

Philippine Clinical Practice Guidelines for the Rational Use of Blood and Blood Products and Strategies for Implementation

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Chapter 1

Introduction

Section 1.1

Background discussion on rational clinical use of blood and blood products

1.1.1 Current Transfusion Practices

A sample government and private blood bank facility were surveyed to determine the current situation in blood bank practices. Both facilities have their own policies and guidelines regarding blood bank operations. The policies and guidelines are for activities such as voluntary blood donation programs, blood screening, collection, storage, distribution and utilization.

Need for Blood Transfusion

In a private tertiary care hospital blood bank facility that only caters to its own need, the average requirement is about 60 units of blood products per day and only 50% of this is served by the blood bank facility. To serve the need/shortage, the facility encourages relative blood donor/replacement or source out their needs from the Philippine National Red Cross. A government tertiary care hospital blood bank facility that also caters to other hospitals blood products needs require about 100 units of blood products per day and claim to serve 100%. In both hospitals, approximately half of the volume is allocated or served in the emergency room.

Both the private and government tertiary care blood bank facilities mandatorily screen their donors and blood products for Hepatitis B, Hepatitis C, HIV/AIDS, malaria and syphilis. The private facility in addition also screen for hepatitis A.

Distribution Procedures

In the private tertiary care hospital, the blood bank personnel is usually the one transporting the blood product while in the government tertiary care hospital the relative of the patient claims the blood product from the blood bank facility. In the past, the DOH provides “blood express” to transport blood to different government and private blood banks. The government blood bank facility is “informally” designated as the distribution facility for other government hospitals, but there is no written agreement or guidelines for its role.

Blood Donation Program

Both private and government tertiary care hospitals have blood donation program. The blood donation program in the private tertiary care hospital is partially funded by the hospital but only conducts activities within the hospital. Sometimes they conduct mass blood donation activities with employees of their partner companies or students from colleges and universities. The blood donation program of the government hospital however is in need of additional funding but the facility is still able to conduct out-of-hospital blood donation activities through its mobile blood bank facility. They also maintain good personal relationship with their voluntary blood donors by sending greeting cards and simple tokens like penlight, pillows or towels.

Unmet Need

While the need for additional facilities is not felt in tertiary care hospitals, it was felt by both institutions that upgrading of facilities are needed in other government and private hospitals that source their blood products need in tertiary care hospitals. Tertiary hospitals felt that their blood donation program is just enough to serve their own needs. Formalizing the network through memorandum of agreements not only in the government sector but also in the private sector is needed.

Another felt need especially in government facility was a standard monitoring forms and strategies to prevent and detect blood transfusion reaction. This strategy however is present in a private tertiary care facility. Currently the DOH through its National Voluntary Blood Service Program (NVBSP) has recommended a standardized form to be used for monitoring and reporting of the status of transfusion and adverse events. But it is not yet widely disseminated and used.

1.1.2 Review of Existing Policy

DOH Administrative Order

The “National Blood Service Act of 1994” with its’ AO 9 s 1995 on rules and regulations for implementation was formulated to ensure safe and efficient blood banking and transfusion practices in the Philippines. Regulation of blood services was under the Bureau of Research and Laboratories. In 2005, the Philippine National Blood Service was created amending some of implementing rules in AO 9 s 1995. Thus a new AO 8 s 2008 was formulated to provide rules and regulation governing blood service facilities.

The objective of the most recent AO is to ensure available licensed blood service facilities with adequate staff, equipment and resources to perform all the required functions safely, efficiently and effectively. The AO defined general and specific guidelines for blood service facilities, issues about ownership and service capability. It also defined who will be responsible for implementing and monitoring the standards and technical requirements. The standards were supposed to be set by the National Voluntary Blood Service Program (NVBSP). The license to operate for hospital based blood service facility will be given through the One-Stop-Shop Licensure for Hospitals by the DOH while those that are not hospital based will be required to get a separate license from the DOH-CHD. However, the AO implementation is currently limited and its impact on blood supply once fully implemented need further study.

PHIC Policies

From the Philippine Health Insurance Corporation, a circular (no. 18, s-2009) was issued to update the case type classification of some illness and procedure. This included conditions that require blood transfusion from case type A to case type B. This will mean that these conditions will now have a higher limit for reimbursement. The circular however did not indicate the conditions for appropriate blood transfusion and non-payment for inappropriate blood transfusion.

1.1.3 Background and Rationale of the Clinical Practice Guidelines and Strategies for Implementation

This clinical practice guideline addresses all issues that could affect the quality, safety, availability and accessibility of blood and blood products. It adopted a set of principles that define a good policy process and a structured approach to policy formulation. The clinical practice recommendations were based on up-to-date scientific, medical and epidemiological evidence, with due consideration of economic, ethical and social factors. They were made in the interests of public health and promote optimal use of available resources. Authority, responsibility and accountability for the implementation of policy decisions, including structural and functional relationships were also defined.

The establishment and endorsement of a good practice and policy recommendation were based on the following principles:

- Evidence-based: maximization of health outcomes when decision-making is based on robust evidence
- Efficiency and cost-effectiveness: prioritization of resource allocation in the context of overall public health and the prudent use of human, technical and financial resources
- Participation and partnership: involvement of relevant stakeholders in the policy process, under the umbrella of the national blood commission/authority, to ensure the legitimacy and effectiveness of policy; stakeholders include ministry of health, national blood transfusion service, regulatory agency, experts in blood transfusion, clinicians, blood donor organizations, nongovernmental organizations, patient associations and the media
- Transparency: clear and open policy process to help ensure the legitimacy and effectiveness of blood policy

Section 1.2

Principles of rational clinical use of blood and blood products

1.2.1 Risks of Blood Transfusion

Transfusion Transmissible Diseases

Blood transfusion can transmit infectious agents, including HIV, hepatitis B, hepatitis C, syphilis, malaria and Chagas disease to the recipient. Blood products can also be contaminated with bacteria and very dangerous if it is manufactured or stored incorrectly. The overall cellular blood product contamination prevalence is 32.4 per 100,000 units. This translates into an approximate rate of 1 bacterially contaminated cellular blood product unit per 3,000 cellular blood product units. Platelets are at higher risk of becoming contaminated as shown in the table below (**WHO, 2002**). In most instances, the incidence of transfusion transmitted HIV has decreased to less than 1 case per 2 million screened and tested units in the US compared to 1 per 1,000 in 1980. Similar improvements have been observed for HBV and HCV. (**Hillyer et al, 2003**)

Table 1 Prevalence of Bacterial Contamination in Different Blood Products

Product	Prevalence of Bacterial Contamination
RBC	2.6 per 100,000
RDP platelet	33.9 per 100,000
SDP platelet	51.0 per 100,000

Blood Transfusion Reaction

Red cell transfusion can cause serious hemolytic transfusion reaction. Transfusion reactions can be classified into simple categories i.e. acute and delayed transfusion reactions. (**WHO, 1997**)

Acute transfusion related reactions are:

- Mild reactions – mild allergic or urticarial reactions

- Moderately severe reactions – moderate-severe urticarial reactions, febrile non-hemolytic reactions, possible bacterial contamination
- Life-threatening reactions - acute intravascular hemolysis, bacterial contamination and septic shock, fluid overload, anaphylactic reactions, transfusion-associated lung injury

Delayed transfusion reaction essentially fall into two categories:

- Transfusion-transmitted infections
- Other delayed complications of transfusion which occur days, months or even years after the transfusion has been completed i.e. delayed hemolytic reactions, post transfusion purpura, graft vs host disease and iron overload in repeated transfusions. **(WHO, 1997)**

Hazards of Transfusion Process (SHOT – UK data)

The Serious Hazards of Transfusion (SHOT) is a surveillance activity in United Kingdom and is on its second decade of reporting. It is one of the longest established hemovigilance systems in the world. Based on its 2007 annual report, a total of 561 cases of adverse incidents were reported and these represent an increase of 5% from 2006 total of 531. The incidence of incorrect blood component transfusion averaged more than 300 per year. The data on incorrect blood component transfused (IBCT) reports 2003-2007 showed an increase from 9.5 per 100,000 to 11.4 per 100,000 while the cumulative transfusion-transmitted infection (TTI) has a total of 43 in 2007. **(SHOT, 2007)**

Table 2 Cumulative Mortality/Morbidity Data, 1996-2007 (SHOT , 2007)

Serious Hazards of Transfusion	No. of Cases
Death in which transfusion reaction was causal or contributory	115
Major morbidity probably or definitely attributed to transfusion reaction	376
Minor or no morbidity as a result of transfusion reaction	3821
Outcome Unknown	15
Total Number of Cases	4327

1.2.2 Definition of Appropriate Transfusion

Appropriate blood transfusion is defined as “The transfusion of safe blood or blood products to treat a condition leading to significant morbidity or mortality that cannot be prevented or managed effectively by other means”. **(WHO, 2002)** A safe blood or blood product is a properly screened, typed and cross-matched blood product coming from a voluntary non-remunerated blood donor. In addition, for transfusion to be safe and appropriate, the quality and safety of blood and blood products must be assured from the selection of blood donors, processing and storage until the administration of the blood product to the patient. **(WHO, 2002)** Blood components are transfused only when there is evidence for potential benefit, there are no valid alternatives, safe and quality products are available, and risks and benefits are carefully assessed before the decision to transfuse is made. **(Grazzini, 2008)**

Thus, as recommended by the WHO, appropriate transfusion of blood or blood products requires the presence of the following: **(WHO, 2002)**

- National standards and specifications for blood products and a system of good manufacturing practice to ensure these standards are maintained at all times.
- The development and correct use of standard operating procedures.
- The training of all blood transfusion service staff and clinicians to develop and maintain their knowledge and skills.
- Monitoring and evaluation (audit) to check that the correct procedures are being used correctly by all staff at all times.
- An effective system of independent inspection and accreditation of the facilities that collect, process and distribute blood products.

Section 1.3

Objectives and intended users of the clinical practice guideline

Objectives of the guideline recommendation

- Develop and implement national policies for promoting rational use of blood and blood products
- Promote rational use of blood and blood products by clinical practitioners

Intended users of the guideline

- Medical and paramedical professionals
- Hospital transfusion committee
- PHIC for quality assurance and accreditation of professionals and institution
- DOH for licensing purpose

Section 1.4

How the Guideline was developed

The development of this clinical practice guideline was divided into four phases:

- Formation of the technical working group
- Development of decision points for practice recommendation
- Formulation of initial draft
- Series of meetings on the draft
- Consensus development
- Dissemination

The role of Aids Society of the Philippines (ASP) was to provide administrative support and management financial assistance from the Global Fund to the project. The technical working group was predominantly responsible for the recommendations. The ASP did not in any way influence the guideline recommendations or how the recommendations and consensus was attained.

A Technical Working Group representing the different stakeholders formulated the initial draft of the clinical practice guideline. The group with the assistance of the scientific committee was also responsible for searching and appraising the medical literature that was used as the basis for the recommendations. The scientific committee was mainly composed of resource persons from the Family Medicine Research Group (FMRG), a group of consultants in family medicine who were trained in the application of evidence based medicine concepts in family practice.

An electronic search using MEDLINE, OVID, and Internet resources was conducted to search for clinical studies limited to humans, any language and all journal publications from 1966 up to the present. The citations generated by the searches were examined for relevance to the issues in question on the basis of article titles and/or clinical abstracts available. The full texts of studies that are assessed to be relevant to the guideline development were retrieved. References of retrieved full texts were also reviewed for articles relevant to the issues at hand, and their own full texts retrieved. Existing clinical practice guidelines on blood transfusion were also reviewed and became the basis of most recommendations.

A systematic assessment of the validity of the retrieved full-text articles will were done using the appropriate guide questions. Evidences from articles that have been checked for validity were categorized into different levels of validity the recommendations were graded based on the grading system shown below.

The initial draft was then presented to the all the members of the technical working group and other stakeholders in a two-day workshop. Discussion was done on each of the recommendation. Disagreements were settled by discussion followed by voting if unresolved. After the workshop, the initial draft was revised. The revised version was then sent to the all the members of TWG and stakeholders via e-mail for Delphi consensus development

Table 3 Grading of Recommendations

	Grade A (All TWG agreed to recommend)	Grade B (Significant majority of TWG agreed to recommend)	Grade C (Slight majority of TWG agreed to recommend)
Level 1 (Evidence from randomized controlled trials)	A1	B1	C1
Level 2 (Evidence from observational or cross-sectional studies)	A2	B2	C2
Level 3 (Evidence from experts' opinion)	A3	B3	C3

Chapter 2

Clinical Practice Guidelines for Blood Transfusion

Section 2.1

Recommendations for the Blood Banking System

2.1.1 Recommendations on Donor Recruitment and Care

Voluntary non-remunerated blood donors are the safest source of blood and the preferred source for blood transfusion. Blood and blood products coming from paid donors are not acceptable. (Grade A; Level 2) (WHO, 2002) A sustainable voluntary blood donation program is therefore necessary. The requirements of a voluntary blood donation and screening program include adequately trained staff, availability of equipment, reagents and testing kits. **(WHO, 1998)**

Pre-donation Education and Counseling

Prospective donors should be asked to read educational materials about the risks of blood donation. The donors' concerns and issues must be addressed adequately by properly trained personnel and this must be indicated in writing by the donor. (Grade A; Level 3) (www.aabb.org, 2006) Thus, leaflets for donor awareness and education should be available at screening area. **(WHO, 1998)** Before the clinical screening process, donors should indicate in writing that they have read and understood the risks of blood donation, that they were given the opportunity to ask questions and given accurate information. **(www.aabb.org, 2006)**

Clinical Screening Recommendations

All donors must undergo a clinical screening process that should includes questions about transfusion-transmissible diseases (WHO, 1998) and physical examination that includes checking of blood pressure, pulse and temperature. (www.aabb.org, 2006) (Grade A; Level 3)

Laboratory Screening Recommendations

The test for the following diseases should be mandatory screening program: human immunodeficiency virus (HIV), hepatitis B, hepatitis C, syphilis and malaria. (WHO, 2002) (National Blood Services Act 1994) All donor information and examination results are confidential and must not be release or made available to unauthorized persons. (Grade A; Level 2)

Donor Counseling Recommendations

A policy or program for donor counseling should be available in blood service facility and should be properly implemented. (Grade A; Level 2) (WHO, 1998) The policy should indicate that:

- a donor should be asked whether he/she would like to be informed of the results of HIV testing and other transfusion transmitted infection
- results should be conveyed maintaining full confidentiality
- staff should be trained to prevent serious medical and psychological implications

Donors who are at high risk or tested positive should be referred to existing government or non-government counselling centers. In areas, where counselling facilities are not developed (especially for HIV counseling), facilities should refer them to designated health care and support services. (WHO, 1998)

2.1.2 Recommendations on the Process of Blood Collection

The following should be done before phlebotomy; registration, verify clinical and laboratory screening saying the donor is fit to donate blood. The steps of the whole blood donation process should be: (Grade A; Level 2) (www.aabb.org, 2006)

- have donor lie down or sit in a reclining chair
- the ante-cubital area is cleansed using appropriate skin disinfectant (70% alcohol and povidone iodine or chlorhexidine solution)
- a new, sterile needle that is connected to plastic tubing and a blood bag is inserted into the ante-cubital vein

- the donor is asked to squeeze repeatedly his or her hand to help blood flow from the vein into the blood bag
- the blood collected is sent immediately to the laboratory for Rh and ABO testing and component preparation
- the donor should be escorted to a donor care area for a brief rest period

Individuals may be disqualified from donating blood (deferred donors) at any point during the testing and collection process. Self-deferral may also be allowed at any point in the donation process when a donor voluntarily chooses not to complete the process (www.aabb.org, 2006)

2.1.3 Recommendations on Blood Processing and Storage

Blood Storage

Blood should be stored only in temperature controlled blood refrigerators and NOT in ward or domestic refrigerators. The different blood products must be stored in temperatures as shown in the table and discussed below. (Grade A; Level 2) (Australian and New Zealand Society of Blood Transfusion Inc. Royal College of Nursing Australia, 2004)

Table 4 Storage Temperature for the Different Blood Products

Blood and Blood Products	Storage Temperature
Whole blood and red cells	+2 °C and +6 °C
Fresh frozen plasma	-20 °C or lower
Platelets	+20 °C and +24 °C with continuous agitation
Cryoprecipitate	below -30 °C

Whole blood and red cells must always be stored at a temperature between +2 °C and +6 °C. The following table summarizes the essential storage conditions for whole blood and packed red cells (red cell concentrates). (WHO, 2005)

Table 5 Storage Temperature for Red Cells

Condition	Temperature Range	Storage Time
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Transport of pre-processed blood	+20°C to +24°C	Less than 6 hours
Storage of Pre-processed or processed blood	+2°C to +6°C	Approximately 35 days
Transport of Processed blood	+2°C to + 10°C	Less than 24 hours

Fresh frozen plasma (FFP) is plasma that has been separated from a unit of whole blood within 6 to 8 hours of collection, and has been rapidly frozen and maintained at all times at a temperature of –20 °C or lower. **(WHO, 2005)**

Cryoprecipitate is the cold insoluble portion of plasma remaining after FFP has been thawed between +1 °C and +6 °C and is useful for correcting certain coagulation defects. The optimal storage temperature is below –30 °C. Table 2 shows the permitted storage times and temperatures for both FFP and cryoprecipitate. **(WHO, 2005)**

Table 6 Storage Time according to Temperature for Fresh Frozen Plasma and Cryoprecipitate

Product	Storage Temperature	Maximum Storage Time
FFP	-65°C or below	7 years
FFP or Cryoprecipitate	-40°C to -64°C	24 months
FFP or Cryoprecipitate	-30°C to -39°C	12 months
FFP or Cryoprecipitate	-25°C to -29°C	6 months
FFP or Cryoprecipitate	-20°C to -24°C	3 months

Platelet concentrates should be stored at a temperature of between +20 °C and +24 °C with continuous agitation. Storage conditions and expiry dates should also be strictly adhered to in order to prevent septic shock for the recipient. **(WHO, 2005)**

Table 7 Length of Time Permitted for the Storage and Transport of Platelet Concentrates within the Temperature Range +20°C to +24°C

Process	Maximum Storage Time
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Storage	6 days
Transport	24 hours
After issue, before transfusion	30 minutes
Open system and/or pooled	4 hours

Plasma derivatives such as albumin or immunoglobulin are concentrated, sterile specific proteins, obtained from large pools of donor plasma through a complex pharmaceutical process called plasma fractionation. It is essential to store all plasma derivatives according to the manufacturer's instructions. Table 4 above gives a general guide for the storage of these products. **(WHO, 2005)**

Table 8 Storage of Plasma Derivatives

Products	Storage	Shelf Life	Other
Albumin	< + 25 °C	3 years	Do not freeze
Plasma Protein Fractions (liquid)	+2°C to +8°C	5 years	
Immune Serum (Lipid)	+2°C to +8°C	3 years	Do not freeze globulin. Use Promptly
Freeze Dried Factor VIII	+2°C to +8°C	2 years	Do not freeze
	<+25°C	Up to 2 years	Use promptly after reconstitution
Freeze Dried Factor IX	+2°C to +8°C	year	Do not freeze.
	Room Temperature	1 month	Use promptly after reconstitution

Always follow the expiry date recommended by the manufacturer.

2.1.4 Recommendations on Transport and Distribution of Blood Products

Blood Cold Chain Policy

All blood service facility must have a blood cold chain standard operating procedure that should specify a series of interconnected activities involving equipment, vehicle, personnel and processes that are critical for the safe storage and transportation of blood from collection to transfusion. (WHO, 2005) The cold chain standard operating procedure shall cover the following items; 1) the staff responsible for the procedure, 2) the education, training and competency of these staff, 3) documentation/checking procedures and 4) validated methods for transporting required blood components. (ANZSBT, 2004)

The blood cold chain equipments for whole blood are freezers, blood bank refrigerators, platelet agitators and transport boxes. Other important equipments are standby generators and temperature monitors that warn personnel as the refrigerator approaches unacceptable temperatures. The policy must also include preventive maintenance and rational use of equipment. **(WHO, 2005)**

The policy must also contain rules in transporting blood or blood products. These include:

- transport in boxes designated for this purposes and should be validated as satisfactory for transporting blood **(ANZSBT, 2004)**
- label the container THIS WAY UP with an arrow
- Ice should be placed above the blood because cool air moves downwards. **(WHO, 2005)**

The recommended transport conditions must be maintained when blood is moved from one location to another, including: — from a mobile or satellite collection site to the laboratory — from the blood bank to a different facility (to a hospital or clinic or another blood bank) — from the blood bank to hospital wards or operating rooms. **(WHO, 2005)** Thus, each blood transport box must have frozen ice packs as coolants in order to ensure an acceptable cold life. **(WHO, 2002)**

The transport method in the policy must specify transport conditions for the different individual blood products as recommended below: **(WHO, 2005)**

- Red cell components - Ice should not be allowed to come into direct contact with the blood as the red cells nearest to the ice may freeze and hemolyse. Appropriate materials and packing arrangements are therefore necessary.
- Plasma - There should be at least as much wet ice in the cold box as there is plasma. If possible, they should have been placed in cardboard boxes before freezing to protect the bags from developing small cracks.
- Platelets - Containers for transporting platelets should be equilibrated at a temperature of +20 °C to +24 °C before use. If outdoor temperatures are extremely high, special chemical, coolant

pouches are available that may be shipped with platelets and will maintain temperatures of approximately +20 °C to +24 °C for up to 12 hours.

- FFP and cryoprecipitate - They are thawed at between +30 °C and +37 °C in the blood bank before issue and transported to the ward at ambient temperature. They must be used immediately and should never be refrozen.

Receiving Facility

Acceptance of blood by the receiving facility is CONDITIONAL upon the discretion of the blood service facility staff and based on evidence of suitable storage and handling while in transit from the issuing facility. (Grade A; Level 2) Any products where there is any doubt regarding the conditions of storage during transport must not be used for transfusion. Any such items must be held in secure quarantine until a decision regarding its fate is made. **(ANZSBT, 2007)**

To facilitate the decision of the receiving facility the following may be done when transporting blood products **(ANZSBT, 2004)**:

- blood products for transport must have documentation slip containing the patients identification details, blood compatibility report and the specific blood component labels
- the time and temperature when blood was removed from the refrigerator and placed into a box
- the time that blood should be returned to the blood bank if it is not used
- a member of appropriately trained staff should check that the correct blood has been delivered and sign the blood collection slip

2.1.5 Recommendations for Pre-transfusion Testing

Every hospital should have standard operating procedures to ensure that blood and blood products to be transfused are compatible with the patient's red cells and the antibodies in the patient's plasma. **(WHO, 2002)** Such SOPs must be prominently displayed in the blood bank area. **Donated blood unit should be routinely tested for ABO and Rh (D) grouping. Pre-transfusion antibody screening of patients and crossmatching with donors' blood using sensitive techniques should be done on all whole blood and red cell transfusions. (Grade A; Level 3) (WHO, 1998)**

Section 2.2

Recommendations for Clinicians

2.2.1 Fresh Whole Blood (FWB)

What is Fresh Whole Blood

Fresh whole blood (FWB) is blood collected within 48 hours into a blood bag with appropriate anticoagulant. It provides RBC, plasma and platelets. After 48 hours it is termed whole blood (WB) contains the red cells and plasma component of donor blood. **(Australian Red Cross Blood Service, 2008)** Platelet viability is decreased upon storage in blood bank refrigerator. It has no functional platelets and labile coagulation factors (V and VIII).

FWB or WB should be of the same ABO and Rh(D) type as the patient whenever possible. When serologically compatible units are not available, incompatible units may be given after consultation between the physician and laboratory. Group O red cells must be selected when the patient's ABO group cannot be determined. Similarly Rh (D) negative red cells should be used if a conclusive Rh(D) group cannot be obtained. (ANZSBT, 2007) Switching to the patient's type may be done when type specific blood is available. (Grade A; Level 3)

Indications for FWB Transfusion

The use of FWB and WB should be discouraged and patients should be given the specific blood products as indicated. (WHO, 1998) However, the following may be considered as indication for FWB or WB transfusion (Grade A; Level 3):

- **Evident massive blood loss and coagulopathy.** Massive blood loss is defined as the loss of significant 1 to 1.5 times the whole blood volume within a 24 hour period. Alternative definitions in acute situations is: 50% of blood volume loss within 3 hours or a rate of loss of 150 ml/min. (British Committee on Standards in Hematology, 2006)
- **Trauma casualties who will be requiring massive transfusion but only when specific blood products are not available or when blood products are not enough to resuscitate the patient**
- **Patients with hemorrhagic shock when optimal specific blood product therapy is not available or when blood products are not enough to resuscitate the patient**
- **Neonatal exchange transfusion.** Use Group O or group-compatible erythrocytes suspended in group compatible or AB plasma. The whole blood should be less than 7 days old to ensure a greater than 90% post-transfusion survival. Utilize leuko-reduced and irradiated cells since exchange transfusion neonates are often than not sick prematures and acutely ill neonates who are considered immunocompromised. (Nathan and Oski, 5th Ed)

Volume and Preparation of FWB

It is usually prepared up to 513 ml total volume but the volume may vary in accordance with local policies. One bag usually has 450 ml donor blood and 63 ml anticoagulant-preservative solution.

Storage Temperature, Handling and Shelf-life of FWB

FWB must be stored only in blood refrigerators with appropriate temperature monitor and not in wards or domestic refrigerators. It must also be transported in boxes (cardboard, styropore or plastic) designated for this purpose and which have been verified as satisfactory for transport and time of storage. (Grade A; Level 3) (BCSH, 1999) If the fresh whole blood is refrigerated within eight hours of collection, it may be stored up to five days. (Joint Theater Trauma System Clinical Practice Guidelines, Updated November 2008) Only FWB stored for less than 24 hours at 20-24°C can be considered a clinical source of viable platelets or therapeutic levels of labile coagulation factors V and VIII. After 24 hours, all room temperature stored FWB units should be destroyed.

Only 1 unit of FWB or WB should be taken at a time for each patient unless rapid transfusion of large amount of blood is needed. Blood should be transfused as soon as possible after delivery to the ward or operating room. If more than 30 minutes has elapsed and a unit of blood is still not transfused or cannot be transfused, the blood should be returned to the blood bank. (BCSH, 1999) (Grade A; Level 3) They should be informed that it has been out of the refrigerator for more than 30 minutes so that the blood bank will dispose of it properly because of the risk of bacterial growth.

Infusion Set and Rate of PRBC Transfusion

Blood should be transfused through a sterile giving set designed for the procedure. The size of the cannula chosen should depend on the size of the vein and the speed at which the blood is to be transfused. A new transfusion set should be used for every new unit to be transfused or if the transfusion set has been used for 6 hours or more in order to prevent bacterial growth. (Grade A; Level 3)

Electronic infusion pumps may be used for the administration of RBC if they have been verified as safe to use for this purpose and according to the manufacturer's instructions. In neonates the use of infusion pump may be helpful. Blood should only be warmed using a specifically designed commercial device with a visible thermometer and audible warning. A blood warmer is indicated at flow rates of $>50\text{ml/kg}^{-1}\text{h}^{-1}$ in adults, $>15\text{ ml/kg}^{-1}\text{h}^{-1}$ in children and for exchange transfusion in infants. (BCSH, 1999) It is also indicated in transfusion for cold agglutinin disease. Improvised infusion pumps and warmers are discouraged.

Never add medication to a unit of blood or administer medication through a transfusion line during the transfusion. (Grade A; Level 2)

Complete transfusion within 4 hours of commencement. Upon completion of the transfusion, the empty bag should be discarded according to the hospital policy for disposing of clinical waste and the blood transfusion compatibility report form should be filed in patients medical records. (BCSH, 1999) (Grade A; Level 3)

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- before starting the transfusion
- as soon as the transfusion is started

- every 15 minutes after starting the transfusion for first hour
- every 30 minutes during transfusion
- on completion of the transfusion
- four hours after completing the transfusion

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (**WHO, 1997**) and 7) subjective complaints of patients. The following should also be recorded in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. (**WHO, 1997**)

2.2.2 Packed Red Blood Cell (PRBC)

What is Packed Red Blood Cell

Red cell concentrate (also called packed red cells (PRBC), concentrated red cells or plasma-reduced blood) is prepared by allowing the blood to separate under gravity overnight in a refrigerator at a temperature of +2°C to +6°C or by centrifuging the blood pack in a special refrigerated centrifuge. Red cell suspension is prepared by removing the plasma into a second empty plastic pack, as described above. An 'additive' diluent solution formulated for the best preservation of the red cells is then transferred from a third plastic pack into the original pack.

PRBC should be of the same ABO and Rh(D) type as the patient whenever possible. When serologically compatible units are not available, incompatible units may be given after consultation between the physician and laboratory. Group O red cells must be selected when the patient's ABO group cannot be determined. Similarly Rh (D) negative red cells should be used if a conclusive Rh(D) group cannot be obtained. (ANZSBT, 2007) Switching to the patient's type may be done when type specific blood is available. (Grade A; Level 3)

General Indications for PRBC Transfusion

The criteria for PRBC transfusion should be based on: 1) hemoglobin level, 2) the patient's clinical condition and 3) risk for inadequate oxygenation. Transfusion is rarely indicated when the hemoglobin concentration is greater than 10g/dl and is almost always indicated when it is less than 6g/dl. Between 6 and 10 g/dl, RBC transfusion should be based on the patient's risks for complications or inadequate oxygenation. The use of PRBC is likely to be inappropriate when Hgb levels is greater than 10 g/L. (Grade A; Level 2) (ASA, 1996) (Finnish Medical Society) (Laudico et al, 2000) (NHMRC, 2001)

Adult Indications for PRBC Transfusion

PRBC may be given in patients with hemoglobin concentration of <10 g/dl if In such cases when there is (Grade A; Level 2) (Finnish Medical Society Duodecim) (Mukhopadhyay, 2003):

- disabling angina pectoris
- myocardial infarction
- congestive heart failure due to severe anemia
- end-stage renal disorder

PRBC transfusion is NOT indicated during chemotherapy since it is not likely to achieve Hgb level optimal for good quality of life or give anticancer therapy the best prospects of success. (Vaupel, 2008) (Grade A; Level 2)

Pediatric Indications for PRBC Transfusion

PRBC is indicated in neonates and premature infants with (Nathan and Oski's, 5th Ed) (Grade A; Level 1):

- hemoglobin level of < 8 – 10 g/dl (hematocrit 0.25 – 0.30) accompanied by tachypnea, tachycardia, recurrent apnea, poor feeding and poor weight
- hemoglobin level of < 130 g/dl in acutely ill neonates with cardiorespiratory disease

- hemoglobin <80 g/L or hematocrit <25% in a stable neonate with clinical manifestations of anemia, namely tachycardia, tachypnea, and poor feeding
- neonates and premature infants when there is shock associated with blood loss or sepsis, cumulative loss of 10%

Above 4 months, the general indication for PRBC transfusion as discussed above applies.

Surgical Indications for PRBC Transfusion

Aggressive and early control of hemorrhage with volume resuscitation using crystalloids and colloids should be considered an integral part of resuscitation. **PRBC is preferred in patients with acute blood loss >2,000 ml or a 40% loss of blood volume. (Management of Bleeding following Major trauma) In normovolemic patients with acute anemia who have cardiac disease or are at risk of cardiac disease may benefit from PRBC transfusion if their Hgb concentration is less than 7 g/dL. (Laudico et al, 2000) (Grade A; Level 2)**

Volume and PRBC Preparation

PRBC is available in bags of 150–200 ml from which most of the plasma has been removed. A bag contains hemoglobin approximately 20 g/100 ml (not less than 45 g per unit) and hematocrit at 55%–75%.

Handling and Storage of PRBC at Transfusion Area

Only 1 unit of PRBC should be taken at a time for each patient unless rapid transfusion of large amount of blood is needed. Blood should be transfused as soon as possible after delivery to the ward or operating room. If more than 30 minutes has elapsed and a unit of blood is still not transfused or cannot be transfused, the blood should be returned to the blood bank. (BCSH, 1999) (Grade A; Level 3) They should be informed that it has been out of the refrigerator for more than 30 minutes so that the blood bank will dispose of it properly because of the risk of bacterial growth.

Infusion Set and Rate of PRBC Transfusion

PRBC should be transfused through a sterile giving set designed for the procedure. The size of the cannula chosen should depend on the size of the vein and the speed at which the blood is to be transfused. A new transfusion set should be used for every new unit to be transfused or if the transfusion set has been used for 6 hours or more in order to prevent bacterial growth. A duration of 2-3 hours is given for PRBC. PRBC should be transfused slowly 10-15 drops/ min for the first 10 minutes. (Grade A; Level 3) (BCSH, 1999) (Finnish)

If blood warmer is needed, a specifically designed commercial device with a visible thermometer and audible warning should be used to warm blood in patients with cold agglutinins or at flow rates > 50 ml/ kg/ hr in adults and > 15 ml/ kg / hr in children. Improvisations, such as warming blood in hot water should not be used (BCSH, 1999).

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion for first hour
- every 30 minutes during transfusion
- on completion of the transfusion
- four hours after completing the transfusion

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (WHO, 1997) and 7) subjective complaints of patients. The following should also be record in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers off all products transfused and 5) any adverse effects. (WHO, 1997)

Response to Transfusion

Infusion of 1 unit of packed RBC increases the hemoglobin of 1 gm/dl and hematocrit by 3%. In patients who are not actively bleeding, repeat hemoglobin determination may be done 15 minutes after transfusion. (Wiener, 1994) (Grade B; Level 2)

2.2.3 Washed Red Cell

Washed Red Cell Preparation

The red cells are washed with 0.9% sterile isotonic saline by a manual method to remove the majority of plasma proteins, antibodies and electrolytes. The washed red cells are then re-suspended in additive solution. (Australian Red Cross Blood Service, 2008) It is depleted of plasma, platelets and leukocytes.

Indications for Washed Red Cell Transfusion

Washed red cell is used in patients with indication for PRBC transfusion but has also the following condition: (Australian Red Cross Blood Service, 2008) (Grade A; Level 3):

- confirmed deficiency of immunoglobulin A
- recurrent severe allergic-type adverse events (fever, generalized urticaria, dyspnea)

It may reduce the incidence of severe recurrent febrile, urticarial and possible anaphylactic transfusion reactions in multi-transfused patients. (Australian Red Cross Blood Service, 2008)

Volume Preparation, Handling, Storage and Transfusion

The volume is usually >130 ml, with hemoglobin \geq 40 g/unit and hematocrit 0.50-0.70. Washed RBC must be transfused within 24 hours after washing. It must be transfused through an intravenous line approved for administration and incorporating a standard (170 to 200um) filter. The time outside required storage conditions prior to commencing transfusion should not exceed 30 minutes. Transfusion of each unit should be completed within four hours of commencing transfusion. (Australian Red Cross Blood Service, 2008) (Grade A; Level 3) Washed red cells can be good up to 28 days at 2-6°C if re-suspended in additive solution. (Australian Red Cross Blood Service, 2008)

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion for first hour
- every 30 minutes during transfusion
- on completion of the transfusion
- four hours after completing the transfusion

each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (WHO, 1997) and 7) subjective complaints of patients. The following should also be record in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers off all products transfused and 5) any adverse effects. (WHO, 1997)

Response to Transfusion

The response to infusion of 1 unit of washed RBC may be lower than the response to PRBC. **In patients who are not actively bleeding, repeat hemoglobin determination may be done 15 minutes after transfusion. (Wiener, 1994) (Grade B; Level 2)**

2.2.4 Leukocytes-reduced Red Cell

Preparation of Leukocyte-reduced Red Cells

Leucocyte-depleted (filtered) red cell is obtained by removing most of the plasma using third generation filter either at blood service facility or patient bedside. The red cells are filtered to remove most leucocytes. **(Australian Red Cross Blood Service, 2008)**

Indications for Leukocyte-reduced Red Cells

In general leukocyte-reduced red cell has similar indication with PRBC but this is given to (Nathan and Oski, 5th Ed) (Grade A; Level 3):

- immunocompromised patients (all premature and acutely ill neonates, patients with congenital deficiency syndromes, patients on chemotherapy, transplant patients) to reduce the risk of CMV and TAGVD
- patients likely to be dependent on long-term red cell support to prevent recurrent febrile non-hemolytic transfusion reactions
- after hematopoietic cell transplantation in patients with severe aplastic anemia to reduce but not totally prevent graft rejection
- fetal/neonatal transfusion

Volume, Handling, Storage and Transfusion

The volume is >200 ml; hemoglobin \geq 40g/unit; hematocrit: 0.05-0.70. Shelf life, storage: 42 days at 2-6°C with the appropriate additives. **Transfuse through an intravenous line approved for administration and incorporating a standard BT filter for centrally prepared leukocyte-reduced RBC. For bedside filtration, the third generation filter serves as the BT set. Transfusion of each unit should be completed within four hours of commencing transfusion. (Australian Red Cross Blood Service, 2008) (Grade A; Level 3)**

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- **before starting the transfusion**
- **as soon as the transfusion is started**
- **every 15 minutes after starting the transfusion for first hour**
- **every 30 minutes during transfusion**
- **on completion of the transfusion**
- **four hours after completing the transfusion**

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (**WHO, 1997**) and 7) subjective complaints of patients. The following should also be recorded in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. (**WHO, 1997**)

2.2.5 Irradiated Blood Components (Red Cells, Platelets, Whole Blood, Granulocytes)

Preparation

Blood components that contain viable lymphocytes may be irradiated to prevent the proliferation of T-lymphocytes, which is the immediate cause of transfusion-associated graft-versus-host-disease. The minimum dose achieved in the irradiation field should be 25Gy, with no part receiving greater than 50Gy. **(Australian Red Cross Blood Service, 2008)**

Indications for Irradiated Blood Components

Irradiated blood products are given to prevent transfusion-associated graft-versus-host-disease (TA-GVHD) and there is general indication for RBC transfusion. (Australian Red Cross Blood Service, 2008) (Standards Committee of AABB) (Grade A; Level 2) They are indicated in:

- recipients of intrauterine transfusion
- neonates who have previously received intrauterine transfusions
- patients with congenital immune deficiencies, hodgkins disease or receiving purine analogue drugs
- recipients of stem cell or bone marrow transplants
- patients with aplastic anemia receiving immunosuppressive therapy
- recipients of directed donations from family members
- recipients of HLA-compatible single donor platelets and granulocyte transfusions

Storage Temperature and Shelf-life

Red cells may be irradiated at any time up to 14 days after collection and thereafter stored for a further 14 days from irradiation. Platelets can be irradiated at any stage in their five day storage and thereafter can be stored up to their normal shelf life of five days after collection. Granulocytes for all

recipients should be irradiated as soon as possible after production and thereafter transfused with minimal delay. **(Australian Red Cross Blood Service, 2008)**

Infusion rate of Irradiated Blood Products

Blood for intrauterine and exchange transfusion should be used within 24 hours of irradiation. Blood for pediatric transfusion should be used within 48 hours of irradiation. (Australian Red Cross Blood Service, 2008) (Grade A; Level 2) Gamma irradiation of red cells increases the rate of efflux of extracellular potassium. Hence, consider the clinical significance of this in determining both the speed and volume of the transfusion and the age of the blood. In general it should follow the rate recommended for the type of irradiated blood product.

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages **(Grade A; Level 3) (WHO, 1997)**:

- **before starting the transfusion**
- **as soon as the transfusion is started**
- **every 15 minutes after starting the transfusion for first hour**
- **every 30 minutes during transfusion**
- **on completion of the transfusion**
- **four hours after completing the transfusion**

At each of these stages, record the following information on the patient's chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output **(WHO, 1997)** and 7) subjective complaints of patients. The following should also be recorded in patient's medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. **(WHO, 1997)**

2.2.6 Random Donor Platelet (RDP)

Preparation

Platelets derived from whole blood within 8 hours of blood donation are called random donor platelet (RDP). It contains $\geq 5.5 \times 10^{10}$ platelets (average content approximately 8.0×10^{10}) per bag in approximately 50 ml of plasma. Anticoagulant is the same as used for whole blood collection.

RDP should be ABO and Rh(D) type compatible with the recipient. However, ABO-incompatible RDP may be used if ABO-incompatible platelets are not available. Platelet concentrates prepared from Rh D positive donors should not be given to a Rh D negative potential child-bearing female. (World Health Organization, 1997) When Rh(D) positive platelets are transfused to an Rh(D) negative female of child bearing potential, prevention of Rh(D) immunization by use of Rh(D) immunoglobulin should be considered. (Australian Red Cross Blood Service, 2008) (Grade A; Level 3)

Indications for RDP

RDP is indicated for patients with the following condition **(Grade A; Level 1)**:

- ongoing massive bleeding to maintain platelet count $>50 \times 10^9$ /L **(BJH, 135)**, if with CNS trauma or bleeding maintain platelet count $>100 \times 10^9$ **(ARC)**
- patients with massive blood transfusion and with platelet count $<20 \times 10^9$
- episodes of hemorrhage or during times of active treatment in chronic, stable, severe thrombocytopenia such as aplastic anemia and myelodysplasia **(JCO, 19)**
- when mucosal bleeding persists in patients with hemolytic disorders **(Haemophilia, 2004)**
- adult patients receiving therapy for acute leukemia at a threshold of 10,000 u/L
- patients with solid tumors receiving aggressive therapy as well as those patients with necrotic tumors to maintain a threshold of 20,000 u/L **(JCO, 19)**
- patients with qualitative platelet dysfunction with bleeding or will be undergoing surgical intervention

Volume and Preparation

Volume 30-50 ml; platelet count > 200 x10⁹/unit; pH (at expiry) 6.4-7.4). **(Australian Red Cross Blood Service, 2008)**

Handling and Storage at Transfusion Area

Platelets must be agitated gently and continuously on a platelet agitator during storage in a single layer. **(Australian Red Cross Blood Service, 2008) (Grade A; Level 3)**

Transfusion Set, Rate and Dose

Transfuse platelets through an intravenous line approved for blood administration and incorporating a clean standard (170-200 um) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours after commencing transfusion. The number of platelet units to be administered depends on the clinical situation of each patient. **(Australian Red Cross Blood Service, 2008)** In neonates it is given at 5-10 ml per kilo and in children it is given at 1 unit per 10 kg. They can also be given as fast as tolerated. **(Grade A; Level 1)**

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages **(Grade A; Level 3) (WHO, 1997)**:

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion for first hour

- **on completion of the transfusion**
- **four hours after completing the transfusion**

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output **(WHO, 1997)** and 7) subjective complaints of patients. The following should also be record in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers off all products transfused and 5) any adverse effects. **(WHO, 1997)**

Post-transfusion Response

To determine the effectiveness of platelet transfusion, a platelet count should be obtained before transfusion, at 1 hour, and at 24 hours after transfusion. (Grade A; Level 2) Generally, expect an adult platelet count increment of approximately 7-10,000/mm³ for each RDP given. **(American Red Cross, 2007)** In neonates and infants, a dose of 5-10 ml/kg of platelet (RDP or SDP should result in a 50-100,000/mm³ increment.

2.2.7 Single Donor Platelet (Platelet Pheresis or SDP)

Preparation

Single donor platelet (SDP) is obtained using automated instrumentation and should contain $\geq 3.0 \times 10^{11}$ platelets (average content approximately $3.5-4.0 \times 10^{11}$) per bag is about 250 ml of plasma. Anticoagulant is ACD. **(American Red Cross, 2007)** SDPs should be ABO-identical with the recipient when possible. **(American Red Cross, 2007)** Platelets may also be “washed” to remove 95%-99% of plasma for recipients who are sensitive to plasma proteins or plasma components. Washed platelets are most commonly used to administer maternal platelets to infants with neonatal alloimmune thrombocytopenia. **(NATP)**

SDP should be ABO and Rh(D) type compatible with the recipient. However, ABO-incompatible SDP may be used if ABO-incompatible platelets are not available. Platelet concentrates prepared from Rh D positive donors should not be given to a Rh D negative potential child-bearing

female. (World Health Organization, 1997) When Rh(D) positive platelets are transfused to an Rh(D) negative female of child bearing potential, prevention of Rh(D) immunization by use of Rh(D) immunoglobulin should be considered. (Australian Red Cross Blood Service, 2008) (Grade A; Level 3)

Indications

Indication for SDP is the same as random donor. But in general SDP should be recommended to older children and adult patients as much as possible, especially those on repeated platelet transfusions. (American Red Cross) (Grade A; Level 3)

Volume

Single donor unit in a volume of 250-300 ml of plasma should contain; 1) at least 55×10^9 platelets, 2) 1.2×10^9 red cells and 3) $<0.12 \times 10^9$ leucocytes. (World Health Organization, 1997)

Handling and Storage at Transfusion Area

It can be stored at 20°C - 24°C (with agitation) for up to 5 days in specialized platelet packs. Longer storage increases the risk of bacterial proliferation and septicemia in the recipient.

SDP should be infused as soon as possible generally within 4 hours. It must not be refrigerated before infusion as this reduces platelet function. (World Health Organization, 1997) (Grade A; Level 3)

Infusion Set, Rate

SDP units should be infused through a fresh standard blood administration set. SDP should be infused over 2-3 hours to a maximum of 4 hours. (World Health Organization, 1997) (Grade A; Level 3)

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion for first hour
- every 30 minutes during transfusion
- on completion of the transfusion
- four hours after completing the transfusion

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (WHO, 1997) and 7) subjective complaints of patients. The following should also be recorded in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. (WHO, 1997)

Post-transfusion Response

To determine the effectiveness of platelet transfusion, a platelet count should be obtained before transfusion, at 1 hour, and at 24 hours after transfusion. (Grade A; Level 2) Generally, expect an adult platelet count increment of approximately 30-60,000/mm³ for each SDP given. (American Red Cross, 2007) To be specific, one unit of platelet concentrate/10 kg body weight in a 60-70 kg adult, 4-6 single donor units containing at least 240 x 10⁹ platelets should raise the platelet count by 20-40 x 10⁹/L. (World Health Organization, 1997) In neonates and infants, a dose of 5-10 ml/kg of platelet (RDP or SDP) should result in a 50-100,000/mm³ increment.

2.2.8 Fresh Frozen Plasma (FFP)

Preparation

Plasma consists of the non-cellular portion of blood that is separated and frozen after donation. It may be prepared from whole blood or collected by apheresis. This is separated from whole blood and frozen at -25°C or colder within 6–8 hours of donation in order to preserve its labile coagulation factors (Factors V and VIII). **(WHO, 2005)**

FFP is frozen at -18°C or colder within 6-8 hour of collection and contains functional quantities of all coagulation factors. Plasma frozen within 24 hours (FP24) and thawed plasma may contain variably reduced levels of Factor V and factor VIII. Despite the differences between FP24, thawed plasma and FFP, they are generally used for the same indications. **(American Red Cross, 2007)**

Plasma for transfusion must be ABO-compatible with the recipients red cells. (Grade A; Level 1)

Indications for FFP Transfusion

FFP is indicated for (BSH, 126) (Grade A; Level 1):

- **multiple coagulation factor deficiencies associated with severe bleeding or disseminated intravascular coagulation with bleeding**
- **single coagulation factor deficiencies when no virus-safe fractionated product is available**
- **bleeding due to hemorrhagic disease of the newborn, neonates with coagulopathy who are bleeding or about to undergo an invasive procedure**
- **for neonatal exchange transfusion AB or type specific FFP may be used to reconstitute maternal blood type specific PRBC (AABB) (Grade A; Level 2)**
- **severe bleeding due to warfarin or patients taking warfarin who will undergo emergency surgical procedure (Grade A; Level 3)**
- **special situation like open heart surgery with more than 6 units PRBC transfused (reference?) (Grade A; Level 3)**
- **they can also be given for trauma casualties with 30% or more blood loss and who will be requiring massive transfusion (Grade A; Level 3)**

Massive transfusion protocols involve the administration of red cells and plasma initially, then adding platelet units or cryoprecipitate later. The purpose is to prevent coagulopathy rather than wait for coagulopathy to develop then treat it. Transfusion with more than five units of red cells together with crystalloid inevitably leads to dilutional coagulopathy as shown in some modeling studies. The benefits of administering blood products in the absence of laboratory tests usually outweigh the risks of transfusion in trauma patient in hemorrhagic shock and with ongoing bleeding. (www.itaccs.com **Section III Transfusion. Clinical Practice**)

FFP should NOT be used for the reversal of warfarin anticoagulation in the absence of severe bleeding. (BSH, 126) (Grade A; Level 3)

When used to correct isolated coagulation factor deficiencies like hemophilia A, B or C for which no concentrated preparation is available (eg factor V or XI) or hemophilia the type of which is not yet determined. The dosing depends on the half-life of the specific factor, the pretransfusion level of the factor, the desired post transfusion level and the duration of raised levels required. (**American Red Cross, 2007**)

Volume

The volume of the unit is approximately 250 ml but variation may be expected. (**American Red Cross, 2007**) The volume may vary from 180 to 300 ml.

Handling and Storage at Transfusion Area

Prior to transfusion, frozen plasma must be thawed in a protective plastic overwrap and dipped in a water bath at 37°C or plasma thawer. It should be infused immediately or stored at 1-6°C for up to 6 hours. (American Red Cross, 2007) If Factor VIII replacement is not necessary, thawed FFP may be stored at 4°C in a blood storage refrigerator as long as transfusion will be completed within 24 hours of thawing. (BSH, 126) (Grade A; Level 3)

Transfusion Dose and Rate

Plasma should be administered in doses calculated to achieve a minimum of 30% of plasma factor concentration and is usually achieved with the administration of 10-20 ml/kg. (Grade A; Level 2) The dose of plasma is determined by the patient size and clinical condition. (American Red Cross, 2007)

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion for first hour
- every 30 minutes during transfusion
- on completion of the transfusion
- four hours after completing the transfusion

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (WHO, 1997) and 7) subjective complaints of patients. The following should also be recorded in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. (WHO, 1997)

Measuring Response to FFP Transfusion

If FFP was given because of bleeding, the clinical response is the best indication of effectiveness of transfusion. If FFP was given to correct abnormal coagulation parameters, the degree of correction should be documented. Monitoring may be through measuring coagulation activities by traditional laboratory techniques. (British Committee for Standards in Haematology, Blood Transfusion Task Force, 2004) (Grade A; Level 1) A prothrombin time (PT) greater than 1.5 times the mid-range of normal, an activated partial thromboplastin time (APTT) greater than 1.5 times the top of the normal

range or a factor assay less than 25% can be used as thresholds at which therapeutic or prophylactic replacement may be indicated in an appropriate clinical setting. **(American Red Cross, 2007)**

2.2.9 Cryoprecipitate

Preparation

Also referred to as cryoprecipitate pool, cryo, pooled cryo, it is prepared by thawing one unit of FFP between 1-6°C and recovering the cold insoluble precipitate. The cryoprecipitate is refrozen within 1 hour. Cryoprecipitate contains concentrated levels of fibrinogen, Factor VIII:C, Factor VIII:vWF (von Willebrand factor), Factor XIII and fibronectin. Each unit of Cryoprecipitate should contain at least 80 IU Factor VIII:C and 150 mg fibrinogen in 5-20 ml of plasma. **(American Red Cross, 2007)** The cryoprecipitate specifications requires that 75% of the packs contain at least 140 mg of fibrinogen and 70 IU/ml of FV III. **(BCSH, 2004)**

Cryoprecipitate is considered to be acellular blood component and that compatibility testing is unnecessary. However it is preferable to use cryoprecipitate that is ABO-compatible with the recipient's red cells. RH type need not be considered. (American Red Cross, 2007) (Grade A; Level 3)

Indications

Cryoprecipitate may be considered in patients with:

- **fibrinogen deficiency where there is clinical bleeding, an invasive procedure, trauma (NHMRC, 2001) (American Society of Anesthesia, 1996) (Grade A; Level 2)**
- **DIC with bleeding (British, 2004) (Grade A; Level 3)**

The use of crypprecipate is NOT generally considered appropriate in the treatment of hemophilia, von Willebrand's disease or deficiencies of factor XIII or fibronectin, unless alternative therapies are unavailable. **(NHMRC, 2001) Cryoprecipitate can be used in Von Willebrand disease when other treatment modalities are not available or have failed. (BSH, 126) (Grade A; Level 3)**

Volume

Volume prepared ranges from 20-40 ml. **(BSH, 126)** The cryoprecipitate specifications requires that 75% of the packs contain at least 140 mg of fibrinogen and 70 IU/ml of FV III. **(BCSH, 2004)** **The dose depends on the clinical situation and its monitoring. (Grade A; Level 3)**

Handling and Storage at Transfusion Area

Frozen cryoprecipitate is thawed in a protective plastic overwrap in a waterbath at 30-37°C up to 15 minutes. Thawed cryoprecipitate should be kept at room temperature and transfused as soon as possible after thawing or within 6 hours if it is a closed single unit or has been pooled prior to freezing. **(Grade A; Level 3)**

Dosing, Transfusion set and Transfusion Rate

Cryoprecipitate must be given using transfusion set designed for the procedure. The frequency of dosing depends on the half life and recovery of the coagulation factor that is being replaced. A typical dose for the treatment of hypofibrinogenemia is one cryoprecipitate unit per 7-10 kg of body weight. It is given as a fast drip. **(American Red Cross, 2007) (Grade A; Level 2)**

The number of cryoprecipitate units can be estimated by using the following calculations:

- $\text{Weight (KG)} \times 70 \text{ ml/kg} = \text{blood volume (ml)}$
- $\text{Blood volume (ml)} \times (1.0 - \text{hematocrit}) = \text{plasma volume (ml)}$
- $\text{Fibrinogen required (mg)} = (\text{desired fibrinogen level, mg/dl}) - \text{initial fibrinogen level (mg/dl)}$ multiplied by plasma volume in ml divided by 100.
- $\text{Bags of cryo required} = \text{mg fibrinogen required} \div 250 \text{ mg fibrinogen per bag of cryoprecipitate. (American Red Cross, 2007)}$

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages **(Grade A; Level 3) (WHO, 1997):**

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion
- on completion of the transfusion
- four hours after completing the transfusion

At each of these stages, record the following information on the patients chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output **(WHO, 1997)** and 7) subjective complaints of patients. The following should also be recorded in patients medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. **(WHO, 1997)**

2.2.10 Cryosupernate

Preparation

Cryo-poor plasma or cryosupernate is the supernate plasma removed during the preparation of cryoprecipitate. **(BCSH, 2004)** It contains most clotting factors in similar amounts to apheresis FFP but is deficient in Factor VIII, fibrinogen, VWF (the high molecular weight multimers are more thoroughly removed than the smaller multimers), factor XIII and fibronectin. **(Australian Red Cross Blood Service, 2008)**

Compatibility tests before transfusion are not necessary but the unit should be ABO group compatible with the recipient's red cells. (Grade A; Level 3)

Indications

Cryosupernate is indicated for (Grade A; Level 2):

- Plasma exchange in TTP

- alternative to FFP for the treatment of coagulopathy where there is no significant reduction in Factor VIII, fibrinogen, factor XIII or VWF
- rapid temporary warfarin reversal in patients requiring emergency surgery
- warfarin overdose with life threatening bleeding in addition to prothrombin complex concentrates

Volume

The volume of 1 unit is 200 ml \pm 10% and can be stored for 12 months at -25°C or colder. **(Australian Red Cross Blood Service, 2008)**

Handling and Storage at Transfusion Area

Thawed plasma and cryosupernatant should be transfused immediately. Keep at 4°C if there is any delay in transfusion. After thawing, and when FV III replacement is not required it may be stored at 4°C in an approved blood storage refrigerator before administration to the patient so long as the infusion is completed within 24 hours of thawing. **(BCSH, 2004) (BSH, 126) (Grade A; Level 2)**

Transfusion, Infusion Set and Rate

Once thawed, it should be infused immediately or allocated by a medical practitioner for a designated patient under his or her care. Before transfusion, mix thoroughly by inversion before and transfuse through an intravenous line approved for blood administration and incorporating a standard (170-200um) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within four hours of commencing transfusion. **(Australian Red Cross Blood Service, 2008) (Grade A; Level 3)**

Monitoring the Patient

For each unit of blood transfused, monitor the patient at the following stages (Grade A; Level 3) (WHO, 1997):

- before starting the transfusion
- as soon as the transfusion is started
- every 15 minutes after starting the transfusion
- on completion of the transfusion
- four hours after completing the transfusion

At each of these stages, record the following information on the patient's chart: 1) patient general appearance, 2) temperature, 3) pulse rate, 4) blood pressure, 5) respiratory rate and 6) fluid balance of oral and IV fluid intake and urine output (WHO, 1997) and 7) subjective complaints of patients. The following should also be recorded in patient's medical chart: 1) time the transfusion is started, 2) time the transfusion is completed, 3) volume and type of all products transfused, 4) unique donation numbers of all products transfused and 5) any adverse effects. (WHO, 1997)

Section 2.3

General Guidelines for Appropriate Blood Administration

2.3.1 Recommendations on Informed Consent

The physician in charge of the patient should be responsible for obtaining informed consent for RBC or plasma administration and the patient's consent should be obtained and recorded in the medical chart. (Grade A; Level 3) (Report of the Expert Working Group 1997) (ANZSBT, 2004) An informed consent for the administration of blood or blood products signifies that the significant risks,

benefits and alternative to transfusion including patients right to refuse the transfusion has been discussed. **(ANZSBT, 2004)** Even before admission to a hospital, patients should be informed that transfusion of RBC, plasma or both is a possible element of the planned medical or surgical intervention and provided with information about its risks, benefits and available alternatives.

2.3.2 Recommendations on Pre-transfusion Procedures

A formal request for pre-transfusion testing (cross-matching) or issuance of blood products must be made and may either be handwritten or in an electronic form using the prescribed format of NVBSP. (Grade A; Level 3) The request form must clearly and legibly identify the patient and the following information must be provided: family name, given name in full, unique hospital record number and/or date of birth, gender and signature and contact details of the sample collector. Requests for the release or issuance of blood and/or blood products must be made in person by a nurse, nurse aide and other health care provider presenting at the laboratory or other acceptable means as stated in hospitals policies. **(ANZSBT, 2007)**

The laboratory must have record system in place to trace every blood or blood products from the requesting unit to its final recipient. (Grade A; Level 3) Blood samples for pre-transfusion testing must be in adequate amount. The sample tube(s) used for collection must be legibly labelled with the ff: 1) patients family name, first name in full and hospital record number or date of birth, 2) date and time of collection and 3) signature or initials of the collector. The patient's identity must be positively confirmed at the time of sample collection by: 1) direct questioning and 2) checking (where available) the patient's hospital identification wristband. Patients who cannot be identified must not be extracted with blood. If the patient is unconscious or cannot be identified, the hospital must have a written policy for temporarily identifying them. **(ANZSBT, 2007)**

2.3.3 Recommendations on Laboratory Pre-transfusion Testing

An ABO and Rh (D) group must be determined for samples submitted for pre-transfusion testing. **The ABO group must be determined by testing recipients red cells with anti-A and anti-B (anti-A, -B, if desired) reagent. A reverse group (of the recipient's serum/plasma tested against A1 and B red cells) must be performed. The Rh(D) group must be determined by direct agglutination using an anti-D reagent. (Grade A; Level 2) (ANZSBT, 2007)**

Pre-transfusion testing must include an antibody screen capable of detecting potentially clinically significant red cell antibodies: indirect anti-globulin test [IAT] performed at 37°C (2) anti-A and –B and –A, B must always be regarded as clinically significant. The antibody screen must be capable of detecting anti-D at a concentration of 0.1 IU/ml or lower. **(ANZSBT, 2007)**

The laboratory must have procedures in place to exclude incompatibility between the recipient and donor using suitable cross-matching techniques such as immediate-spin, IAT or computer cross-matching. The cross-matching procedures must be able to detect ABO incompatibility. A cross-match is initially valid for the lifetime of the sample blood. Once transfusion has commenced, the cross-match will cease to be valid either at the original expiry date/time of the sample or 72 hours from starting transfusion of the unit of red cells, whichever eventuates first. Once a transfusion episode has commenced, subsequent sample from the patient will have an expiry of 72 hours until a gap of three months between transfusions has occurred.

Sample Storage

Samples from patients to whom blood has been transfused should be retained for at least 3-7 days post-transfusion for the purpose of investigation of reported transfusion reactions. (Grade A; Level 3)

Recommendations for Sample Storage

	EDTA whole blood	Separated plasma/serum
18-25°C	Up to 48 hrs	Up to 48 hrs
4°C	Up to 7 days	Up to 7 days
-20°C	N/A	Up to 1 month

2.3.4 Pre-transfusion Procedures in Emergency Situation

In cases of emergency need for a transfusion, pre-transfusion samples should be obtained as soon as possible. Samples must be labeled in accordance with routine pre-transfusion practice and standard pre-transfusion testing performed. If the antibody screen is positive or a subsequent cross-match incompatible, the treating medical officer and the laboratory director must be informed. **If blood is required urgently and there is incompatibility with available blood inform the physician that there may be a delay in the release of compatible blood. (Grade A; Level 3)**

Where blood products are required before pre-transfusion testing can be performed or until an identified compatible blood has been obtained: 1) red cell product to be given must be group O and 2) plasma product to be given should be group AB. (Grade A; Level 2) (ANZSBT, 2007)

If ABO non-identical red cell product was transfused, a return to red cells of the same group as the patient should be done as soon as possible. It is recommended that absence of anti-A or anti-B be confirmed prior to reverting to the patients confirmed blood group. (Grade A; Level 2) (ANZSBT, 2007)

Red cells must NOT be given based prior knowledge of blood group. (Grade A; Level 2) (ANZSBT, 2007)

Red cells issued prior to pre-transfusion testing being completed must be clearly labeled; e.g. 'uncrossmatched blood' or 'emergency issue – compatibility testing not completed'. A waiver may be obtained by the blood service facility personnel before issuing blood prior to completion of pre-transfusion testing. (Grade A; Level 2)

In a massive transfusion event, where the patient has received red cells of their own ABO group, further red cells can be issued without a serologic cross match. ABO incompatibility must still be excluded through appropriate serological confirmation of the blood groups of both patient and selected red cell units.

2.3.5 Recommendations for Pick-up and Delivery Procedures

Before releasing the blood product, the hospital blood bank staff should check the expiry date and inspect blood and blood components before the release of the blood request with particular attention to (BCSH, 1999) (Grade A; Level 3):

- **checking for leaks at the ports and the seams**
- **evidence of hemolysis in the plasma or at the interface between red cells and plasma**
- **evidence of unusual discoloration or turbidity and the presence of large clots**

When blood is issued from the blood bank, the time of issue must always be recorded. To avoid wastage, only one unit of red cells should be taken from the blood bank refrigerator at a time, unless rapid transfusion of large quantities of blood is required. (WHO, 2005) (Grade A; Level 3)

Blood must be transported in containers designated for this purpose and which have been verified as satisfactory for transport and time of storage. (BCSH, 1999) (Grade A; Level 3)

2.3.6 Preparation of Supplies for Blood Component Administration

Transfusion Set

Blood or components must be administered safely through a peripheral or central venous access device. Peripheral Intravenous access should be sufficient to maintain an adequate rate for the transfusion without causing a risk of hemolysis. The size of cannula chosen depends on the size and integrity of the vein. **Blood components particularly red cells and whole blood should be mixed thoroughly by gentle inversion before use and then transfused through an intravenous line approved for blood administration incorporating a standard 170-200 micron filter. A peripheral vein cannula 18-20G size is recommended for adults while 22-24Gg or larger is recommended for pediatric patients. (Grade A; Level 2)** Smaller gauge devices can be used but restrict the flow rate of the transfusion and result in a much longer time to infuse a component. When blood is being administered by syringe to small infants or neonates, the blood should be drawn into the syringe via a 170-200 micron filter. (ANZSBT, 2004)

A new transfusion set should be used for every new unit of blood product. In an emergency or operating room procedure where several units may be administered in a short time, the transfusion set should be changed every 6 hours. A transfusion set used for red cells should NOT be re-used for platelet transfusion since red cell debris trapped in the filter would trap the platelets. (ANZSBT, 2004) (Grade A; Level 3)

Intravenous Fluids

The standard set to be used in a blood transfusion should be primed with normal saline (0.9 NSS) or the blood component. Dextrose containing solutions should not be used for priming the blood transfusion set. The only fluids that can be given concurrently through the same IV device as a red cell transfusion are: (1) normal saline; (2) 4% albumin; (3) plasma protein fractions; or (4) ABO-compatible plasma. Electrolyte and colloid solutions containing calcium or 5% dextrose should NOT be given with blood components. (ANZSBT, 2004) (Grade A; Level 2) Blood transfusion sets should not be 'piggy-backed' into other lines. Similarly, medication should not be added to any blood component prior to its transfusion.

General Blood Transfusion Rates

Unless otherwise indicated by the patient's clinical condition, the rate should be no greater than 5ml/minute for the first 15 minutes. All blood components should be infused within 4 hours unless otherwise specified. (ANZSBT, 2004) (Grade A; Level 3)

Blood Warming Indications and Devices

Red cells should only be warmed using a specifically designed commercial device with a visible thermometer and audible warning. Blood warming devices should undergo at least a 12 monthly maintenance and validation program. (Grade A; Level 3) A blood warmer is indicated when:

- at flow rates of > 50 mg/kg/hour in adults
- at flow rates of 15 mg/kg/hour in children
- for exchange transfusion in infants
- when transfusing patients with clinically significant cold agglutinins

Operating temperature of the commercial blood warmer shall be recorded on the patient's infusion record when used to warm red cells or blood components. Blood and blood components shall not be warmed above 41⁰C. **(ANZSBT, 2004)**

Use of Pressure Devices

External pressure devices approved for transfusion should only be used in an emergency situation and with a large gauge venous access needle. An external device should:

- exert pressure evenly over the entire bag
- have a gauge to measure the pressure

- never exceed 300 mm Hg of pressure
- be monitored at all times when in use
- used with a 170-200 micron filter for RBC product transfusion

Improvised mechanical devices are NOT recommended. (ANZSBT, 2004) (Grade A; Level 2)

Electronic volumetric pumps at specified flow rates are indicated in the following situations: 1) transfusion of patients via a central venous catheter (including PICC and implanted ports) where 'free flow' cannot be guaranteed, 2) transfusion to small pediatric patients where very slow rates are required and 3) only those pumps shown by their manufacturers to be "safe" for blood components. Both pump setting and volume delivered should be monitored hourly to ensure that expected volume is delivered. The attending physician must be informed of any adverse outcome as a result of using a pump. **(ANZSBT, 2004)**

Syringe drivers are devices in which a standard syringe is placed on a housing that depresses the plunger at a given rate. The device is useful for transfusion to neonates and/or for continuous infusion of coagulation factors such as factor VIII or factor IX. Syringes used for transfusing blood components should:

- incorporate an in-line filter 170-200 micron
- be single used only and discarded appropriately
- have leur-lock connections
- have a label attached showing date and time of preparation and expiry date and time
- have identical donor/patient information as the original pack from which the component was drawn. **(ANZSBT, 2004)**

2.3.7 Procedure of Patient Identification

Bedside check is a vital step in preventing transfusion error and staff must be vigilant in checking the patients identification details match those on the blood transfusion prescription or report form and the compatibility label attached to the blood pack. **At least two member of staff, at least one must be a doctor or a registered nurse, should be responsible for carrying out identify check of the patient and the unit of blood at the patients' bedside. (BCSH, 1999) (Grade A; Level 3)** A blood transfusion compatibility report form and/or the blood transfusion prescription sheet must be signed by the member of the staff carrying out the identify check and the date and time of the commencement of the transfusion of each unit of blood or blood component indicated on both.

2.3.8 Recommendations on Pre-medication

The use of acetaminophen or diphenhydramine as pre-medications for patients scheduled for blood administration is NOT recommended. (Grade A; Level 2) Risks associated with the use of acetaminophen may include hepatotoxicity which is a product of acetaminophen's primary metabolites, N-acetyl-p-quinoneimine. Risks associated with the use of diphenhydramine are related to its anticholinergic and antihistaminic effects and may include drowsiness, decreased alertness, impaired cognitive performance, paradoxical restlessness and nervousness and cardiotoxicity and arrhythmias. **(Geiger, 2007)**

2.3.9 Recommendations to Minimizing Transfusion Risks

Transfusion risk may be minimized by the following strategies (Grade A; Level 3):

- **Careful inspection of the safety of blood product packaging**
- **Close monitoring of patient undergoing transfusion**
- **Use of appropriately stored blood product**

Transfusion risks may be minimized inspect packs of blood or blood product before transfusion. When there is flocculation, discoloration, apparent leaks when put under pressure and other unexpected appearance prior to transfusion, the pack should be rejected. **(BSH, 2004)** Close observation and monitoring of the patient is the best way to minimize transfusion reactions. Thus, transfusion should be given in clinical areas where patients can be readily observed by members of the clinical staff. The start and finish times of the infusion of each unit should be clearly indicated on observation charts. **(BCSH, 1999)** Use of blood products less than 3 days old should be avoided as there is an increased risk of transmission of viral infections from fresh blood which may get inactivated on storage. Reducing the exposure of patient to different donors will also decrease the risk of transfusion transmitted diseases. **(WHO, 1998)**

2.3.10 General Recommendations for Monitoring

A policy for the care and monitoring of patients receiving administration of blood and blood components should be in place and shall clearly define the following:

- **the staff responsible for the care and monitoring of transfused patients**

- **the information to be given to the patient about possible adverse effects of transfusion and the importance of reporting immediately any adverse effects including shivering, rashes, flushing, shortness of breath, pain in extremities or in the loins**
- **the parameters for visual observation of the patients**
- **a clear plan of action to be followed in case of an emergency or transfusion reaction (ANZSBT, 2004) (Grade A; Level 3)**

Vital signs (temperature, pulse and blood pressure) should be measured and recorded at baseline (before the start of each unit of blood or blood components) and the end of each transfusion. Vital signs related to transfusion should be recorded in a sheet separate from routine observation and clearly dated. Temperature and pulse should be measured 15 minutes after the start of each unit of blood or blood component for the first hour, then every 30 minutes until consumed. Transfusion reactions should be considered when there is deterioration in patient's condition especially during the first 15-20 minutes following administration of a blood or blood component unit. Further observations during the transfusion of each unit of blood or blood component are at the discretion of each clinical area and need only be taken should the patient become unwell or show signs of a transfusion reaction. **(BCSH, 1999)**

Specific strategies for monitoring are recommended in the previous discussion for each blood component. **In general, for each unit of blood transfused, monitor the patient at the following stages (WHO, 1997) (Grade A; Level 3):**

- **before starting the transfusion**
- **as soon as the transfusion is started**
- **15 minutes after starting the transfusion then every 15 minutes until consumed for fast-drip transfusions or every 30 minutes until consumed for non-fast drip transfusions**
- **on completion of the transfusion and 6) four hours after completing the transfusion.**

At each of these stages, record the following information on the patients chart (WHO, 1997) (Grade A; Level 3):

- **patient general appearance**
- **temperature**
- **pulse**
- **blood pressure**

- respiratory rate
- fluid balance of oral and IV fluid intake and urine output

The following should be record in patients medical chart (WHO, 1997) (Grade A; Level 3):

- time the transfusion is started
- time the transfusion is completed
- volume and type of all products transfused
- unique donation numbers off all products transfused
- any adverse effects.

In cases of suspected severe reaction to blood transfusion, the transfusion episode should be stopped and urgent medical advice sought. The blood administration set should be changed and venous access maintained using normal saline running slowly to keep the vein open (BCSH, 1999) (Grade A; Level 3)

Management of Transfusion Reactions

The blood bank facility must have written procedures for the identification, management, investigation and reporting of suspected transfusion reactions and other transfusion-related adverse events. (Grade A; Level 2) Suspected serious transfusion reactions should be investigated prior to further transfusion. Patient identification and compatibility labels must be rechecked at bedside. This includes checking the identity of the patient on the request forms, pre- and post-transfusion samples, compatibility labels and the pre-transfusion testing records. A visual inspection of unit and segments for signs of clot, hemolysis or discoloration must also be done. The following should be immediately sent to the laboratory accompanied by a request form given full clinical signs and symptoms of the reaction:

- the remains of the product being transfused at the time of reaction, IV administration set and empty bags from previously transfused products
- EDTA, clotted and other samples, as necessary, collected immediately post-reaction and from the opposite arm to the infusion site

The following laboratory testing should be performed:

- Visual examination of the patient's post-transfusion serum/plasma for haemoglobinaemia/hemolysis
- ABO/Rh(D) typing, antibody screen and DAT on patient's pre and post transfusion samples. [A negative DAT post-transfusion does not exclude a severe hemolytic transfusion reaction]
- Checking the ABO/Rh(D) type of the unit being transfused at the time of the reaction and any previously transfused units where available [for platelets and plasma products a reverse group only is required]
- Checking the ABO/Rh(D) type of the unit being transfused at the time of the reaction and any previously transfused units where available [for platelets and plasma products a reverse group]
- IAT crossmatch of all red cells units given against the patient's pre and post-transfusion samples. **(ANZSBT, 2007)**

Section 2.4

Alternative to Blood Transfusion

2.4.1 Blood Sparing Strategies

Pharmacological Agents for Patients with Bleeding Diathesis

Antifibrinolytic agents such as tranexamic acid and aprotinin are NOT recommended to decrease blood loss in trauma but may reduce the need for RBC transfusion during and after surgery. **(WHO, 1998)** **Desmopressive or topical hemostatics such as fibrin glue or thrombin gels may be considered when excessive bleeding occurs. (ASA, 2006) (Grade A; Level 2)**

Crystalloid/Colloids

Rapid administration of crystalloid solutions through large bore (up to 14 gauge) peripheral cannulae often controls hypovolemia . The use of albumin and non-albumin colloids versus crystalloids for volume replacement is still a subject of debate since studies showed that they are clinically equivalent. (BCSH, 2006) (Grade A; Level 1)

Intravenous replacement fluids are the first-line treatment for hypovolemia which can be life saving and provide some time to control bleeding. Normal saline or balanced salt solutions has a similar concentration of sodium to plasma and are effective as replacement fluids. Dextrose (glucose) solutions do not contain sodium and are poor replacement fluids. Crystalloid replacement fluids should be infused in a volume at least three times the volume lost in order to correct hypovolemia. **(World Health Organization. Blood Transfusion Safety.)** All colloid solutions (albumin, dextrans, gelatins and hydroxyethyl starch solutions) are replacement fluids but are not shown to be superior to crystalloids in resuscitations. Colloid solutions should be infused in a volume equal to the blood volume deficit. Plasma should never be used as a replacement fluid. **Plasma-derived colloids are all prepared from donated blood or plasma and should NOT be used simple as replacement fluids. (Grade A; Level 2)**

Normal saline (sodium chloride 0.9%) and/or balanced salt solutions (Ringer's lactate/Hartmann's solution) can be used for replacement of blood volume and other extracellular fluid losses. Pre-cautions in situations where local edema may aggravate pathology (eg. head injury) and may precipitate volume overload and heart failure. Do not use in patients with established renal failure. Dosage is at least 3 times the blood volume lost.

Gelatins (haemaccel, Gelofusine) can be used for replacement of blood volume. Pre-caution in its use since it may precipitate heart failure, caution in renal insufficiency and do not mix haemaccel with citrated blood because of its high calcium concentration. It is contraindicated among patients with established renal failure.

Dextran 60 and Dextran 70 can be used for replacement of blood volume and prophylaxis of post operative venous thrombosis. Pre-cautions for its use include occurrence of coagulation defect, inhibition of platelet aggregation and some preparations may interfere with compatibility testing of blood. Do not use in patients with pre-existing disorders of hemostasis and coagulation. Dextran 60 should not exceed 50ml/kg body weight in 24 hours while Dextran 70 should not exceed 25 ml/kg body weight in 24 hours. Dextran 40 and Dextran 110 are not recommended as replacement fluids.

Hydroxyethyl starch (Hetastarch or HES) can be used for replacement of blood volume. Precautions include occurrence of coagulation defects and may precipitate volume overload and heart failure. This should not be used in patients with pre-existing disorders of hemostasis and coagulation among patients with established renal failure. Dosage should not exceed 20 ml/kg body weight in 24 hours.

Surgical Strategies to Minimize Need for Blood Transfusion

An anesthesiologist or a surgeon prescribing a transfusion of any blood products should be familiar with the indications for and the benefits and risks from the use of these fractions. Documentations that support the transfusion of any of the blood components should be found in the patient's surgical records. **(Guidelines for Red Blood Cells and Plasma Transfusion for Adults and Children 1997)** Correct anemia and replace depleted iron stores before planned surgery. Use intravenous fluid replacement with crystalloids or colloids in cases of acute blood loss.

Good anesthesia and surgical management are recommended (WHO, 1997) (Grade A; Level 2) including:

- **using the best anesthetic and surgical techniques to minimize blood loss during surgery**
- **stopping anti-coagulants and anti-platelet drugs before planned surgery**
- **minimizing the blood taken for laboratory use**
- **salvaging and reinfusing surgical blood losses**
- **using alternative approaches such as desmopressive, aprotinin or erythropoetin**

Pre-Operative Blood Transfusion

All patients undergoing elective surgery should be assessed pre-operatively to identify and treat anemia medically. **(Group, National Blood Users 1999)** There is no single value of hemoglobin level that justifies or requires transfusion. The patients' clinical situation should also be a factor in the decision. **(Guidelines for Red Blood Cells and Plasma Transfusion for Adults and Children 1997)** Surgical patients with asymptomatic anemia usually do not need transfusion before surgery. **(A Guideline For Transfusion of Red Blood Cells in Surgical Patients 1999)** RBC transfusion should be given to alleviate symptoms, signs or morbidity due to inadequate tissue oxygen delivery. In the setting of acute blood loss, RBC transfusion should not be used to expand vascular volume when the oxygen carrying capacity is adequate. **(Grade A; Level 3)**

Pre-operative identification of high risk patients should be performed and all available pre-operative and peri-operative measures of blood conservation should be undertaken. **(The Society of Thoracic Surgeons Blood Conservation Guidelines Task Force 2007)** For an elective surgery,

discontinuing anticoagulation therapy if clinically feasible should be done. The schedule of elective surgery must be done with sufficient time for the effect of anti-coagulants to dissipate. **(ASA, 2006)** Hemoglobin levels ≤ 7.0 g/dl in patients older than 65 years and patients with chronic cardiovascular or respiratory diseases justifies transfusion **(The Society of Thoracic Surgeons Blood Conservation Guidelines Task Force 2007)** Predonation of autologous blood should be considered a therapeutic option for adolescents and adults undergoing elective surgery in which the likelihood of transfusion is substantial (e.g. 10 % or more) **(Report of the Expert Working Group 1997)** A visual assessment of the surgical field should be jointly conducted by the anesthesiologist and surgeon to determine excessive blood losses and should also include checking suction, surgical sponges, and surgical drains. **(ASA, 2006)** **A blood transfusion is indicated for Hemoglobin levels <6 g/dl. In the event of thrombocytopenia in patients who will undergo an invasive procedure or surgery, platelet transfusion should be done to achieve platelet count of $>50,000/uL$ immediately before surgery. (Perioperative platelet transfusion. Recommendations of the French Health products safety agency 2003) (Grade A; Level 2)**

Maximum Surgical Blood Order Schedule (MSBOS)

MSBOS is a table of elective surgical procedures which lists the number of units of blood routinely crossmatched for each procedure pre-operatively. This schedule is based on a retrospective analysis of actual blood usage associated with the individual surgical procedure and it aims to correlate the amount of blood crossmatched to the amount of blood transfused to monitor the efficiency of the scheme. **(British Committee for Standards in Haematology Blood Transfusion Task Force, 1990)** It is a tool for transfusion services, surgical services and anesthesia to predict blood utilization based on historical experience within an institution. The MSBOS is meant as a guide and should not replace the use of clinical judgment related to individual patient needs.

It is recommended that hospital operating rooms maintain an MSBOS. The data in the MSBOS includes the following (Ontario Regional Blood Coordinating Network) (Grade A; Level 3):

- **list of commonly performed elective surgical procedures**
- **number of red cell units ordered by procedure**
- **number of red cells units transfused by procedure; Additional optional data can include ordering physician and the pre-op hematocrit**

Data can be gathered prospectively or retrospectively and a comparison between the number of units ordered and the number of units transfused by procedure can be made either over a specific timeframe or for a pre-determined number of procedures performed. The introduction of a MSBOS in

an institution will have the following advantages (**British Committee for Standards in Haematology Blood Transfusion Task Force, 1990**):

- reduction in crossmatching work load of the blood transfusion laboratory
- reduction in the level of stress
- more efficient use of blood stocks and a reduction in wastage due to out-dating

The implementation of the MSBOS is directly related to the degree of cooperation and commitment by the surgeons, anesthetists and transfusion service medical directors. Flexibility of the ordering process should be observed to allow for individual clinical judgment related to exceptional cases. (**Ontario Regional Blood Coordinating Network**)

Chapter 3

Recommended Strategies for Implementation

Section 3.1

Identification and Assessment of Strategies for Implementation

The strategy options listed below are analyzed according to the following elements:

- Impact on health outcomes and public health: assessing improvements in the quality, safety and availability of blood and blood products
- Access and fairness: assessing the effects on access to safe blood and blood products and the impact on individuals and groups (e.g. region, gender, ethnic, socioeconomic)
- Cost and value for money: assessing cost-effectiveness and correlation with impact
- Operational capacity: assessing the operational capacity of the institutions involved and their compatibility with the requirements of the new policy

Strategy Option 1 – DOH conduct phased implementation of the DOH AO 8 s 2008, starting in areas with the following criteria; 1) mutual willingness of DOH-CHD and LGUs to share in the provision of resources implement the policy and 2) previous history of a successful voluntary blood donation activity.

- Impact on health outcomes and public health – A phased implementation will cushion the effect of potential shortage of blood component supply. A phased implementation of DOH AO policies accompanied by a good voluntary blood donation program will ensure adequate blood component supply.
- Access and fairness – A phased implementation will allow other hospitals and health facilities to improve their capability to meet the new standards set by the DOH AO 8 s 2008. This will also prevent a possible acute shortage of blood supply in areas where the resources and facilities are minimal.
- Cost and value for money – The readiness of PHIC to provide enhanced reimbursement for appropriate blood transfusion will allow facilities to cushion the impact of their investment for newly acquired facilities on their financial status.
- Operational capacity – The phased implementation is also in line with the current operational capacity of DOH where shortage of personnel and resources limit large scale and simultaneous program implementation.

Strategy Option 2 – PhilHealth uses the following criteria for ensuring the delivery of quality services of its health care providers; 1) rational use of blood or blood products as stated in this clinical practice guideline, 2) evidence that the blood or blood products came from authorized blood service facilities and 3) evidence that the patient or the relative has given consent for blood transfusion.

- Operational capacity – PhilHealth medical evaluators and surveyors in accreditation are trained in terms of implementing specific quality standards. Additional training for them on this clinical practice guideline will improve their technical capacity.
- Impact on health outcomes and public health – PhilHealth reimbursement for blood transfusion to be considered appropriate may be determined by matching the type of blood component given and the disease diagnosis of the patient. Paying for appropriate blood component transfusion and ensuring that the unit came only from a reliable source will improve public health outcomes i.e. appropriate clinical response to patient and decrease in transmission of blood-borne infections.
- Access and fairness - In case of inappropriate blood transfusion, PhilHealth may consider non-payment of professional fees of the attending physician as well as non-reimbursement of benefit. The consent for blood transfusion is photocopied and attached to PhilHealth claim form 2 to ensure that the patient or the relative is fully aware of the consequences of transfusion.
- Cost and value for money – Appropriate use of funds will be promoted with the policy.
- Evidence of compliance to policy – The following are evidence of compliance: 1) attached claim form 2 with complete diagnosis and appropriate blood component given, 2) attached serial number of blood component transfused and 3) attached photocopy of consent for blood transfusion.

Strategy Option 3 – The Philippine National Red Cross and the Department of Health develop a national blood donation program that has the following elements; 1) involvement of both the public and private sector, 2) done on a quarterly basis and 3) efficient use of resources.

- Impact on health outcomes and public health – Voluntary blood donation has been shown to be safer than paid blood sources. This will lead to lower rate of transfusion related infections. Regular frequency of blood donation program will also ensure adequate supply and improve the health outcomes of disease requiring blood component transfusion.
- Access and fairness – A regular supply of blood products from a regularly conducted blood donation program will ensure access to such blood products.
- Cost and value for money – Partnership with both the private and public sector will optimize utilization of available resources. Public money is limited and there are private organizations with enough resources who can contribute to the blood donation program.

- Operational capacity – The Philippine National Red Cross has a significant number of volunteers and members across the country and is capable of regularly conducting a voluntary blood donation program.

Strategy Option 4 – Blood bank facilities and the medical professions that utilize blood components form an organizational alliance that will have the following responsibilities; 1) self-regulation, 2) updating, dissemination and implementation of the clinical practice guidelines, 3) maintaining a registry and monitoring of blood component utilization and associated reactions and 4) advocacy for the voluntary blood donation program.

- Impact on health outcomes and public health – Self-regulation will ensure cooperation among the suppliers and users of blood products. This will ensure better compliance to the clinical practice guideline recommendations and therefore better outcomes for blood transfusion interventions.
- Access and fairness – With self-regulation, the fear of regulators encroaching into the autonomy of clinical practice will be avoided.
- Cost and value for money – Self-regulation will also avoid the high cost of external regulation and monitoring.
- Operational capacity – The operation capacity of such alliance however need to be enhanced.

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