in some tests) and the functioning of the reaction.

#### **Control samples**

The HCV SPOT® kit includes a set of three control samples, one negative, one weak positive, and one strong positive. For other kits that do not include control samples, a negative and a positive (preferably weak) sample should be prepared and used regularly to check the tests performances.

Control samples must be tested:

- When the kit is first opened.
- At least once a week, if used frequently, or before each test, if used occasionally.
- When a storage problem is suspected.
- When the test repeatedly gives invalid results.
- When a new operator uses the kit.

#### Kits storage temperature

HIV Uni-Gold®	2°C-27°C*
HIV Determine® Hepatitis B Determine® HCV SPOT® Paracheck® Syphilis SD Bioline®	2°C-30°C*
Malaria Ag P.f SD Bioline® Malaria Ag P.f/Pan (Combo) SD Bioline®	1°C-40°C*

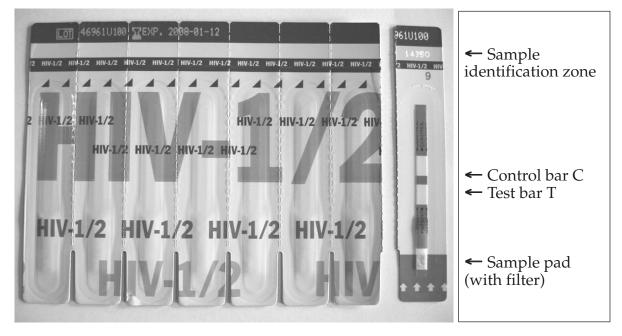
\* If kits are stored at room temperature, choose a cool, dry location.

# 18 - Test HIV 1/2 Determine®

HIV 1/2 Determine<sup>®</sup> is a lateral flow rapid test for the detection of antibodies to HIV 1 and 2.

# Description

- Membrane covered with HIV 1 and HIV 2 recombinant antigens and synthetic peptides.
- Strips individually sealed, attached in cards of 10 (10 cards), packed in an aluminium bag. The bag has a grip closing system and contains a desiccant.



Sealed and unsealed strips

Warning:

- The chase buffer to be used when testing whole blood is not included in the kit and must be ordered separately.
- The HIV 1/2 Determine® strips look very similar to the HBsAg Determine® strips.

## Sample

- Plasma or whole blood (EDTA tube) or serum (plain tube)
- Capillary blood

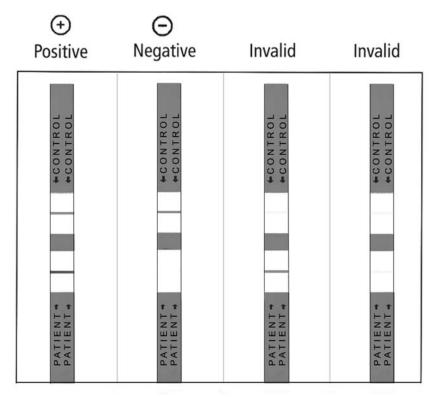
## Procedure

1. Split off the strip(s), at the right hand side of the card, by folding several times along the perforated line. Put the remaining strips in the bag and seal securely.

- 2. Identify the strip by writing the sample number between the 2 plain green-grey bands at the top, using a fine tip permanent marker.
- 3. Carefully tear off the protective foil cover.
- 4. If using whole blood:
  - Apply 50 microlitres to the sample pad.
  - One minute later, apply 1 drop of chase buffer to the sample pad.
  - *If using serum/plasma:*
  - Apply 50 microlitres to the sample pad. DO NOT add chase buffer.

#### Interpretation

- Read the result no sooner than 15 minutes and no later than 60 minutes.
- The test is validated only if the internal control bar is visible. Otherwise, the test is invalid.



Interpretation of HIV 1/2 Determine test®

#### Storage

The kit should be stored between 2°C and 30°C and must not be frozen.

# 19 - Test HIV Uni-Gold®

HIV Uni-Gold® is a lateral flow rapid test for the detection of HIV 1 and 2 antibodies.

## **Description**

– Membrane covered with recombinant immunodominants antigens of HIV 1 (gp 41 and gp 120) and HIV 2 (gp 36).

## Contents of the kit

- 20 devices, individually packed in an aluminium pouch
- 20 plastic capillary pipettes
- 1 vial of wash reagent in a dropper bottle (2 ml)

#### Sample

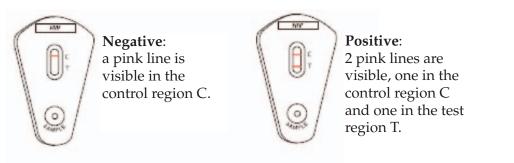
- Plasma or whole blood (EDTA tube) or serum (plain tube)
- Capillary blood

#### Procedure

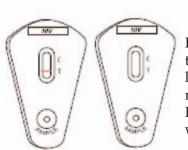
- 1. Open the pouch immediately before use.
- 2. Identify the device with the sample number using a thin permanent marker.
- 3. Apply 2 drops (approx. 60 microlitres) of whole blood, serum or plasma to the circle marked SAMPLE.
- 4. Apply 2 drops (approx. 60 microlitres) of wash reagent to the circle marked SAMPLE.

#### Interpretation

- Read between 10 and 20 minutes after the application of the wash reagent.
- The test is validated only if the internal control line is visible. Otherwise, the test is invalid.



C = internal control line T = test line



**Invalid**: there is no visible line in the control region C. Repeat the test with a new device.

Interpretation of the HIV Uni-Gold®

#### Storage

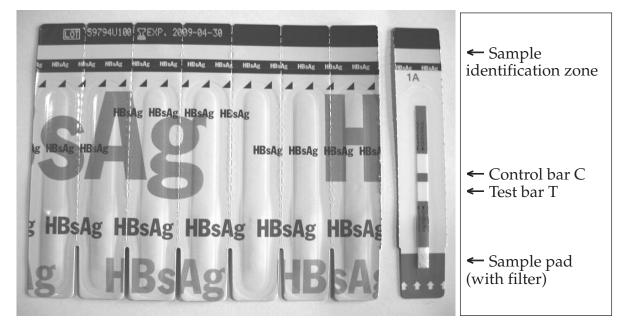
The kit must be stored between 2°C and 27°C and must not be frozen.

# 20 - Test HBsAg Determine®

HBsAg Determine<sup>®</sup> is a lateral flow rapid test for the detection of surface antigen of hepatitis B virus.

## **Description**

- Membrane covered with anti-hepatitis B virus antibodies.
- Strips individually sealed, attached in cards of 10 (10 cards), packed in an aluminium bag. The bag has a grip closing system and contains a dessicant.



Sealed and unsealed strips

Warning:

- The chase buffer to be used when testing whole blood is not included in the kit and must be ordered separately.
- The HBsAg Determine® strips look very similar to the HIV 1/2 Determine® strips.

#### Sample

- Plasma or whole blood (EDTA tube) or serum (plain tube)
- Capillary blood

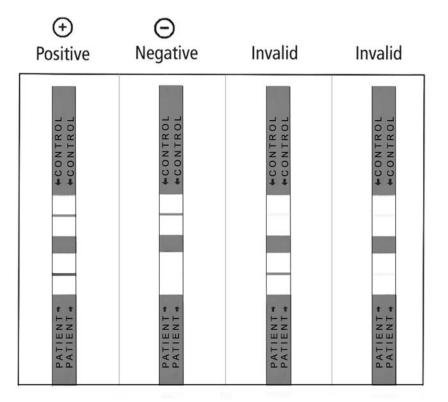
#### Procedure

1. Split off the strip(s), at the right hand side of the card, by folding several times along the perforated line. Put the remaining strips in the bag and seal securely.

- 2. Identify the strip by writing the sample number between the 2 plain dark blue bands at the top, using a fine tip permanent marker.
- 3. Carefully tear off the protective foil cover.
- 4. If using whole blood:
  - Apply 50 microlitres to the sample pad.
  - One minute later, apply 1 drop of chase buffer to the sample pad.
  - *If using serum/plasma:*
  - Apply 50 microlitres to the sample pad. DO NOT add chase buffer.

#### Interpretation

- Read the result no sooner than 15 minutes and no later than 60 minutes.
- The test is validated only if the internal control bar is visible. Otherwise, the test is invalid.



Interpretation of HBsAg Determine test®

#### Storage

The kit should be stored between 2°C and 30°C and must not be frozen.

# 21 - Test HCV-SPOT®

HCV-SPOT® is a 6 step-immuno-enzymatic rapid test for the detection of hepatitis C antibodies.

#### **Description**

The centre of the membrane is covered with hepatitis C antigens and its periphery with a control reagent.

#### Contents of the kit

- 100 devices, packed by 20 in 5 aluminium bags containing a dessicant
   One of the 5 bags is inserted in a clear plastic bag, with a grip closing system, to be used subsequently for the storage of an aluminium bag once opened.
- 1 vial of negative lyophilised control
- 1 vial of weak positive lyophilised control
- 1 vial of strong positive lyophilised control
- 12 vials of lyophilised conjugate, in an aluminium bag inserted in a clear plastic bag, with a grip closing system
- 15 plastic tubes with 1 ml of diluent for reconstitution of controls and conjugates
- 1 plastic bottle of 10 ml blocking buffer
- 1 plastic bottle of 10 ml wash buffer 1
- 1 plastic bottle of 10 ml wash buffer 2
- 1 plastic bottle of 10 ml stop solution
- 4 empty dropper bottles, for each of the four previous reagents, with caps of 4 different colours
- 100 sample pipettes (small)
- 12 reagent pipettes (medium)

#### **Preparation of reagents**

#### Lyophilised reagents

All the lyophilised reagents must be reconstituted at the time the kit is opened:

- Add 1 tube of diluent to each of the three control vials and to one vial of conjugate.
- Write the date of reconstitution on the vials.
- Mix well and allow to sit for at least 10 minutes before use.

#### Other reagents

At the time a new kit is opened, transfer the contents of each plastic bottle to the corresponding dropper bottle.

Abbreviation	Reagent	Colour of the dropper cap
BB	Blocking buffer	Yellow
WB1	Wash buffer 1	Blue
WB2	Wash buffer 2	White
SS	Stop solution	Red

## Sample

- Plasma (EDTA tube) or serum (plain tube)

## Procedure

Identify the device with the sample number, using a fine tip permanent marker.

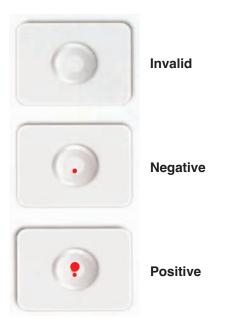
- 1. Add 2 drops of **blocking buffer** (yellow cap) to the membrane and allow it to soak in. If this takes more than 90 seconds, the device is defective and should be discarded.
- 2. Add 1 drop of **sample** and allow it to soak in. Use a sample pipette (or an automatic pipette, calibrated at 45 microlitres, not supplied with kit).
- 3. Add 2 drops of **wash buffer 1** (blue cap) and allow it to soak in.
- 4. Add 2 drops of **conjugate** and allow it to soak in. Use a reagent pipette (or an automatic pipette, calibrated at 90 microlitres, not supplied with kit).
- 5. Add 2 drops of **wash buffer 2** (white cap) and allow it to soak in.
- 6. Add 2 drops of **stop solution** (red cap).

Do not run more than 10 tests simultaneously, in order to prevent the membrane from drying out during the procedure.

## Interpretation

- Result must be read within 10 minutes.
- The small red dot validates the reaction.

- Results:
  - Negative result: clear membrane or overall uniform pink color.
  - Positive result: a well delineated red spot appears in the middle of the membrane.



If the test is repeatedly invalid: use devices from a new pouch, reconstitute a new vial of conjugate, and test the 3 controls.

#### Use of the negative/weak positive/strong positive control samples

Control samples must be tested:

- When the kit is first opened.
- At least once a week, if used frequently, or before each test, if used occasionally.
- When a storage problem is suspected.
- When the test repeatedly gives invalid results.
- When a new operator uses the kit.

#### Storage

- The kit should be stored between 2°C and 30°C and must not be frozen.
- Reconstituted reagents:

	4°C	25°C +/- 3°C				
Reconstituted controls	6 months	1 month				
Reconstituted conjugate	1 month	5 days				
Other reagents	According to the kit expiry date					

# 22 - Test Syphilis 3.0 SD Bioline®

Syphilis 3.0 SD Bioline® is a lateral flow rapid test for the detection of anti-*T. pallidum* antibodies.

# Description

- Membrane covered with recombinant *T. pallidum* antigens
- 30 devices packed individually in an aluminium pouch
- Plastic capillary tubes (20 microlitres) in a plastic bag
- One dropper bottle of buffer

## Sample

- Plasma or whole blood (EDTA tube) or serum (plain tube)
- Capillary blood

## Procedure

- 1. Open the pouch immediately before use.
- 2. Identify the device with the sample number using a thin permanent marker.
- 3. *If using serum or plasma*: apply 10 microlitres to the sample pad S. *If using whole blood*: apply 20 microlitres to the sample pad S.
- 4. Apply 3 to 4 drops of buffer to the sample pad S.

## Interpretation

The test is validated only if the internal control band is visible. Otherwise, the test is invalid.

Read the test:

- After 5 to 20 minutes, if serum or plasma is used.
- After 10 to 20 minutes, if whole blood is used.

#### Positive

Syphilis C T C 2 1	Invalid Syphilis	S = Sample pad
Syphilis C T	Syphilis C T C S	T = Test line C = Internal control band
G 2 1		

Interpretation of Syphilis SD Bioline® test

#### Storage

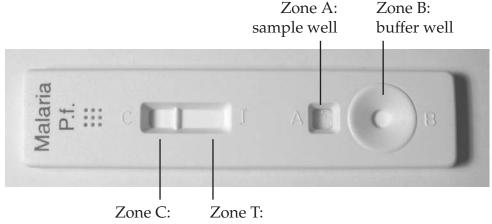
The kit should be stored between 2°C and 30°C and must not be frozen.

# 23.1 - Test Paracheck P.f®

Paracheck P.f<sup>®</sup> is a lateral flow rapid test for the detection of histidine rich protein 2 (HRP-2) specific to *Plasmodium falciparum*.

#### **Description**

- Membrane coated with specific anti-*P. falciparum* HRP-2
- 25 devices packed individually in an aluminium pouch, with a desiccant and a loop
- Clearing buffer in dropper bottle



internal control window test window

Paracheck P.f® device

#### Sample

- Whole blood (EDTA tube)
- Capillary blood

#### Procedure

- 1. Open the pouch immediately before testing. Remove the device and the loop.
- 2. Check the colour of the desiccant: it should be bright blue. If it is pink or faint blue, discard the device.
- 3. Identify the device with the sample number using a thin permanent marker.
- 4. Collect 5 microlitres of capillary blood with the loop. If using a venous sample, dip the loop into the EDTA tube (previously mixed by gentle swirling) or use an automatic pipette adjusted on 5 microlitres. Only the inner circle of the loop should be filled with a drop slightly convex.
- 5. Apply the blood to the sample well A immediately. When using the loop, touch it to the sample pad, in a vertical position then, gently tap the loop on the pad, making sure that the whole specimen is transferred.

The pad should not be completely saturated with blood.



6. Apply 6 drops of clearing buffer into well B by holding the dropper bottle vertically.

#### Interpretation

The test is validated only if a red line appears in the control window C. Results should be read no sooner than 15 minutes and no later than 30 minutes after preparation.

1. Only one band appears, in the control window C: **negative** test for *P. falciparum*.



2. One band appears in the control window C, and one well-delineated band appears in the test window T: **positive** test for *P. falciparum*.



3. There is no band in the control window C: **invalid** test. Repeat the test.



4. One band only appears, in the test window T: invalid test. Repeat the test.



#### Storage

The tests should be stored between 2°C and 30°C and must not be frozen.

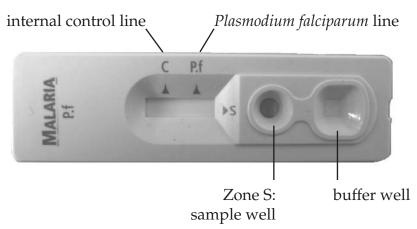
*Note*: test and control bars are well-delineated red bars and must not be confused with the pink background.

# 23.2 - Test Malaria Ag P.f SD Bioline®

Malaria Ag P.f SD Bioline® is a lateral flow rapid test for the detection of *Plasmodium falciparum* histidine-rich protein 2.

#### **Description**

- Membrane coated with specific anti-P. falciparum HRP-2 antibodies
- 25 devices packed individually in an aluminium pouch, with a desiccant
- 25 loops or pipettes
- 25 lancets
- Assay buffer in dropper bottle



Malaria Ag P.f SD Bioline® device

#### Sample

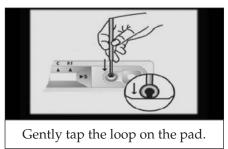
- Whole blood (EDTA tube)
- Capillary blood

#### Procedure

- 1. Open the pouch immediately before testing.
- 2. Check the colour of the desiccant: it should be bright blue. If it is pink or faint blue, discard the device.
- 3. Identify the device with the sample number using a thin permanent marker.
- 4. Collect 5 microlitres of capillary blood with the loop/pipette. If using a venous sample, dip the loop into the EDTA tube (previously mixed by gentle swirling) or use the pipette.

Only the inner circle of the loop should be filled with a drop slightly convex.

5. Apply the blood to the round sample well S immediately. When using the loop, touch it to the sample pad, in a vertical position then, gently tap the loop on the pad, making sure that the whole specimen is transferred. The pad should not be completely saturated with blood.



6. Apply 4 drops of assay buffer into the round well by holding the dropper bottle vertically.

## Interpretation

The test is validated only if the red control line C appears. Results should be read no sooner than 15 minutes and no later than 30 minutes after preparation.

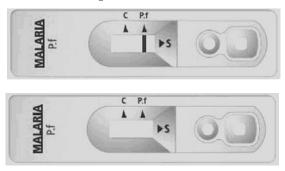
1. Only the line C appears: **negative** test.



2. The lines C and P.f appear: **positive** test.



3. There is no line C: **invalid** test. Repeat the test.



#### Storage

The tests should be stored between 1°C and 40°C and must not be frozen.

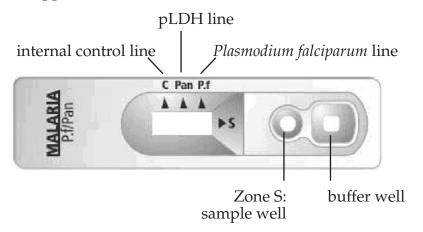
*Note*: test and control lines are well-delineated red lines and must not be confused with the pink background.

# 23.3 - Test Malaria Ag P.f/Pan (Combo) SD Bioline®

Malaria Combo SD Bioline® is a lateral flow rapid test for the combined detection of *Plasmodium falciparum* histidine-rich protein 2 and Plasmodium lactate dehydrogenase (pLDH) of plasmodium species i.e. *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*.

#### **Description**

- Membrane coated with specific anti-P. falciparum HRP-2 and anti-pLDH antibodies
- 25 devices packed individually in an aluminium pouch, with a desiccant
- 25 loops or pipettes
- 25 lancets
- Assay buffer in dropper bottle



Malaria Combo SD Bioline® device

#### Sample

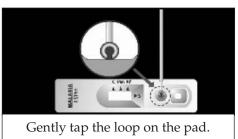
- Whole blood (EDTA tube)
- Capillary blood

#### Procedure

- 1. Open the pouch immediately before testing.
- 2. Check the colour of the desiccant: it should be bright blue. If it is pink or faint blue, discard the device.
- 3. Identify the device with the sample number using a thin permanent marker.
- 4. Collect 5 microlitres of capillary blood with the loop/pipette. If using a venous sample, dip the loop into the EDTA tube (previously mixed by gentle swirling) or use the pipette.

Only the inner circle of the loop should be filled with a drop slightly convex.

5. Apply the blood to the round sample well S immediately. When using the loop, touch it to the sample pad, in a vertical position then, gently tap the loop on the pad, making sure that the whole specimen is transferred. The pad should not be completely saturated with blood.



6. Apply 4 drops of assay buffer into the round well by holding the dropper bottle vertically.

## Interpretation

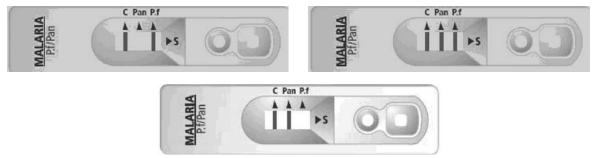
The test is validated only if the red control line C appears.

Results should be read no sooner than 15 minutes and no later than 30 minutes after preparation.

1. Only the line C one appears: **negative** test for all species.



2. The line C appears and one or 2 lines appear in front of the arrows Pan and/or P.f: **positive** test.



3. There is no line C: invalid test. Repeat the test.



#### Storage

The tests should be stored between 1°C and 40°C and must not be frozen.

Notes:

- This simplified interpretation is applicable only for blood donors/donations screening.
- Test and control lines are well-delineated red lines and must not be confused with the pink background.

# 24 - Crossmatch procedure (tile method)

The objective of crossmatching blood units is to verify the compatibility between the red cells of the blood to be transfused and the plasma of the recipient.

Crossmatch is performed in the blood bank/laboratory just before releasing the blood unit (or within 3 days before planned surgery, when the need for transfusion can be anticipated).

When this test is performed on tile at room temperature, it can detect naturally occurring regular (anti-A and anti-B) and some irregular (anti-Lewis a, anti-P) agglutinating antibodies.

## Equipment

- White, smooth tile
- Plastic tube
- Automatic pipette (10-100 microlitres)
- Pipette tip
- Applicator
- Manual or electric centrifuge (to obtain the recipient's plasma rapidly)

#### Samples

Recipient's plasma from EDTA tube (drawn < 3 days)</li>

AND

- Red cells from the blood unit

#### Procedure

- 1. Label the tile with the blood unit number and the recipient's identification number.
- 2. Label the plastic tube with the blood unit number.
- 3. Cut the distal segment of the blood unit tubing.
- 4. Empty the contents of the segment into the plastic tube: the segment contains coagulated blood. Place a tip on the pipette and extract 50 microlitres of free red cells.
- 5. Deposit 50 microlitres of red cells on the tile.
- 6. Deposit 100 microlitres of recipient's plasma on the tile, next to the red cells.
- 7. Mix in a circle of 3 cm diameter with an applicator.
- 8. Rock the tile gently, in a tri-directional movement, for 2 minutes, while observing the reaction.

## Interpretation

- If there is no agglutination: the crossmatch is negative. The blood can be transfused to the patient.
- If there is agglutination: the crossmatch is positive. This indicates that the blood unit is incompatible with the recipient's blood, i.e. the recipient has antibodies directed against the red cells from blood unit: this could provoke a haemolytic reaction. The blood cannot be transfused to the patient.

register
donation
- Blood
22

Circuit	Signature						
Blood kept	or discarded <sup>1</sup>						
Maladia	Malaria						
C.mbilio	smudke						
Hepatitis	U						
Hepa	В						
HIV	#2						
E	#1						
group	#2						
Blood group	#1						
Donation	number						
Data							

Other columns can be added according to needs (type of donation, other tests, etc.).

<sup>&</sup>lt;sup>1</sup> Or "donor selected or excluded" if screening is performed prior to collection.

26 - Blood bank register

According to the transfusion activity, plan one register per blood group or a register divided in 4 sections (A, B, AB and O) with thumbnails. It will be easier to find the blood unit corresponding to the patient's blood group.

	Signature					
of nit*	D					
me o	Щ					
Outcome of the blood unit*	R					
0 the	H					
	Patient file n°					
	Bed No.					
	Ward					
ion	Reason for transfusion					
Patient information	Hb (g/dl)					
ent in	ABO Rh D					
Pati	Sex					
	Age					
	Name					
	Date/time of delivery					
	Expiry date					
<b>+</b>	Vol. (ml)					
Blood unit						
Blo	Date of ABO collection Rh D					
	Blood unit number					

\* T: transfused; R: returned; E: expired; D: discarded

# 27 - Blood request and blood delivery form

		Bloo	d rec	lues	t forn	n				
Patient name:				Surn	ame:					
Age:				Sex:	M/I	F				
Patient file number:				Ward	d:			Bed	No.	
Patient blood group: Hb level: g/dl Indication for transfus	A D	B	AB	0 □		Rh D	Pos [	itive	Nega [	ative ]
Volume requested:	ml	Urge	ncy*:		Date:	/	/	at	h	min
Prescribing physician:					Nur	se:				
Signature:					Sign	ature:				

\* Urgent if needed in < 1 hour

Blood delivery form										
No. of blood unit delivered	Blood unit group	Expiry date		Com	ments					
1.										
2.										
3.										
Blood units handed over to: By: Signatu	ıre:	Date: /	/	at	h	min				

# 28 - Example of monthly data collection

		No. of BU	%	
	National/regional blood banks			
Source of blood	Other external sources			
	Blood collected at hospital (internal source)			
	Total		100	
		No. of BU	%	
	Direct			
Blood donations	Replacement			
blood donations	Voluntary			
	Walking blood bank			
	Total		100	
		No. of donors	%	
Donor selection	Eligible donors			1
Donor selection	Excluded donors			
	Total			
		No. donations tested	No. positive	% positive
17-17-17 · · · · · · · · · · · · · · · · · · ·	HIV No.1			
	HIV No.2			
TTI screening	Hepatitis B			
	Hepatitis C			
	Syphilis			
	Malaria			
		No. of patients transfused	No. of BU transfused	% of BU transfused
	Paediatrics			
	Medicine			
<b>D1</b> 1	OB/Gyn			
Blood use	Operation theater			
	Surgery ward			
	Emergency room			
	0 2			
	Nutrition			
				100
	Nutrition			100
Accidents related	Nutrition Total			100
Accidents related to BT	Nutrition Total No. of ABO incompatibility accidents No. of other major transfusion reactions No. of minor transfusion reactions			100
	Nutrition Total No. of ABO incompatibility accidents No. of other major transfusion reactions			100
to BT	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effectsNo. of deaths due to lack of timely BT			100
to BT Mortality related to BT	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effects			100
to BT Mortality related to BT Quality of	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effectsNo. of deaths due to lack of timely BTNo. of files reviewed by the transfusion			100
to BT Mortality related to BT Quality of transfusion	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effectsNo. of deaths due to lack of timely BTNo. of files reviewed by the transfusion committeeNo. of files with bedside verification cardNo. of files with pertinent indications			100
to BT Mortality related to BT Quality of	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effectsNo. of deaths due to lack of timely BTNo. of files reviewed by the transfusion committeeNo. of files with bedside verification card			100
to BT Mortality related to BT Quality of transfusion procedure	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effectsNo. of deaths due to lack of timely BTNo. of files reviewed by the transfusion committeeNo. of files with bedside verification cardNo. of files with pertinent indicationsNo. of files with correct transfusion			100
to BT Mortality related to BT Quality of transfusion	NutritionTotalNo. of ABO incompatibility accidentsNo. of other major transfusion reactionsNo. of minor transfusion reactionsNo. of death related to BT adverse effectsNo. of deaths due to lack of timely BTNo. of files reviewed by the transfusion committeeNo. of files with bedside verification cardNo. of files with correct transfusion monitoring form			100

# 29 - Transfusion module

The module is divided in sub-modules and contains the necessary equipment for collecting, testing and giving blood for 50 donations/transfusions.

MODULE, TRANSFUSION, 50		MODULE TRANSFUSION, 50		
KMEDWIRAD1_	E, TRANSFUSION, 50 E TRANSFUSION, 50	Indicative price/unit: 2609.18 Keep cool: *CF Justification code: PM		
DESCRIPTION This module contains all the necessary equipment for sampling, testing and giving blood. The quantities are calculated for 50 transfusions. The module contains 150, 250 and 450 ml blood bags. (Cf Transfusion, MSF 2010) INSTRUCTIONS FOR USE The transfusion module is divided in sub-modules. One of the sub-modules contains the equipment: haemoglobino- meter, centrifuge and scale. If you order several transfusion modules, you can ask to receive the equipment part only once! The screening tests should not be performed on whole blood, except the Paracheck. CAUTION: heat sensitive item KMEDMTRA01B MUST be transported by COLD CHAIN with 3		DESCRIPTION Ce module contient tout le matériel nécessaire pour prélever, tester et donner du sang. Les quantités sont calculées pour 50 transfusions. Le module contient des poches à sang de 150, 250 et 450 ml (Cf Transfusion, MSF 2010) CONSEILS D'UTILISATION Le module transfusion est divisé en sous-modules. Un des sous-modules contient l'équipement: hémoglobinomètre, centrifugeuse et balance. Si vous commandez plusieurs modules transfusion, vous pouvez demander de ne recevoir la partie équipement qu'une seule fois! Les tests de dépistage ne doivent pas être effectués sur sang total, à l'exception du Paracheck. ATTENTION: produit sensible à la chaleur ! KMEDMTRA01B DOIT être transporté en CHAINE DE FROID		
temperature monitors: • cold chain monitor card (3M) • freezing indicator (Freeze-tag) • temperature recorder		<ul> <li>avec 3 indicateurs de température:</li> <li>carte de contrôle de la chaîne de froid (3M)</li> <li>indicateur de congélation (Freeze-tag)</li> <li>enregistreur de température</li> </ul>		
KMEDMTRA01B: control with 3M card and Freeze-tag		KMEDMTRA01B: contrôle avec carte 3M et Freeze-tag		
*CF	. 01/	*CF	. 01/	
Windows A, B, C, D white Windows A, B, C blue	=> 0K	Fenêtres A, B, C, D blanches Fenêtres A, B, C bleues	=> 0K => 0K	
Windows A, B, C blue	=> DO NOT use the product!	Fenêtre D bleue	=> NE PAS utili	ser le produitl
Freeze tag displays "ALARM"	=> DO NOT use the product!	Freeze tag affiche "ALARM"	=> NE PAS utili	•
<ul> <li>In case of doubt:</li> <li>Identify clearly the product and keep it refrigerated (between 2° and 8° C) in quarantine</li> <li>Keep the temperature recorder as witness after stopping the recording</li> <li>Contact the pharmacist of your OC or supply centre to know the line to take</li> <li>(Cf Introduction: Thermosensitive products)</li> </ul>		<ul> <li>En cas de doute:</li> <li>Identifiez clairement le prod quarantaine au réfrigérateu</li> <li>Conservez l'enregistreur de après l'arrêt de l'enregistre</li> <li>Contactez le pharmacien de d'achat pour connaître la c (Cf Introduction: Les produits a</li> </ul>	ur (entre 2° et 8° e température co ement e votre OC ou de onduite à tenir	C) mme témoin votre centrale

Included in:	KMEDKSUR1	KIT, SURGICAL, 300 operations (100 beds/1 month) KIT CHIRURGIE, 300 interventions (100 lits/1 mois)
	KMEDKSUR3	KIT SURGICAL, 25 operations KIT CHIRURGIE, 25 interventions

Composed of	MSF Code	Qty	Composé de
MODULE, TRANSFUSION, 50, part 1	KMEDMTRA01A	1	MODULE TRANSFUSION, 50, partie 1
MODULE, TRANSFUSION, 50, part 2, cold chain	KMEDMTRA01B	1	MODULE TRANSFUSION, 50, partie 2, chaîne de froid
MODULE, TRANSFUSION, 50, part 3, equipment	KMEDMTRA01E	1	MODULE TRANSFUSION, 50, partie 3, équipement

Detailed list of articles	MSF Code	Qty	Liste détaillée des articles
MODULE, TRANSFUSION, 50, part 1	KMEDMTRA01A	1	MODULE TRANSFUSION, 50, partie 1
<ul> <li>MARKER, permanent, fine point, black</li> </ul>	ASTAPENM2BS	2	<ul> <li>MARQUEUR, indélébile, pointe fine, noir</li> </ul>
<ul> <li>CARD, BEDSIDE CONTROL, ABO compatibility</li> </ul>	DDGTBLOG1CR	100	CARTE DE CONTROLE AU LIT DU PATIENT, comp. ABO
► TEST, HEPATITIS B HBsAg (Determine) ser/pl/wb, 1 test	DDGTHBTE1T-	100	► TEST HEPATITE B AgHBs (Determine), sér/pl/st, 1 test
► TEST, HEPATITIS C (HCV SPOT), ser/pl, rapid, 1 test	DDGTHCTE1T-	100	► TEST, HEPATITE C (HCV SPOT), sér/pl, rapide, 1 test
TEST, HIV 1 + 2 (Determine), ser/pl/wb, rapid, 1 test	DDGTHIVD1T-	100	TEST, VIH 1 + 2 (Determine), sér/pl/st, rapide, 1 test
TEST, HIV 1 + 2 (Uni-Gold), ser/pl/wb, rapid, 1 test	DDGTHIVU20T	100	TEST, VIH 1 + 2 (Uni-Gold), sér/pl/st, rapide, 1 test
<ul> <li>TEST, MALARIA (Paracheck Pf), whole blood, 1 test</li> </ul>	DDGTMALF25T	100	<ul> <li>TEST, MALARIA (Paracheck Pf), sang total, rapide, 1 test</li> </ul>
<ul> <li>TEST, SYPHILIS (SD Bioline 3.0), ser/pl/wb, 1 test</li> </ul>	DDGTSYPT 30T	100	<ul> <li>TEST SYPHYLIS (SD Bioline 3.0), sér/pl/st, 1 test</li> </ul>
▶ (blds.syst.) TUBE, VACUUM, plastic, EDTA, 4 ml, purple	ELAEBSVT5E-	150	<ul> <li>(s.prél.sang.) TUBE SOUS VIDE, plast., EDTA, 4ml, mauve</li> </ul>
► (blds. syst.) HOLDER for VACUUM TUBE + needle ejector	ELAEBSVV1H-	10	<ul> <li>(s.prél.sang.) CORPS PORTE TUBE + éjecteur d'aiguille</li> </ul>
<ul> <li>(blds.syst.) NEEDLE, sterile, 21G (Vacutainer)</li> </ul>	ELAEBSVV21N	100	<ul> <li>(s.prél.sang) AIGUILLE, stérile, 21G (Vacutainer)</li> </ul>
<ul> <li>(HemoCue Hb 201+/301) CLEANER, box of 5</li> </ul>	ELAEHAEM2CL	1	► (HemoCue Hb 201+/301) NETTOYANT, boîte de 5
<ul> <li>(HemoCue Hb 301) MICROCUVETTES, s.u.</li> </ul>	ELAEHAEM3C-	200	▶ (HemoCue Hb 301) MICROCUVETTES, u.u.
<ul> <li>(pipette autom.10-100 µl Eppendorf) RACK + 96 YELLOW TIPS</li> </ul>	ELAEPIAATYR	1	<ul> <li>(pipette autom.10-100 µl Eppendorf) RACK +96 EMBOUTS JAUNES</li> </ul>
<ul> <li>(tube, haemolysis, Ø 13/15 mm) RACK</li> </ul>	ELAETUHA1R-	1	<ul> <li>(tube à hémolyse, Ø 13/15 mm) PORTOIR</li> </ul>
<ul> <li>TOURNIQUET, elastic, 100 x 1.8 cm</li> </ul>	EMEQTOUR1-	1	<ul> <li>GARROT élastique, 100 x 1,8 cm</li> </ul>
<ul> <li>MONITOR CARD, cold chain, English</li> </ul>	PCOLCONT1CE	5	<ul> <li>CARTE DE CONTROLE, chaîne de froid, anglais</li> </ul>
<ul> <li>FREEZING INDICATOR, electronic (Freeze-tag®)</li> </ul>	PCOLCONT3FT	5	<ul> <li>INDICATEUR CONGELATION, électronique (Freeze-tag®)</li> </ul>
THERMOMETER, MINI-MAXI, -50° to +50° C	PCOLTHER5MM	1	► THERMOMETRE MINI-MAXI, -50° à +50° C
BAG, BLOOD TAKING SET, s.u. + CPDA1 150 ml	SINSBABT1-	20	POCHE A SANG, u.u. + CPDA1 150 ml
<ul> <li>BAG, BLOOD TAKING SET, s.u. + CPDA1 250 ml</li> </ul>	SINSBABT2-	20	POCHE A SANG, u.u. + CPDA1 250 ml
BAG, BLOOD TAKING SET, s.u. + CPDA1 450 ml	SINSBABT4-	10	POCHE A SANG, u.u. + CPDA1 450 ml
CONTAINER, needles/syringes, 51, cardboard inciner.	SINSCONT5C-	2	<ul> <li>CONTAINER aiguilles/seringues, 51, carton incinération</li> </ul>
SET, BLOOD TRANSFUSION, 200 µ filter, sterile, s.u.	SINSSEBG1-	70	<ul> <li>TRANSFUSEUR avec filtre 200 µ, stérile, u.u.</li> </ul>
► GLOVE, EXAMINATION, latex, s.u. non sterile, medium	SMSUGLOE1M-	100	<ul> <li>GANT D'EXAMEN, latex, u.u. non stérile, moyen</li> </ul>
MODULE, TRANSFUSION, 50, part 2, cold chain	KMEDMTRA01B	1	MODULE TRANSFUSION, 50, partie 2, chaine de froid
▶ TEST, BLOOD GROUPING, anti A, 10 ml, dropper bot.	DDGTBLOG1A-	2	► TEST GROUPE SANGUIN, anti A, 10 ml, fl. cpte-gouttes
▶ TEST, BLOOD GROUPING, anti AB, 10 ml, dropper bot.	DDGTBLOG1AB	2	► TEST GROUPE SANGUIN, anti AB, 10 ml, fl. cpte-gouttes
<ul> <li>TEST, BLOOD GROUPING, anti B, 10 ml, dropper bot.</li> </ul>	DDGTBLOG1B-	2	► TEST GROUPE SANGUIN, anti B, 10 ml, fl. cpte-gouttes
RH NEGATIVE CONTR., monoclonal antibodies, 10 ml	DDGTBLOG2C-	2	<ul> <li>RH CONTROLE NEGATIF, anticorps monoclonaux, 10 ml</li> </ul>
▶ TEST, BLOOD GR., RHESUS anti D, 10ml, dropper bottle	DDGTBLOR1T-	2	► TEST GR. SANGUIN, RHESUS anti D, 10ml, cpte-gouttes
MODULE, TRANSFUSION, 50, part 3, equipment	KMEDMTRA01E	1	MODULE TRANSFUSION, 50, partie 3, équipement
<ul> <li>SCALE, mechancial, adult 0-150 kg, grad. 500 g</li> </ul>	EANTSCAL3A-	1	<ul> <li>BALANCE mécanique, adulte 0-150 kg, grad. 500 g</li> </ul>
<ul> <li>CENTRIFUGE, hand-operated + 4 tubes 15 ml</li> </ul>	ELAECENT1M-	1	<ul> <li>CENTRIFUGEUSE, manuelle + 4 tubes 15 ml</li> </ul>
► HAEMOGLOBIN PHOTOMETER (HemoCue Hb 301) trop.	ELAEHAEM3	1	<ul> <li>PHOTOMETRE HEMOGLOBINE (HemoCue Hb 301), trop</li> </ul>
<ul> <li>PIPETTE, disposable, fixed volume (Minipet), 50 µl</li> </ul>	ELAEPIDF50-	4	<ul> <li>PIPETTE, jetable, volume fixe (Minipet), 50 µl</li> </ul>
<ul> <li>TILE, white and smooth</li> </ul>	ELAETILE1-	1	<ul> <li>CAREAU DE CERAMIQUE, blanc et lisse</li> </ul>
<ul> <li>TIMER, electronic</li> </ul>	ELAETIME1E-	1	MINUTEUR électronique
<ul> <li>PRESSURE CUFF, for pouch 500/1000 ml</li> </ul>	EMEQCUFF5-	1	MANCHETTE A PRESSION, pour poche 500/1000 ml
<ul> <li>GLASSES, PROTECTIVE, plastic</li> </ul>	EMEQGLAS1P-	2	<ul> <li>LUNETTES DE PROTECTION, plastique</li> </ul>
<ul> <li>SPHYGMOMANOMETER, one-hand manometer, adult</li> </ul>	EMEQSPHY1A-	1	<ul> <li>SPHYGMOMANOMETRE, manopoire, adulte</li> </ul>
<ul> <li>STETHOSCOPE, one cup, nurse</li> </ul>	EMEQSTET1-	1	<ul> <li>STETHOSCOPE, une face, infirmier</li> </ul>
Blood transfusion + CD-Rom	LOO8TRFG01E	1	Blood transfusion + CD-Rom
<ul> <li>SCALE, kitchen type, 0 to 5 kg, 10 g graduations</li> </ul>	PCOOSCAL05-	1	▶ BALANCE, de ménage, 0 à 5 kg, graduations ts les 10 g

End of list

Related articles	MSF Code	Articles apparentés
CENTRIFUGE, electrical 220V (Hettich EBA 20), 8 tubes	ELAECENT4E-	CENTRIFUGEUSE électrique 220V (Hettich EBA 20), 8 tubes
BAG, BLOOD TAKING, s.u. + CPDA1 (Penta) 450 ml + 4x100ml	SINSBABT4B4	POCHE A SANG, u.u. + CPDA1 (Penta), 450 ml + 4 x 100 ml
REUSABLE SHARPS CONTAINER (RSC), 1.2 litre	SINSCONT1R-	CONTAINER REUTILISABLE POUR OBJETS TRANCHANTS, 1,21

# 30 - Blood bags

#### Presentation

150 ml single bag containing 21 ml of CPDA<sub>1</sub> (anticoagulant-preservative solution) 250 ml single bag containing 35 ml of CPDA<sub>1</sub>

450 ml single bag containing 63 ml of CPDA1

450 ml bag containing 63 ml of CPDA<sub>1</sub>, attached to a set of four 100 ml bags that do not contain CPDA<sub>1</sub> ("penta-bag")

Bags are packed in an aluminium foil pack. The number of bags per pack depends on the type of bags. Each bag is individually packed in a protective pouch. Follow manufacturer's instructions for maximum shelf life after opening the aluminium pack.

#### Inspection

- Prior to collection, inspect the bag for any abnormality or damage.
- Discard the blood bag if:
  - It is damaged (leak, air, etc.).
  - It contains a white precipitate or the anticoagulant solution is cloudy.
  - There is a brown deposit in the tubing near the needle.

#### Storage

- At room temperature, protected from light and freezing.
- Avoid prolonged exposure to temperature  $> 40^{\circ}$ C.

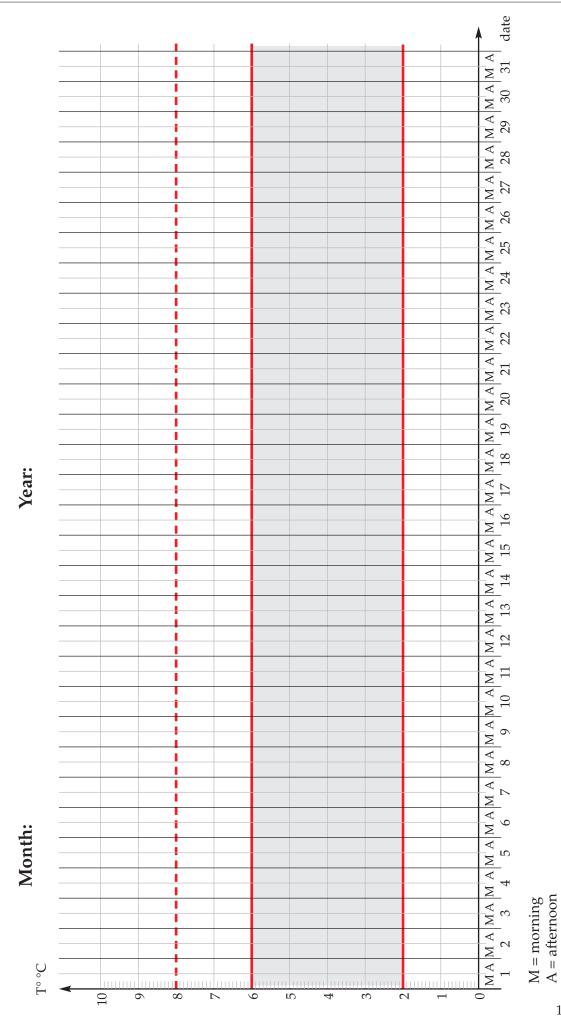
#### Instructions for use

- Remove to blood bag from its protective pouch just before use.
- Do not remove anticoagulant from a blood bag.
- Do not fill partially a blood bag.

# **31 - Tubes for blood samples**

Colour of stopper	Additive	Sample	Tests	
Purple	EDTA	Whole blood	<ul> <li>Haemoglobin</li> <li>Haematocrit</li> <li>RDT for malaria</li> <li>Complete blood count</li> </ul>	
		Whole blood or red cells	Blood grouping (direct method)	
		Plasma	<ul> <li>Any screening test using plasma (all, except RDT for malaria)</li> <li>Crossmatching</li> </ul>	
Red	None (plain tube)	Serum <sup>1</sup>	<ul> <li>Any screening tests using serum (all, except RDT for malaria)</li> <li>Crossmatching</li> </ul>	

<sup>1</sup> Serum is defibrinated plasma, obtained after blood coagulation and complete clot retraction.



# 33 - Freezing indicator device (Freeze-tag®)

Freeze-tag® is a freezing indicator placed in every refrigerator or cold box containing blood that shows if blood kept in the cold chain has been exposed to freezing temperatures.

#### Instructions for use

- Before reading, maintain the Freeze-tag® at a temperature above 0°C for at least 2 minutes.
- Read the result:

The blood was never exposed to a temperature below 0°C.	V.	= OK
The blood was exposed to a temperature below 0°C for longer than 1 hour.	X	= ALARM

If the display remains blank, maintain the Freeze-tag<sup>®</sup> at room temperature and wait at least 2 more minutes. If the display remains blank, check expiry date.

– Once the alarm is activated, the freeze tag cannot be re-used.

#### Storage

Freeze-tag® must not be stored below 4°C.

#### Safety measures

The Freeze-tag<sup>®</sup> contains a lithium battery: do not open or destroy the case of the Freeze-tag<sup>®</sup>; do not incinerate.

# Main references

WHO. *The Clinical Use of Blood*, WHO Blood transfusion safety, Geneva, 2005. http://www.who.int/bloodsafety/clinical\_use/en/Handbook\_EN.pdf

WHO. *Hospital Care for Children. Guidelines for the Management of Common Illnesses with Limited Resources*, Geneva, 2005. www.who.int/child\_adolescent\_health/documents/9241546700/en/index.html

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# Glossary

Alloantigen: a substance present only in some individuals that prompts the generation of specific antibodies when introduced in individuals who do not express this alloantigen.

Alloantibodies: specific antibodies generated after the introduction of an alloantigen.

#### Antibodies:

- Naturally occurring antibodies: are present in individuals with no previous exposure to transfusion or pregnancy. They are of IgM class. They are able to activate complement, and therefore lyse red cells in the blood stream. In transfusion, naturally occurring antibodies refer to anti-A and anti-B, and also to anti-Lewis, anti-P. They have agglutinating properties in vitro at room temperature.
- Acquired (or immune) antibodies: are present in individuals after exposure to transfusion or pregnancy. They are of IgG class, usually unable to activate complement (previously described as incomplete antibodies); therefore they are rarely responsible for intravascular haemolysis. To detect them, specific laboratory procedures are needed, such as incubation at 37°C, use of albumin, enzymes, antiglobulin and low ionic strength solution. Acquired antibodies include anti-Rhesus, anti-Kell, anti-Duffy, anti-Kidd and immune anti-A and anti-B.
- *Regular antibodies*: antibodies that are consistently found in all persons lacking the corresponding antigen (naturally occurring anti-A and anti-B).
- *Irregular antibodies*: antibodies that are not consistently found in all persons lacking the corresponding antigen. They are either naturally occurring (such as anti-Lewis, anti-P) or acquired after transfusion or pregnancy.

**Antigen**: a substance recognised as foreign by the body and prompting an immune response, including the generation of specific antibodies.

**Batch testing**: a laboratory procedure in which one given test is done simultaneously on several specimens.

**Fresh whole blood**: blood that has been drawn within less than 4 hours and has not been refrigerated. Platelets and labile clotting factors functions are fully preserved.

**Haemolysins**: red cell antibodies causing haemolysis. They usually refer to hyperimmune anti-A and anti-B antibodies of dangerous O donors.

**Packed red blood cells (PRBC)**: blood with a minimum of residual plasma. PBRC are prepared by centrifugation (or if not feasible, sedimentation for at least 6 hours).

**Window period**: the time period between contamination and development of detectable infectious markers.

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