MEDECINS SANS FRONTIERES

Blood transfusion

Practical guide for doctors, nurses and other health staff managing blood transfusion activities

Internal document
2019 Edition

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Preface

This guideline is intended for health professionals and support staff involved in supplying, delivering and administering blood in resource-limited health facilities.

It provides practical answers to the main questions and problems faced by staff, drawing on recommendations issued by 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.

Blood refers to whole blood and packed red blood cells. Fresh frozen plasma and platelet concentrates are sometimes supplied by National Blood Services. Other blood components that are rarely available, such as cryoprecipitates or specific coagulations factors are not discussed.

The guideline is divided into four chapters:
– Blood transfusion safety (Chapter 1)
– From donor to qualified blood unit for transfusion (Chapter 2)
– Blood transfusion process (Chapter 3)
– Setting up and managing blood transfusion activities (Chapter 4)

Furthermore various practical tools, such as standard operating procedures and examples of forms and registers, are presented in the appendices.

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

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.

Comments are to be addressed to the laboratory referent of your MSF operational section.

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Abbreviations and acronyms

ACT	Activated cephalin time
CMV	Cytomegalovirus
DIC	Disseminated intravascular coagulation
EDTA	Ethylen diamine tetraacetic acid
G6PD	Glucose-6-phosphate dehydrogenase
GVHD	Graft versus host disease
Hb	Haemoglobin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HTLV ½	Human T-cell lymphotropic virus ½
NBTS	National blood transfusion service
NHFTR	Non-haemolytic febrile transfusion reaction
PRBC	Packed red blood cells
Rh	Rhesus
TACO	Transfusion associated circulatory overload
TRALI	Transfusion-related acute lung injury
TT	Thrombin time
TTI	Transfusion transmissible infection
WHO	World Health Organisation

Chapter 1:
Blood transfusion safety

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. In this chapter, these risks are classified into 3 categories: immunological risks, infectious risks and other (non-immunological, non- infectious) risks.

In order to reduce as far as possible the potential complications of transfusion, specific precautions have to be taken when selecting donors and collecting, testing, processing and administering blood:

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

Despite these precautions, transfusion is never totally risk-free. However, it may be detrimental to the patient to avoid transfusion when it is indicated. Thus, it is the physician's responsibility to evaluate the potential risks and benefits of transfusion for each patient. Following clear indications for transfusion helps prevent unnecessary transfusions. Transfusion, when 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, i.e. the transfused blood has the required qualities to restore the patient's oxygen carrying capacity.
- All effective means to reduce or compensate blood loss (e.g. stop bleeding with mechanical means such as compression, fluid resuscitation, tranexamic acid in trauma or post-partum haemorrhage) are available at all times and used when indicated.
- Blood is used rationally to ensure that it will be available when needed. Unnecessary transfusions may cause a shortage of blood for patients in real need.
- Medical and cold chain equipment, consumable items and quality laboratory reagents are available to ensure that each step of the transfusion safety chain will be correctly implemented.

As transfusion of safe blood is a complex procedure, and blood a scarce resource, all upstream measures to reduce blood needs should be implemented (e.g. early management of anaemia, severe malaria, trauma and complicated pregnancies).

2. Immunological risks

2.1 Immediate immune reactions (< 24 h)

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 as a result of previous transfusions or pregnancies. Lysed leukocytes release pyrogens resulting in a febrile reaction[a].

2.1.3 Acute intravascular haemolytic transfusion reaction

Acute intravascular haemolytic reaction occurs when transfused red cells encounter natural regular IgM antibodies in the recipient's blood. The antigen-antibody reaction triggers the intra-vascular lysis of transfused red cells. This is a severe potentially life-threatening reaction. It may be associated with disseminated intravascular coagulopathy (DIC). The released haemoglobin can cause acute renal failure.
Ninety percent of immediate acute intravascular haemolytic reactions are caused by transfusion of ABO incompatible blood resulting from human error. The remaining ten percent are due to irregular natural antibodies from other blood group systems (e.g. Lewis, P).

2.1.4 Transfusion-related acute lung injury (TRALI)

TRALI is a rare[b] 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. This haemolysis is due to:

– The recipient's acquired antibodies to Rhesus, Kell, Duffy or Kidd. In this event, the transfused red cells are haemolysed.

or

– Hyper immune anti-A or anti-B antibodies (haemolysins) from "dangerous group O donors"[c]. In this event, the recipient's red cells are haemolysed.

Extravascular haemolysis occurs 5 to 10 days after transfusion.

a Leukofiltration, when available, reduces the frequency of NHFTR.

b Estimated at 1:5000 transfusions, however the true incidence of TRALI is not known.

c Some O donors ("dangerous O donors") have acquired hyper immune 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 (Chapter 1, Section 3.1).

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 is rarely life-threatening.

2.2.3 Graft-versus-host disease

Graft-versus-host diseases (GVHD) can occur in neonates and in severely immune compromised patients. The T-lymphocytes in 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[d] is higher in intra-family donations, especially in mother-to-child transfusions. In the event of direct blood donation, for neonates 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.

2.2.4 Alloimmunisation

As there are many different erythrocyte, leukocyte and platelet antigens, it is impossible to transfuse immunologically identical blood. Transfused blood inevitably introduces antigens that are foreign to the recipient. These antigens are called alloantigens. An alloantigen prompts an immune response, including the production of specific antibodies to eliminate this alloantigen. This phenomenon is alloimmunisation.

Alloimmunisation 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 group systems, as they are the most immunogenic.

Alloimmunisation against leukocytes and platelets may also occur through the development of anti-HLA antibodies or specific anti-platelet antibodies. This type of alloimmunisation is relatively common in multi-transfused patients and multiparous women.

The clinical significance of alloimmunisation 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).

Alloimmunisation may complicate possible future transfusions and/or pregnancies in recipients. Prescription of "phenotyped blood", terminology commonly used for full Rhesus and Kell group determination, is the means to prevent most alloimmunisations in multi-transfused patients.

d Irradiating the blood is the only way to effectively prevent GVHD. Leukofiltration, when available, may reduce the severity of the reaction.

3. Blood groups and compatibility

An individual's blood group is defined by the presence of an antigen on the red cell membrane. Individuals who possess the same antigen belong to the same blood group.

Individuals 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 the two most important groups –ABO and Rhesus– for compatibility 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 the plasma[a].

Individuals of group A	have A antigen on their red cell membranes and naturally occurring anti-B antibodies in their plasma.
Individuals of group B	have B antigen on their red cell membranes and naturally occurring anti-A antibodies in their plasma.
Individuals 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.
Individuals of group AB	have A and B antigens on their red cell membranes and no naturally occurring anti-A nor anti-B antibodies in their plasma.

ABO incompatibility reactions occur when the recipient's naturally occurring antibodies destroy the transfused red cells that express the corresponding antigen.

Individuals of group A	may receive group A (identical) or group O (compatible) blood, must **not** receive group B **nor** group AB (incompatible) blood.
Individuals of group B	may receive group B (identical) or group O (compatible) blood, must **not** receive group A **nor** group AB (incompatible) blood.
Individuals of group O	may receive only group O (identical) blood, must **not** receive group A **nor** group B **nor** group AB (incompatible) blood.
Individuals of group AB	may receive group AB (identical), or group A, or group B, or group O (compatible) blood.

Thus, the rule is:

Transfuse only ABO compatible blood
AND
Prefer ABO identical blood

a Except in children under 3 months (because they have not yet developed natural antibodies).

Table 1.1 - ABO compatibility rules for whole blood and red cells transfusion

Recipient ABO group	Blood unit ABO group			
	1st choice	2nd choice	3rd choice	4th choice
O	**O**			
A	**A**	O		
B	**B**	O		
AB	**AB**	A	B	O

Group O donors are often called "universal donors". The transfusion of group O blood to any A, B or AB recipient is possible and will not induce acute ABO incompatibility accidents. However, some donors may carry acquired anti A or anti B haemolysins of high titer, which can induce delayed haemolysis when transfused to A, B or AB recipients. These donors are called "dangerous O donors". In the absence of detection of haemolysins to identify these dangerous O donors, it is preferable to transfuse the least possible amount of non-ABO identical plasma when it is not possible to transfuse ABO identical blood.

Transfusing O blood to non-O recipients must not be routine practice and should be considered only when ABO identical blood is not available. In this event, preferably transfuse packed red blood cells or the least amount of plasma possible.

3.2 Rhesus system

The Rhesus system (Rh) is the second most important system to consider when transfusing patients. It is made up 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. an 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 or moderate delayed haemolysis, but rarely severe acute haemolytic reactions[b].

The rule is:

Prefer Rhesus D identical transfusion

b 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 recipients
Rh D negative blood may be transfused to Rh D positive recipients 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 recipients
Under exceptional circumstances (absolute emergency), Rh D positive blood may be transfused to Rh D negative recipients:
– There will be no immediate transfusion reaction in Rh D negative men and nulliparous women who have never been transfused.
– Incompatibility reactions may occur if the recipient has developed acquired anti-D antibodies through previous transfusion or pregnancy. Since the simple crossmatch method 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 (80% risk) of developing anti-D antibodies after a transfusion with an incompatible Rh D blood unit: 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.

Table 1.2 - Rhesus compatibility rules for whole blood and red cells transfusion

Recipient's Rhesus	Blood unit Rhesus	
	1st choice	2nd choice
Rh D positive	**Rh D positive**	Rh D negative
Rh D negative	**Rh D negative**	See above

Notes:
– It is pointless to administer anti-D immunoglobulin to prevent anti-D alloimmunisation 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. The four other main Rhesus antigens: C, c, E and e are immunogenic, with c and E the most immunogenic. In the event of repeated transfusions it may be important to respect compatibility with these antigens and provide phenotyped Rhesus compatible blood. In this event blood typing of the donor and recipient must be carried out for the 4 antisera (anti-C, anti-c, anti E and anti e).
Like anti-Rh D antibodies, anti-Rh C, anti-Rh c, anti-Rh E and anti-Rh e antibodies are acquired, and undetectable by the simple crossmatch method. However, alloimmunisation caused by Rhesus C, c, E and e antigens is usually not of clinical significance, except in multi-transfused patients.

3.3 Other blood group systems

Kell, Duffy and Kidd systems may be associated with severe transfusion reactions but cannot be tested in contexts with limited resources.

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, Kidd and other 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 multi-transfused 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 Specific case of children under 4 months

Maternal IgG antibodies cross the placenta to the foetus. If the mother carries IgG anti-red cell antibodies, these will be present in the child until they reach 4 months. This implies:

1. Transfused red blood cells must be compatible with the child's and mother's ABO blood group.
2. If an irregular antibody test has been carried out on the mother's blood (which is unlikely in resource limited settings) and the result is positive, the transfused red blood cells must be compatible with the mother's antibodies.
3. If an irregular antibody test has not been carried out on the mother's blood, the transfused red blood cells must be compatible with the mother's Rhesus phenotype, at least the Rh D antigen.

Example: in the case of an O Rh D negative mother and an A Rh D positive child, transfuse O Rh D negative blood to the child (Chapter 3, Section 2.5.2).

3.5 Blood grouping and crossmatch

3.5.1 ABO and Rh D grouping

Determination of ABO and Rh D groups (Appendix 16) is absolutely mandatory to ensure ABO and Rh D compatibility, but does not exclude incompatibility reactions related to other non-tested systems.

3.5.2 Crossmatching

Crossmatching is a means to reduce immunological complications. It is a laboratory procedure that predicts if antigen-antibody 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 immediately destroy the red cells to be transfused.

Simple crossmatch method - Tile method (Appendix 26)

This aims to detect incompatibility between the patient's plasma and the red cells from the blood unit, due to agglutinating antibodies such as naturally occurring antibodies (anti-A, anti-B) and also from other systems antibodies (anti-Lewis a, anti-P).

Other crossmatch methods

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 solutions, test with antiglobulin, gel methods) 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 negative 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. These are transfusion transmitted infections (TTI). The donor selection process (questionnaire and clinical examination, see Chapter 2, Section 3.2 and Section 3.3) and the routine screening of blood for infection markers can eliminate the vast majority of infected donations. The infections which blood donors/donations should be systematically screened for are HIV, hepatitis B and C and syphilis. However, despite these precautions, a residual risk of transfusing infected blood (e.g. human error, window period, test performances, non-screened infections) persists.

4.1 Bacterial infections

Bacterial infections may result from:
- Contamination of blood during collection (error in asepsis is the most common case).
- Transfusion of blood from an infected donor that is asymptomatic at the time of blood donation.
- Bacterial growth in the blood between collection and transfusion (mainly for platelet concentrates because they are stored up to 5 days at 22 °C).

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

4.1.1 Septic complications

Bacteria found in blood units may be Gram-positive (e.g. *S. epidermidis*) or Gram- negative (e.g. *Klebsiella*, *Acinetobacter*, *P. aeruginosa*, *Y. enterolitica:* the two latter 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 in the blood unit[a]:
- Collect blood in a clean area, respecting hand hygiene and rigorous skin disinfection techniques.
- Collect blood using blood bags with a diversion pouch (the first 35 mL of blood collected are not transfused as they are the most likely to contain skin bacteria).
- Allow blood to sit for 2 to 4 hours between blood collection and refrigeration, if the temperature can be kept between +18 °C and +24 °C. This enables white blood cells to carry out their bactericidal effect (see Appendix 11).
- 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

It is compulsory to routinely screen blood for syphilis (*Treponema pallidum*)[1].

a Additional methods to reduce bacterial contamination exist, such as pre-storage leukocyte depletion filtration, but are rarely available in resource-limited settings.

4.2 Viral infections

4.2.1 Human immunodeficiency virus (HIV)

Eighty to one hundred 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[2,3].

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[b] to patients likely to receive repeated transfusions[4].

4.2.3 Hepatitis C virus

Hepatitis C virus (HCV) can cause severe life-limiting liver disease. Screening donated blood for HCV is compulsory.

4.2.4 Other transfusion-transmissible viruses

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

- In endemic areas, such as the Caribbean, blood is routinely screened for HTLV 1/2 by national blood transfusion services, using ELISA tests.
- While relatively harmless in immune competent patients, CMV is pathogenic in immune compromised patients. Transmission rarely occurs if the blood has been stored refrigerated over 72 hours. In settings where CMV testing is available, immune compromised patients should receive CMV-negative blood.
- The Ebola virus may remain detectable in semen, maternal milk, aqueous humour and other fluids or tissues several months after clinical cure. The isolation of viable virus in blood after initial recovery still remains a rare observation. In the absence of internationally agreed recommendations, as a matter of precaution, it is safer to exclude individuals clinically cured of Ebola infection as potential blood donors[5].

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

Plasmodia survive for at least 3 weeks in refrigerated blood[6]. Therefore, the risk of acquiring malaria through transfusion of infected blood is high. Clinical symptoms depend on the malaria immunological status of the recipient.
When malaria is highly prevalent, screening will detect many positive donors. Routine exclusion of positive malaria blood (by rapid diagnostic test (RDT) or microscopy) may lead to blood shortage. Furthermore, carriers with low level parasitemia may not be detected by microscopy or RDT. The decision to screen donors' blood or to give the recipient an empirical antimalarial treatment depends on the epidemiological situation in the area (see Chapter 2, Section 6.2.4).

b Hepatitis B vaccination is also recommended for health staff at risk of blood exposure.

4.3.2 Chagas disease

In endemic areas (Central and South America), the prevalence of Chagas disease has decreased significantly over the past few years[7]. The possibility of transmission through transfusion exists. Screening tests should be used in endemic countries.

4.3.3 Human African trypanosomiasis

This disease is endemic in certain parts of sub-Saharan Africa, often in specific localized areas. Transmission by chronic asymptomatic carriers is possible, but rare[8].

4.3.4 Visceral leishmaniasis

Visceral leishmaniasisis is endemic in numerous countries worldwide. However, the majority of cases occur in north-eastern India, Bangladesh, Sudan, South Sudan, Ethiopia, and Brazil. In other countries, the disease is found in relatively small and localized foci[9].
The risk of infection through transfusion is low and only a few cases of transfusion- acquired visceral lesihmaniasis have been reported.
However since there is a risk, although minimal, screening with a protein rK39 rapid test should be performed in endemic areas.

4.3.5 Filarioses

The accidental transmission by transfusion of live microfilariae has no direct pathogenic power. However, the destruction of transfused microfilariae by anti-helminthic drugs (which are also microfilaricides) can sometimes provoke severe allergic accidents[10].

4.3.6 Other infectious risks

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

5. Other risks

5.1 Circulatory overload

Transfusion-associated circulatory overload (TACO) is a transfusion complication in which cardiogenic pulmonary oedema develops due to high rates or high volume of transfusion. Patients with cardiac or respiratory disease, elderly patients and children are at the highest risk of developing circulatory overload.

5.2 Massive transfusion syndrome

Massive transfusion is defined as:
- The replacement of at least 50% of the total blood volume in less than 3 hours in adults and children.
- Or the transfusion of over 3 units of whole blood or 4 units of PRBC within the first hour in adults.
- Or the transfusion of over 15 mL/kg of PRBC within the first hour in children.

Massive transfusion syndrome is a combination of:
- Hypothermia (transfused refrigerated blood which has not been warmed before administration).
- Hypoxemia (transfused stored red cells do not have immediate optimal oxygen carrying capacity).
- Metabolic disorders: acidosis with hyperkalaemia due to potassium released by stored red cells; hypocalcaemia due to citrate (i.e. the necessary anticoagulant present 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 platelet concentrates) are not available, the only option to minimize the risk of massive transfusion syndrome is to use fresh whole blood (that has not been refrigerated), 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 (which have not been detected at the time of transfusion or may appear a few days after transfusion), or by hypersplenism. In such cases, the benefit of transfusion may be less than or may not last as long as expected.

5.4 Iron overload

Red blood cells contain ¾ of the body's iron. This is why repeated transfusions lead to an accumulation of iron or secondary hemochromatosis in polytransfused patients. This may lead to heart, liver and/or endocrine organs failure.

For symptoms and management of transfusion-related complications, see Chapter 3, Section 5.

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Chapter 2:
From donor to qualified blood unit for transfusion

1. Ethical aspects for blood donation

1.1 Protection of donor's health

Donors' health should not be put at risk by donating blood. A questionnaire and clinical examination before blood donation are essential steps as they authorize, or not, the blood collection (Chapter 2, Section 3.2). The objective of the questionnaire and clinical 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 (Chapter 2, Section 3.4).

The frequency of blood donation should not exceed 3 donations per year for women and 4 for men (to be checked with the national transfusion policy). If blood is donated more often, the donor risks exhausting their iron reserves. The volume of blood collected at each donation should not exceed 500 mL. An interval of at least 8 weeks must be respected between 2 blood donations.

Hepatitis B vaccination should be offered to regular donors[1].

1.2 Protection of recipient's health

The safety of transfusion depends partly on the reliability of information provided by the donor during the questionnaire. The donor should be informed that, in the interest of the recipient, they 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

No one must be forced to donate blood.

Donors must be informed and agree that:
- They may be excluded at any stage of the selection process for various reasons, e.g. medical history, high risk of 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 the event of replacement donation but for another patient, depending on needs.

Generally, verbal consent is sufficient. Written consent is required in certain countries (Appendix 5).

1.4 Non-remunerated blood donation

The International Society of Blood Transfusion, the International Federation of the Red Cross and Red Crescent Societies, the World Health Organization (WHO) and other international organizations recommend that blood services should be based on non-remunerated blood donation, as remuneration carries the following risks[2]:
- Remuneration of blood favours excessive blood donation, especially in low-income populations.

– Remunerated donors may be tempted not to reply truthfully to the questionnaire in order to avoid exclusion from donation.
– Most studies show higher transfusion transmissible infection (TTI) prevalence rates among remunerated donors compared to non-remunerated donors.

However, in certain countries, the national policy for blood donation is to provide donors with allowances or in kind compensation. In such contexts, it is essential to ensure that the incentive system does not lead to abuse (e.g. excessive donation, collection from donors that would normally be refused) and that recruited donors are identified as low risk donors of TTI.

1.5 Anonymous blood donation

The identity of the donor should not be disclosed to the recipient or vice versa.
However, in the event of direct donation, the donor may be non-anonymous if the blood is collected for the immediate needs of a patient in their entourage.

1.6 Confidentiality

Personal information disclosed by the donor and test results are confidential.
The 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.
The donor's identifying information should neither be recorded in the blood donation register nor in the blood stock/delivery register (Appendix 27 and Appendix 29). When feasible, in order to improve confidentiality, the person who collects the blood donation should not be the same as the person who tests it.

1.7 Disclosure of results to the blood donor

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

Above all, the donor should be asked if they agree or not to receive their test results, either during the questionnaire, or when signing the informed consent for blood donation (Appendix 5). Test results cannot be forced on a donor who does not want to receive them.

However, if donors are not informed of unexpected positive results, the opportunity to treat a 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 results disclosure. Disclosure of positive results poses different problems depending on the test:
Informing the donor of positive results for syphilis or malaria does not usually raise major problems: a single positive test is sufficient to offer treatment, these diseases are readily curable and treatment is usually widely available.

Regarding HIV however, the screening strategy for selecting HIV negative blood differs from that used for diagnosing HIV infection in an individual:
– In blood transfusion, a single HIV positive or doubtful test result is sufficient to exclude a donor or a donation. When the result of the first test is clearly negative, a second test is performed on the donated blood on the blood bag tubing. The second test is intended to confirm that the blood to be transfused is HIV-negative. The donor has accepted that their blood will be screened for the safety of the recipient and has been informed that HIV diagnosis is not available through this testing process, as a positive test result that excludes the donor/donation cannot be interpreted as reliable evidence of infection.

– When diagnosing HIV infection in an individual, an HIV testing algorithm must be applied: a first positive or doubtful HIV test is always followed by subsequent test(s) to confirm the HIV serological status. The individual makes an informed choice to learn their HIV status, is aware of potential consequences, and a positive diagnosis is disclosed only when 2 or 3 different tests, depending on local HIV prevalence, are clearly positive.

Thus, donors who donate blood in order to learn their HIV status should be referred to HIV testing services intended to provide appropriate diagnosis, psychological support and treatment, if needed.

For the diagnosis of hepatitis B or C infection, the donor should be referred to an appropriate health facility to carry out further tests and, if needed, to provide clinical management and follow-up of the patient. The donor may carry the virus in the acute, elimination or chronic phase of the disease; or the initial positive test may not be confirmed.

When national policy is to notify the donor of abnormal results, ensure that there is an appropriate process for notification and follow-up, i.e. the donor consents to disclosure before donation and understands that more tests may be necessary.
A reliable diagnosis using appropriate algorithm is provided; the diagnosis of an infection is disclosed only when the outcome of the testing process is unequivocal; confidentiality is ensured at all stages; pre- and post-test counselling, as well as 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. Health facilities can be supplied by direct donation and/or national blood services and/or replacement donors and/or locally recruited voluntary donors.

A country is capable of supplying blood for all patients needing a transfusion when an unpaid, voluntary system of blood donation exists and functions correctly in the whole country. Countries which manage to set up a system exclusively made up of voluntary donors have a higher proportion of regular donors[2]. In countries where access to health care and diagnostic and treatment are limited, the main indications for transfusion are for pregnancies and complicated deliveries, severe anaemia in children (in particular in areas with high prevalence of malaria), haemoglobinopathies (e.g. thalassemia, sickle cell disease) and trauma. If there is a need for regular transfusion activity in these contexts, but the supply of blood is not ensured at national level, the provision of transfusion services directly at health facility level should be considered (Chapter 4).

2.1 Direct donation

Direct donation is an option in health facilities where it is not possible to store blood, either because the medical authorities do not allow it, or because a cold chain has not been or cannot be set up. 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's group, the donor's blood screens negative for TTI and the crossmatch is negative. Once the donor is approved, blood is collected and transfused immediately to the patient.

Direct donation is typically used in small health facilities where blood transfusions are not regularly performed. Direct donation is not recommended if a health facility that carries out more than 2 to 3 transfusions a day.

Direct blood donation should be considered as a **temporary** type of blood donation until the storage of the blood is possible.

2.2 Replacement donation

This is still the most frequent type of blood donation in peripheral health facilities in resource limited countries. Relatives of patients transfused with blood are asked if they themselves would like to donate blood.

Bear in mind that:
- Replacement donation can only be envisaged in medical facilities where blood can be stored.
- No one must be forced to donate blood. People often feel obliged to donate when a family member is concerned: family donors tend not to answer the questionnaire truthfully for fear of not being eligible to donate blood. If families feel under pressure to donate blood, they may seek "professional donors"[a]. This is strongly discouraged given the higher risk of TTI in this type of donor.

a Or remunerated donors.

– Although donors are not openly paid for replacement donations, it is important to watch out for possible hidden financing systems.
– Replacement donation should gradually evolve towards voluntary blood donation if conditions allow.

2.3 Voluntary donation

Blood is collected from voluntary donors who go to donation centres or mobile collection sites on their own initiative, and who may become regular donors. Collected blood is grouped, screened for TTI and stored in a special refrigerator for blood. Blood units are then supplied to wards or to external health facilities according to needs. The donor receives no financial compensation or incentive. A blood donor card can be issued for regular donors, with information concerning the blood group, donation dates and haemoglobin levels.

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

Voluntary donation is to be preferred over other types of blood donation and should be set up at health facility level as soon as the operational context allows. It is important to understand the beliefs and attitudes of the population towards blood donation in order to deliver the right messages. Simple surveys on knowledge, attitudes and practices can indicate factors that may influence blood donation[3,4]. The young educated age group is the most susceptible to adhere to blood donation promotion messages. Voluntary blood donors receive health information and, in turn, can be effective recruiters and promoters of blood donation.

Regular donors are the safest source of blood. Recruitment and development of a pool of regular donors require regular public blood donation promotion campaigns. Their influence is one of the most effective strategies to enlist new donors. The recruitment and retention of donors require specific strategies to target donors that are particularly available. Local radio stations can play an important role in promoting blood donation messages. These donors are the means of ensuring a constant blood supply.

Recruitment of donors among health staff is not recommended in their own health facility:
– It is particularly difficult to ensure the confidentiality of sensitive information, e.g. reasons for exclusion or tests results.
– The risk of stigmatization of those who do not want or are unable to donate blood is high.
– It is difficult to ensure that the staff member will not be over solicited.
– Donation by a member of the health staff, since it is not anonymous, may be prejudicial in the event of a 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 staff wants to donate blood, they should be directed to another facility, with no connections to the facility where they are employed, in order to guarantee confidentiality of information and donor anonymity.

June 14th is world blood donor day. This is an opportunity to organize an event and activities on blood donation, highlight messages, motivate blood donors and recruit new ones.

Mobile blood collection (mobile drives)

Mobile blood collection is a way to reach out to potential donors who cannot travel for various reasons (e.g. time, transport, social reasons, etc.) and to reach out to people who, due to lack of adequate information, do not know why blood donation is useful or do not know how to give blood in practice.

Mobile blood donation can be carried out in different types of places (e.g. heath centres, high schools, markets, offices of a religious or secular organisation, etc.) as long as the environment is suitable in terms of space and hygiene, can ensure confidentiality and is welcoming. The mobile collection site must be evaluated before blood collection takes place. It must have access to water and sufficient sanitation to guarantee hygiene and safety standards for donors as well as for health staff. The opening hours of blood collection sites should take into account when the largest number of people can attend.

Mobile blood collection sessions attract new donors if the place is well chosen. There will be even more new donors if local partners or organizations, particularly high schools, universities and community organizations, participate actively and promote the effort. Mobile collections at regular intervals in the same place increase donor retention.

It is important to consider the cost/effectiveness of mobile blood collection. During the planning of mobile blood collections, the locations chosen should be those where the participation and number of blood donations were highest during previous sessions.

For a blood mobile collection session to be successful, the key points to consider are:
– Choice of place and date
– Participation of partner organizations, especially during preparation of the event
– Organization and rigorous planning of logistics, including cold chain
– The preparation of premises
– Availability of all necessary staff

2.4 “Walking blood bank”

Blood is collected from a registered 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 or because a recipient needs fresh non-refrigerated whole blood.

A “walking blood bank” can be a temporary solution until a transfusion service with blood storage capacity is available instead of or in addition to direct donation. It can also complement a conventional blood transfusion service.

3. Donor selection

The aims of donor selection are to provide blood that is as safe as possible for the recipient and to ensure that blood donation does not harm the donor's health.

3.1 Pre-selection process

The pre-selection process aims to protect the donor. Pre-selection criteria include age, weight, time since last donation, number of donations over the past year, haemoglobin (Hb) level, and for women, pregnancy and lactation (Chapter 2, Section 3.4).

3.2 Pre-donation questionnaire[5,6]

The questionnaire may help identify high-risk donors, thus minimizing the risk of collecting infected blood. Well conducted questionnaires can lead to excluding a quarter of potential donors in certain contexts.

The interview should take place in an area where auditory and visual privacy is ensured. The donor's name should not be recorded on the questionnaire. Answers are also confidential. This must be clearly explained to the donor to encourage them to answer truthfully.

Staff must ensure that the donor understands the questions and why they are being asked. It is important to mention to the donor that they can self-exclude themselves any time if they do not wish to answer the questions.

The questionnaire should not be skipped in an emergency situation or due to concern that the potential donor will change their mind if asked questions about their personal life.

Sensitive questions related to the risk of TTI must be asked and be formulated according to the social and cultural context and local beliefs. Questions regarding high-risk exposure (e.g. unprotected casual sex, multiple partners, men to men sex, IV drug use) must be asked with a non-judgemental attitude.

If at the end of the questionnaire the donor is excluded, the reason for the exclusion must be communicated to the donor if requested.

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 health care worker other than a physician provided that they have been specifically trained for this task, are supervised by a physician and if the national policy allows it. The potential donor must be referred to the physician in the event of abnormality during the clinical examination.

Note: mobile blood collection must use the same pre-selection criteria (including Hb level), and the questionnaire is still required but can be simplified.

3.4 Contraindications for blood donation

Table 2.1 - Absolute and relative contraindications for blood donations

		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	< 2 months Men: max. 4 blood donations/ year if Hb > 13.5 g/dL; Women: max. 3 blood donations/ year if Hb > 12.5 g/dL	If < 3 months, collect a smaller volume (150 or 250 mL)
	Hb level	< 11 g/dL	If < 12.5 g/dL, collect a smaller volume (150 or 250 mL)
HISTORY	**Occupation**	Sex workers	Military, drivers, itinerant workers or people separated from their family (for any reason)
	Chronic illness	HIV, hepatitis, severe asthma, haemopathy including haemoglobinopathy, epilepsy, insulin dependent diabetes, cancer	Refer to the physician if other chronic illnesses (e.g. pulmonary, cardiac).
	Current treatment	Contraindication if rabies vaccination after rabies exposure	Antibiotics, anticoagulants, cardiovascular drugs (ß-blockers, anti-arrhythmics, etc.), insulin. Live attenuated vaccines[a] within the last 4 weeks. Refer to the physician.
	History of		
	– Dental procedure	1 day if simple dental care (e.g. carries, dental descaling), 1 week if other dental care (root treatment, extraction)	
	– Recent fever		Refer to the physician if fever within the 3 last weeks.
	– Confirmed malaria	Within the 3 last weeks	Positive malaria test[b]
	– Jaundice	Unexplained jaundice, regardless of when it occurred	If the cause is known, refer to the physician.
	– Cutaneous wound (infected wound, ulcers...)	Until wound has healed	
	– History of AAR, TB, Q fever, osteomyelitis	Until 2 years after cure	
	– History of dengue	Until 6 months after cure	
	– History of cured Ebola	Definitive exclusion[c]	

		ABSOLUTE	RELATIVE
HISTORY	**History of STI**[d]	< 4 months after cure For syphilis, 1 year after cure	> 4 months after cure
	Blood transfusion	Definitive contraindication if history of past transfusion	
	Surgery or endoscopy	< 6 months if major surgery or endoscopy 1 week if minor surgery	
	High risk exposure	In the last 6 months: unprotected casual sex (not with regular partner), multiple partners, rape, IV drug use, scarification, tattoo, piercing - including earlobes	
SIGNS	**Temperature**	> 37.5 °C axillary[e]	
	Pulse	< 50 or > 100 or irregular	
	Systolic BP	< 100 or > 180 mmHg	
	Conjunctiva	Jaundice	
	Others		Swollen lymph nodes, oral thrush, skin rash: refer to the physician.

a Main live attenuated vaccines: yellow fever, oral polio, measles, rubella, mumps, BCG, varicella.

b Refer to malaria screening, Chapter 2, Section 6.2.4.

c See Chapter 1, Section 4.2.4.

d STI: sexually transmitted infection. A previous STI such as chlamydial infection, gonorrhoea or syphilis are risk factors for HIV and hepatitis acquisition and transmission.

e Screen for malaria in an endemic area. Whatever the cause of the fever, exclude the donor or postpone the donation and refer to the physician.

When there is an identified problem such as low Hb level or abnormal blood pressure etc., the donor will be referred to a health facility to be managed.

4. Pre- or post-donation screening

In direct donation, screening for TTI is always performed before blood collection as it is pointless to collect the blood donation if any result is positive.

In mobile blood collection sessions, or in case of unexpected massive influx of donors in a health facility, screening for TTI is always performed after blood donation, in the laboratory due to organizational constraints.

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.

Table 2.2 - Pre or post-donation screening: advantages and disadvantages

	Advantages	Disadvantages
Screening the **donor** before blood 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 to immediately explain the reasons for exclusion, prompt treatment of the donor if the blood is positive for syphilis or malaria, and immediate referral for other TTI.	Harder to guarantee confidentiality. Use of blood donation as screening for HIV. Risk of stigmatization in the event of exclusion. Requires that staff has time and is able to communicate with donors clearly and respectfully.
Screening the **donated blood** after donation	Easier to guarantee confidentiality. 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 donations. Unnecessary blood donations and waste of supplies. More waste to dispose of (blood bags etc.). Missed opportunity to treat an infected donor for syphilis or malaria and missed opportunity to refer for others TTI.

If at least 5% of blood donations are rejected due to TTI, the recommendation is to screen before blood collection.

If screening is performed before donation:
- Draw a blood sample in an EDTA[a] tube.
- Perform the first blood grouping, the first HIV test[b], and the test for hepatitis B, C and syphilis[c] on the EDTA tube.
- Exclude the donor if any of the TTI test result is positive or doubtful.
- If all TTI tests are clearly negative: collect the blood donation, and then perform the second blood grouping and the second HIV test[d] on the blood in the distal segment of the bag tubing.

If screening is performed after donation:
- Collect the blood donation.
- At the end of collection, fill an EDTA tube, or in the event of a blood bag with a diversion pouch (sampling arm), fill the EDTA tube as soon as the diversion pouch is full.
- Perform the first blood grouping, the first HIV test and the tests for hepatitis B, C and syphilis using the EDTA tube one by one or in batches[e].
- Discard the blood donation if any of the TTI test result is positive or doubtful.
- If all TTI tests are clearly negative, perform the second blood grouping and the 2nd HIV test on the blood of the distal segment of the bag tubing.

In both cases:
If the second HIV test is clearly negative: the blood donation is qualified.
If the second HIV test is positive or doubtful: the blood donation is excluded.

All blood donations with any positive or doubtful test results must be discarded (Chapter 4, Section 7).

For blood collection procedure, see Appendix 11.

When an HIV, hepatitis B or C test is detected positive and the donor wants to know their results, they are referred to an appropriate health facility (Chapter 2, Section 1.7).

a EDTA: Ethylen Diamine Tetraacetic Acid

b First HIV test: HIV 1/2 Determine® is currently the most sensitive test available. It is recommended for blood safety when Elisa tests are not available.

c For syphilis, see also Chapter 2, Section 6.2.3.

d Second HIV test: HIV Stat Pak® or HIV 1/2Uni-Gold®.

e In the event of a high workload, performing the tests in batches will save time but the risk of errors is higher.

5. Collection of blood donation

5.1 Premises, furniture and equipment

The premises where donors' blood is collected must be welcoming and comfortable for both donors as well as staff, and separate from the laboratory. The premises should comply with the following characteristics:
– Registration area
– Waiting room with enough seats
– Room that is well lit and ventilated (or air-conditioned).
– Water point nearby or in the room (to wash hands and forearms)
– Spacious enough for circulation of staff
– Rest room after blood donation: the donor must be in staff's view at all times.

Suitable, regularly cleaned furniture:
– Sufficiently high donor chairs or beds
– Trolleys
– Work surface with sink
– Cupboard to store materials away from sunlight

Staff must be continuously present throughout the entire blood donation process. Nurses, laboratory technicians or assistants, if local legislation allows, are authorized to collect blood. They are trained to respect strict aseptic procedures and how to avoid blood exposure accidents. Staff is always supervised by a physician.

In the event of many donations (over 5 blood donations per day), the presence of many blood donors at the same time, or mobile blood collection, additional equipment may be useful:
– Blood collection monitors that in particular allow one staff member to collect blood from several donors at the same time.
– A blood bag tube sealer.

5.2 Blood collection process

In order to prepare donors and create a positive memory experience which will encourage them to return and make future donations:
– Thank them for their availability and reassure them if needed.
– Check when they last ate and drank. Certain donors may have travelled a considerable distance and have walked a long way.
– Provide a drink to rehydrate if necessary and even something to eat before they donate blood.
– Demonstrate professionalism: have equipment ready and organised, dress smartly, wear a clean medical coat, demonstrate a composed attitude and confident actions etc.
– Check the donor's identity.
– Explain all stages of the procedure before starting to collect blood.

See Appendix 11 and Appendix 34.

5.3. Possible incidents during or after blood collection

– The blood flow is slow or the blood flow stops:
  • Ensure the blood bag is lower than the venipuncture site.
  • Ask the donor to pump their fist in order to increase the flow.
  • Loosen and retighten the tourniquet in order to improve the flow.
  • Move the needle gently.

– The blood flow stops before the minimum volume is reached:
  The collected blood 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 collection of 450 mL).
– 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 with symptoms such as 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 their back with their feet elevated. Once recovered, ensure that the donor is properly hydrated.
– In the event of accidental exposure to blood:
  Follow the recommendations for post-exposure prophylaxis, following the recognized protocol in the country.

6. Blood grouping and transfusion transmissible infections screening

6.1. Donor's blood grouping

For safety reasons, blood grouping must be performed twice:
– Firstly: on the donor's blood, before or after donation.
– Secondly: on the blood donation, using the distal segment of the blood bag tubing.

The tile method is recommended as it is less prone to handling errors than the tube method (Appendix 16).

When blood units are supplied by an external source e.g. a regional/national blood transfusion centre or another hospital, the unit's blood group must be checked and tested again for all TTI[7] using blood from the distal segment of the blood bag tubing, unless the external source has been validated by a competent medical professional (Chapter 4, Section 1.1.2).

6.2 Transfusion transmissible infection (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 (Chapter 1).

Screening tests have to combine:
– High sensitivity in order to correctly detect as soon as possible after contamination infected blood and to avoid false negative test results.
– High specificity to avoid rejecting blood with false positive test results.
Tests must be stable under field conditions (e.g. transport, temperature, humidity) and results must be rapidly available.

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

See Appendices 19 to 25.3.

6.2.1 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 blood safety testing strategy differs from the individual testing algorithm used for HIV infection diagnosis.

The WHO considers the use of one single highly sensitive and specific HIV 1/2 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 error (e.g. in handling or storing tests, labelling tubes, bags and test devices) may result in inaccurate results.

The two HIV tests results must be clearly negative. In the event of a doubtful or positive result in the first test, the donor or the blood donation must be excluded.

Nevertheless, a negative HIV test does not prevent HIV transmission through transfusion if the donor has been infected within the previous 3 to 4 weeks, which is the usual period for detection of HIV antibodies using highly sensitive rapid tests in immune competent individuals. The pre-donation questionnaire and physical examination are therefore essential to select low risk donors and exclude those who may have been infected recently.

6.2.2 Hepatitis B and C

In the event of doubtful or positive results, the donor or the blood donation must be excluded. The average period for hepatitis B surface antigen (HBs Ag) detection is 30 days (7 - 63 days) and 82 days (54 - 192 days) for HCV antibody using rapid tests.

6.2.3 Syphilis

Screening should be performed using a rapid Treponema-specific test (e.g. Syphilis 3.0 SD Bioline®). RPR[a] is no longer recommended as it is neither sensitive nor specific enough.

Syphilis positive blood should not be transfused as it may be infected by *Treponema pallidum*[b]. Furthermore, 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 after 5 days of storage at 4 °C, provided the recipient is simultaneously treated for syphilis.

Table 2.3 - Management of syphilis positive test

If the **donor's test** is positive (screening before donation)	If the **blood unit** is positive (screening after donation)
• Collect blood only in the event of an emergency if no other donor is available. • Treat the donor AND the recipient for syphilis.	• Label the blood unit as syphilis-positive and store it separately from the other units in the refrigerator for 5 days before use[c]. • Use this unit only if there is no alternative. • If the blood is transfused, treat the recipient for syphilis.

a RPR : Rapid Plasma Reagin : non- treponemic test

b A positive syphilis test does not indicate whether the donor has been infected recently or in the past, nor whether they are still infectious. The test can remain positive even after successful treatment.

c *Treponema pallidum* is sensitive to cold. Infectivity decreases when blood is refrigerated (between 2 °C and 8 °C) and blood is no longer infectious after a period of 120 hours (5 days).

First choice treatment is **benzathine benzylpenicillin** IM: 2.4 MIU as a single dose. Alternative treatment is doxycycline PO: 100 mg 2 times daily for 14 days if benzathine benzylpenicillin is not available or in penicillin allergic patients. It is contraindicated in pregnant and lactating women.

6.2.4 Malaria

In low endemic areas or areas of seasonal transmission

Malaria screening should be performed, using an RDT. 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 recent fever or recent malaria infection should be excluded.

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

Blood should not be collected, unless transfusion is needed urgently and no other donor is available. In that case, treat all recipients of malaria positive blood with a full, effective antimalarial treatment.

All neonates should receive a full course of anti-malarial treatment when they receive a blood transfusion. This is regardless of the malaria RDT test result.

In highly endemic areas with stable transmission[8]

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

Depending on the context, 2 options are possible:
- *Option 1*: donors are not screened for malaria 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. Malaria RDT positive blood units must be transfused only to malaria positive adult recipients while systematically giving them antimalarial treatment.

All neonates should receive a full course of anti-malarial treatment when they receive a blood transfusion. This is regardless of the malaria RDT test result.

6.3 Qualified blood unit

A blood unit is qualified for transfusion when a blood donation, or the components issued from it, fulfils all the criteria required for blood safety, i.e.:
- Undamaged bag (no leaks)
- Correct colour of contents
- Minimum length of blood bag tubing, with at least 3 segments
- Tubing correctly closed (tight knots or correct seals)
- Adequate weight
- Negative TTI tests results
- Blood grouping tested twice and concordant
- Clear and complete labelling

7. Possible preparations from whole blood

7.1 Packed red blood cells prepared by sedimentation from a single blood bag of whole blood

See Appendix 12 for procedure.

Packed red blood cells (PRBC) are to be favoured:
– In the event of anaemia without hypovolaemia.
– In patients at risk of circulatory overload, including children.
– In patients transfused with non-identical ABO blood.

The blood unit must not be shaken during transfer to the ward nor during the transfusion, in order to avoid mixing the sedimented red blood cells with the plasma.
The transfusion must be stopped when the plasma reaches the bottom of the blood bag or when the prescribed volume has been administered.

7.2 Preparation of paediatric whole blood units from a penta bag system

See Appendix 13 for procedure.

The penta bag system is a closed system consisting of a 450 mL primary bag containing the CPDA-1 anticoagulant/preservative solution, connected to 4 satellite 100 mL bags that do not contain anticoagulant.

This system allows transfer of the whole blood in the primary bag into the 4 satellite bags for paediatric needs.

The satellite bags must only be filled once the blood donation is qualified for transfusion.

7.3 Preparation of paediatric PRBC units by sedimentation from the penta bag system

The 450 mL primary bag is put to sediment according to the procedure described in Appendix 12, but with the transfusion outlets pointing up.
The remaining procedure is described in Appendix 14.

The plasma is transferred into one of the satellite bags, and discarded because it does not qualify as fresh frozen plasma: it is ordinary plasma of no therapeutic use.

The concentrated red blood cells are distributed:
– Into the other 3 satellite bags to obtain 3 paediatric units of PRBC,
– Or into the other 3 satellite bags and the primary bag to obtain 4 paediatric units of PRBC.

8. Registration and labelling

8.1 Blood donors register

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

The blood donors register is the only document where the link between the donation number and the donor's identity can be found. This link allows tracing back of donors when:
– There is a pool of regular donors including donors called on demand.
– The national transfusion policy may recommend tracing 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 donors register.

8.2 Blood donations register

Information pertaining to the donation (date of donation, donation number, blood grouping and TTI screening results) should be recorded in a blood donations register (see Appendix 27).

The blood donation is identified by a single identification number attributed when the blood donor is declared eligible for blood donation. The donation number remains the same during the qualification and preparation process and all components prepared from this donation keep the same number. The donor's name, age, address or any other identifying information must not be recorded in the blood donations register.

In the event of mobile blood collection, ensure blood is collected using a different donation number series from that used to identify blood collected in the health facility, in order to avoid confusion with blood collected at the facility on the same day.

8.3 Blood unit labelling

Before collection, the empty blood bag is labelled using a permanent marker recording the:
– Donation number
– Blood collection date
– Expiry date
The blood group is only added AFTER the second blood group determination.

On the qualified blood unit, are also clearly marked:
– Tests results, including possible positive test results for malaria and syphilis,
– Type of blood component,
– Volume.

Given that this information is manually written, it is recommended to adopt a convention (decided by the team) to write each piece of information in a given section of the label (e.g. the blood group in the top right corner of the label) whatever the type or brand of the blood bag; this is to facilitate looking for blood units in the fridge and checking them on the wards.

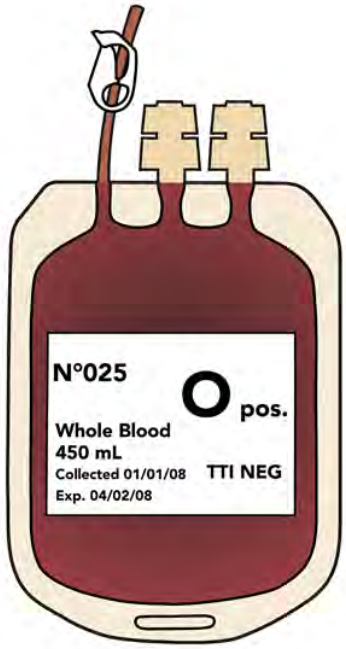


Figure 2.1
Information to be recorded on each blood unit

8.4 Blood stock/delivery register

A blood stock/delivery register is needed to track the use of blood units. It combines information on the qualified blood units and on the recipient (Appendix 29).
The register, divided into 4 sections (one for each ABO 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 qualified for transfusion, should be immediately entered in the register recording the following information: blood unit number, date of collection, blood group ABO Rh D, type of component, volume and expiry date, on the left side of the register.

Once the blood unit is issued, information on the recipient is entered in the register (date, name, age, sex, blood group and Hb level, reason for transfusion, ward, patient file number, cross-match result, time of delivery), on the right side of the register.

If a blood unit is returned without being transfused, it can be re-entered into the stock and issued for another patient, only if it has remained in the cold chain.

8.5 Transfused patients register = recipients register

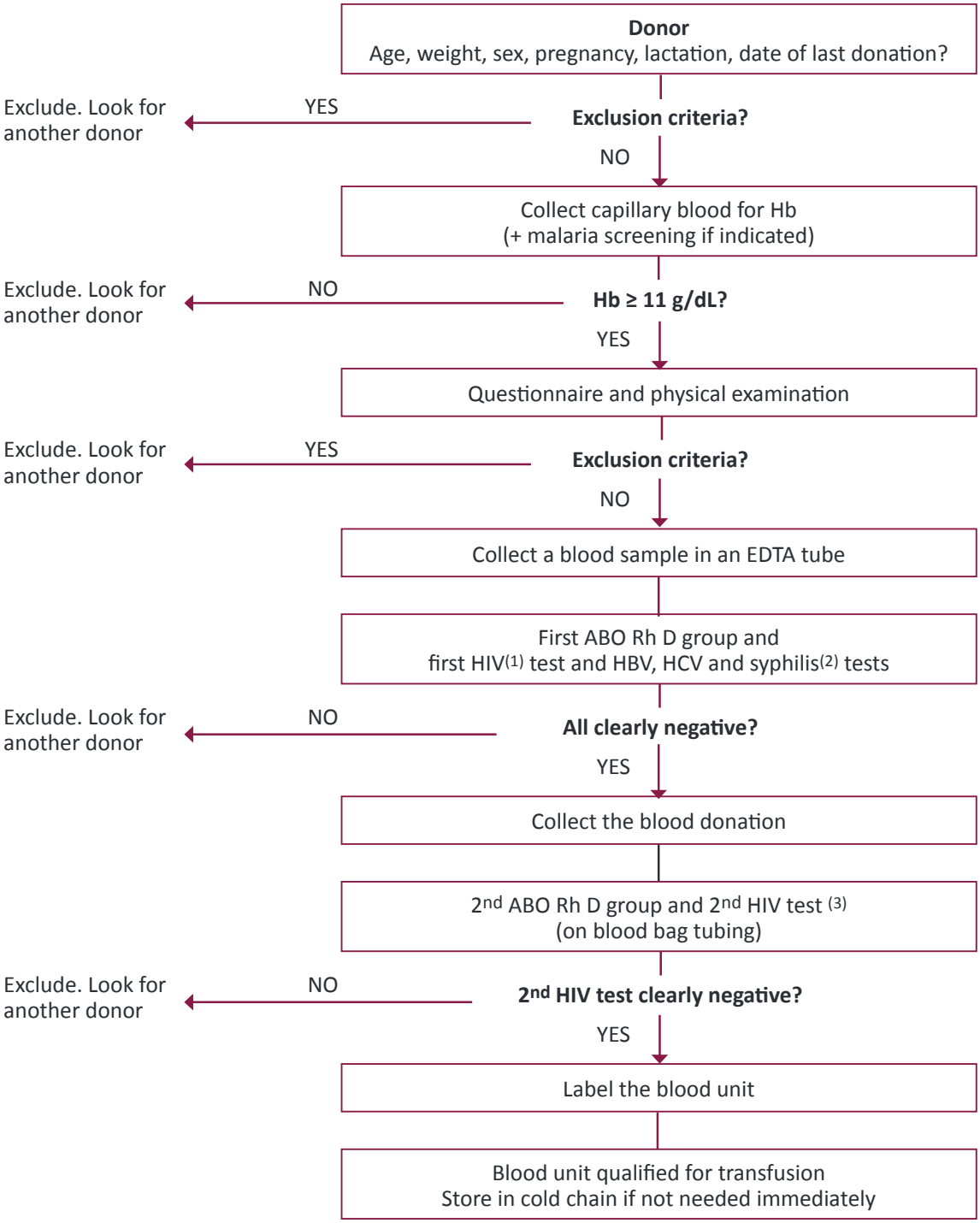
See Appendix 30.

Each blood unit delivered is recorded in this register. The entries on the left side of the register record the blood unit delivery date, recipient information and on the right of the register information on the blood unit(s) delivered.

Note: in a health facility with low transfusion activity (few blood units per week) and therefore a small stock, a transfused patients' register is sufficient instead of keeping both a stock register and a transfused patients register.

9. Decision trees

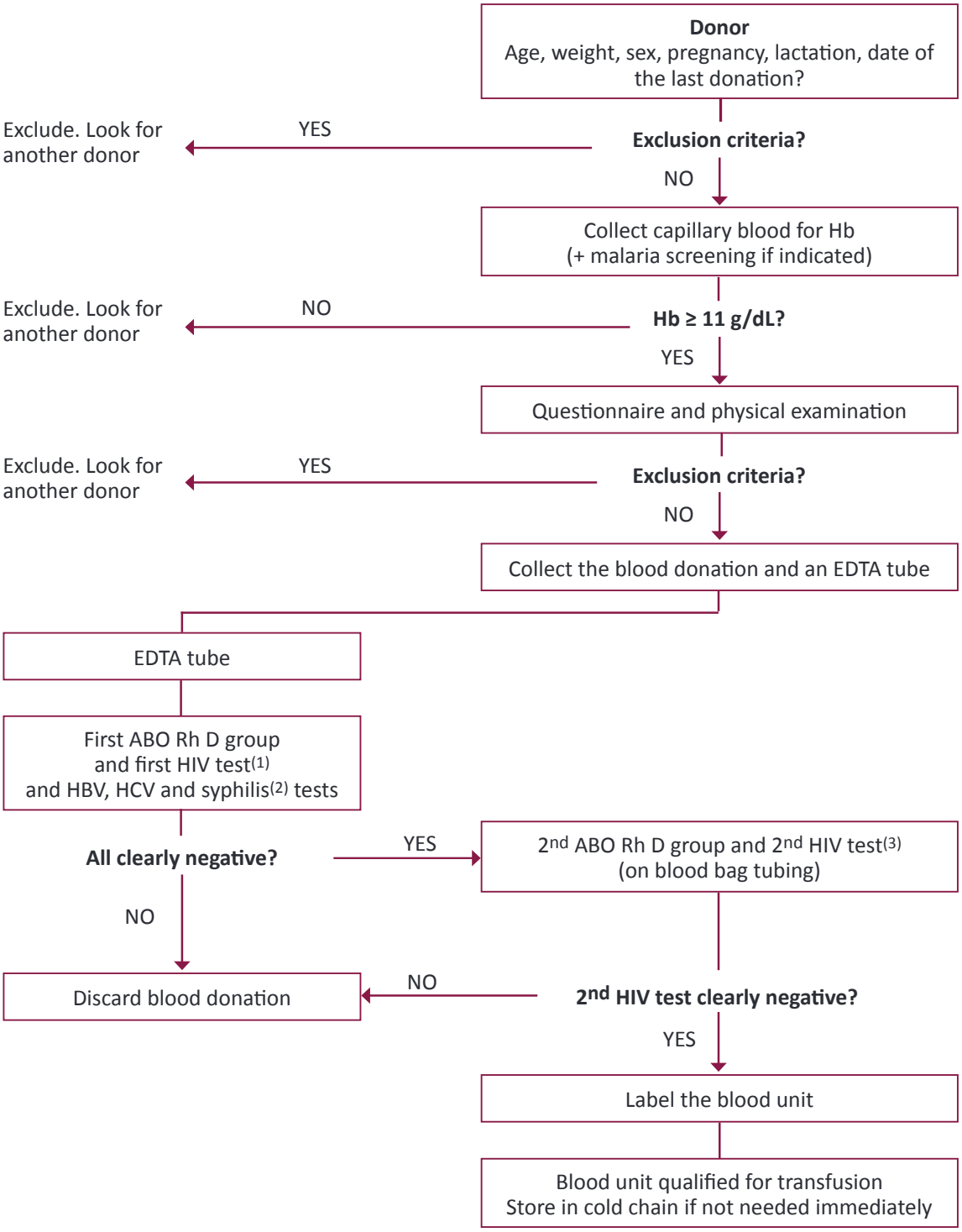
Voluntary donation and replacement donation
If screening is performed **BEFORE** donation



(1) HIV 1/2 Determine®
(2) Refer to Chapter 2, Section 6 in the event of positive syphilis or malaria screening.
(3) Stat Pak® or Uni-Gold®

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

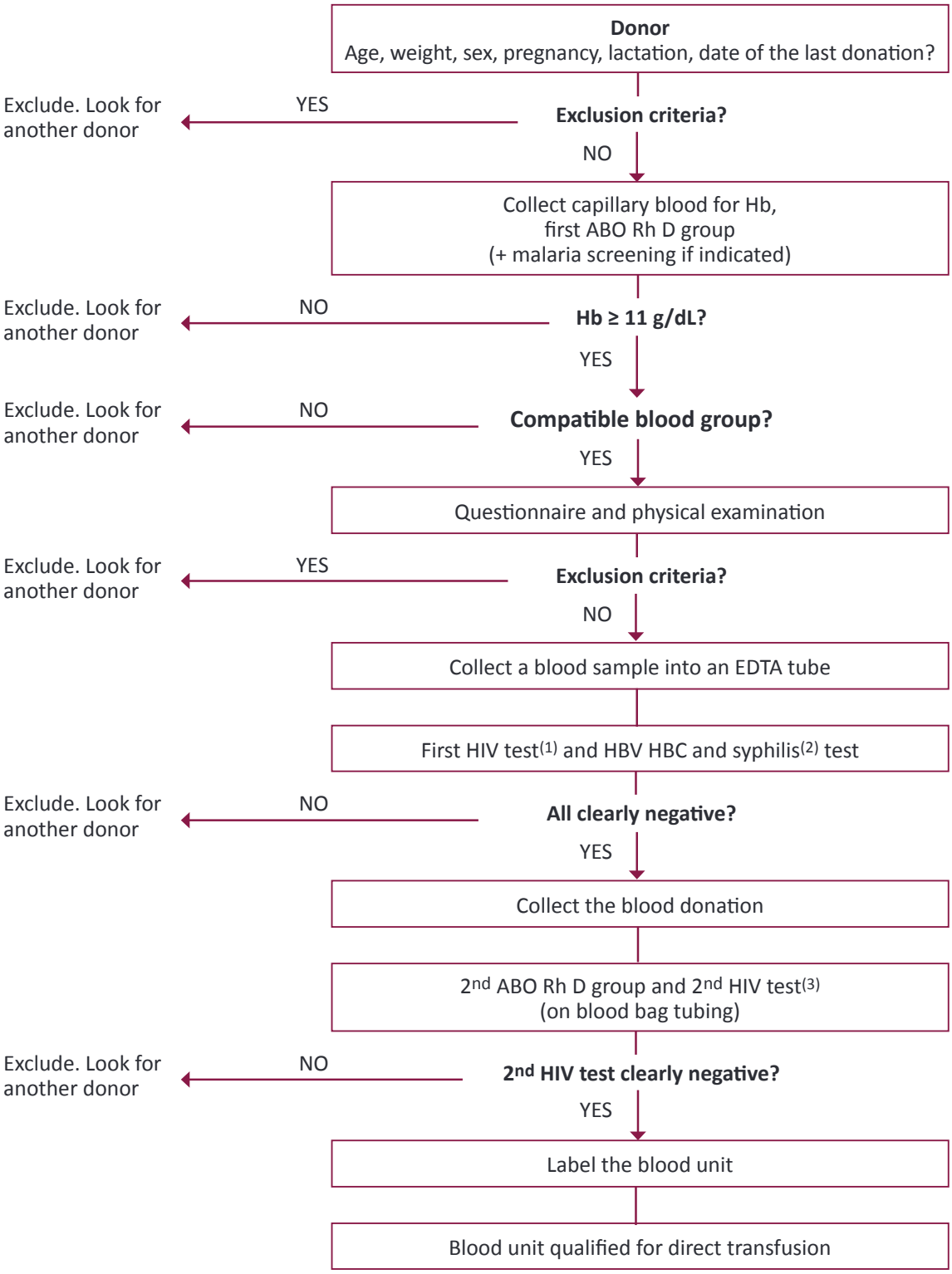
Voluntary donation and replacement donation
If screening is performed **AFTER** donation



(1) HIV 1/2 Determine®
(2) Refer to Chapter 2, Section 6 in the event of positive syphilis or malaria screening.
(3) Stat Pak® or Uni-Gold®

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

Direct donation



(1) HIV 1/2 Determine®
(2) Refer to Chapter 2, Section 6 in the event of positive syphilis or malaria screening.
(3) Stat Pak® or Uni-Gold®

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Chapter 3:
Blood transfusion process

1. Indications of red cells transfusion

Transfusion of red blood cells improves oxygen transport in patients with clinical symptoms of anaemia. Transfusion is indicated to relieve clinical symptoms of decompensation of anaemia or prevent further decompensation in patients at risk. It is not indicated to normalize the patient's Hb level.

1.1 Severe anaemia

Anaemia is defined by a Hb level below reference values for age, sex and for pregnant woman, pregnancy state (see Appendix 1). It results in a decrease in blood oxygen-carrying capacity. However, low Hb levels may be well tolerated. Clinical tolerance is related to the rate at which it develops and the patient's underlying condition.

- The more rapidly anaemia develops, the more likely compensatory mechanisms to maintain the transport and transfer of oxygen to tissues 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 mechanisms will have developed over weeks or months.
- However, many factors such as fever, infection, haemorrhage or haemolysis can precipitate the decompensation of well-tolerated anaemia.
- Decompensation signs of anemia are: respiratory distress, tachycardia, altered mental status, cardiac failure, coronary failure, shock.

Anaemia is considered severe when Hb level falls below critical values (or transfusion thresholds), even if there are no signs of decompensation and/or clinical symptoms. In an episode of severe malaria, Hb level can drop by 2 g/dL per day. In children, the risk of death rapidly increases when Hb level drops below 4 g/dL.[1] Therefore close monitoring of Hb is essential in adults and children with severe malaria and transfusion should be considered when the Hb is approaching transfusion trigger levels.

Note: transfusion thresholds are the Hb values at which transfusion is imperative (except in the event of hereditary anaemia, see Chapter 3, Section 1.4.1).

Table 3.1 - Hb transfusion thresholds

Premature neonate Full-term neonate	**Hb < 7 g/dL** **Hb < 8 g/dL**	Transfusion is indicated if **Hb < 10 g/dL** **AND** There are signs of decompensation
Children	**Hb < 4 g/dL**	Transfusion is indicated if **Hb** is **between 4 and 6 g/dL** **AND** There are signs of decompensation, sickle cell, severe malaria, severe bacterial infection or pre-existing heart disease

Table 3.1 - Hb transfusion thresholds *(continued)*

Pregnant women < 36 weeks	**Hb ≤ 5 g/dL**	Transfusion is indicated if **Hb < 7 g/dL** **AND** There are signs of decompensation, sickle cell, severe malaria, severe bacterial infection or pre-existing heart disease.
Pregnant women ≥ 36 weeks	**Hb ≤ 6 g/dL**	Transfusion is indicated if **Hb < 8 g/dL** **AND** There are signs of decompensation, sickle cell, severe malaria, severe bacterial infection or pre-existing heart.
Adults	**Hb < 7 g/dL** Consider earlier transfusion in patients with signs of decompensation, sickle cell, severe malaria, severe bacterial infection or pre-existing heart disease.	

Adapted from the WHO CD Rom, *Clinical use of blood*, 2005.[2]

1.2 Acute haemorrhage

Acute haemorrhage is associated with hypovolaemia and reduced circulating haemoglobin. Acute haemorrhage causes haemodynamic instability, with reduced tissue perfusion and oxygen delivery. The priorities of management are to control bleeding and restore circulating volume, while maintaining oxygenation. Patients with ongoing, massive bleeding may benefit from limited fluid resuscitation and toleration of moderate hypotension until haemorrhage has been controlled.

Crystalloid solutions should be used for initial correction of hypovolaemia (Ringer Lactate or 0.9% sodium chloride). There is no evidence that colloids (Haemaccel®, Plasmion®, Gelofusin®) are more effective than crystalloids for fluid resuscitation and may be associated with increased adverse effects. Blood should not be used to correct hypovolaemia.

Blood loss equivalent to 30% total blood volume (ACS[a] Class I and II Acute Haemorrhage) can normally be tolerated without blood transfusion, provided that volume replacement is adequate.

The decision to transfuse is based on clinical criteria. Transfusion is indicated when haemodynamic instability and tissue hypoxia persist despite adequate volume resuscitation. It is usually necessary when blood loss exceeds 30-40% total blood volume (ACS Class III and IV). However, earlier transfusion may be necessary if the patient's underlying condition prevents effective compensation of acute anaemia.

At birth, an acute haemorrhage can present with pallor (without jaundice), tachypnea (or gasping respiration), tachycardia and symptoms of hypovolaemia ranging from decreased peripheral perfusion (10% loss of blood volume) to hypovolaemic shock (20-25% loss of blood volume).[3]

1.3 Coagulation disorders

Stored (non-fresh) blood is not effective in correcting haemorrhage secondary to coagulation disorders as it contains neither coagulation factors V and VIII nor functional platelets.

a ACS: American College of Surgeons

1.3.1 Acquired disorders

Early trauma induced coagulopathy is due to release of inflammatory mediators from damaged tissue, dilution of blood with crystalloids, acidosis associated with tissue hypoxia and hypothermia.

Disseminated intravascular coagulation (DIC) is mainly seen in obstetric complications (e.g. abruptio placentae, 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 early trauma induced coagulopathy and DIC and restoring platelets and coagulation factors by the transfusion of fresh whole blood (never refrigerated) or specific blood components, such as fresh frozen plasma and platelet concentrates, if they are available.

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 provide adequate clotting factors and platelets to control haemorrhage if the coagulation disorder is mild to moderate.

1.4. Specific considerations

1.4.1. Hemoglobinopathies

Sickle cell disease

Transfusion is indicated in:
- Acute severe haemolysis: if Hb ≤ 5 g/dL or drop of 2 g/dL below the patient's baseline. Target a Hb level of 9 g/dL.
- Splenic sequestration with Hb ≤ 5 g/dL (the objective is to reach 7-8 g/dL maximum).
- Stroke: if Hb ≤ 9 g/dL; target Hb of 10 g/dL.
- Acute chest syndrome: if symptoms are unresponsive to antibiotics and Hb < 9 g/dL.
- Pregnant woman ≥ 36 weeks with Hb < 8 g/dL.
- Pregnant woman < 36 weeks with Hb < 7 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 is essential for the treatment of chronic iron overload secondary to frequent transfusions. Patients with thalassaemia intermedia do not usually require regular transfusions.

Glucose-6-phosphate-dehydrogenase (G6PD) deficiency

G6PD deficiency can cause acute or chronic haemolysis during severe viral and bacterial infections, or ingestion of certain foods (e.g. fava beans) or exposure to various drugs (e.g. dapsone, nitrofurantoin, 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 a few days following the admission in nutritional centre suggests the correction of a pre-existing haemoconcentration (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 low Hb (related to haemodilution) which does not necessarily require transfusion.

1.4.3. Obstetrics

During delivery, normal blood loss is approximately 500 mL (for vaginal delivery and for caesarean section). If blood loss is not greater than normal and the Hb level was ≥ 8 g/dL before delivery, blood transfusion is rarely necessary.

In the event of elective caesarean section, if the preoperative Hb level is < 8 g/dL prepare two compatible and cross-matched blood units and have them ready for immediate use but do not perform preventive transfusion.

1.4.4. Surgery

In healthy patients, the pre-operative decision for a transfusion depends on the patient's clinical tolerance of anaemia. However, be prepared for transfusion if Hb is < 7 g/dL in a healthy adult undergoing major surgery or surgery with significant blood loss. Have blood units ready for immediate use (compatible and crossmatched), but do not perform preventive transfusion. All patients who undergo elective surgery, even if minor, must have a blood group determination performed.

In adults with low cardiopulmonary reserve (e.g. heart failure, coronary disease, chronic respiratory disease) or in elderly patients, an Hb threshold of 8-9 g/dL is usually recommended before surgery.

Notes:
- When a patient is referred to a surgical facility for elective surgery, certain facilities may organise that a compatible and negatively crossmatched donor selected from the patient's entourage accompanies them in case the patient requires a transfusion.
- Blood recovered from a large, closed haemothorax via an intercostal drain may be re-infused as an alternative to transfusion of donor blood. This must only be undertaken by experienced staff using adequate sterile equipment.

1.4.5 Severe burns

Burns initially do not bleed. In the absence of comorbidity, 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. Extensive burns cause an inflammatory syndrome that prevents haematopoiesis. It is therefore essential to constantly monitor the Hb level throughout the wound healing process. Furthermore, anaemia delays wound healing.

2. Prescription

Only a physician or an anaesthetist nurse (if local legislation allows) can prescribe a blood transfusion. They are responsible for the following steps:

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

The decision to transfuse a patient is based on several parameters:
– Clinical tolerance of anaemia
– Underlying conditions (cardiovascular and pulmonary disease disease, etc.)
– Severity, rate and history of blood loss or of red cell destruction
– Haemoglobin level[a]

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

2.2. Inform the patient about the need for a transfusion and obtain written consent

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

The patient (or legal guardian) MUST give written consent for transfusion. (Appendix 6).
If it is not possible to obtain consent, the transfusion can be administered if the physician considers it is in the best interest of the patient. In this event, the patient must be informed later that they have received a transfusion.

An adult or a legal representative of a child, who is able to give informed consent, may refuse transfusion. In such cases, it is important to understand the reason for the refusal and to explain the benefits of the transfusion. In the event of continued refusal, inform the patient of the consequences of this decision. Any refusal of transfusion must be recorded in the patient's file.

2.3. Request the patient's blood group determination

Even if the patient knows what blood group they are, the blood group must still be determined.

The patient's blood group should be determined twice. The first determination can be done on admission (on capillary blood if venous sampling fails) and the second determination when blood is prescribed (Appendix 16 and Appendix 26).

Notes:
– An EDTA tube is necessary for crossmatching and is drawn when the transfusion is prescribed.
– All blood samples must be labelled with the patient's identity and the date of collection.
– The ABO bedside compatibility test should not be confused with blood group determination.

a Recommended equipment for Hb measurement includes point-of-care analysers (HemoCue Hb 301®) or automated haematology analysers.

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

See Chapter 2.

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

2.5.1 Choice of blood component

In most cases, the choice is limited to whole blood or packed red blood cells (PRBC).

Stored whole blood

The stored whole blood (i.e. kept refrigerated) is the most commonly transfused component and mainly indicated in severe anaemia with hypovolaemia (e.g. trauma, haemorrhage) or in some aetiologies of shock.
In stored blood, red blood cells keep their qualities (oxygen carrying capacity, deformability) but platelets irreversibly self-aggregate at temperatures below 16 °C and thermo-labile coagulation factors deteriorate within 72 hours when stored at 4 °C.

Fresh whole blood

When it is necessary to provide platelets and/or clotting factors, and if specific components are not available:
– Massive haemorrhages in surgical, obstetric and trauma patients: if the volume of blood transfused within 12 hours reaches 50% of the total blood volume, stop transfusing stored whole blood and administer fresh whole blood (blood collected less than 4 hours before transfusion, that has never been refrigerated).
– DIC: if possible transfuse fresh whole blood from the outset.

PRBC

PRBC are preferred:
– For patients with severe anaemia without hypovolaemia (e.g. haemolysis)
– 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 (Chapter 1, Section 3).

PRBC are either:
– Supplied by the national blood transfusion service.
– Prepared from multiple bags after sedimentation and separation into satellite bags.
– In the absence of multiple bags, whole blood units can be stored vertically with the transfusion outlets pointing down, and then carefully transported to the ward so as to not mix the red cells back into the plasma. Only the sedimented red blood cells must be transfused (Appendix 12).

2.5.2 Compatibility rules

Adults & children above 4 months

Use ABO Rh identical blood whenever possible.

If identical ABO Rh D blood is not available, compatible ABO Rh D blood may be transfused only with the prescribing doctor's agreement according to the compatibility rules mentioned in the table 3.2.

Table 3.2 - Compatibility rules for red cells transfusion for adults and children above 4 months

Recipient ABO group	Blood unit ABO group			
	1st choice	2nd choice	3rd choice	4th choice
O	**O**			
A	**A**	O		
B	**B**	O		
AB	**AB**	A	B	O

Recipient's Rhesus	Blood unit Rhesus	
	1st choice	2nd choice
Rh D positive	**Rh D positive**	Rh D negative
Rh D negative	**Rh D negative**	See Chapter 1, Section 3.2

Neonates up to 4 months

The blood must be compatible with both the mother's and child's blood according to the table 3.3. Do not use blood from the mother. For more information, see Chapter 1, Section 3.4.

Table 3.3 - Compatibility rules for red cells transfusion for neonates up to 4 months

Neonates up to 4 months	Mother	Blood to transfuse	Comments
O	A, B or O	O	If mother's blood group unknown: give O group blood
A	A or AB	A (or O)	
	B or O	O	
B	B or AB	B (or O)	
	A or O	O	
AB	AB	AB, A, B (or O)	
	A	A (or O)	
	B	B (or O)	
Rh +	Rh +	Rh +	If mother's Rh unknown: give Rh - blood
	Rh -	Rh -	
		If Direct Coombs test negative in child, possible to give Rh +	
Rh -	Rh +	Rh -	
	Rh -	Rh -	

Notes:
– In all cases, prefer ABO identical blood transfusion when possible.
– When O blood is to be transfused to a non O child, transfuse PRBC, or the least possible amount of plasma.
– Secure Rh negative blood for Rh negative recipients.

2.5.3 Volume to be transfused

Children up to 20 kg including severely malnourished children

The volume to be administered is:
– For whole blood: 20 mL/kg
– For PRBC: 15 mL/kg
See Appendix 7.

To reduce the risk of circulatory overload, preferably use PRBC to reduce the volume to be transfused.
Close and regular monitoring during and after transfusion is critical as an increase in blood volume can precipitate or aggravate heart failure. The physician must be immediately informed of any anomaly.

Notes:
– Transfusion set tubing holds a dead volume of around 15-18 mL; the doctor must take this volume into account when calculating the volume of blood to be ordered.
– If PRBC are prescribed but whole blood is delivered, red cells will start spontaneously sedimenting during the transfusion. Warn the staff and the care giver that this is normal. Do not homogenise. Stop the transfusion when the prescribed volume has been administered or when there is only plasma left in the bag.

Adults

For an average-size adult, one unit of 450 mL of whole blood or one unit of adult PRBC increases the Hb level by 1 to 2 g/dL.

Important notes:
– Fever, even if high, is not a contraindication for transfusion.
– The patient does not need to have an empty stomach; if the patient needs to eat at the beginning of the transfusion, wait 15 minutes after the start of the transfusion.
– Routine administration of furosemide prior to transfusion in order to prevent cardiac failure or pulmonary oedema is not recommended. The decision to administer furosemide (Child: 0.5 to 1 mg/kg/injection; Adult: 20 to 40 mg/injection, by slow IV injection) should be made on a case-by-case basis, according to the patient's clinical condition.

2.5.4 Transfusion rate

Blood units should not be exposed to ambient temperature more than 4 hours and a half (30 minutes for blood delivery and 4 hours for administration) to limit bacterial proliferation.

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

In children without hypovolemia and/or shock, the recommended transfusion rate is 5 mL/kg/hour for PRBC and whole blood (Appendix 7).

In the event of haemorrhagic shock, insert the blood unit into an inflatable cuff or a pressure cuff to increase the flow rate without exceeding a pressure of 300 mm Hg. Ensure further venous access is available in case it is needed.

2.5.5 Urgency of transfusion

In urgent cases, blood is needed within 1 hour or less[b].
In life-threatening emergencies, when the patient's blood group is unknown, the transfusion department can issue O Rh D negative blood (Chapter 1, Section 3.1).

2.5.6. Massive transfusion protocol

A transfusion is defined as massive if:
- In children and adults: over 50% of the total blood volume is replaced by blood components in less than 3 hours (total blood volume is 70 mL/kg in men, 60 mL/kg in women, 80 mL/kg in children and 85-90 mL/kg in neonates).
- Or in adults: 3 whole blood units or 4 PRBC units are transfused in the first hour and further blood components are expected to be needed.
- Or in children: the transfusion of over 15 mL/kg of PRBC in the first hour.

Management in adults

- Hb level, urgent blood group determination and a blood EDTA tube for the crossmatch.
- If available, ask for platelet count, thrombin time (TT) and activated cephalin time (ACT), calcium and potassium.
- If there is no blood stock, identify and test potential compatible blood donors and/or warn the blood transfusion department that a massive transfusion protocol has been activated.
- Order and transfuse according to the protocol below based on the availability of components:

  Step 1
  - 2 whole blood units (the most recent units)
  - Or 2 fresh whole blood units
  - Or 2 whole blood units + 2 FFP
  - Or 2 PRBC + 2 FFP
  - Tranexamic Acid (Exacyl®)[4] is indicated in massive haemorrhage due to trauma and in massive obstetric haemorrhage. The first dose must be given as soon as possible and within three hours after the onset of bleeding (administration of the first dose of tranexamic acid after three hours may be associated with increased risk of mortality).
  - Protocol: inject tranexamic acid 1 g by slow IV bolus in 10 minutes.
  - If bleeding continues, a second bolus of tranexamic acid 1 g slow IV (10 minutes) may be given 3 hours after the first bolus.
  - Systematically add calcium gluconate: 1 g by slow IV in a separate IV line from the blood components. The first dose of calcium gluconate should be given AFTER these two units of blood.

  If the patient is still haemodynamically unstable, or if bleeding persists, continue as follows:

  Step 2
  - 4 fresh whole blood units
  - Or 4 whole blood units (the most recent units) + 1 adult pool of platelets if available
  - Or 4 whole blood units + 4 FFP + 1 adult pool of platelets if available
  - Or 4 PRBC + 4 FFP + 1 adult pool of platelets if available
  - Subsequent doses of calcium gluconate should ideally be based on the serum calcium level.

b The minimum time required for a direct blood donation, including donor selection (questionnaire, blood grouping, TTI screening), blood collection and crossmatching, is approximately 60 minutes when performed by experienced staff.

If the patient is still haemodynamically unstable, or if bleeding persists, continue as follows:

- Repeat either half or all of step 2
- Or according to laboratory test results if available:

Hb < 7 g/dL: transfuse 2 additional PRBC units. TT or ACT > 1.5 the reference value: transfuse 4 additional FFP units. Platelets < 75 x 10^9/L: transfuse 1 additional adult pool of platelets. Ionized calcium < 1 mmol/L: transfuse 10 mL of calcium gluconate by slow IV (10 minutes).

Other measures include: stop/limit the bleeding; maintain a permissive hypotension (SBP of 80-90 mmHg, do not let SBP exceed 90 mmHg except in head or medulla trauma where the SPB can be up to 120 mmHg); prevent or treat hypoxia (SpO_2 > 95%); prevent or correct hypothermia (> 35° C, using a "fluid warmer" for infusions and for all blood components, and an emergency/warming blanket); avoid excess crystalloid infusion; prevent or correct acidosis (pH > 7.38).

Stop massive transfusion protocol when the following criteria have been reached: absence of haemorrhage or DIC, haemodynamic stability, adequate results for Hb (>7 g/dL), platelets (> 75 x 10^9/L), and coagulation tests (TT or ACT < 1.5 the reference value).

The massive transfusion protocol should not be continued if the patient's condition deteriorates to the point that survival is unlikely and further transfusions become futile.

Management in children

Transfuse 20 mL/kg of fresh whole blood.
Or 20 mL/kg of whole blood (the most recent units) and if available 10 mL/kg of FFP et 10 mL/kg of platelets.
Or 15 mL/kg of PRBC and if available 10 mL/kg of FFP et 10 mL/kg of platelets.

Inject tranexamic acid (Exacyl®): 15 mg/kg bolus by slow IV (10 minutes) in the first hour then a second bolus 3 hours after the first bolus if needed (only in case of trauma haemorrhage).

There is no indication for giving calcium gluconate with the first 15 mL/kg of PRBC or 20 mL/kg of whole blood, but if more blood is needed, then inject calcium gluconate by slow IV: up to 10 kg: 0.5 mL/kg and from 11 to 45 kg: 0.3 mL/kg (in a separate IV line from the blood components).

If necessary, repeat the transfusion of the blood components as above according to clinical criteria and/or laboratory results (same parameters as for adults).

2.6. Record all relevant information in the patient's file

Record the reason for transfusion and the patient's Hb level. The patient's blood group indicated on the blood group result form (Appendix 17) is recorded in the patient's medical file.
Record the prescription: type of component, prescribed volume, administered volume, rate, urgency, etc. Record that written consent for transfusion has been obtained (Appendix 6).

2.7. Fill in a blood request and delivery form

The blood request form should provide all required information (Appendix 31). It is sent to the blood transfusion department in duplicate (using NCR[c] duplicate order pads or carbon papers), along with the labelled EDTA tube for crossmatching and the 2nd blood group determination.

c NCR: No carbon required

3. Delivery of blood units

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

3.1. Check the stock register for availability of ABO Rh D identical blood

In case of non-identical blood, the prescriber's agreement is necessary for delivering ABO Rh D non-identical compatible blood.

3.2. Check the blood unit

Check 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 26.

Only negatively crossmatched units may be delivered, whatever the type of donation.
Information on crossmatch (date, blood unit number, patient identification, result) should be recorded in the blood stock/delivery register (Appendix 29).
If there is no laboratory staff available, the crossmatch can be performed at the patient's bedside by placing in contact the recipient's capillary blood and the blood to be transfused using a tile.

3.4. Deliver the blood unit

The blood unit is delivered together with:
– The full request/delivery form, completed with information on the blood unit (Appendix 31). A copy is kept in the blood transfusion department.
– A card for the bedside verification of ABO compatibility (Appendix 18.1 and Appendix 18.2) together with its accessories.

If it takes more than 10 minutes to deliver the blood unit from the transfusion department to the ward or if the blood unit is not to be used immediately but within two hours, place it:
– In a vaccine carrier,
– With 5 pre-conditioned[a] ice packs (one at the bottom and one on all 4 sides),
– Protect the blood unit from direct contact with the ice packs by placing insulation material (e.g. bubble wrap, cardboard) between the blood unit and the ice packs.

If the blood unit is to be used more than two hours later, the reserved blood unit should stay stored in the blood refrigerator (where the temperature control is more precise than in a vaccine carrier).

The transfused patients register (Appendix 30) is filled out at the time of delivery.

a Pre-conditioned ice-pack: ice pack frozen at – 20 °C and partially defrosted under running water so that when placed vertically 5 cm of liquid water is visible at the bottom of the ice-pack.

4. Administration of a blood unit

The prescribing physician is responsible for the entire transfusion process.

The nurse is responsible for the following steps 4.1 to 4.6:

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

– Check on the delivery form the time the blood unit was issued from the transfusion department. Return the blood unit to the transfusion department if it has been out of cold chain for over 10 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 blood transfusion department if: clots are visible; red cells are black, brown or purplish; plasma is pink or pale, or if any other abnormality is observed.
– Check the expiry date of the blood unit.

Notes:
– If the blood reaches the ward within 10 minutes and is to be immediately transfused, there is no need to transport the blood unit in a vaccine carrier.
– If the blood is to be transfused within two hours, it should be transported and kept in a vaccine carrier.
– If the blood is to be transfused more than 2 hours later, it should be kept in the blood refrigerator.

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

The most frequent 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 by asking open questions: what is your name? Can you spell it please? What is your date of birth? Where were you born? A double identity check (i.e. by 2 different people) is recommended.
– If the patient is a child or is unconscious, ask a care giver to identify the patient. A double identity check (i.e. by 2 different people) is recommended.
  Patients who are unconscious or undergoing surgery and children should be identifiable, e.g. wearing a wristband with their last name, first name, age or date and place of birth.
– Compare the patient's identity with the prescription and the blood delivery form to ensure the right patient gets the right blood unit.
– Check that the blood group indicated on the blood unit and on the delivery form are 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 last verification of ABO compatibility at bedside

Even if blood grouping has been performed on both the patient's blood 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 connecting the transfusion set to 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. It is the responsibility of the health staff that carries the transfusion to perform this verification. The interpretation of ABO card must be doubtless.

⚠ In case of any doubt, repeat the ABO compatibility procedure and call the doctor. See Appendix 18.1 and Appendix 18.2.

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

4.4. Carry out the transfusion

Prepare a monitoring form and assess the patient's vital signs (Appendix 8).
Procedure for transfusion process is described in the Appendix 4.

Other monitoring parameters may be added according to the patients: glucose level for neonates and children, particularly in malaria patients.

⚠ Check all basic resuscitation drugs and materials in case of adverse reactions are at hand.

Notes:

- The blood and its components must imperatively be filtered by means of a blood administration set fitted with a 170/200 micron filter.
- If venous cannulation is impossible, the **intraosseous route** can be used (Appendix 3).
- The use of **infusion/blood warmer** is indicated **ONLY** in the event of rapid transfusion (for an adult, rate of over 25-30 mL/kg/hour and for a child rate of over 15 mL/kg/hour).
- **Paediatric administration sets** (blood burette) are used to ensure the transfusion of the precise volume prescribed. For very small volumes of blood transfusion, the rate in drops/minutes is very low and impossible to adjust manually with precision. In the absence of an infusion pump or electric syringe, blood boluses can be administered every 15, 20 or 30 minutes while injecting a saline solution between the boluses to keep the vein open using a 3 way connector.
- A **drip assist** is an electronic droplet counter which displays the infusion rate in number of drops per minute and the total volume administered since the start of the transfusion.
- An **infusion pump** is another means to ensure the exact volume and rate of transfusion are respected as prescribed (caution: a specific transfusion set compatible with the infusion pump is required). Infusion pumps cannot be used to transfuse neonates.
- An **electric syringe** may be used: the 50 mL syringe is filled with blood filtered through a transfusion set using a 3 way-connector. If more 50 mL are to be administered, the syringe will be filled several times through the transfusion set which is kept connected to the 3-way connector.

4.5. Monitor the patient

The patient's condition and vital signs must be closely monitored throughout transfusion, and afterwards, 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, and pain or haemodynamic instability.

Re-assess the patient's condition and vital signs (RR, heart rate, BP) and oxygen saturation:
- 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 or the care giver 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.

Stop the transfusion and alert the physician in the event of warning signs, or if the patient's general condition changes (e.g. altered consciousness, agitation), or if vital signs deteriorate.

All information must be recorded on the monitoring form. Keep the monitoring form in the patient file (Appendix 8).

Table 3.4 - Vital signs (normal values and alert thresholds)

Age	Respiratory rate (breaths/min)	Heart rate (beats/min)	Systolic blood pressure (mmHg)
	Normal range[a]	Normal range	Normal range
< 1 month	30-60	120-160	> 60
2-11 months	30-40	80-120	70-90
1-5 years	25-30	80-120	80-100
> 5-12 years	20-25	60-120	90-110
> 12 years	12-18	60-100	100-120
Adult	12-20	60-100	110-130

Urine output

If an urinary catheter has been inserted, urine output should be measured hourly. It should be:
30-60 mL/hour in adults
1 mL/kg/hour in children
0, 5-1 mL/kg/hour in neonates
1-3 mL/kg/hour in premature neonate

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

a Respiratory rate in malnourished children may be 5 breaths/minute lower than in healthy children.

In the event of macroscopic haematuria, notify the physician. It can be related to the transfusion but may also be unrelated to the transfusion (e.g. acute haemolysis, malaria).

4.6. Once the transfusion is completed

– Reassess the patient's condition and vital signs.
– Continue an infusion at a very slow rate to keep the vein open.
– Inform the physician that the transfusion has been completed and report the time on the monitoring form. The physician must check the patient's general condition.
– Administer malaria and syphilis treatment if indicated (Chapter 2, Section 6).
– The patient will be checked again up to 6 hours after the completion of the transfusion.

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

5. Management of transfusion-related complications[5]

5.1. Immediate complications (< 24 h)

5.1.1. Possible causes of signs/symptoms

Signs and symptoms	Most common causes	Less common causes
Fever (with or without chills)	• A pre-existing infection • Non-haemolytic febrile transfusion reaction (NHFTR)	• Acute haemolytic reaction • Septic transfusion reaction • Transfusion-related acute lung injury (TRALI)[a]
Urticaria, pruritus	• Allergic reaction	
Hypotension or shock	• Patient's underlying condition (e.g. haemorrhage) • Anaphylactic reaction	• Acute haemolytic reaction • Septic transfusion reaction • TRALI
Dyspnoea	• Pre-existing dyspnoea • Transfusion-associated circulatory overload (TACO)[b]	• Anaphylactic reaction • TRALI
Pain	• Patient's underlying condition (e.g. trauma)	• Acute haemolytic reaction (pain at venepuncture site, along the IV line; chest, back or flank pain) • Anaphylactic reaction (abdominal cramping) • TACO (chest pain)
Urinary signs (oliguria, dark urine, haematuria)	• Patient's underlying condition (e.g. haemolytic anaemia) • Acute haemolytic reaction	
Anxiety **Agitation**	• Acute haemolytic reaction	

a TRALI : transfusion-related acute lung injury

b TACO : transfusion-associated circulatory overload

5.1.2. Initial management

During the early stages of a reaction, it may be difficult to determine the cause. In all events:
– Stop the transfusion but **keep the IV line open** with 0.9% sodium chloride.
– Notify the physician immediately.
– Re-check 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 units administered at the same time on the same (or different) ward have been given to the right patient(s)[c]. If necessary, stop transfusions temporarily until all have been checked.
  • Notify immediately the blood transfusion department.
– Assess 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 analyses (Chapter 3, Section 5.3).
– Do not remove the blood unit until a probable or possible diagnosis is made. If the blood unit is removed, do not discard it; return it to the transfusion department for analysis.

5.1.3. Specific management

All transfusion reactions must be noted on a specific form filled on two copies, one for the transfusion department and one kept in the patient's file (Appendix 9).

Allergic reactions

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

A. Minor allergic reaction

Signs and symptoms
– Urticaria (usually associated with pruritus), with no other symptoms

Management
– Temporarily stop the transfusion.
– Administer an antihistamine, e.g. **chlorphenamine** PO:
  Child 1 to < 2 years: 1 mg 2 times daily
  Child 2 to < 6 years: 1 mg 4 to 6 times daily (max. 6 mg daily)
  Child 6 to < 12 years: 2 mg 4 to 6 times daily (max. 12 mg daily)
  Child ≥ 12 years and adult: 4 mg 4 to 6 times daily (max. 24 mg daily; max.12 mg daily in elderly patients)
– The transfusion can be restarted if the patient is stable and no other symptoms are present after 30 minutes. This decision should be made by the physician.

B. 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.

c 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.

Management

– Definitively stop the transfusion, remove the blood unit and send it back to the blood transfusion department.
– High flow oxygen administration.
– Administer **epinephrine** (**adrenaline**) IM, into the antero-lateral thigh, in the event of hypotension, pharyngolaryngeal oedema, or breathing difficulties:
  Use *undiluted* solution (1:1000 = 1 mg/mL) and a 1 mL syringe graduated in 0.01 mL:
  Children under 6 years: 0.15 mL
  Children from 6 to 12 years: 0.3 mL
  Children over 12 years and adults: 0.5 mL

  In children, if 1 mL syringe is not available, use a *diluted* solution, i.e. add 1 mg epinephrine to 9 mL of 0.9% sodium chloride to obtain a 0.1 mg/mL solution (1:10 000):
  Children under 6 years: 1.5 mL
  Children from 6 to 12 years: 3 mL
– At the same time, administer rapidly **Ringer lactate** or **0.9% sodium chloride**: 1 litre in adults (maximum rate); 20 mL/kg in children, to be repeated if necessary.
– If there is no clinical improvement, repeat IM epinephrine every 5 to 15 minutes.
  If shock persists after 3 IM injections, administration of IV epinephrine at a constant rate by a syringe pump is necessary:
  Use a *diluted* solution, i.e. add 1 mg epinephrine (1:1000) to 9 mL of 0.9% sodium chloride to obtain a 0.1 mg/mL solution (1:10 000):
  Children: 0.1 to 1 microgram/kg/minute
  Adults: 0.05 to 0.5 microgram/kg/minute
  If syringe pump is not available, see box page 70.
– In patients with bronchospasm, epinephrine is usually effective. If the spasm persists give 10 puffs of inhaled **salbutamol**.

Note: corticosteroids are not indicated in the initial treatment of anaphylaxis. They may be administered once the patient is stabilised to prevent recurrence in the short term (**prednisolone** PO: 0.5 to 1 mg/kg once daily for 1 to 2 days).

Once the patient has been stabilised, reassess if it is immediately necessary to continue the transfusion. If required, order a new unit of blood which must imperatively be from a different donor.

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 ≥ 38 °C or a change of ≥ 1 °C from the pre-transfusion 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, sepsis or TRALI.

Management

– Temporarily stop the transfusion.
– Administer paracetamol (oral, rectal or IV).
– Carefully restart the transfusion if no other symptoms are present (and after other causes of fever have been eliminated).
  This decision should be made by the physician. If fever continues rising or if the patient develops other symptoms, stop transfusion and look for another diagnosis.

Acute haemolytic transfusion reaction due to incompatibility

Signs and symptoms

Within minutes of starting the transfusion, or possibly later during or after the transfusion:
– Anxiety, agitation, pain at venepuncture site and along the IV line, «feeling of impending doom»/chest pain 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 may be the only signs of acute haemolytic reaction.

Management

– Stop the transfusion and remove the blood unit. Send it back to the blood transfusion department.
– Maintain the BP and renal flow (0.5-1 mL/kg/hour) in order to prevent acute renal failure using crystalloids at 20-30 mL/kg bolus.
– Reassess the patient and adjust according to clinical evolution.
– It may be necessary to induce diuresis, using furosemide IV at a dose of 0.5 to 1 mg/kg/injection.
– 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.
  If there are signs of DIC, administer FFP if available or fresh whole blood.

Septic transfusion reaction

Signs and symptoms

– Within 4 hours of the start of the transfusion:
  High fever (≥ 39 °C) or change of ≥2 °C from pre-transfusion value or hypothermia (< 36 °C), chills, tachycardia, drop or rise of 30 mmHg in systolic BP, nausea, vomiting.
– In severe sepsis or septic shock: profound hypotension, pallor, mottled skin, cold extremities, sweating, thirst, cyanosis, dyspnea, tachypnea in varying degrees, anxiety, confusion, altered consciousness, oligo-anuria.

Management

– Stop the transfusion and remove the blood unit. Send it back to the blood transfusion department.
– Perform blood cultures if available, taking blood samples from the patient and the blood unit.
– Give vascular fluid replacement with **Ringer Lactate** or **0.9% sodium chloride** or **plasma substitute**.

– Use of vasoconstrictors:
  dopamine IV at a constant rate by syringe pump (see box):
  10 to 20 micrograms/kg/minute
  or, if not available
  epinephrine IV at a constant rate by syringe pump:
  Use a *diluted* solution, i.e. add 1 mg epinephrine (1:1000) to 9 mL of 0.9% sodium chloride to obtain a 0.1 mg/mL solution (1:10 000). Start with 0.1 microgram/kg/minute. Increase the dose progressively until a clinical improvement is seen.
  If syringe pump is not available, see box.
– Give large spectrum antibiotics: ampicillin + gentamicin or ceftriaxone + ciprofloxacin.
  ampicillin IV
  Children over 1 month: 50 mg/kg every 6 to 8 hours
  Adults: 1 to 2 g every 6 to 8 hours
  gentamicin IM or slow IV (3 minutes)
  Children ≥ 1 month and adults: 6 mg/kg once daily
  ceftriaxone slow IV[d] (3 minutes)
  Children: 100 mg/kg once daily
  Adults: 2 g once daily
  ciprofloxacin PO (by nasogastric tube)
  Children: 15 mg/kg 2 times daily
  Adults: 500 mg 2 times daily

Once the patient is stabilized with regards to the septic shock, reassess if it is immediately necessary to continue the transfusion. If considered necessary, order a new blood unit which must be from a different blood donor.

Note: in the event of septic transfusion reaction during or after transfusion of a paediatric unit prepared from a pentabag system, all the remaining paediatric units prepared from the same donation of 450 mL must be discarded.

Administration of **dopamine** or **epinephrine** at a constant rate requires the following conditions:
– Dose medical supervision in a hospital setting;
– Use of a dedicated vein (no other infusion/injection in this vein), avoid the antecubital fossa if possible;
– Use of an electric syringe (or infusion pump);
– Progressive increase and adaptation of doses according to clinical response;
– Intensive monitoring of drug administration, particularly during syringe changes.

Example:
dopamine: 10 micrograms/kg/minute in a patient weighing 60 kg
Hourly dose: 10 (micrograms) x 60 (kg) x 60 (min) = 36 000 micrograms/hour = 36 mg/hour
In a 50 mL syringe, dilute one 200 mg-ampoule of dopamine with 0.9% sodium chloride to obtain 50 mL of solution containing 4 mg of dopamine per mL.
For a dose of 36 mg/hour, administer the solution (4 mg/mL) at 9 mL/hour.

d The solvent of ceftriaxone for IM injection contains lidocaine. Ceftriaxone reconstituted using this solvent must never be administered by IV route. For IV administration, water for injection must always be used.

If there is no electric syringe, dilution in an infusion bag may be considered. However, it is important to consider the risks related to this type of administration (accidental bolus or insufficient dose). The infusion must be constantly monitored to prevent any, even small, change from the prescribed rate of administration.

Example for **epinéphrine**:

– In adults:
  Dilute 10 ampoules of 1 mg epinephrine (10 000 micrograms) in 1 litre of 5% glucose or 0.9% sodium chloride to obtain a solution containing 10 micrograms of epinephrine per mL.
  Knowing that 1 mL = 20 drops, *in an adult weighting 50 kg*:
  • 0.1 microgram/kg/minute = 5 micrograms/minute = 10 drops/minute
  • 1 microgram/kg/minute = 50 micrograms/minute = 100 drops/minute, etc.
– In children:
  Dilute 1 ampoule of 1 mg epinephrine (1000 micrograms) in 100 mL of 5% glucose or 0.9% sodium chloride to obtain a solution containing 10 micrograms of epinephrine per mL.
  For administration, use a **paediatric infusion set**; knowing that 1 mL = 60 drops, *in a child weighting 10 kg*:
  • 0.1 microgram/kg/minute = 1 microgram/minute = 6 drops/minute
  • 0.2 microgram/kg/minute = 2 micrograms/minute = 12 drops/minute, etc.

Note: account for all infused volumes when recording ins and outs.

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, distended neck veins and peripheral oedema (e.g. puffy eyes, swollen hands)

Management

– Stop temporarily the transfusion.
– Sit the patient in an upright position.
– Administer oxygen.
– Administer **furosemide** by slow IV:
  Children: 0.5 to 1 mg/kg/injection
  Adults: 20 to 40 mg/injection
  Closely monitor the patient and repeat after 2 hours if necessary.
– Once the patient is stabilized, continue the transfusion if necessary.

Transfusion-related acute lung injury (TRALI)

Signs and symptoms

Within 6 hours after the start of the 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

Stop the transfusion, remove the blood unit and send it to the transfusion department. Treatment is that for respiratory distress syndrome from any cause: oxygen; mechanical ventilation often required. Symptoms may resolve in 24-48 hours.

Once the patient is stabilized regarding respiratory distress, reassess if it is necessary to continue the transfusion. If considered necessary, order a new blood unit from a different donor.

Notes:
It can be difficult to distinguish between anaphylactic reactions, TACO and TRALI.
In anaphylactic reactions, respiratory difficulties are usually associated with muco-cutaneous signs and symptoms (cutaneous eruptions, 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 deducing diagnosis of TRALI.

Table 3.5 - Differences between TACO and TRALI

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

5.2. Delayed complications (> 24 h)

– 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 multi-transfused patients: use chelating agents.

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.
  - Perform a chest X-ray.
  - Perform blood cultures on the patient and on the transfused blood unit.

  Note: plasmatic haemoglobinaemia and haemoglobinuria are suggestive of acute haemolytic reactions.

– Complete a transfusion reaction form (Appendix 9).

– Report all transfusion reactions to the Blood Transfusion Committee.

6. Particular case of fresh frozen plasma[6]

6.1 Sources and characteristics of fresh frozen plasma

Fresh frozen plasma (FFP) is prepared by an authorized blood transfusion facility equipped with a laboratory centrifuge for blood units. It contains all plasma proteins and in particular fibrinogen and thermo-labile coagulation factors V and VIII.

FFP is prepared from centrifuged whole blood or from plasmapheresis that has been fast frozen below - 18°C within a maximum of 6 hours after collection.

FFP is usually available in units of 200 to 300 mL.

6.2 Storage

FFP units are immediately stored in a freezer at below – 18 °C and can be stored up to 3 months. If the storage temperature is below – 25 °C, FFP units can be kept for up to one year.

6.3 Transport

FFP is dispatched to health facilities in negative cold chain containers (iceboxes filled with the most frozen ice packs): the temperature of the cold chain must be constantly monitored to check it remains below zero throughout transport.

6.4 Indications

Indications for the use of FFP are mainly therapeutic and sometimes preventive:
– Massive haemorrhage associated with coagulopathy related to fluid resuscitation and/or transfusion of stored blood products which lack thermo-labile coagulation factors.
– Bleeding related to multiple coagulation factor deficiency associated with reduced synthesis of clotting factors in liver disease or increased consumption of clotting factors in DIC.
– Severe bleeding associated with antivitamin K drugs overdose.
– Bleeding associated with a coagulation factor deficiency when specific concentrated products are not available.
– Rare conditions such as thrombocytopenic thrombotic purpura and some specific plasma proteins deficiencies.

The transfusion of FFP carries similar risks of TTI, allergic reactions and hypocalcaemia due to citrate overload, as the transfusion of packed red blood cells or whole blood.

In no event is FFP to be used for fluid resuscitation or as a nutritional product.

6.5 Prescription

Compatibility

Prescribe FFP units that are ABO compatible, preferably identical. As FFP units have a long storage life, it should always be possible to provide ABO identical FFP units.

However, ABO compatibility rules for the transfusion of plasma are the opposite of those for the transfusion of red blood cells.

Table 3.6 - Compatibility rules for FFP transfusion

ABO group of the recipient	ABO group of the FFP unit			
	1st choice	2nd choice	3rd choice	4th choice
O	**O**	B	A	AB
A	**A**	AB		
B	**B**	AB		
AB	**AB**			

As FFP does not contain red blood cells, there is no need for cross matching.

Volume to be prescribed

The initial therapeutic dose is 15 mL/kg (10 to 20 mL/kg).

In the absence of coagulation tests, additional doses are administered if bleeding persists. When bleeding stops, this indicates the FFP dose is sufficient.

When coagulation tests are available, haemostasis is considered efficient if the TT or ACT is less than 1.5 times the reference value. Nevertheless a return to efficient haemostasis may be transitory and must therefore be monitored. It may be related to underlying conditions (fever in particular).

Duration

In adults, the recommended transfusion rate is one unit in 30 minutes maximum.
In children up to 20 kg, the prescribed dose is 15 mL/kg transfused in one hour.

6.6 Preparation

FFP is thawed between 30 and 37°C in a water bath under continuous agitation. As soon as it has thawed, FFP must be transfused immediately, or stored, while waiting to be transfused, at 4 °C for a maximum of 6 hours.

FFP must always be transfused using a transfusion set with a 170-200 microns filter.

6.7 Monitoring of FFP transfusion

Allergic reactions are common. It is essential to look out for severe anaphylactic reactions and to have basic resuscitation drugs and material ready to be used.

Reminder:

FFP must NOT be used for:
- Volume replacement,
- To increase the albumin level,
- To reverse a coagulopathy that can be reversed by administration of vitamin K,
- To normalize coagulation tests in the absence of bleeding.

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Chapter 4:
Set up and management of transfusion activities

1. Setting up blood transfusion activities

1.1 Initial assessment

1.1.1 Assess blood needs

Health facilities that carry out few transfusions usually perform direct transfusions and do not have stored blood. In facilities that regularly carry out transfusions, setting up a blood transfusion department with stored blood, commonly called a "blood bank", ensures a constantly available supply of blood.

It is essential to estimate the number of blood units needed per week, or month, according to current or expected activity. Demand for blood is high in malaria endemic areas, nutritional centres and hospitals with obstetric and surgical activities, as well as in the event of an influx of wounded.

1.1.2 Assess external sources of blood

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

The capacity of an external source to supply safe blood must be assessed by a health professional with the required competences. Below is a list of questions/criteria to be considered:

- Does the blood source belong to the national blood transfusion service, a governmental organization, a non-governmental organization, a private organization?
- How are donors recruited, selected and retained?
- Are blood donations identified with bar codes?
- Are tests results disclosed to donors and, if so, how?[a]
- Are equipment, consumable items and reagents procured from validated sources?
- Are reagents stored under suitable conditions (temperature, humidity)?
- What test methods are used for blood grouping, red cell antibody screening and transfusion transmissible infections (TTI) screening?
- Are procedures manual or automated? Are results double-checked?
- How are the test results recorded? Manually or using information technology?
- What quality control procedures are there?
- Who is responsible for the supervision of the blood collection department and the laboratory?
- What is the reactivity rate for each TTI in blood donation? What is the local prevalence rate for each TTI in the adult population?
- How are unsafe/untested blood units stored, separated from qualified blood units and ultimately destroyed?
- Is cold chain performance satisfactory and monitored? During storage? Transport?
- Who (what institution) does the blood source report activity data and performance indicators to?
- How many blood units can the supplying facility provide in a given time frame?

If the evaluator cannot determine alone whether the source is reliable or not, they should ask a specialized professional to carry out the assessment.

a Blood transfusion departments that report HIV results directly to the donor may attract high-risk donors looking for individual diagnosis.

Blood supply:
– Can be combined supply from an external source and donor blood collection within the health facility.
– Can be exclusively from either the NBTS or donor blood collection within the health facility.

1.1.3 Determine the feasibility of setting up a blood transfusion service

– Assess the availability of qualified medical staff (physicians, nurses, laboratory technicians) and their competencies in transfusion.
– Assess technical environment (power supply, available space, cold chain equipment and waste management).
– Determine needs in terms of staff recruitment and training, as well as equipment.

Evaluate advantages/disadvantages and cost effectiveness of setting up a blood transfusion department, based on this assessment. Alternatively, it may be appropriate to set up an effective patient referral system.[1]

1.2 Setting up a blood transfusion activity[2]

1.2.1 Obtain authorization from the health authorities and/or the NBTS

Obtain:
– The most recent national blood transfusion policy,
– National, or regional, blood donation promotion documents and donor retention tools.

Obtain authorization to:
– Store blood,
– Collect blood from donors,
– Organize mobile blood collections in specific areas.

1.2.2 Meet local leaders (political, religious or other)

Inform them that donors need to be recruited and try to obtain their collaboration in order to:
– Understand the community's level of acceptance/knowledge concerning blood donation.
– Identify which groups in the community are most susceptible to giving blood.
– Translate blood donation information and promotion tools into the local language.

In sub-Saharan Africa, secondary school pupils (16-18 years old) are a sizeable source of voluntary blood donations. Parental authorization for minors to give their blood must be obtained. Communication with school principals and science teachers is crucial in encouraging voluntary blood donation.

1.2.3 Order equipment according to needs

The transfusion module (Appendix 33) contains all the basic medical and laboratory equipment required to collect and provide 50 safe transfusions.

For cold chain equipment, see Chapter 4, Section 2.

1.2.4 Organize premises and waste management

See Chapter 4, Section 6 and Chapter 4, Section 7.

1.2.5 Train staff and ensure job descriptions are available for each position

Train staff in donor recruitment and selection, screening procedures, blood components indications and administration procedures, cold chain maintenance, consumable stock management, waste management.

For the list of tasks and responsibilities, see Chapter 4, Section 3. Each staff member must fully understand their role and responsibilities.

1.2.6 Ensure procedures are written, adapted to the context and applicable

1.2.7 Set up a data collection system

Data analysis helps evaluate if the transfusion activity matches needs in terms of quality and quantity. Data are usually collected on a monthly basis. A data collection tool, to be adapted to the context, is described in Appendix 32. In particular, monitor the reactivity rate of each TTI in blood donors, the rate of discarded qualified blood units and the average stock of blood units.

1.2.8 Set up the health facility's blood transfusion committee

This committee is responsible for the implementation of good transfusion practices.
It includes the hospital director, at least one physician prescribing transfusions, the head nurse, the blood transfusion department supervisor, the pharmacist, the designated logistician or biomedical engineer and the designated health promoter. See Chapter 4, Section 4.

2. Storage, transport and stock management of blood units

The safe storage and transport of blood units is an integral component of blood safety.[3]

2.1 Cold chain

2.1. Equipment required in a blood transfusion department

Refrigerators for storage of blood units

– Blood units should be stored in a special refrigerator with the following characteristics:
  • Electric-powered.
  • Super-insulated, with sufficient holdover time[a] to keep the temperature below 8 °C for at least 12 hours in the event of power failure.
  • Cooling system, to maintain uniform temperature at all levels of the refrigerator.
  • External thermometer display, for continuous monitoring of the temperature inside the refrigerator.
  • Visual and audio alarm system, that signals when the temperature rises above 6 °C or falls below 2 °C.

  These refrigerators should be used **exclusively** for the storage of blood. The number/size of refrigerators to be ordered depends of the estimated number of units to be stored. Due to its robustness and long holdover time the Electrolux MB 3000 G is one of the models recommended for storing blood units: chest format (horizontal door), holds 100 x 450 mL bags, walls lined with ice packs filled with water result in very efficient thermal inertia.

  Gas-powered and petrol-powered refrigerators should not be used for blood storage: they do not perform as well as electric 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 (e.g. risk of blood freezing in the event of contact with the walls of the refrigerator, rapid rise in temperature in the event of power failure).

– Reagents and diagnostic tests should be stored in a separate refrigerator (e.g. Vestfrost MK204® or Sibir V170®).

Cold boxes and vaccine carriers

– Cold boxes (e.g. Electrolux RCW®) are essential:
  • To transport blood from an external source or mobile collection sites;
  • To temporarily store blood, in the event of refrigerator dysfunction or during refrigerator defrosting.
– Vaccine carriers e.g. Gio'Style® are necessary to deliver blood from the blood transfusion department to wards if the delivery time exceeds 10 minutes.

a Holdover time is the period of time a refrigerator is able to maintain its internal temperature below 8 °C at a given external temperature (usually 43 °C) during a power failure. Check the manufacturer's specifications.

Freezer and ice packs

A freezer (e.g. Vestfrost MF 114 (ou 214)®) is necessary to produce ice packs and, if applicable, store FFP.

Temperature-monitoring devices

Every refrigerator must contain 3 types of temperature monitoring devices:
– A min-max thermometer records the minimum and maximum temperatures (temperature range –50 °C to +50 °C) reached since the last reset.
– A "Fridge Tag 2" temperature data logger fitted with an external probe placed in a glycol vial. The device displays the temperature inside the refrigerator without opening the door and records all temperatures over the last 30 days. The glycol mimics blood temperature and is insensitive to air temperature variations when opening the fridge door (see Appendix 36.1).
– A freezing indicator device: such as Freeze-tag®. This device indicates when the temperature inside the refrigerator/cold box has dropped to 0 °C (± 0.3 °C) for over one hour (Appendix 36.2).

Remote alarm system

When the blood refrigerator is in a place where staff is not present 24/7, a simple robust remote alarm system can be connected to the dry relay contacts of the blood refrigerator. The alarm alerts healthcare staff on duty within a range of 50 metres in the event of any abnormal temperature fluctuations. Alerted staff informs the person in charge of blood storage.

2.1.2 Electric power supply

Electricity can be supplied by a local provider, by a generator or by solar panels, provided the power is sufficient, the voltage is stable, and the supply is uninterrupted. If there is a risk of power cuts/breakdowns lasting over an hour, backup power (i.e. batteries) must be set up and ready. The blood transfusion department supervisor together with the logistics officer, are responsible for the correct functioning of the electric power supply and training staff how to use the back-up system.

2.1.3 Cold chain maintenance

The logistics officer ensures the maintenance of cold chain equipment: checking and maintaining refrigerator gaskets, monthly checking of alarm systems and thermostats, changing alarm systems batteries and cleaning condensers every 6 months.
The blood bank supervisor ensures that the refrigerators are clean and regularly de-iced.

2.2 Blood storage conditions

2.2.1 Blood storage temperature

Long term storage temperature to keep red cells functional and inhibit bacterial growth is between 2 °C and 8 °C. The refrigerator thermostat is set at 4 °C +/- 2 °C. An upper limit of 8 °C is correct.

If blood is not intended to be transfused within 4 hours, leave it to cool down at a temperature between 18-24 °C (in a temperate cool box or in an air-conditioned place or under a ventilator by using a wet linen) for 2 to 4 hours. This allows the donor's white blood cells to exercise their bactericidal effect. In addition, this avoids placing warm blood in the blood refrigerator. Then blood must be stored in cold chain with a thermostat set at 4 °C +/- 2 °C.

Notes:
– If TTI tests have not been completed make sure the blood bags are clearly labelled as non-qualified for transfusion and stored completely separate from qualified blood units.
– During mobile collection sessions, blood donations are placed in a cool-box maintained between 2 °C and 8 °C until they can be stored in the refrigerator.
– Once stored in the refrigerator, blood units are not removed until they are to be transfused, except for performing tests on the distal tube and preparation of paediatric units.
– Blood must never be frozen, as freezing causes red cell haemolysis.

Storage in blood refrigerator

Avoid repeated opening and closing of refrigerators. To ensure the correct circulation of cold air, avoid overfilling refrigerators.
If there are only a few blood units in a refrigerator, fill bottles or icepacks with non-frozen water to increase the thermal inertia of the refrigerator.

Storage in cold box

Ensure that blood units are not in direct contact with ice packs. Frozen ice packs are pre-conditioned. Use pieces of cardboard or bubble wrap to prevent the blood units from touching the 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 °C.
– Exposed to freezing temperatures (freezing indicator device displays ALARM).

2.2.2 Temperature monitoring

A staff member from the transfusion service or the laboratory must be specifically appointed and trained to monitor the temperature of all cold chain appliances. A second person should be identified to replace this person in the event of absence.

The logistics officer responsible for maintenance of the cold chain must be informed immediately in the event of a cooling system dysfunction.
Depending on the cause/duration of the break in the cold chain and the refrigerator holdover time, the transfusion department supervisor will decide whether to transfer blood to another refrigerator or, failing that, to cool boxes.

Refrigerator temperatures must be checked and recorded on the monitoring sheet (Appendix 35) twice daily, 7 DAYS PER WEEK.
Min-max thermometers must be reset after each reading.

Temperatures must be monitored in the same way if blood is temporarily stored in cold boxes during refrigerator breakdown or de-icing periods.

Note: temperature devices inside cool boxes must be checked at delivery point.

2.3 Transport of blood units

From the transfusion department to the wards
Blood units to be used within 2 hours must be transported in a vaccine carrier if it takes more than 10 minutes to take them from the blood refrigerator to the ward. If the transfusion is delayed, blood units must be returned to the refrigerator in the blood transfusion department and kept reserved for the recipient.

From mobile collection to the blood transfusion department
Blood donations, once pre-cooled at between 18 - 24 °C, are placed and transported in a cool box at between 2 °C and 8 °C until they can be stored in the refrigerator.

2.4 Blood shelf life

Blood shelf life depends on the preservative solution used (e.g. CPDA-1, SAGM)[b]. Check the manufacturer's recommendations. Usually:
– CPDA-1: whole blood and PRBC can be stored for 35 days.
– SAGM: PRBC can be stored for 42 days. This type of blood bag is only used in transfusion centres equipped with blood bag centrifuges.

2.5 Blood stock management

Tested blood units are stored in a refrigerator:
– By blood group (A, B, AB, O and Rh D positive and negative) and expiry date; e.g. all A Rh D positive units are placed together in a basket with the unit expiring first at the front of the basket.
– In an upright position, outlet port pointing down if concentrated red cells are to be transfused (Appendix 12).

Note: if non-tested blood units need to be stored, place them apart in the refrigerator in a specific basket clearly labelled 'not-qualified for transfusion'.

2.6 Stock follow-up

A blood stock/delivery register is used to record entries and deliveries of blood units (Appendix 29). The register must be used to choose the most appropriate blood unit according to the patient's blood group and specific needs as well as the expiry date.

A whiteboard is used to keep a daily updated record of blood available in stock. The board must be visible at all times by the clinical staff and needs to be updated every day.

A physical inventory must be carried out once a week to check unit by unit that the units in storage (physical stock) match the units noted in the stock register. This is an opportunity to note either units that are in the physical stock but not recorded in the register, or units that have been issued but not recorded as taken out of stock in the register. Possible errors can be detected and corrected by checking the transfused patients register or the blood order/delivery forms.

The minimum stock level should be determined according to transfusion activity and the distribution of blood groups in the population. Group O blood should always be available in stock. To be noted, 50 % of the population is group O nearly everywhere in sub-Sahara Africa. A minimum security stock to cover 10 days of consumption is recommended. Ordering of blood units and/or organizing mobile blood collection sessions must be scheduled to maintain a sufficient stock of blood.

Small health facilities often have insufficient stocks and as a consequence:
– The lack of blood leads to families being pressured into blood donation which is strongly discouraged.
– If the family or relatives cannot find a donor(s), the family may resort to paying for donors; this must be avoided at all costs.

b CPDA-1 = Citrate Phosphate Dextrose Adenine; SAGM = Saline-Adenine-Glucose-Mannitol; CPD = Citrate Phosphate Dextrose

When there are a large number of blood units to be discarded, identify the underlying causes (e.g. stock management problems, frequent breaks in the cold chain, screening after donation in an area with a high prevalence of TTI, reduction in blood requirements) and find solutions to address these issues.

2.7 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 each blood unit's details: unit number, type of blood component (whole blood, PRBC), group, volume, date of collection and expiry date.
Check if the delivery form matches the initial order and the units supplied.

Check transport conditions

Check time elapsed in transport, and the temperature devices inside the cold box:
– The temperature should be between 2 °C and 8 °C.
– The freezing indicator device should not display ALARM.
– The blood units should not be 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 °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.

Check each blood unit

– Check that the information on the label is readable and complete (blood group, date of collection and expiry date, type of component, volume, TTI test results).
– 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 content[c].
  Discard the unit (or return to the 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 correctly filled and if in doubt, weigh the blood units. For example, filled bags of whole blood gross weight is approximately:
  • 150 mL bag: between 188 g and 219 g
  • 250 mL bag: between 301 g and 354 g
  • 450 mL bag: between 528 g and 622 g
  Check the weight of the empty bags with the health facility that has provided the blood or the manufacturer.
– Repeat the blood grouping and TTI screening on the distal segment of the tubing, unless the external source of blood supply has been assessed by a competent medical professional and is considered reliable.

c A blood unit cannot be opened 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. The proportion of sedimented red cells in a unit of whole blood should be at least 33%.

3. Staff responsibilities

Position	Tasks and responsibilities
Chief Medical Officer (or Hospital Director or medical referent)	• Obtain authorization from the Ministry of Health to set up blood transfusion activities in health facility. • Assess the quality/capacity of external sources of blood, in collaboration with a laboratory/transfusion advisor, if necessary. • Organise training sessions with the head nurse, physicians and laboratory technicians. • Ensure that written, updated and context adapted procedures are available and followed. • Oversee the blood transfusion activity including analysis of quality indicators.
Physicians/ Anaesthetists	• Assess the risks/benefits of transfusion for each patient. • Answer patient's questions and concerns related to transfusion. • Obtain written informed consent from the patient or their legal guardian or witness. • Prescribe the transfusion and note the reason for transfusion in the patient file. • Fill in and sign the blood request form. • Manage transfusion adverse reactions. • Examine the patient at the end of the transfusion and record observations in the patient's file. • Fill in the transfusion reaction form in the event of an adverse reaction. • Supervise staff in charge of donor selection.
Ward nurses	• Collect and label blood samples. • Perform Hb level and blood grouping if there are no laboratory technicians available. • Check patient's identity and concordance with the blood unit to be transfused and the delivery form. • Perform bedside ABO compatibility test prior to transfusion. • Carry out the transfusion. • Monitor the patient before, during and after transfusion and fill in the monitoring sheet. • Alert the physician in the event of adverse reactions and fill in the transfusion reaction form. • Supervise waste management on the ward.
Health promotors	• In the health facility: participate in informing families about how important it is to 'replace' the blood their relative has received. • In the community: together with local leaders, identify suitable sites to promote blood donation. • Involve local radio stations in blood donation promotion messages. • Participate in drafting blood donation documents and oral and visual messages. • Facilitate the creation of a local blood donors association. • Participate in the organization of world blood donor day on June 14th.

Position	Tasks and responsibilities
Staff in charge of blood collection	• Recruit donors and promote blood donation. • Select donors (questionnaire, physical examination, Hb test); refer donors to physician in the event of doubt (e.g. if on medication) or in the event of abnormality on physical examination. • Answer donors 'questions/concerns. • Ensure that the blood collection room is clean, welcoming and comfortable. • Perform blood collection. • Take care of the donor during and after collection. • Ensure adequate waste management in the collection room.
Laboratory technicians	• Measure Hb and perform donor and patient blood grouping, TTI screening tests and crossmatching. • Issue compatible blood units. • Fill in and sign delivery forms. • Fill in registers. • Manage the blood stock. • Order, receive and check blood units from external sources. • Ensure proper storage of blood units. • Check that the cold chain is functioning correctly (including temperature monitoring). • Notify the logistics officer in the event of cold chain problems. • Ensure correct waste management in the blood transfusion service.
Blood transfusion department supervisor	• Organize staff duty roster. • Organize the training of laboratory staff, ward nurses, blood collection nurses. • Ensure all documentation (registers, forms) is updated and all records saved and archived. • Participate in donor recruitment: raising family awareness, promotion of voluntary blood donation, organization of mobile blood collection. • Prepare the weekly or monthly consumable orders. • Collect, analyse and transmit monthly data.
Pharmacist	• Manage the stock of materials and tests/reagents in the pharmacy. • If blood is stored in the pharmacy, monitor the cold chain. These responsibilities can be shared with the laboratory technician, depending on the human resources available and the division of tasks.
Logistics officer	• Plan the layout of the laboratory/blood transfusion department with the blood transfusion supervisor and head of the facility. • Supervise the construction and organization of the premises. • Set up and ensure maintenance of the cold chain, including backup power. • Set up a waste management system. • Organize transport (vehicles for blood drives/blood units from external sources).

4. Hospital Transfusion Committee

Safe and effective transfusion practices require a multidisciplinary approach.
The hospital transfusion committee's role is to ensure the implementation of transfusion safety, good transfusion practices and quality assurance.[4]

Composition of the hospital transfusion committee

The hospital transfusion committee should be headed by the clinician of one of the wards with most transfusion needs, or by the hospital director.

The hospital transfusion committee should include a member of each profession involved in the transfusion chain:
- Prescriber of blood components,
- Head nurse,
- Supervisor of the blood transfusion department,
- Pharmacist,
- Logistics officer,
- Health promoter.

The role of the hospital transfusion committee is to:
- Elaborate policies and procedures (donor recruitment and selection, blood component indications, patient information, identification of samples and blood components, storage and transport conditions of blood components, blood administration , waste management etc.), and give advices on their implementation.
- Ensure a non-interrupted supply of blood and a sufficient blood stock.
- Ensure the rational use of blood and regularly carry out reviews of patient 'files.
- Set up a haemovigilance system: systematic data collection on adverse effects, discussions with clinicians and transfusion service staff to establish if a major adverse event was definitely, probably or unlikely related to transfusion and if appropriate corrective measures were taken.
- Carry out critical analyses of data, including the number of blood units discarded.
- Approve HR and material/equipment needs, and provide technical support if needed.
- Facilitate staff training.
- Analyse causes of error or dysfunction and implement corrective measures.
- Transmit activity reports to the national blood transfusion service.
- Elaborate a contingency plan for mass casualties or an unusually high need of blood.
- Ensure the safety of staff and patient at all stages.

Meetings should initially be held monthly, then every 3 months when transfusion activities are running satisfactorily. Ad hoc meetings may be held in the event of serious incidents or exceptional events.

5. Quality assurance in blood transfusion

The quality assurance system rests on four pillars:

5.1 Staff

Staff should be:
– Qualified,
– Trained in the application of standard procedures,
– Aware of their tasks and responsibilities,
– Supervised.

5.2 Procedures

Procedures are:
– Appropriate to the context and available equipment,
– Acknowledged, understood and implemented by staff,
– Updated at least once a year.

5.3 Premises and equipment

– Premises are functional and suitable for the activity.
– Equipment comes from a validated source, is checked and maintained regularly.
– Reagents/kits and blood bags come from a validated source and stored according to the manufacturer's recommendations.
– Laboratory equipment is calibrated on installation and at regular intervals.

5.4 Documentation

Documentation includes:
– Organizational details and description of the transfusion process (procedures, flow charts, etc.).
– Staff safety policy (hepatitis B vaccination for all staff exposed to blood, procedure in the event of accidental exposure to blood, etc.).
– Reference and training documents.
– Instruction leaflets for equipment, reagents, test kits.
– Standard operating procedures for every test carried out.
– Registers.
– Workbench logbook (tests performed, reagent quality control, etc.).
– Forms (order/delivery forms, pre-donation questionnaire, monitoring and transfusion reaction forms, stock cards, etc.).
– Archived documents (forms and registers, results, quality controls, activity reports, etc.).

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

5.5 Follow-up and methods for improving practices

The quality assurance process aims to improve practices with the active participation of all staff involved.

Problems and errors must be discussed and analysed by the blood transfusion committee, in order to understand how and why, and to quickly take corrective action that is communicated to all health staff.

6. Layout of premises

A transfusion department must include:

1. A waiting area for blood donors.
2. A consultation room for conducting the questionnaire and examining donors. This room must be designed to provide the necessary confidentiality conditions for medical interview.
3. A well ventilated blood collection room.
4. A recovery area where the donor is monitored after blood collection for 15 minutes after the donation; donors must always be in view of staff.
5. A laboratory room.
6. A storage room with cold chain equipment. The room should be air conditioned or at least well ventilated. Allow enough space (50-60 cm) behind the refrigerator(s) for air circulation.

Notes:
– Areas 2 and 3 may be set up in the same room if there are only few donors at a time (less than 5 donors per day).
– Areas 5 and 6 may also be in the same room.

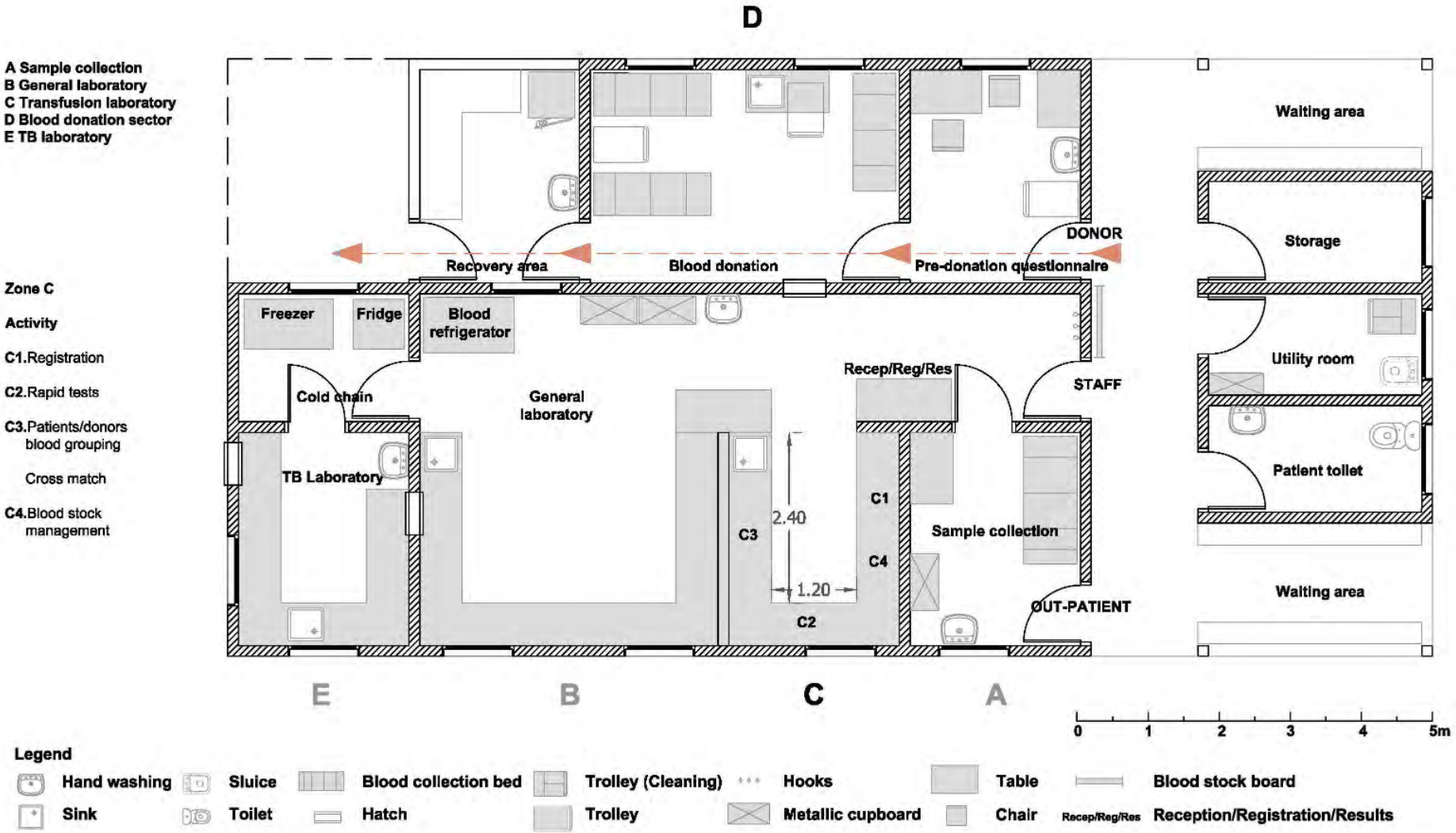
See standard layout on the following page.

STANDARD LAY-OUT

GENERAL LABORATORY / TUBERCULOSIS (TB) BLOOD TRANSFUSION DEPARTMENT

NOT-NEGOTIABLE

1.Reception-Results release at same place
2.Reception close to sample source
3.Sample drawing and blood donation areas separated from laboratory
4.Blood donors in recovery area are always visible by staff



7. Waste management

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

Adequate medical waste management must be set up from the start of transfusion activities, regardless of whether the transfusion service is set up in an emergency or stable setting. If there is a hygiene/infection control committee in the health facility, it must play a central role in medical waste management.[5]

In order to minimize the risk of accidental exposure to blood, staff in charge of waste management (laboratory technician, cleaners) should be adequately protected (i.e. gloves, goggles, protective clothing) when handling and disposing of blood. It is recommended to offer vaccination against hepatitis B and tetanus. If possible, waste from transfusion activities should be treated on site to avoid contamination risks or re-use.

The disposal of large volumes of infected, 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 used (infected, expired or exposed to a break in the cold chain) must be discarded quickly. Blood units that cannot be discarded immediately should be removed from the refrigerator and placed under lock and key in a container clearly labelled “blood for destruction” (to avoid the intentional or mistaken use).

7.1 Waste disposal methods[6]

Incineration

Blood units and sample tubes must be incinerated without being emptied beforehand. This technique requires a powerful incinerator, since blood, like any liquid, will extinguish a fire that is not strong enough. **The incinerator must be preheated**. Blood units must be placed in the incinerator one by one. Fuel should be added as required. It is important that the incineration process is correctly carried out to avoid the production of toxic gases such as dioxins or furans.

Burying

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

Organic pit
The blood of unused blood units may be emptied into an organic pit, then the bags can be discarded as for empty blood bags (see below). The bags should be cut with scissors to avoid blood splashing. Bags should not be pierced.

7.2 Waste material

Empty blood bags after transfusion

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

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 must then be disposed of as contaminated medical waste. This method is only possible if the use of chlorine is authorised in the sewage system. If chlorine use is not authorised, the sample tubes must be incinerated.

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

Needles

Needles are never recapped and are discarded in sharps containers.

If large quantities of blood units need to be destroyed, ask the national blood transfusion service for technical advice.

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Appendices

Appendix 1. Normal haemoglobin values and thresholds defining anaemia (WHO)

	Normal haemoglobin values (g/dL)	Anaemia	
		Haemoglobin (g/dL)	Haematocrit[a] (%)
Neonates	13.5 to 18.5	< 13.5	< 34
Children 2 to < 6 months	9.5 to 13.5	< 9.5	< 28
Children 6 months to < 6 years	11 to 14	< 11	< 33
Children 6 to 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^{str} and 3rd trimester	11 to 14	< 11	< 33
2nd trimester	10.5 to 14	< 10.5	< 31

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

a The haematocrit (%) is approximately equal to 3 times the Hb concentration (g/dL) **ONLY** when red cells are normal i.e. normochromic (normal mean corpuscular Hb concentration) and normocytic (normal mean corpuscular volume), which is not usually the case in patients with anaemia.

Appendix 2. Acute haemorrhage: assessment, classification and indication of transfusion

1. Normal blood volume

Neonates 85 to 90 mL/kg of body weight

Children 80 mL/kg of body weight

Adults 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%
Heart rate (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/ Unconscious
Respiratory rate (breaths/min)	Normal	20-30	30-40	> 45 or slow breathing
Urine output (mL/hour)	> 30	20-30	5-20	< 5
Replacement fluids	Crystalloids	Crystalloids or colloids	Crystalloids/ colloids AND blood likely to be required	Crystalloids/ colloids AND blood required

Adapted from the WHO and the American College of Surgeons.

Standard estimated blood loss in adults

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

3. Hypovolaemia in children

Hypovolaemic class	Class I	Class II	Class III	Class IV
Blood loss (% of blood volume)	< 15%	15%-25%	25%-40%	> 40%
Heart rate (beats/min)	Increased	> 150	> 150	Increased or bradycardia
Systolic BP	Normal	Reduced	Very reduced	Undetectable
Capillary refill	Normal	Prolonged	Very prolonged	Absent
Mental state	Alert	Irritable	Lethargic	Coma
Respiratory rate (breaths/min)	Normal	20-30	30-40	> 45 or slow breathing
Urine output (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.

Appendix 3. Intra-osseous transfusion

3.1 Overview

Indications

Intra-osseous (IO) needle installation must be performed by a physician trained in the technique or by a trained nurse working under the supervision of a physician.

The IO route is only used if an IV catheter cannot be inserted in a life-threatening emergency (i.e. after three failed attempts at inserting an IV line within 90 seconds); the only exception is cardiopulmonary arrest when every second counts.

In experienced hands, IO access can be established within 1 minute. Although primarily used in young children, it can also be used in older children and adults.

Contraindications

- Fractured or infected limb
- Limb with vascular problems or skin problems (burn or infection)
- IO needle insertion in the previous 24 hours in the same site (risk of extravasation due to previous perforation)
- Osteosynthesis material or prosthesis in the bone used as an access site
- Recent surgical procedure near the insertion site

Risks

- Fracture of the bone during insertion (especially in neonates)
- Growth plate injury
- Dislodging of the IO needle
- Extra medullary (intramuscular, sub-cutaneous) infusion with risk of compartment syndrome
- Infection or osteomyelitis (the risk is minimal if aseptic procedures are followed; proceed with caution in children with Kwashiorkor).

Precautions

- The procedure must be performed under strict aseptic conditions: handwashing[a], disposable material, disinfection of the insertion site.
- Limit attempts at placement to one attempt per site.
- Insert a peripheral IV cannula as soon as possible. The IO needle should not remain in place for more than 24 hours.

Monitoring

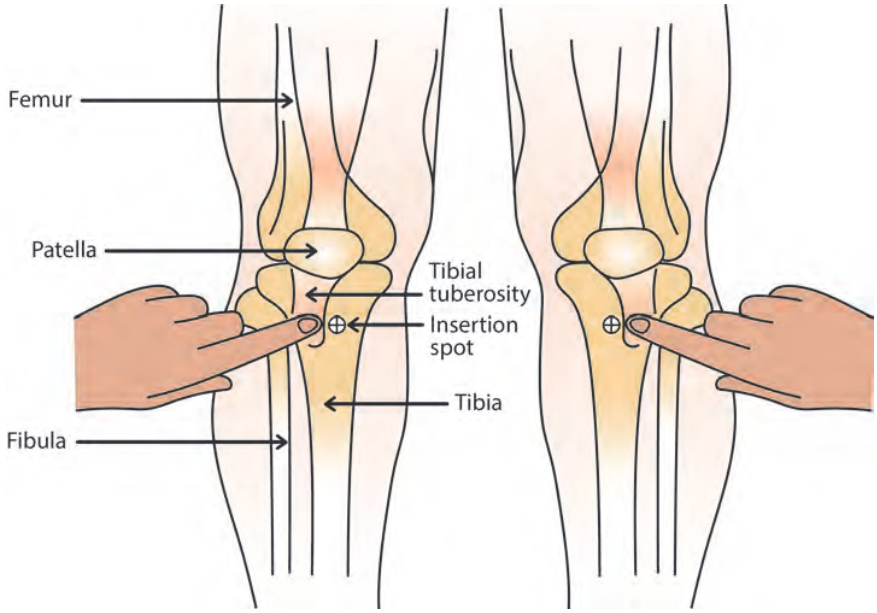
- Colour of the limb
- Position and fixation of the needle, patency of the IO route, appearance of the insertion site
- Presence of subcutaneous oedema, increasing limb size (extravasation)
- Time elapsed since placement

3.2 Insertion sites

The best site is the flat antero-medial aspect of the proximal tibia as it lies just under the skin and can easily be located.

a Wash with soap and water or disinfect with an alcohol-based handrub (ABHR).

Possible insertion sites in adults: proximal tibia, distal tibia, proximal humerus.
In children > 2 years old: prefer the proximal and distal tibia.
In children ≤ 2 years old: prefer the proximal tibia.



Proximal Tibia (best site)

Insert the IO needle in the proximal tibia about 2 cm below the patella and on the flat surface located distal and medial to the tibial tuberosity (not on the tibial ridge).

3.3 Method using a mechanical intra-osseous insertion device

The EZ-IO is a battery powered medical drill fitted with a trocar and IO needle used to pierce the bone and insert the IO.

Equipment

– EZ-IO battery powered medical drill
– EZ-IO needle set, single-use, sterile
  Three types of needle exist: they only differ in length and colour. The gauge stays the same.
  • 15 mm needle, pink, for children from 3 to 39 kg
  • 25 mm needle, blue, for children above 40 kg and adults
  • 45 mm needle, yellow, for obese adults and for humeral site in adults
– EZ-infusion set extension, sterile, single-use
– Transfusion set
– Non-sterile disposable gloves
– Sterile compresses, 10% polyvidone iodine
– 5 or 10 mL syringe of Ringer lactate
– Adhesive, sterile, single-use dressing
– Infusion set + Ringer lactate bag

Note: do not use adult needle in children less than 40 kg (high risk of traumatic complications).

Insertion of the EZ-IO needle in proximal tibia

1. Prepare the patient, stabilize the leg (e.g. using a rolled towel under the knee), in slight external rotation.
2. Determine the insertion site.
3. Wear disposable gloves (after hand washing or disinfection with ABHR).
4. Disinfect the insertion site with 10% polyvidone iodine.
5. Open IO kit and needle's sterile packaging, place needle on the EZ-IO drill.

Concurrently, prepare and flush the EZ-Connect extension tubing using a syringe (preferably a luer lock i.e. screw-top) filled with Ringer lactate.

6. Take the cap off the needle. Position the needle on the insertion site at 90° to the bone (perpendicular).
7. Start the drill by pressing the trigger. Proceed gently, do not use force. Stop the drill as the needle passes through the cortex (a "give" release of resistance is felt).
8. With one hand, securely hold the needle in place. With the other, take the drill off the needle, unscrew the stylet and connect the flushed extension tubing.
9. Check for a flash (small amount of blood) in the catheter to confirm the proper placement of the needle. If the flash is not seen proceed as in step 10 to check IO needle placement.
10. Confirm correct needle placement by injecting a rapid flush of 5 to 10 mL of Ringer lactate with a syringe. The rapid flush is essential. No flush = no flow. Repeat flush if the flow does not seem sufficient. If the IO needle is functional the flush should flow freely without excessive pressure on the syringe.
11. Connect the EZ infusion set extension to the IO needle and then the transfusion set.
12. Secure the catheter (EZ sterile adhesive bandage or sterile gauze and adhesive tape). Beware of sudden movements, as for a peripheral IV.
13. Start the transfusion. The transfusion can be started by gently pressing the blood unit.
14. Indicate the date and time of placement of the IO on the monitoring sheet. If available, also attach the IO identification bracelet (supplied with the IO kit) with date and time of placement of the IO needle.
15. Monitor the transfusion at least every 15 minutes during the first hour.

If the attempt at IO needle placement is unsuccessful, remove the needle and try on the other leg with another needle.

IO needle removal

1. Stop transfusion.
2. Wear disposable gloves (after hand washing or disinfection with ABHR).
3. Remove fixation.
4. Remove the extension tubing.
5. Fit a luer lock syringe to the IO needle and pull the needle out with a twisting motion. In the absence of a luer lock syringe, unscrew by hand.
6. Dispose of the needle in a sharps container.
7. Disinfect the site with 10% polyvidone iodine.
8. Apply pressure to the insertion site for a few minutes if necessary.
9. Cover the insertion site with a sterile dressing (sterile gauze).

3.4 Manual insertion method

Equipment

– Disposable sterile IO needle, 16G or 18G according to age and weight
– EZ-infusion set extension, sterile, single-use
– Non-sterile disposable gloves
– Sterile compresses, 10% polyvidone iodine
– Syringe with 5 or 10 mL of Ringer lactate
– Adhesive, sterile, single-use dressing
– Infusion set + transfusion set+ Ringer lactate bag

Insertion of the IO needle

The procedure is the same as above (using a mechanical drill) in terms of preparation, skin cleansing, patient positioning and verification of needle placement, flow and fixation but:
– Grasp the needle in the palm of the hand, index and middle fingers approximately 2 cm from the tip;
– Insert the needle at 90° to the entry site using downward pressure and a twisting motion until resistance decreases as the needle passes through the cortex of the bone.

IO needle removal

As above when using the mechanical device but gently rotate the needle and remove it slowly.

Appendix 4. Transfusion procedure

1. If the blood unit has just been taken out of the refrigerator, leave at room temperature for 10 minutes before transfusion. Cold blood administered at very high rates (i.e. > 25-30 mL/min for an adult or > 15 mL/min for a child) can cause cardiac arrest. It is therefore important to have an infusion/blood warmer available in the resuscitation room. If there is no infusion/blood warmer available, it is critical to keep the patient warm.
   However, blood should never be warmed in hot water as this can lead to haemolysis.
   ⚠ Have basic resuscitation drugs and equipment within reach in case 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 solution, tourniquet, IV catheter, adhesive tape, possibly 3-way connector).

3. Measure and record on the monitoring form pre-transfusion vital signs: temperature, heart rate, blood pressure, respiratory rate and oxygen saturation.

4. Wash hands, or disinfect them with an alcohol-based solution. Wear gloves.
   Insert the IV catheter, check that it is correctly placed and secured.
   Connect the blood giving set to the bag, with the flow regulator closed.
   Squeeze the drip chamber to fill it.
   Open the flow regulator, prime the tubing, then 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 all blood giving sets, **the dripping chamber delivers 15 drops/mL of whole blood or PRBC**.

   ⚠ 

   The pictogram printed on some packaging of blood giving sets means 20 drops/mL, which can be a source of confusion because the number refers to 20 drops of **water/mL** and **not of blood/mL**.

   Example of calculation of transfusion rate in drops/minute for 250 mL of PRBC over 3 hours:

Calculate the number of drops to be transfused	250 (mL) x 15 (drops) = 3750 drops
Calculate the transfusion duration 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

   Transfusion rates in drops/minute in children can be found in Appendix 7.

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, rate, anticipated end time, etc.

Note: if the blood flow slows down or stops, rotate/adjust the needle 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.

Appendix 5. Informed consent for blood donation

Donor's last name: _____ **Donor's first name**: _____

Date of birth: _____

Address: _____

Telephone number : _____

I confirm that:

– My personal data and contact information mentioned above are correct.
– I have received and understood all the information concerning blood donation.
– I have received all necessary explanations regarding my health and that of the patient who will receive my blood.
– I have answered the medical questionnaire to the best of my knowledge.
– I know that the information contained in the medical questionnaire is confidential.
– I know that my blood will be tested to detect infectious diseases that can be transmitted by blood.
– I accept that the blood I will voluntary give will be used to treat patients that need it and who are not necessarily part of my family.

I give my informed consent to give my blood.

Regarding the results of the blood tests:

☐ I accept to be informed of the results of the biological tests.

☐ I do not accept to receive the results of the biological tests.

Date: _____ /_____ /_____ *(day/month/year)*

Donor's signature

or Legal guardian
(last name, first name and signature)

Appendix 6. Informed consent for a blood transfusion

I, the undersigned,

Last name: _____ **First name**: _____

Date of Birth: _____

Certify that I have been informed by:

Dr (Last name and first name): _____

Of the necessity of a blood transfusion.

I *(the patient)* confirm that:

- I understand the medical reasons for a blood transfusion.
- I understand the expected benefits of a blood transfusion.
- I understand that during or after the blood transfusion, I may suffer an unexpected reaction.
- I understand that in spite of the negative test results on the unit(s) of blood which will be transfused to me there exists a small risk of being contaminated by an infectious disease.
- I have received all the necessary explanations.
- I understand that if I refuse the blood transfusion, my health situation may deteriorate further, even possible leading to death.

☐ I accept the blood transfusion.

☐ I refuse the blood transfusion.

Date: _____ /_____ /_____ *(day/month/year)*

Donor's signature

or Legal guardian
(last name, first name and signature)

Appendix 7. Transfusion volumes and rates - Neonates and children without hypovolemia and/or shock

(including severely malnourished children)

Weight (kg)	Whole blood 20 mL/kg at 5 mL/kg/hour			PRBC 15 mL/kg at 5 mL/kg/hour		
	Volume (mL)*	Rate (drops/min)	Duration	Volume (mL)*	Rate (drops/min)	Duration
3	60	4	4 hours	45	4	3 hours
4	80	5	4 hours	60	5	3 hours
5	100	6	4 hours	75	6	3 hours
6	120	7	4 hours	90	7	3 hours
7	140	9	4 hours	105	9	3 hours
8	160	10	4 hours	120	10	3 hours
9	180	11	4 hours	135	11	3 hours
10	200	12	4 hours	150	12	3 hours
11	220	14	4 hours	165	14	3 hours
12	240	15	4 hours	180	15	3 hours
13	260	16	4 hours	195	16	3 hours
14	280	17	4 hours	210	17	3 hours
15	300	19	4 hours	225	19	3 hours
16	320	20	4 hours	240	20	3 hours
17	340	21	4 hours	255	21	3 hours
18	360	22	4 hours	270	22	3 hours
19	380	24	4 hours	285	24	3 hours
20	400	25	4 hours	300	25	3 hours

* 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 transfusion department will issue a 150 mL or 250 mL whole blood unit. For a patient over 20 kg, order a blood unit of 450 mL.

To ensure that the prescribed volume is administered, at the correct hourly rate, the **duration of administration** and **drops per minute** shown in the above table must be respected.
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 per minute over 4 hours. At the end of 4 hours, the transfusion must be stopped (as 120 mL will have been given), and the remaining blood must be discarded.

Appendix 8. Transfusion monitoring form

Date: ____ / ____ / ____ Ward: _____

Patient

Name: _____ Medical file No: _____

Age: _____ Sex:_____

Blood group: _____ Weight:_____

Transfusion

Blood unit number: _____

Prescribing physician: _____ Whole blood ☐ PRBC ☐

Nurse in charge: _____

Volume of blood to be administered:_____ mL

Duration of transfusion: _____ Rate (drops/min): _____

Transfusion start time: _____ Anticipated end time: _____

Monitoring

	Time	T°	Heart rate	BP	RR	SpO_2	Urine output	General condition
Before transfusion								
5 min								
15 min								
30 min								
45 min								
1 h								
1 h 30								
2 h								
2 h 30								
3 h								
3 h 30								
4 h								
4-6 h after the end of the transfusion								

Transfusion end time: _____ Volume administered:_____

Signature of the nurse in charge:

Appendix 9. Transfusion reaction form

Patient name: _____ Age: _____ Sex: _____

Ward: _____ Bed No. _____ Medical file No. _____ Date: ___/___/___

Patient's blood group:_____

Blood unit group: _____ Blood unit number: _____

Indication for transfusion: _____

Transfusion start time: _____ Time the reaction occurred: _____

Volume transfused: _____ mL

Signs and symptoms:

Initial hypothesis:

Management and evolution:

Transfusion removed: ☐ No ☐ Yes Time: _____

Blood unit returned to the transfusion department: ☐ No ☐ Yes

Samples sent to the transfusion department: ☐ No ☐ Yes

Observations and additional examinations performed:

Type of transfusion reaction: ☐ Very likely ☐ Possible

Physician's name and signature Nurse's name and signature

Appendix 10. Example of pre-donation questionnaire

Pre-selection process

1) Questionnaire

Questions	Donor's answers	Comments
How old are you?		Exclude if < 15 or > 65 years.
How much do you weigh?		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.
Have you given birth or had a miscarriage in the last 6 months?		Exclude if yes.
Are you currently breastfeeding? Is the child exclusively breastfed?		Exclude if exclusively 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 or separated from their family. See contraindications, Chapter 2.

Questions	Donor's answers	Comments
Are you suffering from a chronic illness (epilepsy, diabetes, cancer, heart, kidney, blood disease)?		See contra-indications, Chapter 2.
Are you taking any medical treatment?		See contra-indications, Chapter 2.
In the past, have you suffered from jaundice?		See contra-indications, Chapter 2.
Have you had any dental procedure in the past 3 days?		If yes, exclude temporarily, see Chapter 2.
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 2.
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, diarrhoea or 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 2. 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 2.
In the past 6 months: Have you been hospitalised? Have you had surgery or endoscopy?		See contra-indications, Chapter 2.
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? ☐ Yes ☐ No

Do you wish to receive your tests results? ☐ Yes ☐ No

Can we contact you in future? ☐ Yes ☐ No

Physical examination

Criteria	Results	Comments
Weight (if unknown)		Exclude if < 45 kg.
Temperature		Exclude if axillary T° > 37.5 °C and test for malaria in endemic area.
Heart rate		Exclude if heart rate < 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 examination.

Donor excluded ☐ Permanently ☐

Temporarily ☐ Until ___ / ___ / ___ *(Day/Month/Year)*

Donor selected ☐

Maximum volume to collect _____ mL

Snack[a] ☐

a A snack may be given before donation if the donor is fasting.

Appendix 11. Blood donation 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 carried out with one single puncture, strict aseptic technique and respecting the principle of a sterile closed system.

> One bag = One needle = One puncture

Equipment

- Blood bag (Appendix 34)
- Dressing tray
- Non-sterile, single use gloves
- Protective glasses
- Non-sterile compresses
- Antiseptic solution (polyvidone iodée 10%) for skin desinfection
- Tourniquet
- Adhesive tape
- Scissors
- EDTA tube
- Electronic scale for blood bags, or blood collection monitor (refer to end of procedure for its use)
- Support for the scale (e.g. stool, small table)
- Sheet to place under donor's arm
- Sharps container
- Chlorhexidine or 0.5% chlorine solution (or another disinfectant) for material and surface disinfection
- Fine tip permanent marker

Procedure

1. Explain the procedure to the donor.
2. Inspect the donor's arms: the skin should be free of scars and lesions. The puncture site must be clean. If necessary, ask the donor to wash his/her forearms with soap and water, 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 material and place the electronic scale or the blood collection monitor 20-30 cm lower than the donor's arm to use gravity during the blood collection. Place a sharps container as close as possible of the donor's arm.
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 blood stock 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 of collected blood 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. Check the bag is in correct condition: no leaks, anticoagulant clear and colourless.
- Label the bag with the donation number, collection date and expiry date. The donation number is unique. All the components issued from this donation keep the same number. It allows traceability between recipient and donation/donor.
- 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 11.1).

Figure 11.1

7. With the empty blood bag on it, adjust the electronic scale to 0, so that the scale displays only the weight of the blood collected (see below, at the end of the procedure, how to use a blood collection monitor).

8. Prepare the venipuncture site:
   - Put a clean sheet under the donor's arm, to protect the armrest/bed from blood spills.
   - Put the tourniquet on 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. Make sure you do not splutter on the disinfected site, or wear mask.

9. Perform the puncture, while slightly pulling the skin towards the hand with the needle bevel upwards:

   9.a. *Bag without sampling arm (=without diversion pouch)*
   - Open the clamp only after the needle has penetrated into the skin.
   - As soon as a few mL of blood are in the bag, start mixing the blood with the anticoagulant by gently rocking the bag, off the scale.
   - When blood flow is satisfactory, secure the needle and the tubing with adhesive tape on the forearm.

   9.b. *Bag with sampling arm (= with diversion pouch)*
   - Close the 2 clamps (main line and diversion line) before the puncture. Fold the "breaker" to open it (Figure 11.2).

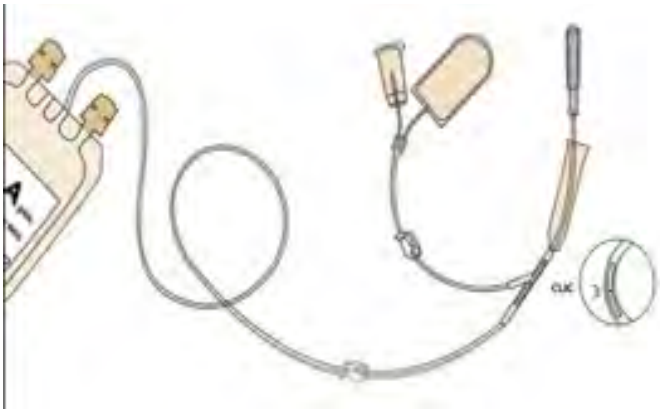


Figure 11.2

- Open the clamp only after the needle has penetrated into the skin.
- As soon as the diversion pouch is filled, close the clamp to the diversion pouch, and open the main collection line clamp.
- As soon as a few mL of blood are in the main bag, mix the blood with the anticoagulant by gently rocking the bag, off the scale.
- When blood flow is satisfactory, secure the needle and the tubing with adhesive tape.
- If tests are performed after blood donation, immediately fill the EDTA tube from the tube holder attached to the diversion pouch and label the tube with the donation number.

10. Collect blood
    - Blood collection usually takes 7 to 8 minutes and should not last more than 12 minutes.
    - Repeat the manual mixing manoeuvre every minute until the bag is filled. Regularly check the weight of the blood bag. Stop the collection when the correct weight (volume) is reached (± 10%).

    Final weight of a filled blood bag (Terumo bags)

Blood bag size (in mL)	**Minimum-maximum volume to be collected** (in mL)	**Weight of collected blood in g** (minimum-maximum) alone (no bag, no anticoagulant)	**Expected final weight**[a] **in g** (minimum-maximum) including bag and anticoagulant
150	135-165	157 (142-173)	203 (188-219)
250	225-275	262 (236-289)	327 (301-354)
450	405-495	472 (425-520)	575 (528-623)

11. Stop blood collection
    - Release the tourniquet.
    - Close the clamp prior to removing the needle; otherwise air will be introduced into the bag and may contaminate the blood.
    - Remove the needle.
    - 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.
    - Tighten the loose knot near the needle. The bag is now safely closed.

a Blood density: 1.05 g/mL

12. **If tests are performed after donation**, collect sample (Figure 11.3), in case of bag without sampling arm:
    - Cut the bag tubing between the knot and the needle, close to the knot. When cutting the tubing, beware of blood spills. Position a compress to absorb the blood when cutting the tubing.
    - Open the EDTA tube and empty the blood from the cut off piece of tubing.
    - Close the EDTA tube and label it immediately with the donation number and date.

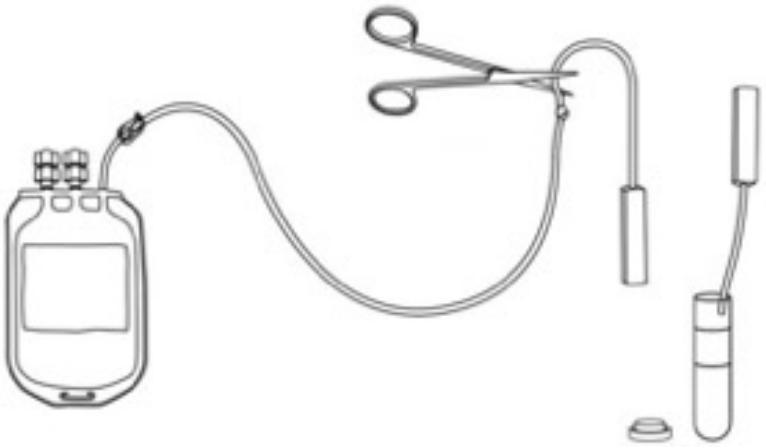


Figure 11.3

13. Discard immediately the needle in the sharps container.

14. Final steps of blood collection
    - If a tube stripper is available, strip the giving line twice to get anticoagulated blood in the giving line.
    - Make 5 tight knots in the tubing at intervals of 10-15 cm, creating 4 segments to be used for further testing: 2nd blood group, 2nd HIV test, crossmatch (Figure 11.4).
      Or make segments with the tube sealer.

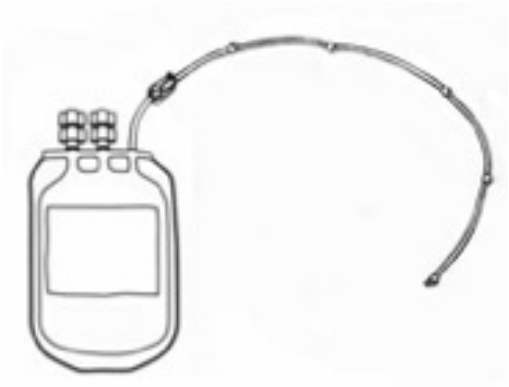


Figure 11.4

- Disinfect the armrest using a 0.5% chlorine (chlorhexidine) solution and dispose of waste.
- Disinfect the scissors using a 0.5% chlorine (chlorexidine) solution and rinse thoroughly with running water to avoid cross-contamination with the following sample.
- 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.

15. 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. The donor should then be kept under observation and rest for 10 minutes. Encourage them to drink (500 mL); advise them to avoid strenuous activity for a few hours.

16. Blood storage
    - If the collected blood is 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. Also, "pre-cooling" blood bags reduces the risk of raising the temperature inside the blood refrigerator.
    - Blood must then be stored in a refrigerator between 2-6 °C.

Note: if not all the required tests have been performed, make sure that untested blood bags are stored separately from qualified blood units, in a clear manner for all staff.

Blood collection with a blood collection monitor

– Set up the volume of the selected bag.
– Place the satellite bags on the tray with the primary bag on top.
– Slide the giving line in the metal clamp.
– After the needle has penetrated into the skin, start the collection monitor: the clamp will open automatically, and the tray will start rocking.

The monitor constantly measures the weight of collected blood and displays the corresponding volume, measures the collection flow, signals in the event of slow blood flow, clamps and triggers a visual and audible signal when the target volume is reached.

Possible incidents during or after blood donation

– Blood flows slowly or stops flow in:
    - Check the blood bag is 30 cm lower than the puncture site.
    - Ask the donor to close and open the fist (pump).
    - Adjust the tourniquet.
    - Move delicately the needle in order to place it in the lumen of the vein.

– Blood collection had to be stopped before the minimum required volume is reached:
    - Blood cannot be used. Discard the bag. Each bag must be filled so that the ratio anticoagulant/blood is adequate.
    - If donor accepts, try a second puncture on the other side, using a new blood bag. Its size will depend on the volume already drawn in order not to exceed the maximum authorised volume per donation (e.g. if 150 mL have been collected, use a bag of 250 mL for the second try, if the donor is able to give 450 mL).

– Fainting:
  Up to 5% donors faint during or after blood collection.
  Anxiety or getting up too abruptly are facilitating factors.
  Donor feels weakness, malaise associated with profuse sweating, eye sight deterioration, brief episode of unconsciousness and looks pale.
  In case of loss of consciousness, stop definitively blood collection. Put the donor on his back with raised legs. Once he has recovered, ensure he is correctly hydrated.

– In case of exposure to blood:
  Follow standard procedure.

Appendix 12. Preparation of PRBC by sedimentation from a single bag of whole blood

Packed red blood cell (PRBC) concentrates are preferred for:
– Patients with anaemia without hypovolaemia,
– Patients at risk of developing fluid overload,
– Patients transfused with non-ABO identical blood.

PRBC prepared by centrifugation are sometimes provided by national/regional transfusion services but are unlikely to be available in many settings.

PRBC can be prepared by storing the blood bag of whole blood in the refrigerator, in an upright position, placing the transfusion set outlet pointing down, for 24 to 48 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 blood unit must be carefully transported from the transfusion department to the ward in order for the red cells not to be mixed back with the plasma. The sedimented red cells must not be disturbed during transfusion as well.

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.

Whole Blood	Sedimented red cells occupy a volume of
450 mL bag	205 mL
250 mL bag	115 mL
150 mL bag	69 mL
100 mL paediatric bag	41 mL

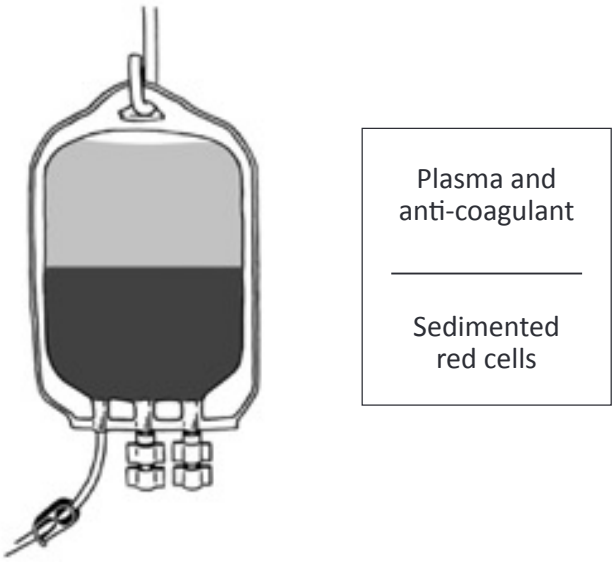


Figure 12.1
Packed red blood cells prepared by sedimentation

Appendix 13. Preparation of paediatric whole blood units from penta bag system

Paediatric units can only be prepared once grouping and TTI screening have been performed on the donor or on the donated blood.

The penta bag system is a closed system made up 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 transfer the blood collected in the primary bag into 4 sub-units of less than 150 mL, while keeping the system closed and sterile, for paediatric use.

Equipment

– Hook or stand to hang the primary bag
– Scissors
– Compresses
– Chlorhexidine solution
– Non-sterile, single use gloves
– Protective glasses
– Fine-tip permanent marker
– Electronic scale for blood bags
– Tube sealer if available

Procedure

1. Wear gloves and protective glasses.
2. Label the four satellite bags. Write on each bag:
   - The blood donation number of the 450 mL bag, plus an index number for each unit from 1 to 4,
   - The collection and expiry dates,
   - The ABO Rh D group,
   - The TTI testing results,
   - The type of component: whole blood.
3. Fill the 4 satellite bags:
   - Homogenize the blood thoroughly 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.
   - Firmly fold the “breaker” to open the circuit (Figure 13.1).
   - The four satellite bags will fill up simultaneously and equally, until the primary bag is empty. If not, check that the “breaker” is fully open. Once the 4 satellite 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 + 63 mL of anticoagulant).
4. Refill the tubing back with blood to allow performing the crossmatch on the tubing:
   - Press gently on bag N°1 to evacuate the air from the tubing and fill it with blood (Figure 13.2).
   - Close the clamp.
   - Repeat for bag N° 2, N° 3 and N° 4.
   - Once the 4 clamps are closed, unhook the primary bag.

5. Close each bag and separate them:
   - For each bag, tie a knot in the tubing below and near 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, or use the tube sealer.
6. Waste management:
   - Disinfect the scissors with a chlorhexidine solution and rinse thoroughly under running water.
   - Safely dispose of the empty 450 mL bag.
7. Weigh each paediatric bag, subtract 20 g (weight of the plastic) and note the weight/volume on each bag (Figure 13.3).
8. Enter the four paediatric units of whole blood in the blood stock register.
9. Store them in the blood refrigerator.

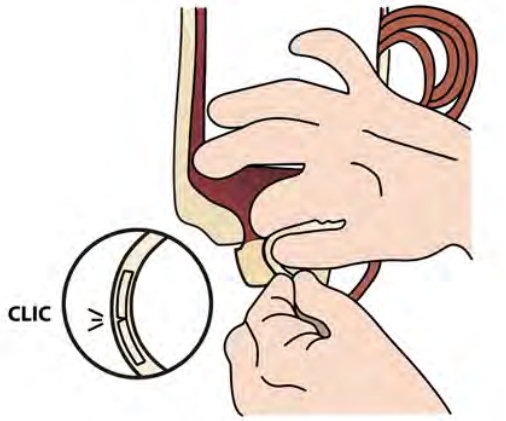


Figure 13.1
Fold the "breaker"

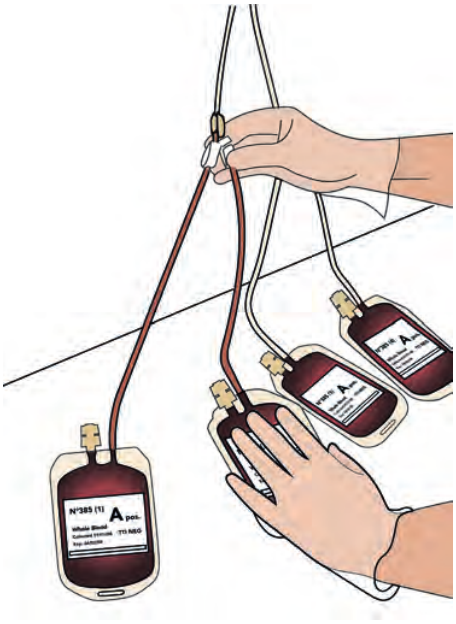


Figure 13.2
Refill the tubings back with blood

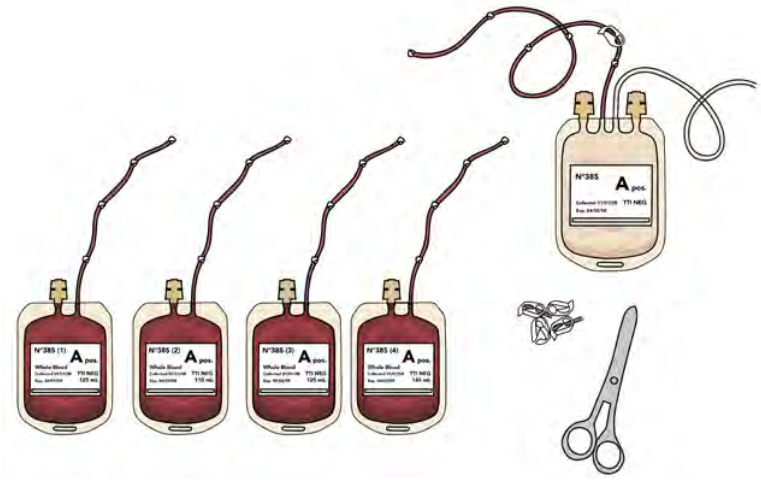


Figure 13.3
4 paediatric whole blood units filled, closed, separated and labelled

Notes:

– To obtain volumes inferior to 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. Fill the bag until the desired weight (volume) is reached, i.e. 79 g for a unit of 75 mL and 52 g for a unit of 50 mL. Indicate the volume of whole blood on the label.

– All the remaining units prepared from the same 450 mL donation must be discarded if:
  • An abnormality is detected in one satellite unit.
  • A septic transfusion reaction occurs during or after transfusion of one paediatric unit.

– Paediatric whole blood units may be stored in an upright position, placing the transfusion set outlet pointing down, for a minimum of 24 hours, to obtain units of paediatric concentrated red cells (Appendix 12).

Appendix 14. Preparation of paediatric PRBC units from penta bag system

Paediatric units can only be prepared once grouping and TTI screening have been performed on the donor or on the donated blood.

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 transfer in a sterile manner the blood collected in the primary bag into 4 sub-units of less than 150 mL, while keeping the system closed, for paediatric use.

Equipment

- Plasma extractor
- Scissors
- Electronic scale for blood bags
- Compresses
- Chlorhexidine solution
- Non-sterile, single use gloves
- Protective glasses
- Fine-tip permanent marker
- Tube sealer if available

Procedure

1. The penta bag of whole blood is placed in the refrigerator, in an upright and stable position, placing the transfusion outlets pointing upwards, for 24 to 48 hours. This allows the red cells to sediment. The longer the sedimentation time the more distinct the separation between red cells and plasma.
2. 2.Take the penta bag system delicately out of the refrigerator and check that the red cells/ plasma separation is clear and that the height of the plasma corresponds to at least half of the height of the bag's content. Immediately hang it vertically on the wall or place it delicately in the plasma extractor.
3. Wear gloves and protective glasses.
4. Label 3 of the 4 satellite bags. Write on each bag:
   - The blood donation number of the 450 mL bag and an index number on each unit: (1) on bag 1, (2) on bag 2, (3) on bag 3,
   - The collection and expiry date,
   - The ABO Rh D group,
   - The TTI testing results,
   - The type of component: PRBC.
5. Close the clamps of the 3 labelled satellite bags.
6. Firmly fold the "breaker" to open the circuit (see Appendix 13, Figure 13.1).
7. While releasing slowly the spring of the plasma extractor or applying a constant pressure on the 450 mL bag with a flat object, transfer the plasma to the non-labelled satellite bag. Leave 2 cm height of plasma above the red cells. Clamp (see Figure 14.2).

8. Unhook the primary bag. Homogenize thoroughly the concentrated red cells by rocking the primary bag (see Figure 14.3).
9. Transfer the concentrated red cells in each of the 3 labelled satellite bags by opening and closing the respective clamp (see Figure 14.4). According to the desired paediatric unit volume, the concentrate red cells can be separated into the 3 satellite bags, or into the 3 satellite bags and the primary bag which will then be labelled as PRBC with the index number 4 (see Figure 14.5).
10. For each bag, tie a knot in the tubing just below the clamp and tighten securely. Cut the tubing between the knot and the clamp while protecting from spills with a compress.
11. Tie two more knots in the tubing, or use the tube sealer.
12. Disinfect the scissors, and rinse thoroughly under running water.
13. Waste management: safely dispose of the remaining plastic material and the bag of plasma: it is not fresh frozen plasma, but ordinary plasma which has no therapeutic use.
14. Weigh each PRBC paediatric unit, subtract 20 g for the plastic (and 40 g for the primary bag) and note the weight/volume on each bag.
15. Enter the 3 or 4 PRBC paediatric units in the blood stock register.
16. Store them in the blood refrigerator.

Note:

– All the remaining units prepared from the same 450 mL donation must be discarded if:
  - An abnormality is detected in one satellite unit.
  - A septic transfusion reaction occurs during or after transfusion of one paediatric unit.

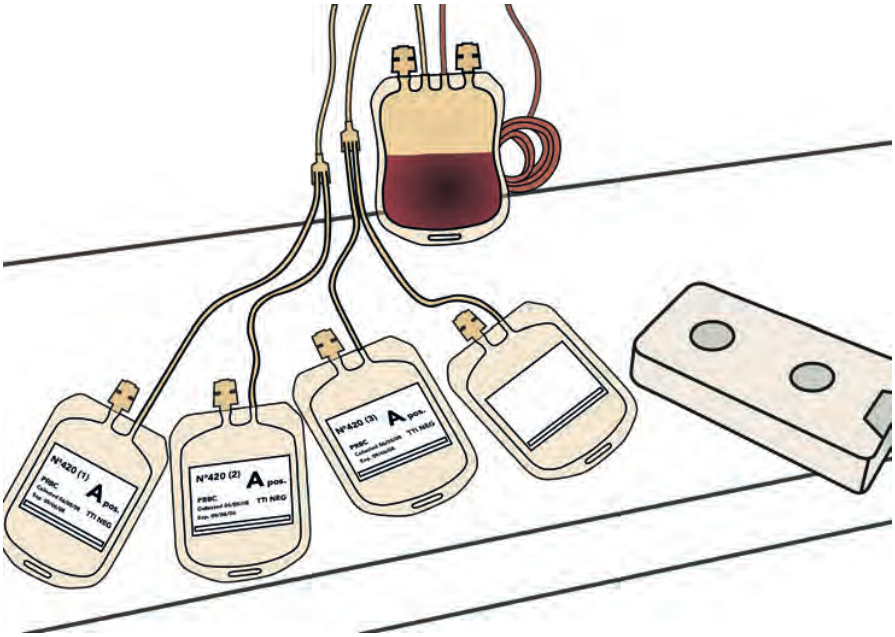


Figure 14.1
Sedimented whole blood bag ready for plasma transfer

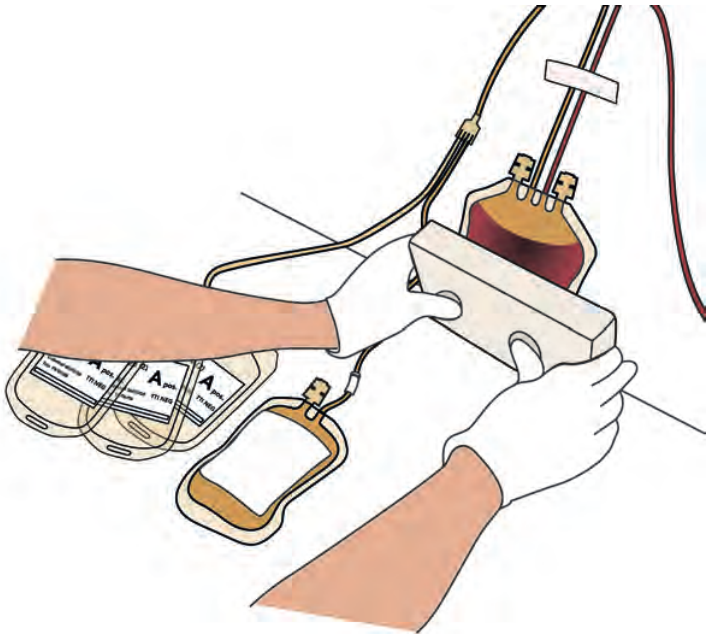


Figure 14.2
Transfer of plasma to the non-labelled satellite bag

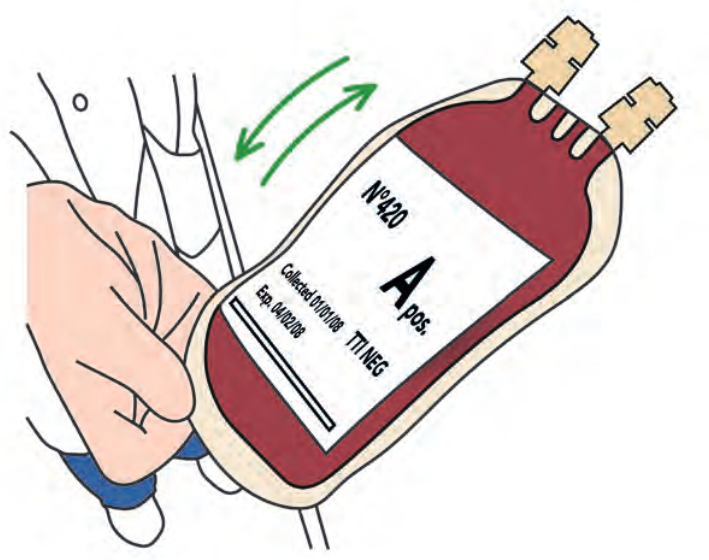


Figure 14.3
Homogeneisation of concentrated red cells

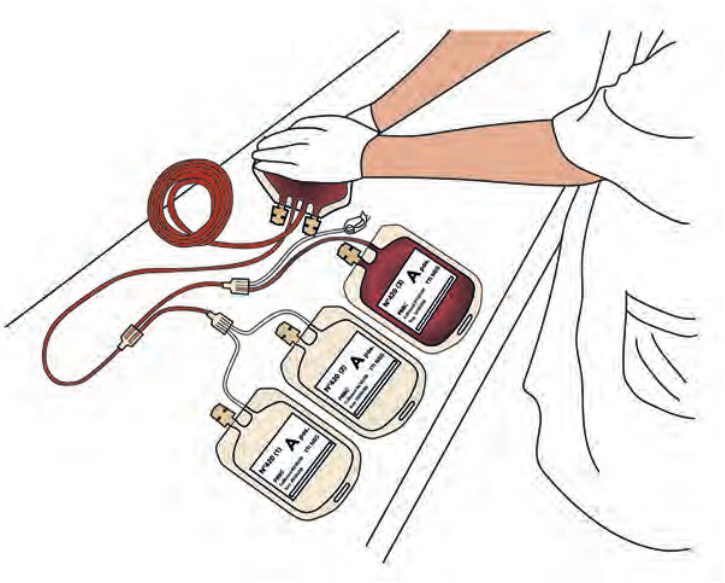


Figure 14.4
Transfer of concentrated red cells to satellite bags

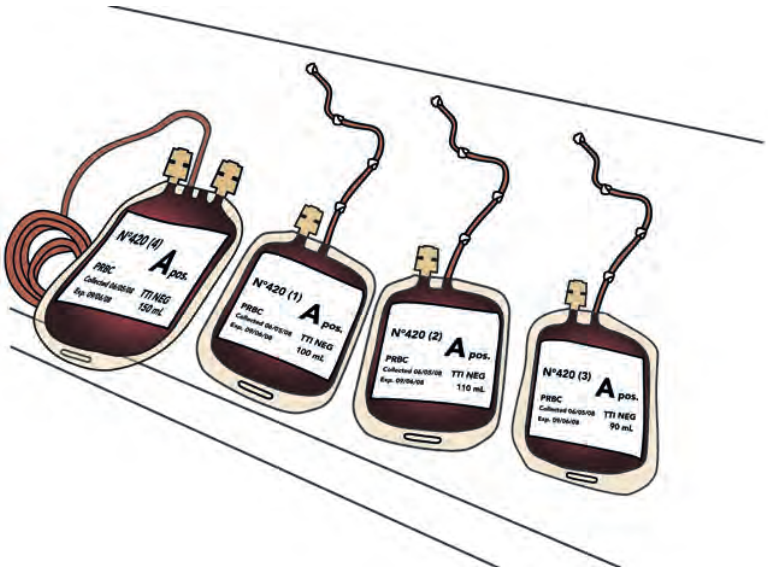
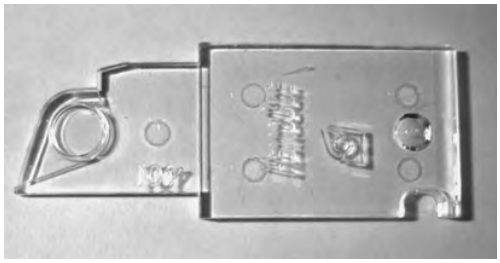


Figure 14.5
Four units of pediatric PRBC (3 units in satellite bags, 1 unit in primary bag) separated, closed, and labelled

Appendix 15. Haemoglobin measurement using HemoCue 301®

HemoCue 301® is a hand-held analyser allowing quantitative determination of Hb from capillary or venous blood samples.

HemoCue301®



HemoCue 301® cuvette

Equipment

- HemoCue 301® analyser
- HemoCue 301® cuvettes
- 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 201 cuvettes in the HemoCue 301®, and vice versa.

Sample

- Capillary blood, for immediate testing.
- After capillary prick, wipe off the 2 first drops. Make sure the puncture site is dry.
  Warning: to ensure good capillary flow, make sure the puncture site is warm by gently massaging or applying a warm wet cloth; ensure the puncture site is lower than the heart; choose a site with thin skin (e.g. ear lobe)

Procedure

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

• Introduce the pointed end of the cuvette into the centre of the drop of blood holding it horizontally. • Let the cuvette fill (10 microliters of blood) by capillary action in one continuous process. It must be filled **completely** and uniformly.	
Wipe off excess blood on the outside of the cuvette with a compress, without removing blood from inside the cuvette.	
Ensure that no air bubbles are present in the cuvette.	
• Pull the cuvette holder to the loading position. • Insert the cuvette in the cuvette holder. • Gently push the cuvette holder. It will close automatically.	

– 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 10 times in order to homogenize the blood sample. Apply one drop of blood on a clean glass slide or any waterproof surface 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
– Blood taken from the perfused side
– Finger or heel not warmed, too much pressure applied to the puncture site

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 301® cuvettes 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.

Appendix 16. ABO and Rh D grouping procedure (direct method on tile)

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

Equipment and reagents

– Smooth white ceramic tile (approx. 15 x 30 cm), degreased and dry
– 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** colourless (the reagent must be from the same manufacturer as the anti-Rh D antiserum).

The vial labels 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 all colourless, and can easily be confused.
Keep the set of 5 grouping vials 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 bag:
– 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 or patient's name or donor's name
     - 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 and negative control.
4. Deposit 1 drop of each reagent in its respective labelled area of the tile.

5. Deposit 1 small drop of whole (approximatively 20 microliters), 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).
7. Rock the tile gently, in a three-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.
   If no agglutination with anti Rh D is visible at 2 minutes, extend agitation and observation to 3 more minutes: the reaction is slower and agglutinates are thinner than with anti-A and anti-B antisera.

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.

Interpretation chart – Direct ABO Rh D blood grouping

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
+ ou –	+ ou –	+ ou –	+ ou –	+	No interpretation possible

+ : Presence of agglutination – : Absence of agglutination

Reporting and registering the result

– A, B, O letters must be written in capital letters.
– Rh D group must be written in letters i.e. pos. or neg.
– Record the ABO Rh D group:
  - For a blood donor/donation, in the donations register and on the blood bag label using a permanent marker.
  - For a patient, in the patients' blood group register, the blood group result form, the medical file and the blood request/delivery form.

Common causes of error

– Sample clotted or haemolysed
– Cross-contamination of reagents (by swapping caps)
– Cross-contamination of the reaction zones during mixing on the tile
– Cord blood contaminated with Wharton's jelly in neonates

Main causes of interpretation difficulties

Weak agglutination:
– Repeat the test using less blood (fewer red cells) and/or more antiserum.
– Agglutination may be incomplete if the patient was recently transfused with non- ABO or Rhesus 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.
  • Auto-agglutination 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 normal saline to a few drops of whole blood in a new plastic tube, mix, centrifuge (1000 g[a], 2 minutes), and discard the supernatant.
  • Perform a second washing and use the washed red cells to perform the grouping 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 collected blood as the blood group cannot be determined. This is however exceptional.
  • When grouping a patient: consider the patient as an O Rh neg. recipient.

When cold agglutinin is suspected, perform the blood group on a warm tile (approx 37 °C) and using warmed washed red blood cells and warm antisera.

a g : centrifugal force

Appendix 17. Blood group result form

Patient's last name:_____ First name: _____

Date of birth: _____ Place of birth: _____

Medical file number: _____

1st determination	2nd determination
Capillary blood ☐ Venous blood ☐	Capillary blood ☐ Venous blood ☐
Drawn by:	Drawn by:
Ward:	Ward:
Date: ___ / ___ / ___ Time:	Date: ___ / ___ / ___ Time:
Determination done by:	Determination done by:
Result:	**Result:**

Concordance ☐ Yes ☐ No

Laboratory technician's signature

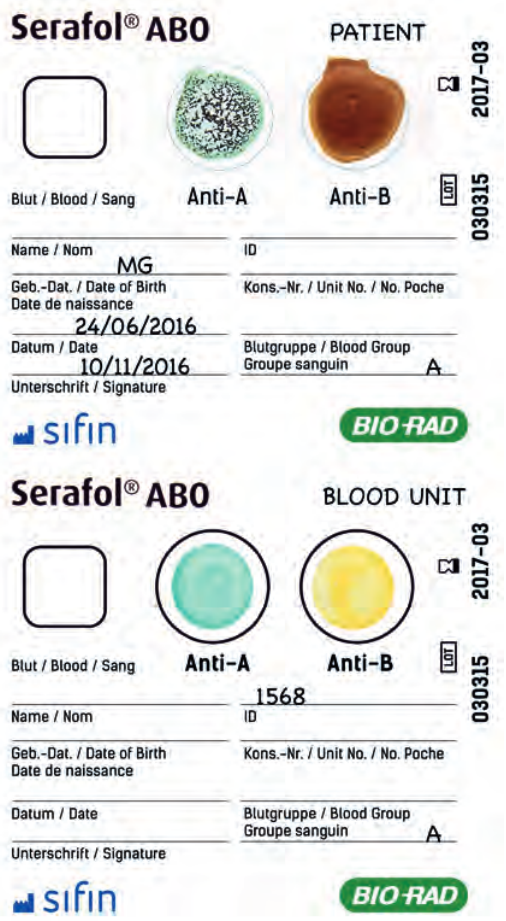
Appendix 18.1. Bedside verification of ABO compatibility using Serafol® ABO

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 verification 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 (taken from finger, heel, or ear lobe) 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 sheet of transparent adhesive
– 1 lancet
– One 5 mL vial of normal non-sterile saline solution

Procedure

1. Note on the upper part of the card (recipient section) the recipient's identification (full name, date of birth and medical file number).
2. Note on the lower part of the card (blood unit section) the blood unit number in the box "Unit No.", the date of the control and the operator's name.
3. Apply 1 drop of normal saline solution on each drop of desiccated reagent.
4. Apply 1 drop of the recipient's capillary blood on the upper square. Ensure that there is enough blood to allow an obvious interpretation of the reaction. If necessary, massage and/or warm the puncture site.
5. Cut the extremity of the segment of the blood unit tubing and apply 1 drop of blood 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. Rock the card in a three-directional movement for 1 minute and read.
10. Note the interpretation (in the recipient section and in the blood unit section) 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 the recipient.

    ⚠ Interpretation must be unequivocal. In the event of any doubt, the procedure must be repeated unquestionably.

Any reaction that shows agglutination with the blood unit and no agglutination with the patient's blood categorically contra-indicates 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 verification does not replace a blood grouping test and is not a cross-match procedure.**

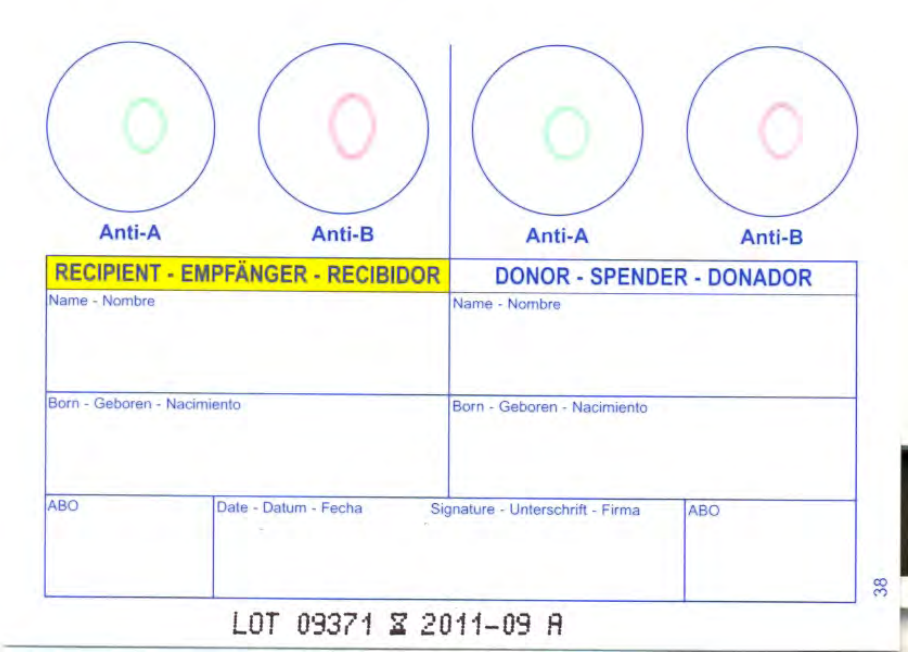
Appendix 18.2. Bedside verification of ABO compatibility using Eldoncard® 2551

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 verification 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 (taken from finger, heel or ear lobe) 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

Procedure

1. In the RECIPIENT zone (left side, yellow bar), note the recipient's identification (full name, date of birth and medical file number).

2. In the DONOR zone (right side), note the blood unit number (in the box “Name”).
3. Note date, time and operator's name.
4. Apply 1 drop of normal saline solution on each drop of desiccated reagent.
5. Apply 1 small drop of the recipient’s capillary blood on the RECIPIENT anti-A and anti-B circles. It is essential to apply enough blood to ensure an unequivocal reading of the reaction. If necessary, massage and/or warm the puncture site.
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. Rock the card in a three-directional movement for 1 minute and read.
9. Note the interpretation (in the RECIPIENT zone and in DONOR zone) 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 the recipient.

   
   Interpretation must be unequivocal. In the event of any doubt, the procedure must be repeated.

   Any reaction that shows agglutination with the blood unit and no agglutination with the patient’s blood categorically contra-indicates 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: the cards are not individually packaged and may stick to each other in humid conditions.

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

Appendix 19. HIV 1/2 Determine® test

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

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 pouch. The pouch 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.

Sample

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

Procedure

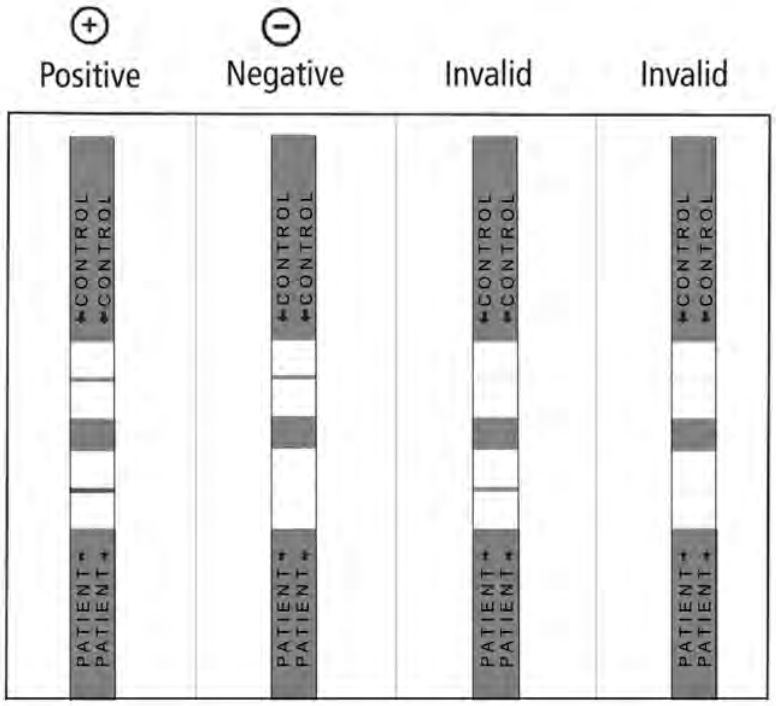
1. Break off the strip(s), at the right hand side of the card, by folding several times along the perforated line. Put the remaining strips back into the pouch with the desiccant and seal securely.
2. Mark the sample number on the strip between the 2 plain green-grey bands at the top, using a fine tip permanent marker.
3. Carefully tear off the protective foil cover.

4. If using whole blood:
   - Apply 50 microliters to the sample pad.
   - One minute later, apply 1 drop of chase buffer to the sample pad.

   If using serum/plasma:
   - Apply 50 microliters 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. Check the expiry date.

Appendix 20. HIV Uni-Gold® test

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

Description

– Membrane covered with recombinant immunodominant 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

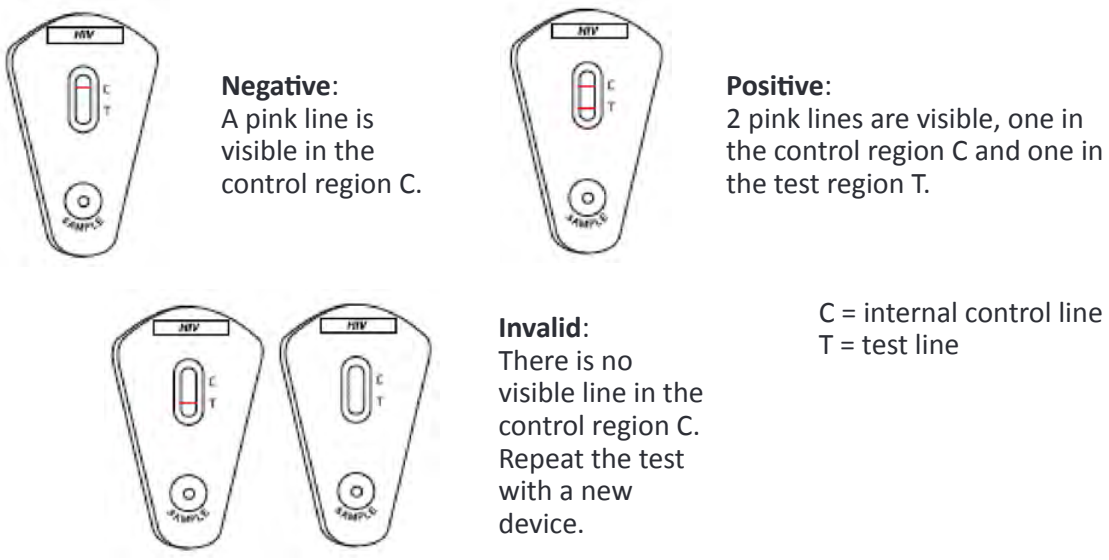
– Plasma or whole blood (EDTA tube) or serum (plain tube)
– Capillary blood

Procedure

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

Interpretation

– Read between 10 and 12 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.



Negative:
A pink line is visible in the control region C.

Positive:
2 pink lines are visible, one in the control region C and one in the test region T.

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

C = internal control line
T = test line

Interpretation of the HIV Uni-Gold®

Storage

The kit must be stored between 2 °C and 27 °C and must not be frozen. Check the expiry date.

Appendix 21. HIV 1/2 Stat-Pak® Chembio test

HIV 1/2 Stat-Pak® test is a lateral flow rapid test for the detection of anti-HIV-1 and anti-HIV 2 antibodies.

Description

The membrane is coated with HIV 1 and 2 antigens on the test band (T), and immunoglobulins G on the internal control band (C).

Contents of the kit

– 20 devices, packed individually in an aluminium pouch with a desiccant bag
– 20 disposable plastic loops for sampling 5 microliters
– 1 dropper bottle of running buffer

Sample

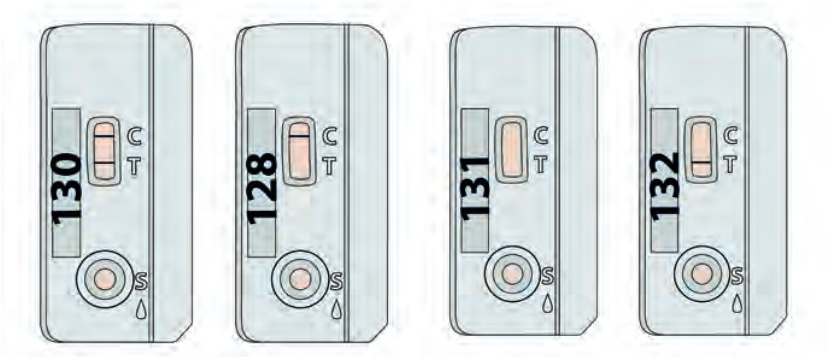
– Plasma or whole blood (EDTA, or heparin, citrate) or serum (plain tube)
– Capillary blood

Procedure

1. Open the pouch immediately before performing the test. If the test has been stored in the refrigerator, leave the device and running buffer to reach ambient temperature.
2. Mark the device with the sample identification number.
3. Fill the loop with the sample.
4. Apply the sample to the circle noted S while holding the loop vertically to transfer the 5 micrograms to the membrane.
5. Apply 3 drops of running buffer to the circle S while holding the vial vertically.

Interpretation

– Read the test between 5 and 20 minutes after adding the buffer.
– The test is validated only if the internal control band is visible. If not, the test is invalid.



Positive Negative Invalid Invalid

Storage

The kit must be stored at a temperature between 2 °C and 30 °C and must not be frozen. Check the expiry date.

Appendix 22. SD Bioline HBsAg WB® test

SD Bioline HBsAg WB® test is a lateral flow rapid test for the qualitative detection of hepatitis B surface antigen.

Description

– Membrane covered with mouse monoclonal anti-HBs Ag virus antibodies.
– The SD Bioline HBs Ag WB kit (ref. code: 01FK10W) contains:
  • 30 test cartridges with desiccant in individual pouch
  • Package insert

  Materials required but not provided:
  • Automatic pipette, adjustable volume 10-100 microliters
  • Tips, yellow for automatic pipette, 10-100 microliters

Sample

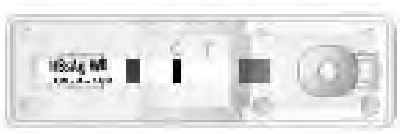
– Plasma or whole blood (EDTA, heparin or citrate tube) or serum (plain tube)

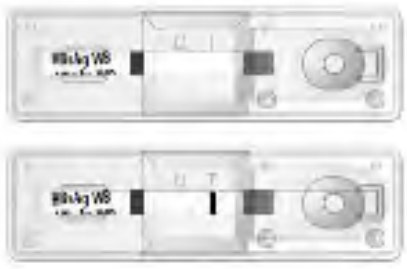
Note: the test is not pre-qualified for use on capillary blood.

Procedure

1 Serum/plasma should be centrifuged for approximately 5 minutes at 1,000-1,300 g (approx. 3,000 rpm with Hettich EBA 200).
2. Allow all components of the test to reach room temperature (15- 40 °C) prior to testing.
3. Check the pouch for damages and holes and discard if damaged. Open the foil pouch and look at the test device and the desiccant. The humidity indicator should be yellow. If dessicant is not present or its colour is green, discard the test.
4. Label the device with patient identifier.
5. Transfer 100 microliters of serum, plasma or whole blood specimen using a precision pipette.
6. Dispense 100 microliters of serum, plasma or whole blood specimen into the specimen well.
7. Interpret the test result after 20 minutes and maximum 30 minutes after adding the sample.

Reporting and interpretation of results

Non-reactive The presence of only the control line (C) within the result window indicates a non-reactive result.	
Reactive The presence of the test line (T) and the control line (C), regardless of which line appears first, indicates a reactive result. *Caution*: the presence of any test line, no matter how faint, is considered a reactive result.	

Invalid If the control line(C) is not visible, the result is considered invalid. Instructions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen is retested using a new test device.	

Quality control

– The test device has letter 'T' and 'C' representing 'test line' and 'control line' on the surface of the case. Both lines are not visible before applying the specimen.
– The internal control line is a procedural control and should always appear if the test procedure is performed properly. The presence of the control line shows that the active ingredients on the strip are functional and that the migration was complete. It is not an assurance that the specimen has been properly applied.

Causes of error

– Insufficient volume of sample applied to the test device.
– Reading test results at 10-15 minutes may result in a weak band and reddish background. Reading at 20-30 minutes results in clear background and accurate result.
– Storage outside 1-40 °C, especially for prolonged times.

Limitations and notes

– The test device is sensitive to both heat and humidity. Check the humidity indicator on the desiccant for color change (Ok if yellow, discard if green). Perform the test immediately after removing the test device from the foil pouch.
– Although this test has been demonstrated to be able to detect common genotypes of hepatitis B, it is limited in its ability to detect virus mutants.
– Due to inherent design of qualitative IVD tests, a faint or absent test line (false non-reactive) may occur in specimens containing high concentrations of HBs Ag (prozone effect).
– Do not use the test kit beyond its expiration date. The expiration date of the test is printed on the outer package.
– Do not use the kit if the pouch is damaged or the seal is broken.
– A non-reactive result does not preclude the possibility of infection with HBV.

Storage

The test kit should be stored at 1-40 °C. Check the expiry date.

Shelf-life upon manufacture

24 months

Appendix 23. SD Bioline HCV® test

SD Bioline HCV® test is a lateral flow rapid test for the detection of anti-HCV antibodies.

Description

– Membrane covered with recombinant (core, NS3, NS4, NS5) HCV antigens
– Devices packed individually in an aluminium pouch with desiccant
– One dropper bottle of buffer

Sample

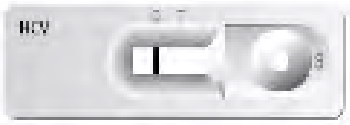
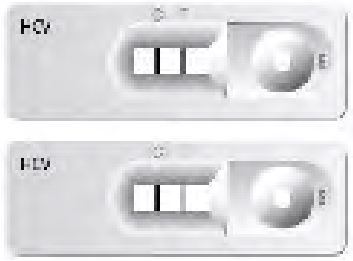
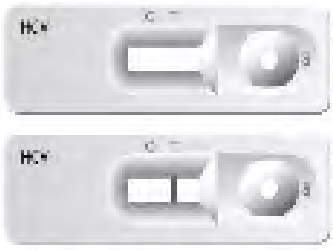
– Plasma or whole blood (EDTA tube) or serum (plain tube)

Procedure

1. Open the pouch immediately before use. Look at the test device and the desiccant. The humidity indicator should be yellow. If desiccant is not present or its color is green, discard the test.
2. Mark the sample identification on the device using a thin permanent marker.
3. Apply 10 microliters of plasma with an automatic pipette to the sample well S.
4. Apply 4 drops of buffer to the sample well S.

Interpretation

Read the test after 10 but before 20 minutes.
The test is validated only if the internal control band is visible. Otherwise, the test is invalid.

Non-reactive The presence of only the control line (C) within the result window indicates a non-reactive result.	
Reactive The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a reactive result. *Caution* : the presence of any test line, no matter how faint, is considered a reactive result.	
Invalid If the control line(C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen is retested using a new test device.	

Storage

The kit should be stored between 2 °C and 30 °C and must not be frozen. Check the expiry date.

Appendix 24. SD Bioline Syphillis 3.0® test

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

Description

– Membrane covered with recombinant *T. pallidum* antigens
– 30 devices packed individually in an aluminium pouch
– Plastic capillary tubes (20 microliters for testing on whole blood) in a plastic bag
– One dropper bottle of buffer

Sample

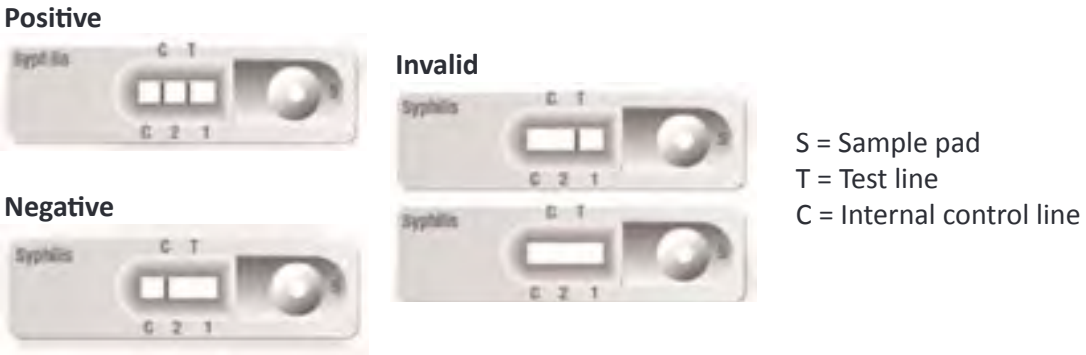
– Plasma or whole blood (EDTA tube) or serum (plain tube)
– Capillary blood

Procedure

1. Open the pouch immediately before use.
2. Mark the sample identification on the device using a thin permanent marker.
3. If using serum or plasma: apply 10 microliters to the sample pad S.
   If using whole blood: apply 20 microliters 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 line 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.



Interpretation of SD Bioline® Syphilis test

Storage

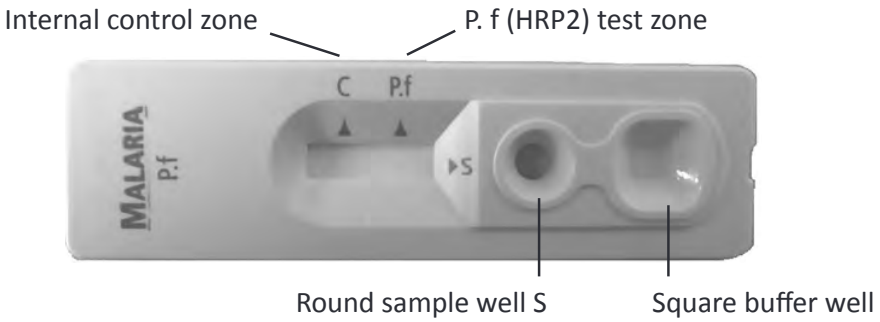
The kit should be stored between 2 °C and 30 °C and must not be frozen. Check the expiry date.

Appendix 25.1. SD Bioline Malaria Ag P.f® test

SD Bioline Malaria Ag P.f® test 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 inverted cups to collect 5 microliters of blood
– 25 lancets
– Assay buffer in dropper bottle



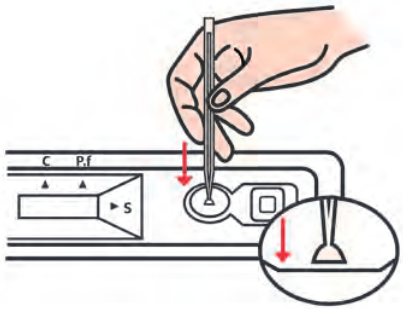
Malaria Ag P.f SD Bioline® device

Sample

– Venous 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 yellow/orange. If it is green, discard the device.
3. Mark the sample identification on the device using a thin permanent marker.
4. Collect 5 microliters of capillary blood with the inverted cup by touching the drop of blood. If using a venous sample, dip the inverted cup into the EDTA tube (previously mixed by gentle swirling) making sure there is no air bubble trapped in the cup, or use an automatic pipette adjusted to 5 microliters.
5. Immediately apply the blood to the membrane of the round sample well S. When using the inverted cup, touch it to the sample pad, in a vertical position.



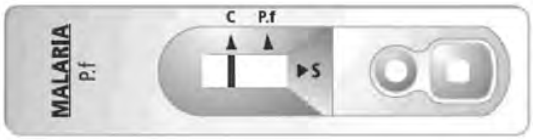
6. Apply 4 drops of assay buffer into the square well by holding the dropper bottle vertically.

Interpretation

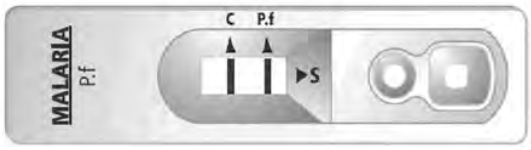
Results should be read no sooner than 15 minutes and no later than 30 minutes.
The test is validated only if the red control line C appears.

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

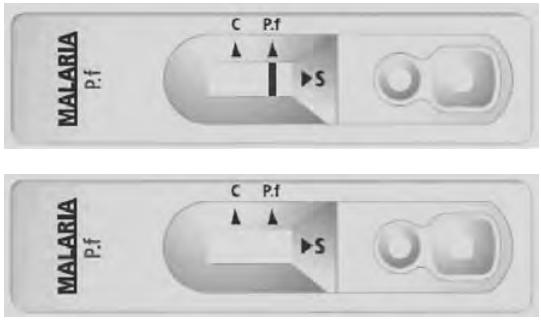
1. Only the line C appears: **negative** test.



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



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



Storage

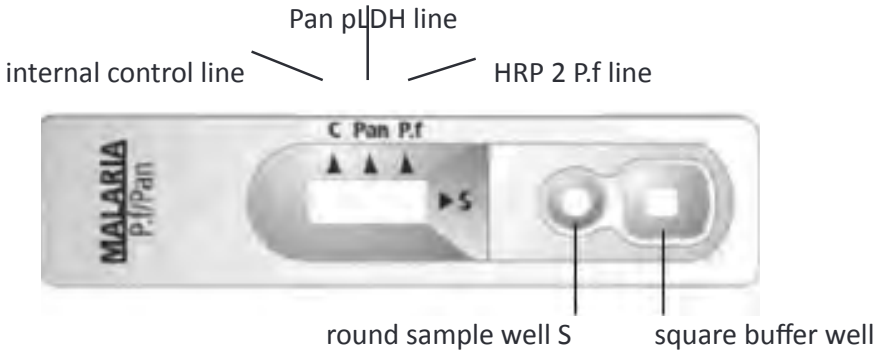
The tests should be stored between 1 °C and 40 °C and must not be frozen. Check the expiry date.

Appendix 25.2. SD Bioline malaria P.f/Pan® (Combo) test

SD Bioline malaria P.f/Pan® (Combo) test is a lateral flow rapid test for the combined detection of *Plasmodium falciparum* histidine-rich protein 2 (HRP2) and Plasmodium lactate dehydrogenase of all plasmodium species i.e. *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae* (Pan pLDH).

Description

- Membrane coated with specific anti-*P. falciparum* and anti-Pan pLDH antibodies
- 25 devices packed individually in an aluminium pouch, with a desiccant
- 25 inverted cups
- 25 lancets
- Assay buffer in dropper bottle



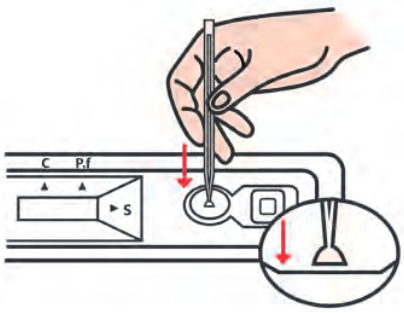
Malaria Combo SD Bioline® device

Sample

- Venous 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 yellow/orange. If it is green, discard the device.
3. Mark the sample identification on the device using a thin permanent marker.
4. Collect 5 microliters of capillary blood with the inverted cup. If using a venous sample, dip the inverted cup into the EDTA tube (previously mixed by gentle swirling) making sure there is no air bubble trapped in the cup or use the automatic pipette.
5. Immediately apply the blood to the round sample well S. When using the inverted cup, touch it to the sample pad, in a vertical position.



6. Apply 4 drops of assay buffer into the square 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.

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

1. Only the line C 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. Check the expiry date.

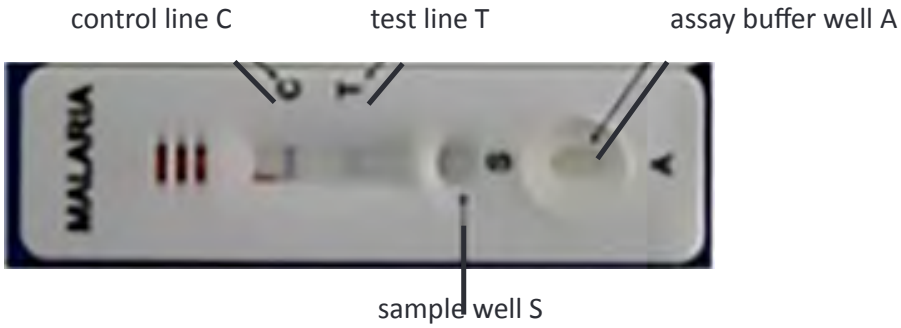
Note: This simplified interpretation is applicable **ONLY** for blood donors/donations screening.

Appendix 25.3. CareStart Malaria pLDH® (Pan) test

CareStart Malaria pLDH® (Pan) test is a lateral flow rapid test for the detection of Plasmodium lactate dehydrogenase common to of all plasmodium species i.e. *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae* (Pan pLDH).

Description

- Membrane coated with specific anti-Pan pLDH antibodies
- 60 devices packed individually in an aluminium pouch, with a desiccant
- 60 inverted cups
- 60 lancets
- 60 Alcohol swabs
- Assay buffer in dropper bottle

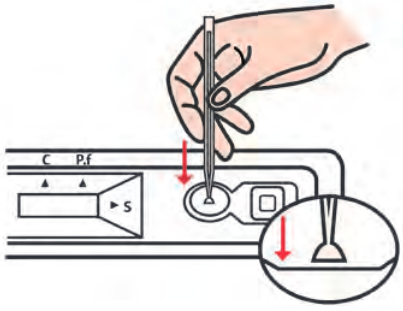


Sample

- Venous whole blood (EDTA tube)
- Capillary blood

Procedure

1. Open the pouch immediately before testing.
2. Mark the sample identification on the device using a thin permanent marker.
3. Collect 5 microliters of capillary blood with the inverted cup. If using a venous sample, dip the inverted cup into the EDTA tube (previously mixed by gentle swirling) making sure there is no air bubble trapped in the cup or use an automatic pipette set at 5 microliters.
4. Immediately apply the blood to the square sample well S, using the inverted cup, by touching the sample pad in a vertical position.



5. Apply 2 drops of assay buffer into the round well “A” by holding the dropper bottle vertically.

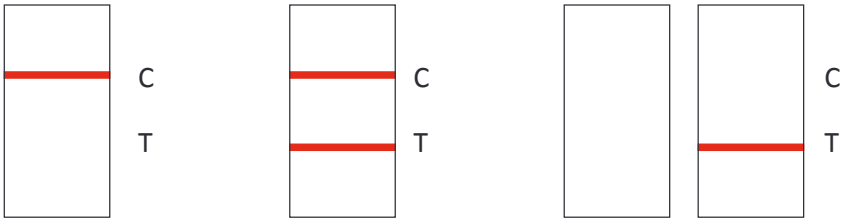
Interpretation

The test is validated only if the red control line C appears.
Results should be read no sooner than 20 minutes and no later than 30 minutes.

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

Reading and Reporting Results

Line T: line Test
Line C: internal control



Interpretation of the test

– Negative result
  The presence of one single colour line ("C" Control line) within the result window indicates a negative result.
– Positive result
  Both lines, line T (Test) and line C (Control) are visible.
– Invalid result
  If the control line does not appear in the result window, the test is invalid. The directions may not have been followed correctly or the test may have been deteriorated. The specimen must be retested.

Limitations and remarks

– If the background is red, too much blood was applied: a weak line may be masked.
– Good sensitivity to detect *P. falciparum* and *P. vivax*, a bit lower for *P. ovale* and *P. malariae*.
– The test does not differentiate between species.

Storage

The tests should be stored between 4 °C and 30 °C and must not be frozen. Check the expiry date.

Appendix 26. 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 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) AND
- Red cells from the blood unit

Procedure

1. Mark the blood unit number and the recipient's identification number on the tile.
2. Mark the blood unit number on the plastic tube.
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 20 microliters of free red cells.
5. Deposit 20 microliters of red cells on the tile.
6. Deposit 100 microliters 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 three-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 the blood unit: this could provoke a haemolytic reaction. The blood cannot be transfused to the patient.

Appendix 27. Blood donations register

Date	Donation number	Blood group # 1	HIV # 1	Hepatitis		Syphilis	Malaria	HIV # 2 on bag tubing	Blood group on bag tubing	Donor/ Donation qualified	Signature
				B	C						

Appendix 28. Patients' blood groups register

LAST NAME first name	Date of birth /age	Medical file N°	First blood group					Second blood group					Final result	Lab tech's signature
			Date/ Time	Place blood taken	Drawn by	Group done by	Result	Date/ Time	Place blood taken	Drawn by	Group done by	Result		

Appendix 29. Blood stock/delivery register

Depending on the level of transfusion activity, plan one register per blood group or a register divided into 4 sections (A,B,AB, O) with thumb nails. It will be easier to find the blood unit corresponding to the patient's blood group.

Blood unit						Patient									Cross-match	Lab tech sign	Delivered to	Time
Unit N°	Collection date	ABO Rh D	Component	Volume	Expiry date	Date	Last name, first name	Age	Sex	ABO Rh D	Hb (g/dL)	Reason for transfusion	Ward	Medical File N°				

Appendix 30. Transfused patients register

Patient									Blood unit							
Fist name LAST NAME	Age	Sex	ABO Rh D	Hb	Reason for transfu-sion	Compo-nent Volume requested	Ward	Doctor	Unit N°	ABO Rh D	Compo-nent	Volume	Expiry date	Cross-match	Date/ Time	Lab. tech. signature

Appendix 31. Blood request and delivery form

Blood request form

Patient's Last name:	**First name:**	**Sex: M/F**
Age or date of birth:	Place of birth:	Weight:
File number:	Ward:	Bed n°:

Patient blood group: Hb: g/dL

Reason for transfusion: Malaria test result:

Previous transfusions: ☐ No ☐ Yes Date: ___ / ___ / _____

Unit number(s):

PRESCRIPTION Urgent*:

Planned transfusion: date of surgery ___ / ___ / _____

Volume requested: mL Type of component:

Volume to be transfused: mL Date: ___ / ___ / _____ Time:

Prescribing doctor: Nurse:

Signature: Signature:

* Urgent if delivery < 1 hour

Blood delivery form

N° of blood unit, type of component, volume	Blood unit group	Expiry date	Comments
1.			
2.			
3.			
4.			
5.			

Prepared by: Signature:

Date: ___ / ___ / _____ Time:

Received by: Ward: Time:

Appendix 32. Example of monthly data collection

Source of blood		**No. of blood units**	**%**	
	National/regional blood centre			
	Other external sources			
	Blood collected within health facility (internal source)			
	Total		100	
Type of blood donations		**No. of donations**	**%**	
	Direct			
	Replacement			
	Voluntary			
	Walking blood bank			
	Total		100	
Donor selection		**No. of donors**	**%**	
	Eligible donors			
	Excluded donors by medical questionnaire and exam.			
	Total		100	
Blood donations collected within health facility		**No. donations collected**	**%**	
	On single bags			
	On penta bags			
	Total		100	
TTI screening		**No. donations tested**	**No. positive**	**% positive**
	HIV No.1			
	HIV No.2			
	Hepatitis B			
	Hepatitis C			
	Syphilis			
	Malaria			
Blood use		**No. of BU transfused**	**%**	
	Paediatrics			
	Medicine			
	OB/Gyn			
	Operation theater			
	Surgery ward			
	Emergency room			
	Nutrition			
	Other wards			
	Units delivered outside the hospital			
	Total		100	
Accidents related to BT	No. of ABO incompatibility accidents			
	No. of other major transfusion reactions			
	No. of minor transfusion reactions			
Mortality related to BT	No. of deaths due to BT adverse effects			
	No. of deaths due to lack of blood			
Quality of transfusion procedure (patient files reviewed)	No. of files reviewed during the hospital transfusion committee meeting			
	No. of files with bedside verification card			
	No. of files with pertinent transfusion indications			
	No. of files with correct transfusion monitoring form			
Blood stock management	No. of Blood Units expired			
	No. of BU discarded due to cold chain failure			
	Mean stock end of the week (over 4 or 5 weeks)			
	No. days of stock (mean stock / monthly consumption x 30)			

Appendix 33. Transfusion module

LABORATORY MODULES | MODULES LABORATOIRE

MODULE, TRANSFUSION, 50 MODULE TRANSFUSION, 50

KMEDMTRA01-	MODULE, TRANSFUSION, 50 MODULE TRANSFUSION, 50	Thermosensitive: ***CF** Justification Code: **PM**

SPECIFICATIONS

This module contains all the necessary equipment for sampling, testing and giving blood (transfuse).

The quantities are calculated for 50 transfusions. The module contains 150, 450 ml and penta (450ml + 4x100ml) blood bags.

(Cf Blood transfusion, MSF, 2010)

INSTRUCTIONS FOR USE

The transfusion module is divided in sub-modules. One of the sub-modules contains the equipment: haemoglobinometer, 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 malaria test: HRP-2/pan pLDH (SD Bioline).

CAUTION: heat sensitive item !

KMEDMTRA01B MUST be transported by COLD CHAIN with 3 temperature monitors.

KMEDMTRA01B: control with 3M card and Freeze-tag	
***CF**	
Windows A, B, C, D white	=> OK
Windows A, B blue	=> OK
Windows C, D blue	=> PROBLEM!
Freeze tag displays "ALARM"	=> PROBLEM!

(Cf Introduction: Thermosensitive products)

Storage

- Keep refrigerated between 2º - 8º C.
- Do not freeze!

SPÉCIFICATIONS

Ce module contient tout le matériel nécessaire pour prélever, tester et donner du sang (transfuser).

Les quantités sont calculées pour 50 transfusions. Le module contient des poches à sang de 150, 450 ml et penta (450ml + 4x100ml).

(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 test malaria: HRP-2/pan pLDH (SD Bioline).

ATTENTION: produit sensible à la chaleur!

KMEDMTRA01B DOIT être transporté en CHAINE DE FROID avec 3 indicateurs de température.

KMEDMTRA01B: contrôle avec carte 3M et Freeze-tag	
***CF**	
Fenêtres A, B, C, D blanches	=> OK
Fenêtres A, B bleues	=> OK
Fenêtres C, D bleues	=> PROBLEME!
Freeze tag affiche "ALARM"	=> PROBLEME!

(Cf Introduction: Les produits thermosensibles)

Conservation

- Au réfrigérateur entre 2º - 8º C.
- Ne pas congeler!

Included in:	**KMEDKHAX30P**	AMP, PART COMPLEMENT if electricity, compulsory PMA, PARTIE COMPLEMENT si électricité, obligatoire
	KMEDKHWE1C0	WARD, PART medical equipment ward 20-40 beds compulsory HOSPITALISATION, PARTIE équip.médical 20-40 lits obligatoire

MSF Code	Composed of | Composé de	Tot Qty
KMEDMTRA01A	MODULE, TRANSFUSION, 50, part 1 MODULE TRANSFUSION, 50, partie 1	1
KMEDMTRA01B	MODULE, TRANSFUSION, 50, part 2, cold chain MODULE TRANSFUSION, 50, partie 2, chaine de froid	1
KMEDMTRA01E	MODULE, TRANSFUSION, 50, part 3, equipment MODULE TRANSFUSION, 50, partie 3, équipement	1

End of list

MSF Code	Detailed list of articles | Liste détaillée des articles	Qty
KMEDMTRA01A	MODULE, TRANSFUSION, 50, part 1 MODULE TRANSFUSION, 50, partie 1	1
ELABMARK1B-	MARKER, permanent, black, fine point MARQUEUR, permanent, noir, pointe fine	2
ELABPIATYR-	(aut.pip.) TIP YELLOW, 2-200µl, rack (Eppdf) (pip.aut.) EMBOUT JAUNE, 2-200µl, rack (Eppdf)	288
ELABTUBE12R	(tube Ø 13/15 mm, 5 ml) RACK (tube Ø 13/15 mm, 5 ml) PORTOIR	1
ELAEHAEC001	(HemoCue Hb 201+/301) CLEANER, 5pcs, HE139123 (HemoCue Hb 201+/301) NETTOYANT, 5pcs, HE139123	2
ELAEHAET305	(HemoCue Hb 301) MICROCUVETTE, s.u. (HemoCue Hb 301) MICROCUVETTE, u.u.	200
EMEQTOUR1--	TOURNIQUET, elastic, 100 x 1.8 cm GARROT élastique, 100 x 1,8 cm	1
PCOLMONI1CE	MONITOR CARD cold chain (3M) English CARTE DE CONTROLE chaîne de froid (3M) anglais	5
PCOLMONICSC	MONITOR CARD refrigeration (Stop!Watch) CARTE DE CONTROLE réfrigération (Stop!Watch)	1
PCOLMONIFFE	FREEZING INDICATOR (Freeze-tag) electronic INDICATEUR DE CONGELATION (Freeze-tag) électronique	5
SINSBABS1--	BLOOD BAG + sampling arm, single, CPDA1, 150 ml, s.u. POCHE A SANG+ poche échantillon, unique, CPDA1, 150 ml, u.u.	20
SINSBABS4--	BLOOD BAG + sampling arm, single, CPDA1, 450 ml, s.u. POCHE A SANG+ poche échantillon, unique, CPDA1, 450 ml, u.u.	20
SINSBABS4B4	BLOOD BAG + sampl. arm, Penta, CPDA1, 450 ml + 4x100ml, s.u. POCHE A SANG + échant., Penta, CPDA1, 450 ml + 4 x 100 ml	10
SINSCONT2P-	CONTAINER, sharps, 1 to 2 l, plastic CONTAINER, récupération aiguilles 1 à 2 l, plastique	4
SINSSEBG1--	SET, BLOOD TRANSFUSION, with 200 µ filter, sterile, s.u. TRANSFUSEUR, avec filtre 200 µ, stérile, u.u.	70
SMSUGLOE1M-	GLOVE, EXAMINATION, latex, s.u. non sterile, medium GANT D'EXAMEN, latex, u.u. non stérile, moyen	100
SSDTBLOC1--	BEDSIDE CONTROL CARD, ABO compatibility (Serafol) CARTE CONTROLE AU LIT DU PATIENT compatibilité ABO (Serafol)	100
SSDTBLOC101	(bedside control card Serafol) ADHESIVE FOIL (carte contrôle au lit du patient Serafol) FEUILLE ADHESIVE	100
SSDTBLOC102	(bedside control card Serafol) MIXING STICK, plastic (carte contrôle au lit du patient Serafol) BATONNETS plast.	100
SSDTHBTE30T	HEPATITIS B TEST HBsAg (SD Bioline), ser/pl/wb,1test 01FK10W TEST HEPATITE B AgHBs (SD Bioline), sér/pl/st, 1test 01FK10W	120
SSDTHCTE25T2	HEPATITIS C TEST (SD Bioline), ser/pl/wb, 1 test 02FK16 TEST HEPATITE C (SD Bioline), sér/pl/st, 1 test 02FK16	100
SSDTHIVD10T	HIV 1 + 2 TEST (Determine), ser/pl/wb, 1 test 7D2343 TEST VIH 1 + 2 (Determine), sér/pl/st, 1 test 7D2343	100
SSDTHIVS20T	HIV 1 + 2 TEST (STAT-PAK), ser/pl/wb, 1 test, 60-9500-0 TEST VIH 1 + 2 (STAT-PAK), sér/pl/st, 1 test, 60-9500-0	100
SSDTMALP25T	MALARIA HRP-2/pan pLDH TEST (SD Bioline), wb,1 test 05FK60 TEST MALARIA HRP-2/pan pLDH (SD Bioline), st,1 test 05FK60	125
SSDTSYPT30T	SYPHILIS TEST (SD Bioline 3.0), ser/pl/wb, 1 test 06FK10 TEST SYPHILIS (SD Bioline 3.0), sér/pl/st, 1 test 06FK10	120
STSSBSVT5E-	(blds.syst.) TUBE, VACUUM, plastic, K2EDTA, 4ml, purple (s.prél.sang.) TUBE SOUS VIDE, plastique, K2EDTA, 4ml, mauve	150
STSSBSVVH1-	(blds. syst.) HOLDER for VACUUM TUBE with needle ejector (s.prél.sang.) CORPS PORTE TUBE avec éjecteur d'aiguille	10
STSSBSVVN21	(blds.syst.) NEEDLE, sterile, 21G (Vacutainer) (s.prél.sang) AIGUILLE, stérile, 21G (Vacutainer)	100
STSSLANCSAM2	SAFETY LANCET, medium flow, needle 21G x 1.8mm, green, s.u. LANCETTE DE SECURITE débit moyen, aig.21Gx1,8mm, vert, u.u.	100
KMEDMTRA01B	MODULE, TRANSFUSION, 50, part 2, cold chain MODULE TRANSFUSION, 50, partie 2, chaine de froid	1
ELAEHAET301	(HemoCue Hb 301) CONTROL SOLUTION, kit 3 x 2 bottles (HemoCue Hb 301) SOLUTION DE CONTROLE, kit 3 x 2 flacons	1

MSF Code	Detailed list of articles | Liste détaillée des articles	Qty
SSDTBLOG1A-	BLOOD GROUPING TEST, anti A (Lorne), 10 ml, dropper bot. TEST GROUPE SANGUIN, anti A (Lorne), 10 ml, fl. compte-gtt	2
SSDTBLOG1AB	BLOOD GROUPING TEST, anti AB (Lorne), 10 ml, dropper bot. TEST GROUPE SANGUIN, anti AB (Lorne), 10 ml, fl. compte-gtt	2
SSDTBLOG1B-	BLOOD GROUPING TEST, anti B (Lorne), 10 ml, dropper bot. TEST GROUPE SANGUIN, anti B (Lorne), 10 ml, fl. compte-gtt	2
SSDTBLOG1C-	RH NEGATIVE CONTROL (Lorne),monoclonal antibodies, 10ml, bot RH CONTROLE NEGATIF (Lorne),anticorps monoclonaux, 10ml, fl.	2
SSDTBLOG1D-	BLOOD GROUPING TEST, RHESUS anti D (Lorne), 10 ml, drop.bot. TEST GROUPE SANGUIN, RHESUS anti D (Lorne), 10 ml, fl.	2
SSDTHIVS201	(test HIV 1+2 Stat-Pak) CONTROLS 3 x 0.25 ml, 60-9549-0 (test VIH 1+2 Stat-Pak) CONTROLES 3 x 0,25 ml, 60-9549-0	1
KMEDMTRA01E	MODULE, TRANSFUSION, 50, part 3, equipment MODULE TRANSFUSION, 50, partie 3, équipement	1
EANTSCAL3A-	SCALE, mechanical, adult 0-150 kg, grad. 500 g BALANCE mécanique, adulte 0-150 kg, grad. 500 g	1
ELABPIAA0100	PIPETTE, AUTOMATIC, adjustable vol. 10-100 µl (Eppendorf) PIPETTE AUTOMATIQUE, vol. réglable 10-100 µl (Eppendorf)	1
ELABTILE1--	TILE, blood grouping, white and smooth CARREAU DE CERAMIQUE, groupage sanguin, blanc et lisse	10
ELABTILE5--	PLATE, blood grouping, smooth, with 5 cavities PLAQUE, groupage sanguin, lisse, avec 5 cavités	2
ELABTIME1E-	TIMER, electronic MINUTEUR électronique	1
ELAECENE1M-	CENTRIFUGE, hand-operated for 4 tubes 15 ml CENTRIFUGEUSE, manuelle pour 4 tubes 15 ml	1
ELAEHAEE3--	HAEMOGLOBIN PHOTOMETER (HemoCue Hb 301) tropicalized PHOTOMETRE HEMOGLOBINE (HemoCue Hb 301), tropicalisé	1
ELAESCAE5--	SCALE, electronic for blood bank (Kern), 0 - 2200 g, 1 g BALANCE électronique banque de sang (Kern), 0 - 2200 g, 1 g	1
EMEQCUFF5--	PRESSURE CUFF, for pouch 500/1000 ml MANCHETTE A PRESSION, pour poche 500/1000 ml	1
EMEQGLAS1P-	GLASSES, PROTECTIVE, plastic LUNETTES DE PROTECTION, plastique	2
EMEQSPHY1A-	SPHYGMOMANOMETER, one-hand manometer, velcro, adult SPHYGMOMANOMETRE, manopoire, velcro, adulte	1
EMEQSTET1--	STETHOSCOPE, single head, adult diaphragme STETHOSCOPE, simple, diaphragme adulte	1
L002TRFM01E-P	Blood transfusion + CD-Rom Blood transfusion + CD-Rom	1
L002TRFM01F-P	Transfusion + CD-Rom Transfusion + CD-Rom	1

End of list

MSF Code	Related Articles | Articles apparentés	Type Relation
ELABF0BB1--	TUBE STRIPPER, for blood bag tubing, manual PINCE A REFOULER, pour tubulure poche à sang, manuelle	is Related to
ELABPLSS1--	PLASMA SEPARATION STAND, manual PRESSE A PLASMA, manuelle	is Related to
ELAEBBRE3--	BLOOD BANK REFRIGERATOR (MB3000G), 230V, 100 bags 450ml REFRIGERATEUR BANQUE DE SANG (MB3000G), 230V,100poches 450ml	is Related to
ELAEBBRE8--	BLOOD BANK REFRIGERATOR (GBR50AC), 230V, 42bags 450ml REFRIGERATEUR BANQUE DE SANG (GBR50AC), 230V,42poches 450ml	is Related to
ELAEBDRE2--	BLOOD COLLECTION MONITOR, 230V (Hemotek2) AGITATEUR DON DE SANG, 230V (Hemotek2)	is Related to
ELAECENE9--	CENTRIFUGE, electrical (Hettich EBA 200), 8 tubes, 230V CENTRIFUGEUSE électrique (Hettich EBA 200), 8 tubes, 230V	is Related to
ELAESEAE1--	BLOOD BAG TUBE SEALER (Delcon HemoWeld T), 115-230V SOUDEUSE de TUBULURE POCHE SANG (Delcon HemoWeld T),115-230V	is Related to
SINSCONT1R-	REUSABLE SHARPS CONTAINER (RSC), 1.2 litre CONTAINER REUTILISABLE POUR OBJETS TRANCHANTS, 1,2 litre	is Related to

End of list

Appendix 34. Blood bags

Presentation

- 150 mL single bag containing 21 mL of $CPDA_1$ (anticoagulant-preservative solution)
- 250 mL single bag containing 35 mL of $CPDA_1$
- 450 mL single bag containing 63 mL of $CPDA_1$
- 450 mL bag containing 63 mL of $CPDA_1$, attached to a set of four 100 mL satellite bags that do not contain $CPDA_1$ (called “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 any brown deposit in the tubing.

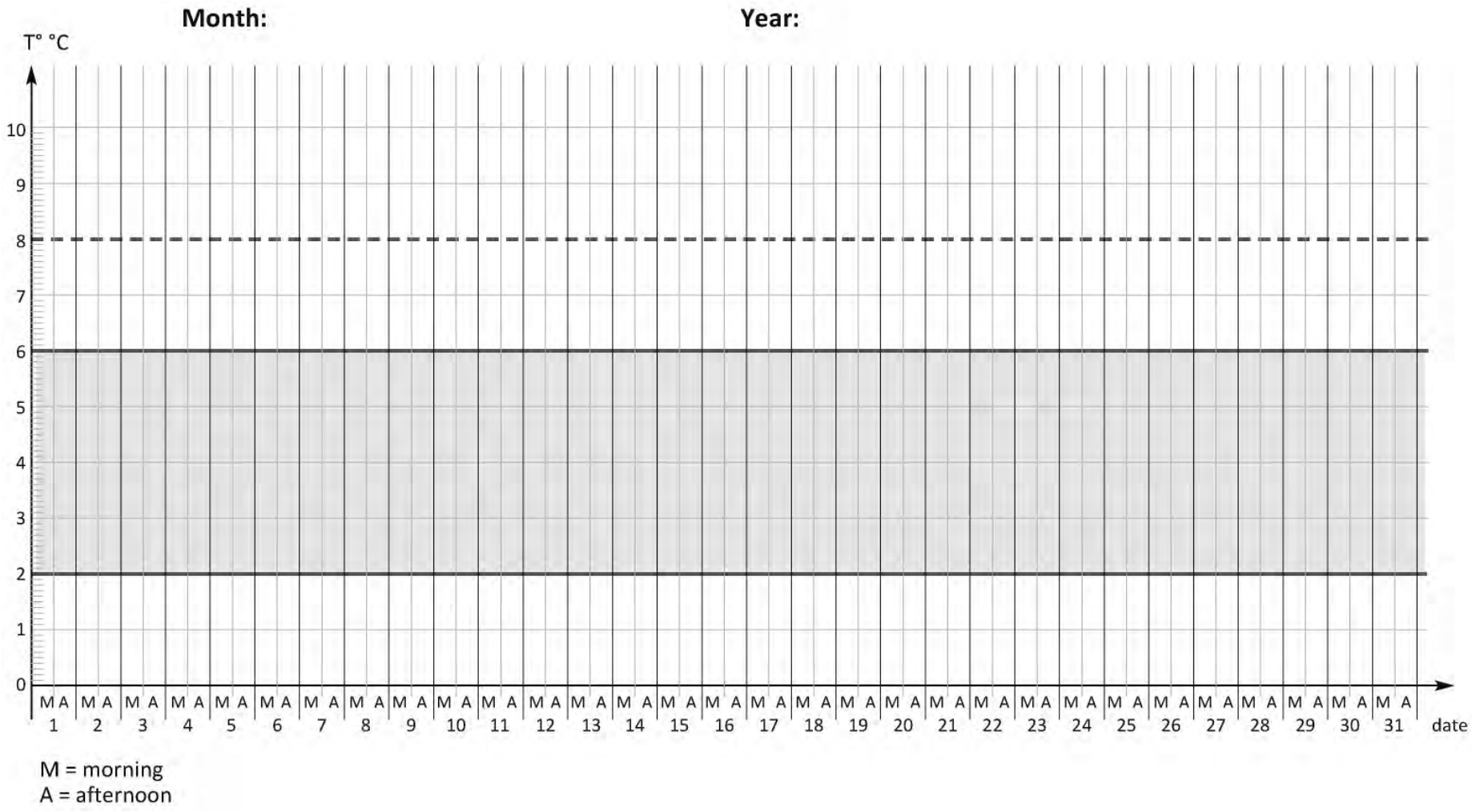
Storage

- At room temperature, protected from light and freezing.
- Avoid prolonged exposure to temperature > 40 °C.

Instructions for use

- Remove blood bag from its protective pouch just before use.
- Do not remove anticoagulant from a blood bag.
  - Do not let air in at the beginning nor at the end of blood collection.
  - Do not fill partially a blood bag.

Appendix 35. Refrigerator temperature monitoring sheet



Appendix 36.1. Fridge-tag®2 with external sensor in a glycol vial

Fridge-tag® 2
with external sensor (PCOLMONITF2B)
in a glycol vial (PCOLMONIEF2)

Description

In a refrigerator for blood storage, the temperature data logger Fridge-tag®2, with an external sensor placed in a glycol vial, displays the inside temperature of the refrigerator without opening the door and records temperatures over the last 30 days. A visual alarm flashes when the temperature falls outside the set range.

The sensor placed in a leak-proof vial of glycol records the temperature of a viscous liquid similar to blood. The measured temperature is therefore insensitive to the short temperature variations of the air when opening the fridge door.

Installation

1. Activation and setting of date, time and temperature in °C format. This is done by the local logistician or biomed engineer.
2. Pre-set of the duration of lower and upper alarms limits to 15 minutes: the alarm will activate only after 15 minutes outside the desired temperature range.
3. Pre-set of the temperature alarm trigger:
   a. Lower alarm : + 2 °C
   b. Upper alarm : + 6 °C
4. Connect the cable to the reader.
5. Fix the reader on the wall behind the refrigerator for a chest refrigerator, or on the side of a vertical blood refrigerator, at eye level for easy reading.
   The reader should be removable in order to be able to download the 30 last day temperatures using the USB cable located at the top of the reader.

Use

Place the glycol vial with the sensor inside the blood refrigerator at upper basket level, either between cooled blood bags, or hung between the upper baskets.

Remarks

– Ensure the glycol vial is not in contact with any freshly collected blood (which is not yet fully refrigerated) or the refrigerator sides or is not close to the bottom of the refrigerator.
– The temperature displayed by the Fridge-tag®2 reader may be different from that displayed at the front bottom right of the refrigerator by up to 1 °C. The built-in sensor of the MB 3000 G is located lower and close to the wall of the refrigerator and displays a “calculated” temperature, not the real temperature inside the refrigerator. Take into account the temperature displayed by the Fridge-tag®2.

Appendix 36.2. 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.		**= OK**
The blood was exposed to a temperature below 0 °C for longer than 1 hour.		**= ALARM**

If the display remains blank, maintain the Freeze-tag® at room temperature and wait at least 2 more minutes. If the display remains blank, check expiry date.

– Once the alarm has been activated, the device cannot be re-used.

Storage

Freeze-tag® must not be stored below 4 °C.

Safety measures

The Freeze-tag® contains a lithium battery: do not open or destroy the case of the Freeze-tag®; do not incinerate.

Glossary

Alloantigen: an antigen present only in some individuals that prompts the generation of specific antibodies when introduced in individuals who do not express this antigen.

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 IgM class antibodies that 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, as well as anti-Lewis and 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 IgG class antibodies, usually unable to activate complement (previously described as incomplete antibodies) and therefore rarely cause intravascular haemolysis. To detect them, specific laboratory procedures are required, 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 antibodies of other blood groups systems and immune anti-A and anti-B antibodies.
- *Regular antibodies*: antibodies that are consistently found in all individuals lacking the corresponding antigen (e.g. naturally occurring anti-A and anti-B).
- *Irregular antibodies*: antibodies that are not consistently found in all individuals lacking the corresponding antigen. They are either naturally occurring (such as anti-Lewis, anti-P) or acquired after transfusion or pregnancy.

Antigen: a foreign substance that enters the body and prompts an immune response, including the generation of specific antibodies.

Batch testing: a laboratory procedure in which one given test is carried out simultaneously on several specimens.

Dangerous O donors: group O donors who carry acquired IgG class anti-A and anti-B antibodies of high titer that can induce delayed haemolysis if their blood is transfused to non-O recipients.

Fresh whole blood: blood that has been drawn less than 4 hours prior to use and has not been refrigerated. Platelets and labile clotting factor functions are fully preserved.

Haemolysins: red cell antibodies causing haemolysis. They usually refer to hyper-immune anti-A and anti-B antibodies of dangerous O donors.

Packed red blood cells (PRBC): blood with a minimum of residual plasma. PRBC are prepared by centrifugation (or, if not feasible, by sedimentation for at least 24 hours).

Qualified blood unit: a blood donation
– With the correct blood/anticoagulant ratio,
– That has undergone all pre-transfusion tests (immuno-haematological tests and TTI markers),
– Appropriately sealed, with a minimum of 3 segments on the giving line,
– Is correctly labelled,
– And has been stored at the right temperature.
A qualified blood unit is suitable for transfusion. This definition applies also to the components issued from such a donation.

Window period: the time period between infection and the development of detectable markers of infection.

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