TRANSFUSION PRACTICE GUIDELINES FOR CLINICAL AND LABORATORY PERSONNEL

NATIONAL BLOOD CENTRE
MINISTRY OF HEALTH
MALAYSIA
3rd Edition March 2008
TRANSFUSION PRACTICE GUIDELINES FOR CLINICAL AND LABORATORY PERSONNEL
Foreword by the Director-General of Health, Malaysia

The utilization of blood and blood products is increasingly becoming an important and indispensable component of clinical care especially in the surgically-related fields. In line with the emphasis of the Ministry of Health (MOH) on patient safety, the safety of blood and blood product transfusion is paramount. Ensuring the safety of blood and blood product transfusion will require the concerted and committed efforts of all MOH personnel at all levels, from the procurement of safe blood all the way to the process of transfusion in the ward or elsewhere.

In line with advances in field of blood and blood product transfusion, risks associated with it have shifted from the transmission of infections to deficiencies in the overall process of delivering safe transfusions. In this era of evidence based medicine, the role of practice guidelines is increasingly critical in ensuring the best practices are delineated so that effective implementation can ensue. Evidence-based guidelines act as models of good practice and adhering to them will result in the desired outcomes for our valued patients, i.e. safer health care.

Hospital Transfusion Committees have vital role to play in delivery of safe blood and blood product transfusions especially in assurance of adherence of staff to the guidelines. The culture of monitoring and evaluation of transfusion practices will be given added impetus if these transfusion committees are committed to their mission of ensuring that only best practices are implemented.

I am pleased that 3rd edition of the Transfusion Practice Guidelines for Clinical and Laboratory Staff has materialized, thanks to the untiring efforts of the working Committee comprising experts in the field. This committee has laboured tirelessly to update the best practices delineated in the previous editions and come up with much improved version for use in 2008 and beyond.
The utility of a Guideline can only be realized with proper and judicious implementation and it is my hope that all MOH staff be well versed with it and most importantly, implements the recommendations stated in the guidelines. Only in this way can our blood transfusion services become much safer and thereby contribute to the branding of the Ministry of Health as a provider of safe and effective health care.

TAN SRI DATUK DR HAJI MOHD ISMAIL MERICAN
Director General
Ministry of health
Foreword Chairman of Working Group

Transfusion practice is dynamic. In the last 3 years since the 2nd edition of the Transfusion Practice Guidelines for Clinical and Laboratory Personnel was published new information has become available. This 3rd edition is aimed at updating facts and information and making the necessary changes suggested to enhance and maintain the quality of the transfusion service and the blood supply. As with the second edition, these guidelines represent accepted performance that maybe exceed in practice. The guiding principle of this document is to be helpful rather than restive.

Safe donors and safe donations remain an important issued while emphasis on careful donor screening and laboratory procedures continues to be a major part of ensuring safe blood supply. Greater emphasis should also be made in transfusion process and clinical transfusion medicine.

Blood banks and transfusion service are encouraged to be more rigorous in improving their process and procedures and their internal requirement.

I am especially grateful to all contributions and reviewers of this edition for their assistance. Their comments and suggestion have been valuable and greatly appreciated.

Dato’ Dr Yasmin Ayob
Director
National Blood Centre
Kuala Lumpur
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1.0 INTRODUCTION

The purpose of having a standardized transfusion practice guidelines for clinical and laboratory personnel as well as clinicians is to improve the quality of the blood transfusion service in the country as well as to ensure the safety of donated blood. Standard operating procedures (SOPs), covering all aspects of transfusion practices, should be in place in all hospitals and these SOPs should be comprehensive and should be reviewed regularly.

Special attention should be focused on training and assessment of the competency of nursing and junior medical staff who are directly involved in transfusion practices. Senior staff and clinicians should follow established guidelines for the appropriate use of blood and blood components and should be adequately trained to take responsibility for the prescription of allogeneic blood and blood components. Every effort should be made to avoid transfusion of blood and blood products unless it is absolutely necessary.

The quality of hospital transfusion practice is difficult to measure. It is adversely affected by several factors, including the lack of agreed standards, diversity of staff involved and their training, the lack of national recommendations and the wide variation in systems or practice. Error in bedside transfusion practices have also been shown to be the major cause of morbidity and mortality associated with transfusion. A quality system should be put in place to allow the continuous monitoring of the whole transfusion process, starting from the time the blood is donated by a volunteer donor until the time it is transfused into a patient. The system should allow for the monitoring of prescriptions and all the other documentation to ensure compliance with agreed protocol.

The formation of a hospital transfusion committee is necessary to allow for the monitoring of transfusion practices in the particular hospital. It will also facilitate the input of expert advice on a regular basis. It is recommended that all clinicians and laboratory managers in the hospital to be kept informed of all matters pertaining to transfusion practices in the hospital such as blood ordering schedule; procedures for requesting and transfusing blood and blood products, in elective and emergency situations; bedside and clinical transfusion practices, including the handling and reporting of adverse reactions and documentation of clinical outcomes; and information on the use of blood product and blood components, the dosages, transfusion related risks, storage, administration, contraindications and available alternatives.
2.0 CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.

2. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directives should be respected.

3. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.

4. A profit motive should not be the basis for the establishment and running of a blood service.

5. The donor should be advised of the risks connected with the procedure; the donor’s health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standard.

6. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.

7. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.

8. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality, religion or political beliefs. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.

9. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.

10. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.

11. Donors and recipients should be informed if they have been harmed.

12. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.

13. Genuine clinical need should be the only basis for transfusion therapy.

14. There should be no financial incentive to prescribe a blood transfusion.

15. Blood is a public resource and access should not be restricted.

16. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.

17. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorized to do so should be in compliance with this code of ethics.
Transfusion Practice Guidelines for Clinical and Laboratory Personnel 3rd edition March 2008

2.0 KOD ETIKA BAGI PEMINDAHAN (TRANSFUSI) DAN PENDERMAAN DARAH

1. Pendermaan darah termasuklah pendermaan dari jenis tisu-tisu haematopoietik bagi tujuan transplantasi, di dalam apa jua keadaan mestilah terdiri daripada penderma-penderma sukarela dan tidak berbayar; para penderma juga perlu merasakan diri mereka tidak dipaksa. Setiap penderma adalah perlu menyatakan persetujuan di atas dermaannya samada melibatkan darah atau komponen darah serta urutan-urutan yang berlaku di atas penggunaan darahnnya oleh perkhidmatan transfusi.

2. Para pesakit mestilah dimaklumkan terhadap risiko-risiko yang mungkin dihadapi dan kebaikan-kebaikan yang boleh diwujudkan dengan prosedur yang dijalankan; kesihatan dan keselamatan penderma-penderma mestilah sentiasa dilindungi. Sebarang prosedur yang bersangkutan dalam pemberian bahan-bahan bagi menambahkan lagi kepekatan komponen darah, mestilah mematuhi dan diterima oleh piawaian antarabangsa.


4. Motif yang bersifat keuntungan seharusnya tidak diletakkan sebagai asas dalam mendirikan dan menjayakan sesebuah perkhidmatan darah.

5. Unit-unit darah mestilah dikutip di bawah pengawasan dan tanggungjawab ahli-ahli yang mempunyai kelayakan yang sesuai, pengamal-pengamal perubatan yang berdaftar.

6. Semua perkara yang berkaitan dengan penderma darah biasa atau haemapheresis mestilah diterima oleh piawaian antarabangsa.

7. Penderma seharusnya mengetahui dan memahami risiko-risiko yang akan ditanggung oleh orang lain sekiranya darah yang diberikan telah dijangkiti dan mereka ini secara etikanya bertanggungjawab terhadap penerima tersebut.

8. Penderma darah yang dipilih mestilah berdasarkan pada kedudukan kesihatan yang terbaik dan bukannya ditentukan melalui diskriminasii pada sebarang isu termasuklah jantina, bangsa, pegangan politik atau kepercayaan agama. Malah, tidak seorang pun samada penderma atau penerima berhak untuk mengalakkan agar diskriminasii tersebut diamalkan.


10. Seboleh-bolehnya seseorang pesakit itu hanya menerima komponen-komponen (sel darah merah, plasma atau derivatif plasma) tertentu sahaja, wajar dan dari segi klinikal mampu memberikan keselamatan yang optima.

11. Perawatan transfusi mestilah diletakkan di bawah pengawasan dan pengawalan yang menjadi perkhidmatan antarabangsa.


13. Insentif kewangan hendaklah tidak dijadikan sebagai faktor dalam menentukan kesairan pendermaan darah itu.

14. Dermaan darah itu datangnya dari sumber awam, oleh itu peluang untuk mendapatnya tidak sepatutnya disekat.

15. Sebarang bolehnya seseorang pesakit itu hanya menerima komponen-komponen (sel darah merah, plasma atau derivatif plasma) tertentu sahaja, wajar dan dari segi klinikal mampu memberikan keselamatan yang optima.

16. Pembaziran hendaklah dielakkan bagi menjamin kebajikan dan kepentingan semua pesakit yang berpotensi untuk mendapatkan transfusi darah serta kepada para penderma.

17. Pengalaman sesebuah perkhidmatan transfusi darah samada ianya ditubuhkan diperincat kebangsaan atau badan-badan kesihatan antarabangsa dan lain-lain agensi yang cekap serta menjamin kebajikan dan kepentingan semua pesakit yang berpotensi untuk mendapatkan transfusi darah serta kepada para penderma.

18. Pengalaman sesebuah perkhidmatan transfusi darah samada ianya ditubuhkan diperincat kebangsaan atau badan-badan kesihatan antarabangsa dan lain-lain agensi yang cekap serta menjamin kebajikan dan kepentingan semua pesakit yang berpotensi untuk mendapatkan transfusi darah serta kepada para penderma.
3.0 BLOOD DONATION

Blood donors shall be recruited from suitable healthy individuals that do not have any risk of infection with HIV, HBV, HCV and Syphilis. He or she must also comply with the standard acceptance criteria.

3.1 Donor Criteria

Safe blood comes from safe donors. Blood donation must be on a voluntary non-remunerated basis. Donors must not be coerced into donating their blood. Only donors who are healthy, free of diseases and who do not have a significant medical history shall be allowed to donate blood.

The criteria for donor acceptance are:

(a) Age : between 18 to 65 years.
   (note : Donors at 17 years of age - a written consent from the parents/guardians is compulsory.
   Between age 60 – 65 years: requires a yearly medical check up which includes chest X-Ray, ECG, LFT, Renal Profile, Fasting Serum Lipid, Fasting Blood Sugar and Full Blood Count or produce a letter from a physician certifying that he/she is fit to donate.)

(b) Gender: Male and Female.

(c) Weight : Minimum 45 kg

(d) General appearance: Donors must appear to be in good health.

(e) Donors must not have medical history that could harm themselves or the potential recipient of their blood. These include inherited bleeding disorders, recent illness or consumption of medication.

(f) Blood donors must have a minimum of 5 hours of sleep.

(g) Haemoglobin level must be between 12.5g/dl – 18.0g/dl.

(h) The interval between the last donations of whole blood should not be less than 8 weeks and not less than 2 weeks for plasma or platelet donation.

(i) If a whole blood donor wishes to become an apheresis donor, the donation interval should not be less than 8 weeks and the haemoglobin level is $\geq 12.5$ g/dl.

(j) If an apheresis donor wishes to revert back to whole blood donation he/she must comply with the following criteria :-
   
   - the interval should be more than 2 weeks from the last date of donation
   - the haemoglobin level is $\geq 12.5$g/dl
• loss of red blood cells of more than 100ml during the last apheresis
donation. If more than 100ml, the donor shall be deferred for at least 8
weeks.

(k) Individuals with conditions mentioned in the Guidelines for Donor Deferral
(Appendix 2) are to be deferred from donating their blood temporarily or
permanently as appropriate.

(l) Frequency

i. Whole blood donation – minimum 8 weeks provided
haemoglobin level ≥ 12.5 g/dL (i.e. stable)

Note : If the donor donates regularly every 8 weeks, iron stores should
be estimated at least annually

ii. Apheresis donation - every 2 weeks or maximum of
15 litres/year

3.2 Pre-Donation Questionnaire & Interview

All potential donors should read and understand the self-deferral criteria and pre-
donation questionnaire before donating. Assistance from staff should be rendered to
persons who may not be able to comprehend. All potential blood donors are
interviewed by the blood bank personnel before donation. This is to ensure the
exclusion of persons with high risk behaviors that exposed them to infectious
diseases such as HIV, Hepatitis B, Hepatitis C and Syphilis.

The Blood Bank must ensure that all potential blood donors:

(a) complete the Blood Donor Enrolment Form (Appendix 3), give consent for
blood samples to be taken for testing of viral markers and put down his/her
signature sign in the presence of the interviewer or the interviewer should
verify the signature if the donor had already sign earlier.

(b) have their ABO blood group performed

(c) have their haemoglobin levels determined

(d) have their weight measured

(e) self defer if for some reason they think that their blood is not safe

(f) inform the Blood Bank as soon as possible if they feel that the blood they
donated would cause harm to the recipient. This includes risk behavior or
medical reason such as abdominal pain, on medication, feeling unwell or
develops medical illness after donation. The blood must be removed and
disposed. All information will be kept strictly confidential.

(g) directed blood donation is not recommended except in certain special
circumstances e.g. rare blood groups.

3.3 Blood Collection
Refer to Appendix 1 – (Para 7)

3.4 Donor Deferral
Refer to Appendix 2
4.0 BLOOD COMPONENT PROCESSING

Component production must be in accordance with the principle of Good Manufacturing Practice (GMP). There must be a Standard Operating Procedure (SOP) and/or work instruction to ensure quality, safety and consistency. All personnel must follow these written procedures when performing their task.

4.1 Material

The starting material namely whole blood and apheresis products must meet established criteria before processing.

After collection, blood bags should be stored under appropriate temperature condition and transported to the processing site for component preparation.

For preparation of platelet concentrate, the temperature of the whole blood upon arrival at the component processing area must be within the range of 20°C to 24°C. Therefore it should be monitored and recorded.

4.2 Procedure

The procedure should detail the specification for the components to be prepared. Time limits should be define for the processing of blood components. Beyond this time, the procedure must be validated to ensure the products meet the established specification.

A multiple bag configuration or sterile docking system should be used in accordance with a validated procedure for closed system processing to ensure sterile system.

For any new method or changes in the procedure or material, a proper evaluation study must be carried out prior to implementation.

4.3 Equipment

All equipments such as centrifuge, platelet agitator, freezers, refrigerators as well as cold room and freezer room must be validated and maintained to suit its intended purpose. Maintenance, cleaning and calibrating should also be performed regularly and recorded.

4.4 Labelling

All products must be adequately labelled and the following information should be shown on the label:

- A unique number to ensure traceability
- The date of collection
- The ABO group and Rh
- The name of blood component
- The volume or weight of blood component
- The unique identity number must be maintained for all component derived from the blood bag.
- The date of expiry

Labelling of blood product must be done by two persons one of whom should do the actual labeling while the other does the verification.
4.5 **Storage**

Storage condition should be controlled, monitored and checked, during their shelf life.

Unscreened blood and blood component must be quarantined in a separate storage compartment from those that are screened.

All blood components including those quarantined should be kept at their specified storage temperature as shown in the table below.

The alarm system for refrigerator, freezer, cold room and freezer room should have both alarm signals - low and high alarm temperature and must be regularly tested and recorded. Appropriate action in response to alarms should be defined and documented.

The maximum shelf life of the pooled components must not exceed the expiry date of the oldest constituent component as shown in the table below.

<table>
<thead>
<tr>
<th>Component</th>
<th>Shelf life</th>
<th>Storage temperature</th>
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<tr>
<td>Platelet</td>
<td>5 days</td>
<td>20°C - 24°C</td>
</tr>
<tr>
<td>Red Cells/ Whole Blood</td>
<td>28 – 42 days*</td>
<td>2°C - 6°C</td>
</tr>
<tr>
<td>Fresh Frozen Plasma (FFP)</td>
<td>3 month</td>
<td>(-18°C) - (-25°C)</td>
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<tr>
<td></td>
<td>36 month</td>
<td>&lt; - 25°C</td>
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* Depends on the anticoagulants/ preservative solution used

4.6 **Post-Quarantine Release**

There must be a system in place to ensure that all blood released into stock have been tested negative for Transfusion Transmitted Infection (TTI) as well as comply with defined standard and specification. There should be a system of administrative and physical quarantine for blood and blood component that they cannot be released until all mandatory requirements all met. The process must be carried out by two persons, one of whom should verify the procedure. The process and procedure must be documented to ensure only those components that are safe would be released into stock for use.

4.7 **Quality Control**

Quality control requirement should be defined for each type of blood and blood components produced. The testing should be performed as recommended and the performance must be regularly assessed as in the following table.

<table>
<thead>
<tr>
<th>Blood and Blood Component</th>
<th>Parameter</th>
<th>Quality Requirement (Specification)</th>
<th>Frequency of Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood</td>
<td>a) Volume (450)</td>
<td>450 ml ± 45</td>
<td>1 % of all units with a minimum of 4 units per month</td>
</tr>
<tr>
<td></td>
<td>Volume (350)</td>
<td>350 ml ± 35</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Volume (250)</td>
<td>250 ml ± 25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b) Haemoglobin</td>
<td>&gt; 45 g/unit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c) % Hemolysis</td>
<td>&lt; 0.8 % of red cell mass</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Volume</td>
<td>Haematocrit</td>
<td>Haemoglobin</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Red Cells</td>
<td>228 ml ± 37</td>
<td>0.65 – 0.75</td>
<td>&gt; 45g/unit</td>
</tr>
<tr>
<td>Red Cells, in Additive Solution</td>
<td>340 ± 38</td>
<td>0.5 – 0.7</td>
<td>&gt; 45g/unit</td>
</tr>
<tr>
<td>Filtered Red Cells</td>
<td>To be defined for the system used</td>
<td>60 % ± 10 %</td>
<td>&gt; 40g/unit</td>
</tr>
<tr>
<td>Buffy Coat Poor Red Cells</td>
<td>To be defined for the system used</td>
<td>50 - 70</td>
<td>&gt; 43g/unit</td>
</tr>
<tr>
<td>Platelet Poor Red Cells</td>
<td>355 ml ± 46</td>
<td>60 % ± 10 %</td>
<td>&gt; 43g/unit</td>
</tr>
<tr>
<td>Platelet concentrates</td>
<td>50 ml ± 10</td>
<td>&gt; 60 x 10⁹ / unit</td>
<td>&lt; 0.2 x 10⁹ / unit</td>
</tr>
<tr>
<td>Plateletpheresis</td>
<td>&gt; 40 ml per 60 x 10⁹ platelets</td>
<td>&gt; 200 x 10⁹ / unit</td>
<td>&lt; 1.0 x 10⁹ / unit</td>
</tr>
<tr>
<td>Fresh Frozen Plasma</td>
<td>283 ml ± 50</td>
<td>207 ml ± 51</td>
<td>195 ml ± 20</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>35 ml ± 5</td>
<td>&gt; 70 IU/unit</td>
<td>&gt; 140 mg/ unit</td>
</tr>
</tbody>
</table>

* 90% of the units sampled should fall within the values indicated
### 4.8 Definition

<table>
<thead>
<tr>
<th>Blood Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Whole Blood</strong></td>
<td>Whole blood for transfusion is blood taken from a suitable donor using a pyrogen-free anticoagulant container. The major use of whole blood is as source material for blood component preparation.</td>
</tr>
<tr>
<td><strong>Red Cells</strong></td>
<td>A component derived by removing part of the plasma from whole blood.</td>
</tr>
<tr>
<td><strong>Red Cells, In Additive Solution</strong></td>
<td>A component derived from whole blood by centrifugation and removing plasma with subsequent suspension of the red cell in nutrient additive solution.</td>
</tr>
<tr>
<td><strong>Filtered Red Cells</strong></td>
<td>A component derived by removing most of the leukocytes from a red cell preparation by filtration.</td>
</tr>
<tr>
<td><strong>Buffy Coat Poor Red Cells</strong></td>
<td>A component derived from whole blood by centrifugation and removing plasma and buffy coat with subsequent suspension of the red cell in nutrient additive solution.</td>
</tr>
<tr>
<td><strong>Platelet Poor Red Cells</strong></td>
<td>A component obtained by double centrifugation (soft and hard spin) to remove the plasma and platelet with subsequently addition to the red cells of an appropriate nutrient solution.</td>
</tr>
<tr>
<td><strong>Platelet Concentrates</strong></td>
<td>A component derived from fresh whole blood by centrifugation which contain majority of platelet content in therapeutically effective form.</td>
</tr>
<tr>
<td><strong>Apheresis Platelet</strong></td>
<td>A component obtained by platelet apheresis of a single donor using automated cell separation equipment.</td>
</tr>
<tr>
<td><strong>Fresh Frozen Plasma</strong></td>
<td>A component prepared either from fresh whole blood or from plasma collected by apheresis, frozen at an appropriate temperature to preserve the activity of labile coagulation factors.</td>
</tr>
<tr>
<td><strong>Cryoprecipitate</strong></td>
<td>A component containing the cryoglobulin fraction of plasma obtained by further processing of fresh frozen plasma prepared from hard-spun cell free plasma and concentrated to a final volumes required.</td>
</tr>
<tr>
<td><strong>Cryosupernatant</strong></td>
<td>A component prepared from plasma by removal of cryoprecipitate</td>
</tr>
</tbody>
</table>
Irradiated Red Cells : A component containing red cells that has been irradiated to inactivate lymphocytes to prevent GVHD

Virus Inactivate of Plasma : Plasma that has undergone viral inactivation process such as methylene blue/ultraviolet light to reduce the risk of viral transmission

5.0 INVENTORY MANAGEMENT

5.1 All blood banks must establish the optimal number of blood components of ABO and Rh type that are needed to be kept in their laboratory at all times. This shall then be monitored in their inventory (to ensure adequate supply to patients who may need blood).

5.2 The inventory management must develop policies to foster better management of blood supply. This include the availability of emergency O blood in certain wards, the duration blood is kept in reserve for a patient once it has been crossmatched, blood components request, etc.

5.3 Where the age of the blood is of no importance, a policy of “first in first out policy” should be adopted.

5.4 All hospital blood banks must establish their own MSBOS (Maximum Surgical Blood Ordering Schedule) to suit their local use.

5.5 All blood banks must maintain a reserve of ABO compatible blood and Rh negative blood in case of emergency or unexpected requirement.

5.6 Hospital blood banks must establish a reliable emergency blood delivery system.

5.7 Inventory managers must work closely with donor recruitment or blood suppliers to ensure adequate supply at all times.

5.8 Monitoring system must be established to ensure effective inventory management.

5.9 The optimal number of units of blood and blood component to be kept in the inventory can be established by various methods. One of the ways is to establish empirically as below:

   (a) Collect the weekly usage over a 6 months period.
   (b) Arrange them according to ABO and Rh group
   (c) Total them up and divide by 26. This will give the average of weekly usage
   (d) Smaller hospitals of 150 beds or less can safely keep a 2 week inventory at all times, while a hospital with 150 – 500 beds might want to keep a 1 - week supply. Hospitals of over 500 beds may want to have 2 - 3 days supply in their inventory.
6.0 SCREENING FOR TRANSFUSION TRANSMITTED INFECTION (TTI)

Laboratories responsible for screening donated blood must ensure that proper processes and procedures are in place. Criteria for setting up a laboratory for screening transfusion transmitted infection are outlined in Appendix 4.

Procedure for collection and labeling of blood samples are extremely important. The sample should correspond with the blood bag and error must be avoided.

Personnel must follow all the required procedures to ensure reliable results are released. There must be a system to ensure that the inventory would only have blood that has been screened and found to be non-reactive.

6.1 All donated blood must be screened for:

(a) HIV
(b) Hepatitis C virus
(c) Hepatitis B virus
(d) Syphilis

Screening for other infectious diseases may be carried out if deemed necessary.

6.2 Only validated tests licensed by responsible and reputable regulatory agencies should be used.

6.3 Laboratories are recommended to use WHO algorithms (Appendix 5).

6.4 A plan should be put in place to ensure the following:

(a) All staff involved in screening must receive adequate training. The competency of the personnel should be assessed on a regular basis.
(b) Regular maintenance and calibration of equipments.
(c) Test materials and reagents must be stored in proper conditions and storage facilities must be regularly monitored.

6.5 To ensure quality in screening of donated blood, the following measures should be in place.

(a) Daily internal quality control for both reagents and techniques must be carried out.
(b) Participate in external proficiency exercises.
(c) In the setting up new techniques or using new reagents, confirmations of positive and negative results are necessary. The appropriate microbiological reference laboratory should carry out such confirmation. Panels of known sera, which have been prepared by comparison with standards available, must be included in the validation process.

6.6 Procedures must be in place to handle all reactive samples. These procedures should include:

(a) Repeat testing on segments of the blood bag for all initial reactive samples.
(b) All other screening centres are required to send repeatedly reactive donation samples for Anti-HIV and Anti-HCV to Pusat Darah Negara for confirmation.

(c) All screening centre must perform confirmation test for Hepatitis B.

(d) Disposal of all reactive blood bags.

All blood that has been screened and found reactive must be removed from the stock. All tainted blood bags will be autoclaved by the laboratory staff and subsequently incinerated by the hospital support service.

6.7 Proper documentation of test procedures and records of results such as worksheet and printed results must be available in written form (hard copy). The worksheet should include essential information such as:

- The personnel performing the test
- Date of testing
- Reagent lot number and expiry date
- The personnel verifying the test results
- The sample position
- Random sampling of sample position

6.8 Test result must be verified by authorized personnel before it can be released.

6.9 Any process which involved the change of custody such as personnel who releases and receives the result at any stage should be documented. Similarly the personnel who release the blood bag and the personnel who receive the blood bag for retesting should also be recorded.

6.10 All test results must be kept confidential. There should be a system for limiting access to these data to only authorized personnel and donor status. All records must be retrievable in case of future need.

7.0 DONOR BLOOD GROUPING

7.1 ABO and Rh grouping must be performed on all donated blood.

7.2 ABO grouping should be done by forward grouping using anti-A, anti-B, anti-AB antisera and reverse grouping by using known A1 cell, B cell and O cell.

7.3 It is recommended that Rh D should be tested in duplicate with two IgM monoclonal anti-D blood-grouping reagents, with one which should not detect D\textsuperscript{Vi}. Rh negative donors should be re-typed using a different antisera and phenotyped for C, c, E & e antigens.

7.4 Blood grouping should be carried out by microtiter plate, tube or gel method. 

Tile method MUST NOT be used.

7.5 All unanticipated findings should be investigated.

7.6 Daily internal quality control for both reagents and techniques must be carried out.

7.7 All results must be documented and maintained.

7.8 Rare donor registry must be maintained and regularly updated.
8.0 BLOOD GROUPING FOR PATIENTS, ANTENATAL CASES UNIFORM PERSONNEL, FOREIGN WORKERS, MEDICAL CHECK-UP AND OTHERS

8.1 The objective of determining the blood group of these individuals is for the purpose of transfusion especially in an emergency situation.

8.2 ABO grouping should be done by forward grouping using anti-A, anti-B, anti-AB antisera and reverse grouping by using known A1 cell, B cell, O cell.

8.3 It is recommended that Rh D should be tested in duplicate with two IgM monoclonal anti-D blood-grouping reagents, with one which should not detect DVI. Rh negative donors should be re-typed using a different antisera and phenotyped for C, c, E & e antigens.

8.4 Blood grouping should be carried out by either microtiter plate, tube or gel method. Tile method MUST NOT be used.

8.5 All unanticipated findings should be investigated.

8.6 Daily internal quality control for both reagents and techniques must be carried out.

8.7 All results must be documented and maintained.

8.8 Infant less than 6 month old do not require reverse grouping.

9.0 ORDERING BLOOD FOR TRANSFUSION

The decision to transfused, like any other therapeutic decision should be made based on clinical judgment. The benefit and risk must be assessed, and alternative therapy considered. Blood transfusion is meant to benefit the patient. Nevertheless, it carries with it various risks to the health of the patient including transmission of infectious disease agents (e.g. HIV, Hepatitis, Syphilis) transfusion reactions and even risk of transfusing wrong blood, which may be fatal. Process and procedure should be in place to ensure patient safety.

Most transfusion mishaps are due to human errors that occur when samples are taken from patients or when blood is administered. The practical precautions given in this section are therefore extremely important.

9.1 Consent for transfusion

The patient must give informed consent for transfusion. The clinician in-charge of the patient has a responsibility to explain the benefits, risks and alternatives to transfusion therapy and to ensure that the patient comprehends the issues discussed. Other than in emergency, the patient should be given an opportunity to ask questions, and his/her informed decision be documented. If the patient is unable to give consent, a responsible family member must be asked to do so. If no family member is available or in emergency when the need for transfusion leaves no time for consent, it is prudent to note this in the patient’s medical note. Refer to Appendix 6 for sample of consent form.
9.2 **Patient identification and blood sampling for compatibility testing** (Appendix 7).

The process of taking and labeling blood samples must be done in one process at the bedside, one patient only at any one time.

The doctor performing this must ensure:

(a) The patient is correctly identified. The doctor taking the blood sample must read the wristband, if available, and whenever possible, ask the patient to state his/her full name. This information must be checked against the case notes. The local SOP must be developed and followed.

(b) Unconscious patients MUST be identified by the information given on the identity band, such as the wristband.

(c) An emergency casualty who cannot be reliably identified must be given an identity band with a unique number. This number must be used to identify this patient until full and correct personal details are available.

9.3 **Labeling of sample:**

(a) The person who takes the blood and the person who labeled the blood sample must be the same person.

(b) The sample must be labeled clearly and accurately at patient's bedside immediately after blood taking. Use only hand written label and never use pre printed label for labeling sample. The label should include the patient's full name, hospital registration number or Identity Card (IC) number, date and time of collection and the initial/signature of the person taking the blood.

(c) The doctor’s name and signature and name on the request form also implies that he/she has ensured that the sample has been accurately identified.

(d) Never label 2 or more patient’s samples at the same time.

9.4 **Blood sample requirement for elective surgery or elective transfusion**

Samples should be sent to the Blood Bank in a biohazard-labeled plastic bag during office hours at least 24 hours before the blood is required. The following is the requirement for blood samples sent for pre-transfusion testing:

(a) sample from infant less than 4 months of age
   - infant's blood sample should be accompanied by a sample of the mother's blood
   - 2.5ml blood sample in EDTA / plain tube from the infant and 5 - 10ml blood sample in EDTA / plain tube sample from the mother
   - both samples are to be sent to the Blood Bank using one request form
(b) sample from patient above 4 months of age i.e. children and adult

- 5 - 10ml blood sample in EDTA / plain tube sample accompanied by one request form
- In cases of massive bleeding when many units of blood/components are required, more samples and request forms may be needed.
- If the patient requires repeated transfusions during the current admission, a new blood sample is needed for each request.

9.5 **Blood sample requirement for blood components other than red cells**

(a) Request for blood component other than red cells must be sent with blood sample and request form. Refer para 9.3 and 9.4.

(b) However, if a patient had received a transfusion of blood within the previous 3 months in the same hospital and the procedure was without any complications, a new blood sample need NOT accompany requests for more blood components other than red cells. However a copy or carbon copy of the old request form should be attached to the new request form.

(c) In all other circumstances or if the previous request form is not available, a fresh sample should be sent to the laboratory to determine the patient's blood group.

9.6 **Rejection of samples**

Blood samples sent for pre-transfusion testing should have the suggested minimum requirements. Refer para 9.3 and 9.4.

The blood samples should be rejected if:

(a) The labels are not hand written

(b) Date of collection or initial/signature of the person who took the blood was not written on the label.

(c) The samples are inadequately labeled, insufficient, lysed or in the wrong container.

(d) The request form is inadequately filled such that essential patient information.

(e) There are discrepancies between the information on the sample label and the request form. Exceptions are made only in life threatening situation where these discrepancies are corrected by the treating doctors.

Any deviation from the above should comply with the hospital policy.
9.7 Request forms

Prescribing blood and blood products is the responsibility of the doctor managing the patient. However, the doctor is encouraged to consult the doctor in-charge of the Blood Bank on the products to be given, the quantity, the duration of infusion, the precautions to be taken and any other related matters.

(a) The request form should be completely filled and contain relevant patient information, i.e. name, identity card number, sex, reason for transfusion, blood group (if known), previous transfusion reaction and any other relevant information (Appendix 8).

(b) The hospital registration number (R/N) should be used on the request form for patients who, at the time of admission, cannot be reliably identified. This R/N must be ‘unique’ and any investigations for this patient must be identified using this number. When the patient's full and correct details are available the ward personnel should accurately communicate this information to the Blood Bank.

(c) The quantity and the approximate time when the blood and blood component would be required must be stated. Requests for blood to be made available “as soon as possible” should be avoided as this would not assist the blood bank personnel in determining priorities. The timing of blood required for planned procedures should comply with local SOP and the quantity requested for elective surgical patients should follow local surgical blood ordering schedules.

(C) The request form should be signed by the requesting doctor and his/her name should be stamped or written clearly in block letters.

9.8 Receiving request

Blood bank personnel must ensure that the request form is properly filled and the corresponding samples are correctly labeled before accepting the request.

10.0 PRETRANSFUSION TESTING

The patient's ABO and Rh D groups must be determined by full grouping procedure (forward and reverse methods). Patient's serum is also screened for the presence of any unexpected antibodies to red cells. The patient's serum is then tested directly for compatibility with the red cells of the units of blood to be transfused. Before the blood units are assigned to the patient, the patient’s blood is regrouped to ensure the patients blood group tallies with that of the blood unit assigned. The regrouping (forward blood grouping only) should be performed by a Medical Laboratory Technologist other than the one who performs the cross matching. Compatible units of blood are then labeled specifically for the patient and may be issued or held in the blood bank to be issued later upon request.
10.1 Red Cell (ABO) Grouping

ABO grouping (full grouping procedure: forward and reverse method) must be determined on all requests for blood or blood components. Blood grouping should be carried out by one of the following methods:

- Tube Method
- Gel Method

**Tile method should not be used**

ABO grouping is done by forward grouping using known anti-A, Anti-B, Anti-AB antisera and reverse grouping using known A1 cells, B cells and O cells. Infants less than 4 months old do not require reverse grouping.

All unanticipated findings noted during procedure for ABO grouping must be resolved before selection of blood for cross matching. In a life threatening situation, group O packed red cells may be issued.

10.2 Rh Grouping

Rh D grouping should be carried out for all patients who need transfusions using Monoclonal IgM/IgG blend antisera by one of the following methods:

- Tube method
- Gel method

**Note : Tile method should not be used**

It is recommended that Rh D should be tested in duplicate with two IgM/IgG blend monoclonal anti-D blood-grouping reagents, with one which should not detect D\(^{VI}\).

Rh D negative patients should be phenotyped for C, c, E & e antigens.

All unanticipated findings noted during procedure for Rh grouping should be investigated.

Transfusion of Rh D positive blood to a Rh D negative recipient should proceed only in a life threatening situation after discussion with the doctor in charge of the blood bank. *(Appendix 9)*

10.3 Antibody screening

10.3.1 Techniques used for antibody screening shall be those that are capable of detecting clinically significant red cell antibodies reactive by haemolysis and/or haemagglutination at Room Temperature, and 37°C. These shall include a 37°C incubation phase and an indirect antiglobulin test.

10.3.2 Reagent red cells shall consist of at least two group O red cells, NOT POOLED, and should express the following antigens: C, c, D, E, e, M, N, S, s, K, k, Fy\(^a\), Fy\(^b\), Jk\(^a\), Jk\(^b\). Where possible, one cell should be of the R1R1 phenotype (CDe phenotype) and the other of R2R2 phenotype (cDE phenotype). Additional antigens may be included to reflect the antigenic profile of the local population.
10.4 Antibody identification

10.4.1 If antibody screening test is positive and/or incompatible cross-match detected, antibody identification should be performed using a reagent red cell panel that covers all the significant antigens. It should be able to demonstrate the presence of antibody. Referral to a Reference Laboratory may be necessary for definite identification.

10.4.2 When a clinically significant red cell antibody is identified in a patient's serum, every effort should be made by the transfusion laboratory to provide blood that is negative for the corresponding antigen. This is done to avoid the risk of a haemolytic reaction or amnestic response. This may lead to more samples needed and a considerable delay in provision of compatible blood.

10.4.3 In situations where fully compatible blood is not available and a patient needs transfusion urgently required and it is anticipated that there will be delays in finding truly compatible blood, the doctor in charge of the blood bank should be consulted on the use of the least incompatible blood. The potential risk of adverse reactions must be balanced with the risk of delaying the transfusion.

10.4.4 In patients with autoantibodies reactive at 37°C, additional tests should be performed which allow the detection of coexisting alloantibodies. Further test may be required for patients transfused within the previous three months.

10.5 Group, Screen and Hold Protocol

A Group, Screen and Hold (GSH) protocol consist of an ABO (full grouping procedure: forward and reverse method) and Rh D grouping and an antibody screen on the patient’s serum / plasma. Serum/ plasma is retained for 48 hours in the blood bank in the event that crossmatched blood is required within this period.

In circumstances where the likelihood of blood needed for transfusion, is minimal a GSH protocol is recommended in the first instance. If blood is required following a GSH, cross-matched blood should be available for issue within 20 minutes. A GSH protocol should be used in conjunction with a Maximum Surgical Blood Order Schedule (MSBOS). Every hospital must develop their own MSBOS. A guideline to develop the schedule is given in Appendix 10.

10.6 Crossmatching

10.6.1 The patient's serum is tested directly for compatibility with the red cells of the units of blood to be transfused after ABO and Rh D determination with or without antibody screening. The crossmatching is carried out at room temperature, 37°C and with antihuman globulin (AHG/IAT) phase.

10.6.2 In cases where clinically significant antibodies are present or where there is history of clinically significant antibodies, antigen negative blood should be crossmatched until AHG/IAT phase.

10.6.3 In blood banks that do not have antibody screening and/or identification facility:-
• In the event of incompatible crossmatch in a life-threatening situation, more blood should be crossmatch to find units that are fully compatible.
• In non-urgent situation, sample should be sent to a referral laboratory for antibody identification and supply of compatible blood.

10.6.4 Samples from patient to whom the crossmatched blood is transfused should be retained for at least 7 days post transfusion for the purpose of investigation of any reported transfusion reactions.

10.6.5 Once a transfusion has commenced, new sample is required for further transfusion. Sample should always accompanied by request form. However, if the second crossmatch gives an incompatible result eventhough specific antigen-negative group is given and similar to the previous transfusion, a re-investigation for antibody must be performed.

10.6.6 Units that have been crossmatched but not transfused within 48 hours shall be subjected to pretransfusion testing against a new sample from the patient.

10.6.7 When referring to a reference laboratory, the following must be complied:

(a) Send 10 ml of whole blood in EDTA tubes.
(b) Label the tubes correctly and clearly. Ensure that the same patient's sample tube and request form are attached together
(c) Write complete patient's demographic information
(d) Provide the reference laboratory with patient's clinical history including previous transfusion.
(e) Provide the reference laboratory with initial laboratory findings.
(f) Consult reference laboratory's Specialist/Medical Officer before sending the sample

10.7 Selection of red cells for transfusion

For routine transfusion, packed red cells should be used in preference to whole blood.

Red blood cell products should be of the same ABO and Rh D type as the patient whenever possible.

If the antibody screen is positive:

i) The presenting clinically significant antibody or antibodies have to be identified through antibody identification test. Once the antibody is identified, blood should be selected which is negative for the relevant antigen. Where possible antigen typing should be confirmed by the laboratory performing the compatibility testing.

ii) If the patient has a history of clinically significant red cell antibody, even though it cannot be detected in the current antibody testing, negative antigen blood should be selected according to the relevant antibody. This is to avoid amnestic response. Where possible, antigen typing should be done to verify previous result.
iii) When transfusion is unavoidable, serologically least incompatible blood may be given after consultation between the doctor managing the patient and the Transfusion Specialist/Haematologist.

iv) For patients with antibodies to A1, P1, Le\textsuperscript{b}, M or N reactive at room temperature but not at 37°C, the blood selected need not be antigen negative.

v) In newly diagnosed thalassemia patient or anticipated multiply transfused patient, full antigen phenotyping is necessary before commencing any transfusion.

vi) When transfusing patient that have cold agglutinin antibody, the following should be carried out:

a) Warm the blood at room temperature for 15-20 mins
b) Pre-warm patient for 20 minutes (e.g: blanket)
c) Transfuse the blood slowly
d) Observed the patient during transfusion
e) Stop transfusion immediately if patient develop transfusion reaction

### Selection Of Suitable Red Cell Units For Transfusion In The Presence Of Antibodies

<table>
<thead>
<tr>
<th>Specificity</th>
<th>Clinical significance</th>
<th>Selection of units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rh antibodies</td>
<td>Yes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>Kidd antibodies</td>
<td>Yes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>Duffy antibodies</td>
<td>Yes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>Kell antibodies</td>
<td>Yes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>Anti-S, -s</td>
<td>Yes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>Anti- A1, -P1, -N</td>
<td>Rarely</td>
<td>Red cells compatible by AHG at 37°C</td>
</tr>
<tr>
<td>Anti-M</td>
<td>Rarely</td>
<td>Red cells compatible by AHG at 37°C</td>
</tr>
<tr>
<td>Anti-M reactive at 37°C</td>
<td>Sometimes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>Anti-Le\textsuperscript{a}, - Le\textsuperscript{a-b} Anti-Le\textsuperscript{b}</td>
<td>Rarely</td>
<td>Red cells compatible by AHG at 37°C</td>
</tr>
<tr>
<td>Anti-Le\textsuperscript{a}, - Le\textsuperscript{a-b} Anti-Le\textsuperscript{b} reactive at 37°C</td>
<td>Sometimes</td>
<td>Antigen negative</td>
</tr>
<tr>
<td>High titre low-avidity antibodies</td>
<td>Unlikely</td>
<td>Seek advice from Reference Laboratory</td>
</tr>
<tr>
<td>Antibodies against low/ high frequency antigens</td>
<td>Depends on specificity</td>
<td>Seek advice from Reference Laboratory</td>
</tr>
</tbody>
</table>
10.8 Selection of non red cell products

(a) Recommended ABO group for plasma products (FFP, cryoprecipitate and cryosupernatant)

<table>
<thead>
<tr>
<th>Patients ABO blood group</th>
<th>ABO group of plasma to issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown (request sample for baseline grouping)</td>
<td>Issue AB if urgent</td>
</tr>
<tr>
<td>O</td>
<td>O or A or B or AB</td>
</tr>
<tr>
<td>A</td>
<td>A or AB</td>
</tr>
<tr>
<td>B</td>
<td>B or AB</td>
</tr>
<tr>
<td>AB</td>
<td>AB (A or B if AB unobtainable)</td>
</tr>
</tbody>
</table>

(b) Platelet concentrates in order of preference should be:

i. patient’s own ABO group
ii. ABO antigen compatible (but plasma incompatible)
iii. ABO antigen incompatible

10.9 Pretransfusion testing in newborn less than 4 months of age

10.9.1 Samples from mother and neonates should be obtained and the ABO and Rh D groups determined. The baby’s ABO group is determined from the red cells alone (forward grouping) since the corresponding antibodies will be weak or absent in the serum.

a) The maternal serum should be screened for the presence of atypical antibodies.
b) Direct antiglobulin test (DAT) must be performed on the neonate’s red cells.

10.9.2 If the maternal blood is unavailable the neonatal serum/plasma sample should be screened to exclude atypical antibodies. The serum may contain passively transferred maternal antibodies.

10.9.3 If the antibody screen and /or DAT is positive, serological investigation and a full compatibility testing will be necessary.

10.9.4 Cross-matching should be carried out with the maternal serum. - In cases where maternal serum is not available, infant serum can be used. However this is not encouraged.

10.9.5 The choice of red cells:

1. Group O packed red cells are generally suitable for top-up transfusion.
2. Use infant’s own ABO group if cross-matching is done using infant’s blood.
3. Blood for exchange transfusions in neonatal jaundice cases are as provided in the following table.
10.10 Transfusion in special circumstances

10.10.1 Emergency transfusion

i. In an emergency, standard pretransfusion testing should be applied. SOP to identifying emergency casualty and blood sampling should be established in all hospitals and they must be adhered to. In Malaysia, where Rh D negative is uncommon, Group O Rh D positive packed cells are used as emergency O.

ii. In life threatening situations, clinicians can make the decision to transfuse group O packed cells for resuscitation which is available in selected places e.g. the Accident and Emergency Departments, labour rooms, intensive care units and Blood Banks.

iii. Decisions to transfuse un-crossmatched emergency group O blood must only be made after the clinician has fully assessed the patient's condition. The decision should not be made in haste. The requesting doctor must state the reasons for such a decision on the request form and sign it. If possible a sample of blood is taken before the transfusion to determine the blood patient's blood group.

iv. Emergency blood can be released after cross matching at Room Temperature is compatible. After releasing, full blood grouping (forward and reverse method) and cross matching procedure at 37°C and indirect antiglobulin phase (IAT) must be undertaken immediately by using the segment from the released blood bag. Problems encountered during the cross matching must be notified to the clinician concerned immediately to enable timely patient intervention.

v. If there is insufficient time to perform a complete full compatibility testing, blood that is provided must match the patients' ABO and Rh D groups. This can usually be issued within 15-20 minutes from the time the blood bank received the patient's blood sample. Local arrangements may vary. Personnel who are likely to be involved in urgent blood ordering must make themselves familiar with the local system.
vi. All emergency requests should be accompanied by a phone call to the doctor on-call or person in the blood bank to facilitate the process. The names of the persons who made the request and who received the request should be documented.

10.10.2 Transfusions in multiply transfused patients

i. Patient’s red cells should be phenotyped for Rh, Kell, Kidd, Duffy and MNSs before the first transfusion especially for Thalassemic patients.

ii. ABO and Rh compatible blood or blood products should be supplied unless prior approval has been obtained from the doctor in charge of the Blood Bank.

iii. Buffy coat poor packed cells (BCPPC), less than 2 weeks old, are recommended to prevent Febrile Non Haemolytic Transfusion Reactions (FNHTR). If possible, filtered BCPPC is recommended.

iv. Irradiated cellular blood products should be given to patients who are candidates for Bone Marrow Transplants, immunosuppressed or immunocompromised patients.

v. For patients who continue to develop FNHTR even after receiving BCPPC, leucocytes filters must be used.

vi. The following investigations should be carried out before the start of transfusion programme for baseline result and every 6 months thereafter.

   1. Red cells antibody screening;
   2. Virology screening for HBsAg, Anti HIV and Anti HCV.

10.11 Transfusion Record

All records of transfusion requests must be kept in the Blood Bank. This includes those cases of group, screen and hold and those cases where blood was not transfused. Patient name and identity card number must be kept for easy reference in case of further request for blood. Records may be in the form of recipient cards or in computerized form.

(a) Written record of recipient should be kept for 20 years in the blood bank.

(b) Where computerised system is used the following is recommended:

   i. Online for three years for active records
   ii. Archive database for 10 years
   iii. Permanent records- CDROM or microfiche
11.0 ISSUE, STORAGE AND TRANSPORT OF BLOOD TO THE WARD

Unscreened blood must **NOT** be transfused. There must be a system in place to prevent such an occurrence.

11.1 Issue of blood and blood products

Depending on the local SOP, blood may be released by the blood bank on request or may be stored in a designated blood refrigerator to be released by the blood bank staff to an authorized staff from the ward when required. Blood Bank staff must ensure that the correct blood and blood product is issued out to the requesting person. A checklist (*Appendix 11*) is provided.

11.2 Collection

The person collecting the blood must bring documentary proof of the patient’s identity. At the time of collection, blood bank personnel must check that these details match those of the blood unit to be collected. The blood bank personnel must record down the date and time of issue and collection. The record should also contain details of the person who issues and the person collecting the blood.

11.3 Storage and Transport

Blood and blood component should be kept in the blood bank until the blood or blood component is to be transfused. This is especially so for platelets, fresh frozen plasma and cryoprecipitate. This is to ensure that these compounds are kept at the optimal storage condition. If blood or blood component is not kept at the recommended temperature and condition it will no longer be suitable for transfusion. This is to be avoided as far as possible to prevent wastage.

Blood and blood products must be kept at the appropriate temperature in blood fridge and freezers and returned to the blood bank immediately if not used. *Appendix 12.*

12.0 ADMINISTRATION OF BLOOD COMPONENTS

12.1 Identification check of intended recipient

Local procedure manuals must specify the identification checks to be carried out and the designated staff who may perform this procedure and must be documented.

Each unit of blood component supplied from the Blood Bank should be accompanied by a compatibility label. This should carry the following information:

(a) Patient’s full name  
(b) Patient’s identity card or passport number  
(c) Patient’s hospital registration number  
(d) Patient’s ABO and Rh blood group  
(e) Unique pack number (donation number) of the blood product  
(f) Date of issue
12.1.1 At the time of transfusion the information on the compatibility label accompanying the blood component must be checked carefully against the patient’s identification details on the blood request form and patient’s case notes, including the patient’s wristband.

12.1.2 Blood should not be transfused if any of the details, especially the name and identification card number of the patient do not match exactly with that given on the accompanying compatibility label or the blood request form.

12.1.3 Blood should not be transfused if there is deviation from the usual condition. It should be checked macroscopically for any alteration in colour of the blood, presence of clot, leakage, etc. The blood bank should be informed immediately for appropriate measures to be taken and the blood must be returned to the blood bank.

12.2 **Patient monitoring**

While receiving blood transfusion, patients must be monitored closely.

The patient’s vital signs, including temperature, pulse rate and blood pressure should be recorded before, periodically during the transfusion and after the completion of each transfusion. The patient should be carefully and closely observed and monitored for the first 5 to 10 minutes of the transfusion. For red cell transfusion, the first 50 ml of each unit should be transfused slowly as it serves as an in vivo compatibility testing. An unconscious patient should have the vital signs checked at 15 minutes intervals during transfusion. Patient should be periodically observed during the transfusion for any clinical features of acute transfusion reactions. (See Section 9 for transfusion reactions).

12.3 **Record keeping**

Details of all blood products transfused, including the donation number of each unit, must be recorded into the patient’s case note together with the blood request form, which contain the compatibility report, provided by the Blood Bank.

12.4 **Time limits for infusion of blood components**

**Red cells:**

There is a risk of bacterial contamination if a pack of red cells is kept at room temperature. For this reason, the infusion of red cells must start within 30 minutes of removing the pack from the blood refrigerator. Transfusion should take not more than 4 hours to completion.

**Platelets:**

Platelet should be kept at 20-24°C. NEVER put platelets in refrigerators. Infusion of platelets should start as soon as the pack is received from the blood bank and infusion should not be more than 30 minutes.
Plasma:

Start the transfusion as soon as the thawed pack is received from the blood bank. Once thawed, infusion of plasma should be completed as tolerated by the patient.

12.5 Blood administration sets

All blood components must be infused through a blood administration set containing an integrated filter (170 μm) to trap any large aggregates. For infusion of platelets, always use a fresh administration set, not one that has been used for infusion of red cells.

12.6 Microaggregate filters

Filters of 20-40 μm pore size can trap small aggregates of degenerating platelets, fibrin strand and leucocytes which are formed in all blood stored beyond 5-10 days. There is no indication to use these filters with small volume (2-4 units) transfusion in an adult. Even with very large transfusion volumes there is no evidence that microaggregates can cause respiratory problems in the recipient. Thus the use of these filters is recommended only in patients transfused during cardio-pulmonary bypass and large volume transfusion in patients with pre-existing lung disease. Routine use of microaggregate filters is not indicated in exchange transfusion of neonates as the blood use is less than 7 days old.

Microaggregate filters must NEVER be used for granulocyte and platelet transfusions.

12.7 Leucocyte reduction filters

Leucocyte reduction filters are available for red cells and platelet transfusions and are designed to remove most of the leucocytes in cellular blood components. For red blood cell (RBC), the leucocyte is reduced to less than $5 \times 10^6$ per unit. For platelet derived from whole blood, the filtration should reduce the leucocyte to less than $8.3 \times 10^5$ per unit. These filters should only be used for infusion of packed cells or platelet concentrates. Leukocyte reduced blood and blood components are indicated:

a) to prevent febrile non-hemolytic transfusion reactions in patients who have experienced two or more such reactions
b) to minimise the risk of transfusion related CMV transmission
c) to reduce the rate of platelet alloimmunization

Leucocyte reduction filters should NEVER be used for granulocyte transfusions.

12.8 Blood warmers

There is no evidence that warming blood is beneficial to patient when infusion is slow (1 unit over 2 hours). Blood warmers are used to minimise the incidence of cardiac arrest and arrhythmias associated with massive transfusion of cold blood components. Use of blood warmers should be limited to patients receiving multiple, rapid transfusion at rates of >50 ml/kg/hr in adult and >15ml/kg/hr in children, and infants undergoing exchange transfusion. Blood warmer to be used must have a visible thermometer and an audible warning device. If blood is placed in a common blood warmer, the unit must be rechecked again against the intended recipient before the infusion is commenced.
Blood must NOT be warmed by placing it into hot water, in microwave, on radiator, under running water or near any uncontrolled heat source.

Blood which has been warmed must not be re-refrigerated for later use or reissued. Warming tends to accelerate red cell metabolism producing haemolysis and may permit bacterial growth.

12.9 Simultaneous administration of drugs and fluids

Red cell concentrates may be diluted with sodium chloride 0.9% to improve the flow rate. This is most simply achieved by using a Y pattern blood administration set. No other solutions should be added to any blood components as they may affect the properties of the blood components. For example, Ringer lactate which contain calcium additive can cause citrated blood to clot, and 5% Dextrose solution can cause haemolysis.

Drugs should never be added directly to any blood components; if there is an adverse reaction it may be impossible to determine if this is due to the blood or the medication that has been added, or to an interaction of the two.

In a situation when the transfusion line is the only venous access available and a medication has to be given, the transfusion must be stopped and the tubing should be flushed with 0.9% normal saline before and after injecting the medication to prevent direct mixing of the blood and medication. The transfusion can then be resumed.

12.10 Used blood or remnants of blood

Blood discontinued for any reason must not be used again and must be returned to the Blood Bank as soon as possible. Details of the transfusion and reasons for discontinuing the transfusion must be stated. All discontinued blood must be labeled as “USED BLOOD” before it is returned to the Blood Bank.

12.11 Return of used blood bags

Upon completion of blood transfusion, the ward staff must ensure that the Recipient Card attached to each bag of blood component is filled completely and returned to the Blood Bank, together with the blood bag containing remnants of the blood transfused. This must be documented properly. The used blood bags should be stored in the refrigerator marked “USED BLOOD BAGS” for not more than 7 days before they are disposed of. Should a recipient develops a delayed transfusion reaction, these bags can be retrieved for further investigation.

12.12 Return of un-used blood bags

All un-used blood bags issued to the ward must be sent back to the blood bank within 12 hours after releasing. However, the temperature of the blood must be kept within 2°C to 8°C at all time. Therefore, the temperature of the blood bag must be monitored closely starting from releasing from the blood bank, storing at the ward and sending back to the blood bank. This includes the transportation to and fro from the blood bank.
13.0 **TRANSFUSION IN NEONATES**

Specially designed blood components are required for prenatal transfusions or infant transfusions. The following aspects concerning neonates must be considered:

(a) Smaller blood volume  
(b) Viral inactivated  
(c) Crossmatch compatible with mother’s plasma

Components for transfusion *in utero* or to children under 1 year of age must be prepared from blood donated by regular donors, which was negative for all mandatory microbiological markers.

13.1 **Neonatal pre-transfusion testing**

Please refer to chapter 10, para 10.9

13.2 **Neonatal exchange transfusion**

13.2.1 Exchange transfusion (ET) may be used to manage severe anemia at birth, particularly in the presence of heart failure, and to treat severe hyperbilirubinemia, usually caused by hemolytic disease of newborn (HDN).

13.2.1 In treatment of HDN, the aim is to remove both the antibody-coated red cells and the excess bilirubin.

13.2.3 Exchange transfusion is a specialist procedure associated with a potential for serious adverse events. As such, it should be undertaken only by staff who are experienced in the procedure.

13.2.5 In infant with ABO hemolytic disease, group O blood compatible with maternal plasma, should be used for transfusion. Below are two component criteria for ET in ABO hemolytic disease of newborn:

(a) Known as Emergency O: group O red cells with low titer plasma anti-A and anti-B and low titer hemolysin  
(b) Known as Safe O: group O red cells (fresh red cell) suspended in AB plasma (fresh frozen plasma).

**NOTE:** In Malaysia both Emergency O and Safe O are RhD positive.

13.2.6 Emergency O is the best component for ET. It will expose the neonates to only one donor, compared to Safe O where two different donors will be pooled together as one unit of blood product.

13.2.7 For HDN due to anti-D, use group O RhD negative blood. For HDN due to anti-Rh c, use group O RhD positive that does not have the c antigen.
13.3 **Neonatal (small volume) transfusions**

13.3.1 Most neonatal transfusions are in small volumes. Therefore it is essential to divide a component unit into several satellite units and dedicate the entire satellite unit for the patient.

13.3.2 Dedicating aliquots from single donation of red cells (or apheresis platelet) to allow sequential transfusions (top-up transfusion) from the same donor for neonates and small children who are likely to be repeatedly transfused is a good practice. This can avoid the risk of exposure to several donors.

13.3.3 However, the satellite units are reserve for the patient (neonate) for 14 days. The unit age more than 14 days after aliquoting must be discard.

13.4 **Component specification and procedure**

13.4.1 Red cell components for exchange transfusion (ET)
   (a) group O or ABO compatible with maternal and neonatal plasma, RhD negative for RhD infant
   (b) negative for any red cell antigens to which the mother has antibodies
   (c) crossmatch compatible with maternal plasma at IAT phase
   (d) age 7 days old or less (to ensure optimal red cell function and low supernatant potassium levels)
   (e) irradiated and transfused within 24h of irradiation

13.4.2 Red cell for small volume transfusion
   (a) ABO compatible with mother and infant, and infant’s Rh D group. Refer to chapter 10, para 10.9.5
   (b) crossmatch compatible with maternal serum at IAT phase (if available) or neonate’s plasma
   (c) preferably irradiate if possible
   (d) aliquot to few satellite units from one single unit, dedicated to one infant

13.4.3 Platelets for neonatal transfusion
   (a) ABO identical or compatible
   (b) HPA compatible in infants with alloimmune thrombocytopenia

13.4.4 Fresh frozen plasma for neonatal transfusion
   (a) group AB or compatible with recipient’s ABO red cell antigens
   (b) viral inactivate if appropriate
14.0 TRANSFUSION REACTION

14.1 All transfusion reactions must be investigated.

14.2 All personnel involved in ordering and administering transfusions must be able to recognize the signs and symptoms of transfusion reactions and be able to manage them. Regular continuous medical education (CME) should be carried out to ensure this.

14.3 The causes of transfusion reactions include acute and delayed haemolytic transfusion reactions, bacterial contamination, febrile non-haemolytic transfusion reactions, urticaria and anaphylaxis, transfusion-related acute lung injury, post-transfusion purpura and transfusion associated graft versus host disease. Appendix 12 lists the various types of transfusion reactions and their management.

14.4 Signs and symptoms that may occur with impending or established transfusion reaction include:

(a) Feeling of apprehension
(b) Fever
(c) Chills
(d) Rigors
(e) Pain, at infusion site, or in chest, abdomen or flanks
(f) Changes in blood pressure, either hypotension or hypertension.
(g) Respiratory distress
(h) Skin changes
(i) Nausea
(j) Vomiting
(k) Acute onset of sepsis
(l) Anaphylaxis
(m) Renal shutdown
(n) Abnormal bleeding

14.5 If an adverse transfusion reaction is suspected, the transfusion should be stopped immediately. The doctor in-charge of the patient must be informed urgently to assess the patient. Further management depends on the type and severity of the reaction. The following steps have to be taken to allow for investigation into the reaction:

(a) An ‘immediate’ venous blood sample (at least 8-10 c.c.) should be taken in a plain tube for antibody identification.
(b) Another 2-5 mls venous sample be taken for Full Blood Picture.
(c) A urine sample should be collected and inspected as soon as possible before being sent to the laboratory. This specimen may contain haemoglobin and albumin and often contains red cells as well.
(d) The remaining blood bag, containing the partially transfused blood, and all the blood bags cross-matched for the same patient at the same time of the request should be examined for the presence of free haemoglobin or discoloration before being sent to the laboratory.
(e) All tubings should also be changed.
(f) 24 hours after the detection of the adverse reaction:
- another venous blood sample should be taken (again at least 8-10c.c in a plain bottle) for further tests
- another blood sample in EDTA bottle for full blood picture; and
- another urine specimen for haemoglobinuria

(f) The “Report of Reaction to Blood or Plasma Transfusion” form (in Appendix 15 and 16) must be completed.

(g) Once the transfusion adverse event investigation is complete, fill up the transfusion adverse event form in duplicate and send to the local hospital blood bank and to the National Blood Centre. (refer to Appendix 17 and 18)

14.6 All transfusion reaction reports should be discussed at the hospital transfusion committee meeting and appropriate measures implemented.

15.0 MANAGEMENT OF REACTIVE DONORS

15.1 All repeat reactive donors should be contacted and investigated.

15.2 Reactive donors should be counseled to determine any risk factor.

15.3 Sample should be taken from the donor to confirm that the original sample during the donation, came from the donor.

15.4 All confirmed reactive donor should be referred to the physician or infectious disease clinics for management.

15.5 All confirmed reactive donors must be informed that they should never donate blood again. This should be documented in the donor records.

16.0 MANAGEMENT OF SEROCONVERT DONORS AND PATIENTS

(Appendix 19: Look Back & Recall)

16.1 Seroconvert donors

Definition: A donor who is confirmed positive for a particular transfusion transmitted infection marker in his current donation but was negative in the previous donation.

All donors found to be infected with HIV, Hepatitis B, Hepatitis C or Syphilis should be informed and counseled by the collection centre/blood bank doctors before being referred to the appropriate physician for further management.

The recipients of his last non reactive donation and donations in the six months period prior to this should be traced by the blood bank and their respective clinicians informed. These recipients should be counselled, preferably by a team made up of the primary clinician together with a physician specialized in infectious disease and a counselor. The clinician should emphasize that the infection is but a possibility and may not be a certainty. As a precautionary measure, the recipients should be tested for the appropriate infection.
16.2 **Transfusion Recipients who seroconvert.**

**Definition:** A patient who is confirmed to be positive for a particular marker for transfusion transmitted infection after receiving blood transfusion.

Recipients of transfusions may develop HIV, Hepatitis B, Hepatitis C or Syphilis resulting from:

(a) transfusion of contaminated blood donated within the window period of the infection, or
(b) from other sources not related to the blood transfusion.

However, it is recommended that donors of the blood that has been transfused to the patient in the 12 months period prior to the detection of the infection be contacted for testing. The Blood Bank should be informed to identify the blood donors and their status determined.

If a donor is identified as the source of infection, other recipients of his or her blood should be traced and investigated as in 10.1.

16.3 **Submission of report to National Blood Centre**

Report all adverse events relating to transfusion should be submitted using the Adverse Transfusion Events forms (*Appendix 17*) to:

The National Coordinator on Surveillance of Adverse Events in Transfusion.
National Blood Centre, Kuala Lumpur,
Jalan Tun Razak
50400, Kuala Lumpur

Tel: 03-26955555
Confidential Fax No: 03-26925826

16.4 **Counseling of patients who recipients of seroconverted donors**

The counseling doctor can be the treating doctor or a team consisting of the treating doctor, physician (infectious disease) and a counselor appointed by the Hospital Transfusion committee and should have sound knowledge of:

(a) Transfusion transmitted diseases.
(b) Mode of transmission of these diseases other than through blood transfusion.
(c) Understand the risk of infection through blood transfusion.
(d) Current tests available and result interpretation
(e) Giving information about tests results
(f) Available treatment and therapeutic options.
(g) Disease progression
(h) Ethical considerations

During the counseling session, the doctor should discuss and provide information to the patient to enable him or her to decide when, how and what to disclose to their spouse and other family members.
16.5 Investigation for transfusion transmitted diseases in recipients

The following tests should be done on the recipient.

(a) Hepatitis B virus  
(b) Hepatitis C virus  
(c) HIV  
(d) Syphilis

For cases referred from treating physician, i.e. patients suspected to have seroconverted, perform the necessary assays to confirm if recipient is truly infected with the said TTI, and for the recalled donor and/or remaining products, perform assays as in above table.

Note:

NR = Non Reactive  
RR = Repeatedly Reactive  
PA = Particle Agglutination  
LIA = Line Immunoassay  
RIBA = Recombinant Immunoblot Assay  
TPPA = *Treponema pallidum* Particle Agglutination

Table of investigation for Transfusion Transmitted Infections

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Assay</th>
<th>Previous Donation Results</th>
<th>Current Donation Tests</th>
<th>Test For Recipient</th>
<th>Comment</th>
</tr>
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<tr>
<td>Syphilis</td>
<td>RPR</td>
<td>RPR NR</td>
<td>RPR RR</td>
<td>RPR</td>
<td>TPPA</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>HBsAg</td>
<td>HBsAg NR</td>
<td>HBsAg RR Neutralization Positive</td>
<td>HBsAg AntiHBcore AntiHBe HBeAg</td>
<td>Final results will be available 2 weeks from date of donation/ request</td>
</tr>
<tr>
<td>HIV</td>
<td>Anti-HIV</td>
<td>Anti-HIV NR</td>
<td>Anti-HIV PA Anti-HIV Detected LIA Positive</td>
<td>AntiHIV PA AntiHIV (LIA to check for progression of band detection)</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>Anti-HCV</td>
<td>Anti-HCV NR</td>
<td>Anti-HCV RR RIBA Positive</td>
<td>AntiHCV RIBA or HCV RNA detection (RIBA to check for progression of band detection)</td>
<td></td>
</tr>
</tbody>
</table>

*Note: *Treponema pallidum* Particl Agglutination
17.0 AUDIT IN TRANSFUSION PRACTICES

Regular audit should be carried out to ensure that all procedures are being carried out in compliance with the SOP. The following audits are recommended:

a) Blood donation procedure
b) Preparation of blood components
c) Procedure for testing of Transfusion Transmitted Diseases.
d) Quarantine and release procedures
e) Disposal of tainted blood
f) Issue of blood and blood components
g) The use of blood
   - whole blood
   - packed red cells
   - platelet concentrates
   - cryoprecipitate
h) Crossmatch /transfusion Ratio (CT ratio)
i) Transfusion Reaction Investigation Reports
j) Adverse event reporting & investigation.

18.0 HOSPITAL TRANSFUSION COMMITTEE

A Hospital Transfusion Committee should be set up to promote safe and appropriate transfusion practice. It reviews practices and policies with regard to blood collection and usage in hospitals. The HTC should have the authority to take necessary actions to improve transfusion practice within the hospital.

18.1 Membership

The members of the Hospital Transfusion Committee (HTC) should include representatives from the hospital administration, clinical users and providers.

Members of the committee may include the following:

Administration - Medical Administrator (Chairman)
                 - Nursing Administrator

Clinical Users  - Surgeons
                - Anaesthetists
                - Gynaecologists & Obstetricians
                - Paediatricians
                - Orthopaedic Surgeons
                - Physicians
                - Haematologists
                - Oncologists

Providers       - Hospital Blood Bank } Secretariat
                - Blood Collection Centre

The director of the hospital should chair the HTC.
18.2 Terms of Reference

While the terms of reference should be tailored to suit the user institution, the following areas should be considered:

(a) Promote best practice through local protocols based on the national guidelines.
(b) Have the authority to review practices, modify and improve existing blood transfusion protocols/practices and introduce appropriate change to practice.
(c) Monitor provision and use of blood and blood products
(d) Follow up transfusion reactions and appropriate remedial measures taken.
(e) Carry out audit on transfusion practices against the hospital policy and national guidelines, focusing on critical points.
(f) Provide feedback on audit of transfusion practice and the use of blood to all hospital staff involved in blood transfusion.
(g) Development and maintenance of Maximum Blood Ordering Schedule (MBOS)
(h) Promote the education and training of all clinical, laboratory and supporting staff involved in blood transfusion.
(i) Manage, supply/demand problems if any and develop local contingency plan and management of blood during periods of shortages and disaster.
(j) Report regularly to the state Transfusion Committee and through them to the National Blood Transfusion Committee.
(k) Ensure all transfusion adverse events are investigated and reported to the Haemovigilance Unit of the National Blood Centre.

The committee should aim to meet at least 2 times a year. The HTC should report to the State HTC.

19.0 HAEMOVIGILANCE IN BLOOD TRANSFUSION

Blood transfusion safety can be defined as a series of processes implemented to either remove or reduce allogeneic blood transfusion related immunologic or infectious risks. Haemovigilance is a system of surveillance and alarm, from blood collection to the follow-up of the recipients, gathering and analyzing all untoward effects of blood transfusion in order to identify, correct their cause and take remedial measures to prevent recurrence.

Monitoring a risk involves setting in place steps to control it, thus justify the implementation of:
- an alert system
- Recipient Surveillance System
- Blood Collection Surveillance System

This must be properly coordinated and should be handled at the National Blood Centre, which act as the Haemovigilance coordinating centre for the Ministry of Health. The functions of this coordinating center are:
(a) Maintaining record and registry of seropositive donors for the whole country.
(b) Evaluate transfusion practices toward improvement.
(c) Evaluate residual risk among population.
(d) Explore strategies in blood screening to improve safety of donated blood donation.
(e) Evaluate and dissemination of current information regarding transfusion transmitted diseases to public and health personnel.
(f) Recording of adverse events (immunologic and non-immunologic) in transfusion
(g) Coordinate audit and inspection
(h) Identify training needs.

To ensure that accurate data can be collected, evaluated and act upon, the support from the state director, hospital directors, doctors and other allied health personnel are needed. Method:

1. Upon receipt of the “Report of Reaction to Blood or Plasma Transfusion” forms by the Blood Transfusion Center, the reporting format for “Adverse Transfusion Event (Appendix 17) will be issued to the ward / doctor concerned by the Hospital Blood Transfusion Unit/Center.

2. The “Adverse Transfusion Event” (Appendix 17) form shall be returned in duplicate to the Hospital Blood Bank and National Blood Center within one week.

   Note : The Blood Transfusion Unit shall collect/ remind the ward doctor in charge to return the “Adverse Transfusion Event”.

3. Send a copy of this form (Appendix 17) to the National Blood Center (refer to the flowchart for reporting of adverse transfusion events - Appendix 18).

20.0 TRAINING OF STAFF

20.1 Training is a systematic process of developing knowledge, skills, techniques, attitudes and behavior towards producing proficient, competent and professional personnel. Therefore, appropriate and adequate training shall be provided to all personnel who directly and indirectly involved in blood transfusion services and they shall be furnished with initial and continued training in order to assure the quality and safety of blood and blood components.
20.2 In order to support lifelong learning, training should be carried out through various mechanisms including meeting, discussion, dialogue, course, seminar, conference, workshop, hands-on practice, on-line tutorial, Continuous Medical Education (CME), orientation, rotation and attachment. Input shall be delivered theoretically or practically and sometimes both depending on the situation.

20.3 Training should be conducted either regularly or based on the requirement and suitability. Personnel should also be assessed regularly.

20.4 Staff performing critical function should be credentialed for the task they perform.
GUIDELINE FOR BLOOD DONOR MANAGEMENT

1. Introduction

The blood transfusion service is responsible for adequate and safe blood supply through recruitment and retention of voluntary blood donor. The Blood Transfusion Service should have a donor management unit consisting of well trained personnel.

2. Objective

The objectives of establishing blood donor management unit are as follows:

2.1. To establish a panel of regular, voluntary non-remunerated donors.
2.2. To ensure that blood donation does not harm either the donor or the recipient of the blood.
2.3. To identify any factors that might make an individual unsuitable as a donor.
2.4. To provide appropriate training for all staff.
2.5. To ensure that all donors receive professional and pleasant reception.

3. Personnels

The donor management unit should have the following staff

3.1 Staff categories: Medical Officers
Nurses
Medical Assistants

3.2 The scopes of works are:
Donor recruitment and retention of safe donor
Donor Dare
Blood collection
Ensuring adequate blood stock

4. Blood Donor Selection

4.1 Pre-donation counseling is an essential part of donor selection because it enables donor clinic staff to make a preliminary assessment of the donor’s state of health.
4.2 Provide information about risk factors.
4.3 Assess the donors understanding of risk factors.
4.4 Explain the procedures involved in blood donation and the reasons why they are taken, including the medical history the basic health check, venepuncture and post donation care.
4.5 Laboratory tests that are performed on all donors' blood.
4.6 Answer the donors questions and provide reassurance in cases of anxiety.
4.7 Obtain the donors informed consent to donation and to the procedures that will follow.
5. **Medical History**

The purpose of recording a donor medical history at the time of donation is to decide on the following:

5.1 Accept the donor  
5.2 Defer the donor temporarily  
5.3 Defer the donor permanently

6. **Health Check**

This activity focused on collecting information from donors about health conditions or other factors that might either endanger their own health if they give blood or adversely affect the health of the recipients.

6.1 Questioning donors to assess the likelihood of risk behavior and counseling them to self-exclude, where appropriate.  
6.2 Interviewing donors to assess their health status, using a medical history questionnaire.  
6.3 Identifying any drugs or medicines being used by donor and assessing their significance for the safety of blood donation.

The following assessments need to be made as part of the health check each time a donor comes to give blood.

6.4 Blood Pressure  
6.5 Haemoglobin estimation either by screening with Copper Sulphate Solution or Haemocue  
6.6 Body Weight  
6.7 Physical assessment of the donor for such symptom as skin rashes and swollen glands or needle mark, pallor or jaundice.  
6.8 The time of the donor last meal. Not having a light meal in the last 12 – 24 hours may lead to a fainting attack.

The care of blood donor to ensure that all donors who come to give blood receive standard care and that their experience of donation is safe, efficient and pleasant.

6.9 Recognizing and managing adverse reaction such as mild reaction, moderate reaction like fainting and severe reaction like convulsion  
6.10 Haematoma  
6.11 Nerve or vessel injuries  
6.12 Ability to perform cardiopulmonary resuscitation whenever required.
7. Blood Collection

7.1 Donor Identification

7.1.1 A careful check must be made to verify the Donor’s identity against the Blood Donor Enrolment Form.

7.1.2 Verify the name, blood group and barcode number on the Blood Donor Enrolment Form with the labels on the blood bags at the bedside before venepuncture.

7.2 Equipment used at the blood donation session should include as follows:

7.2.1 Record of Validation and Calibration of equipment where applicable.

7.2.2 All blood bags and containers should be checked on the validity or any defects before use for example expiry date, appearance of the anticoagulant solution and any defect or leakage of bags or tubes.

7.3 Preparation of venepuncture site must be strictly following the Standard Operation Procedures.

7.4 Need for successful venepuncture and proper mixing of blood.

7.4.1 Bleeding should be carried out in the flowing manner. Needle should be inserted into the vein at first attempt. A second clean venepuncture with a new needle at a separate site is acceptable.

7.4.2 Proper mixing of the blood with the anticoagulant should be done.

- Blood must be immediately mixed: Flow of the blood must be sufficient and uninterrupted.

- Manual mixing of blood bags must be inverted every 30 – 45 seconds.

- When an automated blood mixer is used, an appropriate validation system is required.

7.5 Bleeding should NOT be longer than 12 minutes.

Note:

1. If the bleeding time is longer than 12 minutes it should not be used for platelet preparation.

2. If the bleeding time is longer than 15 minutes it should not be used for direct transfusion or the preparation of coagulation factor.
7.6 At the end of donation take blood samples directly from the donor venepuncture tubing into the sample tubes. DO NOT SQUEEZE FROM THE BLOOD BAG. The blood bag and the corresponding samples should not be removed from the donor bedside until all the sample tubes has been labeled with the correct barcode which corresponds to the barcode number assigned to the donor.

8. Handling of filled containers and samples

8.1 Containers should be checked before and after donation for any defect.
8.2 Verification of blood sample container with donor’s identification.
8.3 Labelling and withdrawal of blood samples at bedside.

9. Confidentiality is a vital part of a professional service

All information relating to the donor must be kept confidential. This includes the following:

9.1 During donor screening and blood collection
9.2 Donor record
9.3 Consent
9.4 Published information

10. Training

All staff involved in blood procurement must be trained in:

10.1 Donor criteria and selection
10.2 Donor health assessment
10.3 Donor collection
10.4 Sampling and labeling
10.5 Storage and transport of blood

11. Credentialing of Staff for Bleeding Of Donors

All staff involved must be credentialed before they are allowed to perform the task assigned to them.

6.1 Must pass written and practical examination set by PDN.
6.2 PDN would issue proficiency certificate to allow personnel to perform the task of blood collection.
6.3 Reevaluation in 2 years time
## GUIDELINES FOR DONOR DEFERRAL

### A. Conditions Necessitating Temporary Deferral

<table>
<thead>
<tr>
<th>Condition</th>
<th>Period of Deferral</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Aged below 18 years</td>
<td>Acceptable if written parental/guardians consent is obtained</td>
</tr>
<tr>
<td>2 Abortion</td>
<td>Defer for 6 months</td>
</tr>
<tr>
<td>3 Acne</td>
<td>Defer for 2 years if on Ruaccutaine or Tigason</td>
</tr>
<tr>
<td></td>
<td>Defer for 6 months if on Retin A Cream</td>
</tr>
<tr>
<td>4 Alcohol/Liquour Intoxication</td>
<td>Defer for 24 hours</td>
</tr>
<tr>
<td>5 Allergy</td>
<td>Defer for 72 hours</td>
</tr>
<tr>
<td></td>
<td>Defer for 1 year</td>
</tr>
<tr>
<td>6 Contact with infectious diseases</td>
<td>In general defer for 4 weeks after contact.</td>
</tr>
<tr>
<td>7 Dental Treatment</td>
<td>Defer for 3 months</td>
</tr>
<tr>
<td></td>
<td>Defer for 24 hours</td>
</tr>
<tr>
<td>8 Immunisation</td>
<td>Defer for 2 weeks</td>
</tr>
<tr>
<td></td>
<td>Defer for 1 year</td>
</tr>
<tr>
<td></td>
<td>Defer for 1 year</td>
</tr>
<tr>
<td></td>
<td>Defer for 48 hours</td>
</tr>
<tr>
<td></td>
<td>Defer for 4 weeks</td>
</tr>
<tr>
<td></td>
<td>If unsymptomatic need not defer</td>
</tr>
<tr>
<td>9 Lactating Women</td>
<td>Defer during lactation period</td>
</tr>
<tr>
<td>10 Medical Conditions/Infections</td>
<td>Defer for 3 weeks</td>
</tr>
<tr>
<td></td>
<td>Defer for 3 weeks after treatment</td>
</tr>
<tr>
<td></td>
<td>Defer for 1 month after recovery</td>
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<tr>
<td></td>
<td>Defer for 3 weeks after recovery</td>
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<tr>
<td></td>
<td>Defer for 3 weeks after recovery</td>
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<tr>
<td></td>
<td>Defer until 4 - 6 weeks after recovery</td>
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<td></td>
<td>Defer for 3 months</td>
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<tr>
<td></td>
<td>Defer for 4 weeks after recovery</td>
</tr>
<tr>
<td></td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td></td>
<td>Defer for 1 month</td>
</tr>
<tr>
<td>Condition</td>
<td>Period of Deferral</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Generally unwell/unspecific febrile condition</td>
<td>Defer until potential donor recovers</td>
</tr>
<tr>
<td>Glandular Fever</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Infectious Mononucleosis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Influenza</td>
<td>Defer for 1 month after recovery</td>
</tr>
<tr>
<td>Osteomyelitis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Malaria</td>
<td>Defer for 6 months</td>
</tr>
<tr>
<td>Measles</td>
<td>Defer for 3 months</td>
</tr>
<tr>
<td>Meningitis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Mumps</td>
<td>Defer for 3 weeks</td>
</tr>
<tr>
<td>Rubella</td>
<td>Defer for 4 weeks after recovery</td>
</tr>
<tr>
<td>Scarlet Fever</td>
<td>Defer for 4 weeks after recovery</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>Defer until potential donor recovers</td>
</tr>
<tr>
<td>Tetanus</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Thrombophlebitis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Tick Bite Fever</td>
<td>Defer for 2 months after recovery</td>
</tr>
<tr>
<td>Tonsilitis</td>
<td>Acceptable after recovery</td>
</tr>
<tr>
<td>Toxoplasmosis</td>
<td>Acceptable after recovery</td>
</tr>
<tr>
<td>Trypanosomiasis</td>
<td>Defer for 3 weeks after recovery</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Defer for 5 years after off all therapy</td>
</tr>
<tr>
<td>Typhoid</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Typhus</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>Defer for 6 months after recovery</td>
</tr>
<tr>
<td>Pyelitis</td>
<td>Defer for 3 months after recovery</td>
</tr>
<tr>
<td>Minor/Major Operation e.g.</td>
<td>Defer for 6 months</td>
</tr>
<tr>
<td>Appendicectomy</td>
<td></td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td></td>
</tr>
<tr>
<td>Fracture</td>
<td></td>
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<tr>
<td>Gallstones</td>
<td></td>
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<tr>
<td>Glaucoma</td>
<td></td>
</tr>
<tr>
<td>Haemorrhoidectomy</td>
<td></td>
</tr>
<tr>
<td>Hernia Repair</td>
<td></td>
</tr>
<tr>
<td>Hysterectomy</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Period of Deferral</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Lumpectomy (Breast)</td>
<td>Acceptable after 5th day of menstruation</td>
</tr>
<tr>
<td>Thyroidectomy</td>
<td></td>
</tr>
<tr>
<td>Menstruation</td>
<td>Defer for 1 week after stopping medication. Acceptable if HRT is for menopausal symptoms or for osteoporosis prevention /infertility</td>
</tr>
<tr>
<td>Medication</td>
<td>Minimum 8 weeks interval between donations. Hb level must be at least 12.5 g/dl.</td>
</tr>
<tr>
<td>eg antibiotics</td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td></td>
</tr>
<tr>
<td>Hormone Replacement Therapy</td>
<td></td>
</tr>
<tr>
<td>Pregnant/Post-Delivery</td>
<td>Defer for 6 months post-delivery</td>
</tr>
<tr>
<td>Previous history of sexual relationships with Hepatitis B Positive</td>
<td>Defer for 6 months</td>
</tr>
<tr>
<td>Recipient of blood/ blood components</td>
<td>Defer for 6 months</td>
</tr>
<tr>
<td>Repeat blood donor</td>
<td>Defer for 3 months after recovery</td>
</tr>
<tr>
<td>Snake Bite</td>
<td>Defer for 6 months</td>
</tr>
<tr>
<td>Tatoo</td>
<td>Defer until weight is 45 kg and above</td>
</tr>
<tr>
<td>Underweight (weight below 45 kg)</td>
<td>Defer for 3 weeks after recovery.</td>
</tr>
<tr>
<td>Severe Acute Respiratory Syndrome (SARS) (wef: 06 May 2003)</td>
<td>Defer for 2 weeks if having close contact with a person who has been diagnosed with SARS or suspected to have SARS in the last 2 weeks. (Close contact refers to having cared for / direct contact / lived or have visited a person with / suspected with SARS at home or hospital.)</td>
</tr>
<tr>
<td>West Nile Virus (WNV) (It is spread by the bite of an infected mosquito. This virus can infect people, horses, many types of birds and animals.)</td>
<td>Defer for 28 days from the onset of symptoms or until the patient has been without symptoms for 14 days. Defer for 28 days from the date of the implicated donation if the donor whose blood or components potentially were associated with a transfusion-related WNV transmission.</td>
</tr>
<tr>
<td>Symptoms of WNV include: Malaise anorexia nausea fever vomiting eye pain headache myalgia rash (maculopapular or morbilliform) lymphadenopathy weakness gastrointestinal symptoms change in mental status (ataxia and extrapyramidal signs &amp; cranial nerve abnormalities)</td>
<td></td>
</tr>
</tbody>
</table>
B: Conditions Necessitating Permanent Exclusion/Deferral

1. Age above 60 years.
2. Endocrine Disorders eg, Hyperthroidism, Thyrotoxicosis
3. Having had treatment with Human Growth Hormone
4. Having had corneal or duramater transplants
5. Having lived in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man or the Channel Island) from 1980 to 1996 for a period of 6 months or longer.
6. Having lived in Europe from 1980 to the present for a period of 6 months or longer.
7. High Risk Groups:
   - Sexual Relationship with HIV infected person
   - Multiple sex partners
   - Intravenous Drug Users
   - Bisexuals
   - Sexual Relationship with Hepatitis B Positive person
   - Exposure to prostitutes
   - Homosexuals
   - Prostitutes
8. Medical History Of:
   - Acquired Haematological Disorders eg Polycythemia Vera
   - Arrythmia
   - Autoimmune Disorders e.g. SLE
   - Asthma with course of steroid therapy
   - Cancer
   - Chancroid
   - Congenital Bleeding Disorder
   - Congenital Blood Disorder
   - Colitis
   - Dermatitis e.g. Psoriasis
   - Diabetes with complications
   - Emphysema
   - Epilepsy
   - Gonorrhoea
   - Hepatitis B
   - Hepatitis C
   - Heart Diseases e.g. Heart Failure/Angina Pectoris/Coronary Artery Disease
   - HIV/AIDS
   - Hypertension with complications
   - Hypotension
   - Malignancy
   - Mental Retardation/Cerebro-vascular Disease
   - Multiple Sclerosis
   - Myeloproliferative Disorders
   - Nephritis
   - Peptic Ulcer
   - Psychiatric Disorder
   - Raynauds Disease
   - Sarcoidosis
   - Severe Allergies
   - Shingles
   - Syphilis
   - Total Gastrectomy
PENDAFTARAN PENDERMA DARAH

PERHATIAN KEPADA SEMUA PENDERMA

Penderma darah Yang Budiman,

Tabung Darah sentiasa memerlukan darah yang selamat untuk merawat pesakit. Pihak kami mengucapkan ribuan terima kasih atas kesudian anda untuk menderma darah. Darah anda boleh menyelamatkan nyawa.
Bagaimanapun, ada kemungkinan bahawa darah anda tidak sesuai untuk didermakan. Sila jawab semua soalan-soalan berikut. Maklumat yang diberikan akan membantu kami menentukan jikalau darah anda selamat untuk digunakan.

Penyakit-penyakit yang menyebabkan darah anda tidak sesuai untuk didermakan:

1. Sindrom Penyakit Kurang Daya Tahanan/Jangkitan HIV
   [“Acquired Immune Deficiency Syndrome (AIDS)/HIV Infection”]
   HIV adalah sejenis virus yang menyebabkan penyakit AIDS. Ia boleh dijangkiti melalui perhubungan seks dengan seorang pembawa virus, bertukar-tukar jarum tercemar seperti yang digunakan dalam penyalihgunaan dadah melalui suntikan, transfusi darah yang tercemar dan oleh seorang wanita hamil yang dijangkiti virus kepada anak dalam kandungannya.
   Kebanyakan pembawa virus tidak tahu yang mereka dijangkiti penyakit HIV kerana mereka nampak dan rasa sihat. Akan tetapi, mereka boleh menjangkiti orang lain melalui darah yang didermakan.
   Oleh itu, mereka yang mengamalkan gaya hidup yang mendedahkan diri kepada virus HIV tidak sepatutnya menderma darah. Sila jangan menderma darah sekiranya anda adalah dari golongan yang berikut:
   - Mereka yang pernah menyalihgunaan dadah secara suntikan.
   - Mereka yang pernah bertukar-tukar pasangan seks.
   - Mereka yang pernah mengamalkan seks sejenis.
   - Mereka yang pernah melanggani pelacur.
   - Mereka yang pernah memberi khidmat seks.
   - Mereka yang pernah menjadi pasangan seks kepada mana-mana golongan di atas.

2. Hepatitis
   Hepatitis ialah sejenis jangkitan virus yang mengakibatkan radang hati. Hepatitis disebabkan oleh beberapa jenis virus berlainan seperti Hepatitis A, B dan C. Jikalau anda dijangkiti hepatitis B atau C, sila jangan menderma darah anda kerana virus ini boleh disebarkan melalui transfusi darah tercemar dan ia berkemungkinan menyebabkan akibat yang teruk kepada pesakit yang menerima transfusi tersebut.

3. Siflis (“Syphilis”)
   Jikalau anda dijangkiti penyakit siflis ataupun penyakit kelamin (“veneral disease or sexually transmitted disease”), darah anda tidak sesuai untuk pendermaan.

4. Malaria
   Penyakit malaria adalah disebabkan oleh parasit Plasmodium yang menjangkiti sel darah merah. Ia boleh disebarkan melalui transfusi darah.
Sila jangan menderma darah anda jikalau anda berpendapat darah anda tidak selamat diberikan kepada orang lain. Anda bolehlah mendapatkan maklumat lanjut daripada pegawai perubatan yang bertugas.
Jika atas sebarang sebab anda berasa bahawa darah yang anda baru dermakan itu mempunyai risiko yang tinggi, anda boleh secara sulit berbincang dengan pegawai perubatan yang bertugas.

"BEKALAN DARAH YANG SELAMAT
BERMULA DENGAN ANDA!"
BORANG PENDAFTARAN PENDERMA

Sebelum anda menderma, sila baca dan jawab soalan-soalan berikut. Sekiranya anda menghadapi masalah menjawab mana-mana soalan, sila rujuk kepada kakitangan yang bertugas. Terima Kasih di atas keprihatinan anda.

Nama: ________________________________

No. K/P (Baru) : _____________________ - ______ - __________
No. K/P (Lama) : __________ - __________.

Polis/Tentera : ________________________ No. Pasport : ______________________

Umur : ______________________________

Jantina:  □ Lelaki □ Perempuan  Pekerjaan: ______________________________

Keturunan:  □ Melayu □ Cina □ India □ Lain-lain (nyatakan)  Taraf Perkahwinan:  □ Sudah Kahwin □ Bujang □ Bercerai

Alamat (rumah): ____________________________ Alamat (Pejabat): ____________________________

____________________________________  ______________________________________

____________________________________  ______________________________________

Poskod: ____________________________  Poskod: ____________________________

No. Tel. (Rumah.) : ____________________________ No. Tel. (Pejabat.) : ____________________________

Tel Bimbit : ____________________________

Untuk diisi oleh Pegawai T/Darah

No. Barkod: ____________________________

Kekerapan menderma darah: ________ (PDN) ______ (Lain Hosp.Kerajaan) _______ (Hosp.Swasta)

Jenis Pendermaan:  □ Darah □ Apheresis Tarih Akhir Pendermaan: ____________________________

<table>
<thead>
<tr>
<th>Ujian Darah</th>
<th>Keputusan</th>
<th>Dilakukan Oleh (Nama &amp; Tandatangan)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Berat badan (kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Tahap Haemoglobin (g/dl)</td>
<td>Copper Sulphate [√ Tenggelam Hb ≥ 12.5 g/dl]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Haemocue</td>
<td></td>
</tr>
<tr>
<td>3. Kumpulan Darah</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Tekanan Darah (mmHg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Kumpulan Rhesus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Pendaftaran</td>
<td>Tarih:</td>
<td></td>
</tr>
</tbody>
</table>
Sila tandakan ✓ pada jawapan yang sesuai.

1. Adakah anda sihat hari ini?  
   ☐ Ya ☐ Tidak

2. Pernahkah anda menghadapi masalah ketika menderma darah?  
   ☐ Ya ☐ Tidak

3. Dalam seminggu yang lepas, adakah anda:
   a. mengambil ubat aspirin?  
      ☐ Ya ☐ Tidak
   b. mengambil sebarang ubatan selain aspirin? Jika ya, sila nyatakan:  
      ☐ Ya ☐ Tidak
   c. mengidap selsema atau batuk atau migrain?  
      ☐ Ya ☐ Tidak
   d. mengidap sebarang jangkitan lain? Jika ya, sila nyatakan:  
      ☐ Ya ☐ Tidak

4. Adakah anda menerima sebarang immunisasi atau suntikan dalam tempoh 3 minggu yang lepas?  
   ☐ Ya ☐ Tidak

5. Adakah anda menerima rawatan pergigian dalam tempoh 24 jam yang lepas?  
   ☐ Ya ☐ Tidak

6. Adakah anda pernah bertindik di mana mana bahagian badan anda termasuk akupunktur, tattoo dan berbekam dalam tempoh 1 tahun yang lepas?  
   ☐ Ya ☐ Tidak

7. Adakah anda pernah mendapat rawatan di klinik atau hospital baru-baru ini? Jika ya, sila nyatakan jenis penyakit dan rawatan yang diterima:  
   ☐ Ya ☐ Tidak

8. Adakah anda pernah mengidap:

<table>
<thead>
<tr>
<th>Penyakit</th>
<th>☐ Ya</th>
<th>☐ Tidak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sakit kuning/jaundice</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Lelah/Asthma</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Batuk Kering/</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Tuberculosis</td>
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<tr>
<td>Penyakit Kelamin/</td>
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<td>☐</td>
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<tr>
<td>Venereal Disease</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Penyakit</th>
<th>☐ Ya</th>
<th>☐ Tidak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Kencing manis/</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Diabetes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Darah Tinggi/</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Hypertension</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Penyakit jantung</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Penyakit mental</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Sawan/Fits</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

9. Adakah anda pernah mengidap apa-apa penyakit lain? Jika ya, sila nyatakan:  
   ☐ Ya ☐ Tidak

10. Nyatakan pertalian keluarga jika mereka pernah mengidap penyakit seperti di bawah:
   a. Hepatitis B atau Hepatitis C?  
      ☐ Ya ☐ Tidak
   b. Penyakit mental?  
      ☐ Ya ☐ Tidak

11. **Penderma Wanita Sahaja**
   a. Adakah anda mungkin atau sedang mengandung atau mempunyai anak yang berumur kurang daripada satu tahun?  
      ☐ Ya ☐ Tidak
   b. Adakah anda kedatangan haid?  
      ☐ Ya ☐ Tidak
12. Dalam masa 6 bulan yang lepas, pernahkah anda:
   a. Menerima transfusi darah?  
      [ ] Ya  [ ] Tidak
   b. Menjalani sebarang pembedahan?  
      [ ] Ya  [ ] Tidak

13. Pernahkah anda menerima:
   a. Rawatan menggunakan “human growth hormone”?  
      [ ] Ya  [ ] Tidak
   b. Transplant cornea?  
      [ ] Ya  [ ] Tidak
   c. Transplant selaput otak (“duramater”)?  
      [ ] Ya  [ ] Tidak

14. Anda TIDAK BOLEH MENDERMA JIKA:
   - anda dan pasangan adalah HIV positif
   - anda melakukan perhubungan sejenis
   - anda pernah bekerja sebagai pelacur
   - anda bertukar-tukar pasangan seks
   - anda pernah mengambil dadah secara suntikan (termasuk dadah untuk membina badan)
   - anda pernah ada hubungan seks dengan pelacur

   a) Adakah anda termasuk dalam golongan di atas?  
      [ ] Ya  [ ] Tidak

   b) Adakah anda pasangan seks kepada golongan di atas?  
      [ ] Ya  [ ] Tidak

15. Adakah tujuan anda menderma darah ialah untuk ujian HIV dan HEPATITIS?
    [ ] Ya  [ ] Tidak

16. Pernahkah anda tinggal di United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, atau Channel Island) atau Republik Ireland dari tahun 1980 hingga 1996 untuk tempoh 6 bulan atau lebih?
    [ ] Ya  [ ] Tidak

17. Pernahkah anda tinggal di negara-negara di Europa dari tahun 1980 hingga sekarang untuk tempoh 6 bulan atau lebih?
    [ ] Ya  [ ] Tidak

---

**SILA TANDATANGAN DI HADAPAN PENEMUDUGA**

**PENGAKUAN**

Saya mengaku bahawa semua jawapan yang saya berikan adalah benar.

Saya faham saya tidak boleh menderma darah sekiranya saya termasuk dalam golongan yang berisiko tinggi seperti jangkitan HIV/Hepatitis/Sifilis (lihat “PERHATIAN”).

Saya membenarkan pengambilan darah/komponen darah saya dan penggunaan darah ini untuk ujian bagi Sifilis, HIV, Hepatitis B dan Hepatitis C atau untuk tujuan-tujuan lain yang difikirkan perlu oleh pihak Pusat Perkhidmatan Darah, Hospital dan Kementerian Kesihatan Malaysia. Saya faham bahawa semua keputusan ujian dan maklumat yang diberi adalah dianggap sulit.

.................................................  .................................................
(Tandatangan Penderma)                  (Nama & Tandatangan Penemuduga)

.................................................
(Tarikh).....................................

.................................................
(Tarikh).....................................
<table>
<thead>
<tr>
<th>Tugas yang dijalankan:</th>
<th>Nama Pegawai</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pegawai yang menyambut penderma</td>
<td></td>
</tr>
<tr>
<td>2. Anesthetik diberi</td>
<td>☐ Ya ☐ Tidak</td>
</tr>
<tr>
<td>3. 'Venepuncture' – masa mula:</td>
<td></td>
</tr>
<tr>
<td>4. Pengambilan Sample – masa berhenti:</td>
<td></td>
</tr>
<tr>
<td>5. Jumlah baki barkod:</td>
<td></td>
</tr>
</tbody>
</table>

Untuk diisi oleh Pegawai Yang Bertugas

Pemohon adalah ☐ layak untuk menderma darah. ☐ Tidak layak untuk menderma darah

Sebab:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Amaun ml ☐ single bag ☐ double bag ☐ triple bag

(Tandatangan Peg. Yang Bertugas)

(Tarikh)..

Nama Pegawai:

1. Pegawai yang menyambut penderma
2. Anesthetik diberi
3. 'Venepuncture' – masa mula:
4. Pengambilan Sample – masa berhenti:
5. Jumlah baki barkod:

Untuk diisi oleh Pegawai Yang Bertugas

Amaun ml ☐ single bag ☐ double bag ☐ triple bag

(Tandatangan Peg. Yang Bertugas)

(Tarikh)..

Nama Pegawai:

1. Pegawai yang menyambut penderma
2. Anesthetik diberi
3. 'Venepuncture' – masa mula:
4. Pengambilan Sample – masa berhenti:
5. Jumlah baki barkod:
ATTENTION TO ALL DONORS

Dear Donor,

The Blood Bank is always in need of safe blood to treat patients. Thank you for volunteering to donate your blood. Your blood can save the life of another person.

However, there are times in which your blood may not be suitable for donation. Please answer all the questions in this questionnaire. The information provided will help us to determine if your blood is safe to be used by another person.

Conditions that make your blood unsuitable for donation:

1. **Acquired Immune Deficiency Syndrome (AIDS)/HIV Infection**
   HIV is a virus that causes AIDS. It can be spread through sexual contact with an infected person, sharing contaminated needles like those used by intravenous drug abusers, transfusion of contaminated blood and by an infected pregnant woman to her unborn baby.

   Most people who have been infected with HIV do not know that they carry the virus because they may look and feel completely well. But these infected people can pass the infection on to those who receive their blood.

   Thus, persons who are at an increased risk of being exposed to HIV must not donate blood. Please do not donate if you fall into any of the following groups:

   - Persons who take drugs intravenously.
   - Persons who have had sex with multiple partners.
   - Persons who have had sex with partners of the same sex.
   - Persons who have had sex with prostitutes.
   - Persons who have had provided sexual favours for money.
   - Persons who have had sex with any of the above groups.

2. **Hepatitis**
   Hepatitis is a viral disease that affects the liver. Hepatitis can be caused by different hepatitis viruses e.g. hepatitis A, B and C. If you have had hepatitis B or C, you must not donate blood because the virus can be spread through transfusion of contaminated blood with serious consequences for the patient receiving the transfusion.

3. **Syphilis**
   If you have had syphilis or any other type of venereal disease or sexually transmitted disease (VD or STD), your blood is unsuitable for donation.

4. **Malaria**
   Malaria is caused by the plasmodium parasite that attacks the red blood cells. It can be transmitted through a blood transfusion.

Please do not donate if you think your blood is not safe. If you have any queries, do not hesitate to ask our medical officer on duty.

If, for any reason you feel that the blood you have just donated is unsafe, please inform the medical officer on duty. The information will be kept confidential.

"SAFE BLOOD BEGINS WITH YOU"
BLOOD DONOR ENROLMENT FORM

Please read and answer the following questions before you donate. Should you have any difficulty answering any of the questions, please refer to the staff on duty.

Name: ________________________________

I/C No. (New): ________________ - __________ - __________

I/C No. (Old): ________________ - __________ - __________

Police/Army: ________________

Passport No: ________________

Age: ________________

Sex: [ ] Male  [ ] Female

Race: [ ] Malay  [ ] Chinese  [ ] Indian  [ ] Others (Specify)

Occupation: ________________________________

Marital Status: [ ] Married  [ ] Single  [ ] Divorced

Address (Hse): ____________________________________

__________________________________

__________________________________

__________________________________

Postcode: ________________

Tel No (Hse.): ________________

Tel H/P No. : ________________

Address (Off): ____________________________________

__________________________________

__________________________________

__________________________________

Postcode: ________________

Tel No. (Off.): ________________

Tel: ________________

To be filled by the Officer I/C: ________________________________

Barcode No: ________________________________

No. of donation: _______ (PDN) _______ (Other Govt.Hospital) _______ (Other Non-Govt Hospital)

Type Of Donation: [ ] Whole Blood  [ ] Apheresis

Last Donation Date: ________________________________

<table>
<thead>
<tr>
<th>Observation/Blood Test</th>
<th>Results</th>
<th>Performed by (Name &amp; Initial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weight (kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Haemoglobin Level (g/dl)</td>
<td>Copper Sulphate Method [ √ If sinks (Hb ≥ 12.5g/dl) ] Haemocue Method [ ] [ ]</td>
<td></td>
</tr>
<tr>
<td>3. Blood Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Blood Pressure (mmHg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Rhesus Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Registration</td>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

Transfusion Practice Guidelines for Clinical and Laboratory Personnel 3rd edition March 2008
Please fill this section by ticking ☐ the correct answer.

1. Do you feel well today? ☐ Yes ☐ No

2. Did you have any problems during previous blood donations? ☐ Yes ☐ No

3. Have you ever been deferred from donation before? ☐ Yes ☐ No

4. In the past 1 week, have you:
   a) taken any aspirin? ☐ Yes ☐ No
   b) taken any other medication other than aspirin? ☐ Yes ☐ No
      If yes, please specify:
   c) had any cough or cold or migraine? ☐ Yes ☐ No
   d) had any other illnesses? If yes, please specify:

5. Have you had any vaccination or injection within the last 3 weeks? ☐ Yes ☐ No

6. Have you had any dental treatment in the past 24 hours? ☐ Yes ☐ No

7. Have you had any tattoos/acupuncture/ear-piercing in the last 1 year? ☐ Yes ☐ No

8. Have you had any treatment recently at any clinic or hospital? If yes, please specify type of illness and treatment received: ☐ Yes ☐ No

9. Have you had any of the following diseases:
   Jaundice ☐ Yes ☐ No
   Hepatitis B ☐ Yes ☐ No
   Hepatitis C ☐ Yes ☐ No
   Asthma ☐ Yes ☐ No
   Tuberculosis ☐ Yes ☐ No
   Venereal Disease ☐ Yes ☐ No
   Malaria ☐ Yes ☐ No
   Diabetes ☐ Yes ☐ No
   Hypertension ☐ Yes ☐ No
   Heart Disease ☐ Yes ☐ No
   Mental Illness ☐ Yes ☐ No
   Fits/epilepsy ☐ Yes ☐ No

9. Have you had any other medical history of disease? If yes, please specify: ☐ Yes ☐ No

10. Please state the relationship if any of your family members ever had:
    a) Hepatitis B or Hepatitis C? ☐ Yes ☐ No
    b) Any mental illness? ☐ Yes ☐ No

11. Female Donors Only
    a) Are you pregnant or have a baby under 1 year old? ☐ Yes ☐ No
    b) Are you having menstruation now? ☐ Yes ☐ No

12. In the last 6 months, have you had:
    a) any blood transfusion? ☐ Yes ☐ No
    b) any operations? ☐ Yes ☐ No
13. Have you ever received:
   a) treatment with human growth hormone?  [Yes No]
   b) cornea transplant?  [Yes No]
   c) transplant of brain membranes (dura mater)?  [Yes No]

14. You should NEVER GIVE BLOOD IF:
   • you and your partner are HIV positive
   • you are a man who has had sex with another man
   • you have multiple sex partners
   • you have ever worked as a prostitute
   • you have ever injected yourself, even once, with drugs
     (including body building drugs)
   • you have had sex with prostitute

   a) Are you one of the above?  [Yes No]
   b) Are you a sex partner of the above?  [Yes No]

15. Do you donate blood to test for HIV or HEPATITIS ?  [Yes No]

16. Have you ever lived in the United Kingdom (England, Northern
    Ireland, Scotland, Wales, the Isle of Man, or the Channel
    Island) or Republic of Ireland from 1980 to 1996 for a period of
    6 months or longer?  [Yes No]

17. Have you ever lived in Europe from 1980 to the present for a
    period of 6 months or longer?  [Yes No]

PLEASE SIGN IN FRONT OF THE INTERVIEWER

DECLARATION

I declare that all the answers to the above questions are true.

I realise that I shall not donate blood if I belong to any of the groups of persons at risk of HIV infection
(please refer to “Attention” note).

I give my permission voluntarily for my blood to be withdrawn and tested for Syphilis, HIV, Hepatitis B
and Hepatitis C in whatever manner deemed appropriate by the Blood Services Centre, Hospital and the
Ministry of Health, Malaysia. I understand that all results will be kept confidential.

..................................................    ..................................................
(Signature of donor)    (Name & Signature of Officer on Duty)
(Date)......................    (Date)......................

To be filled by the Medical Officer /Officer On Duty

The above person is  [ ] eligible to donate.

Amount  [ ] ml  [ ] single bag  [ ] double bag  [ ] triple bag

[ ] Not eligible to donate.

Reason : ..................................................
..................................................
..................................................
..................................................

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Done By(Name &amp; Initial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Donor received by</td>
<td></td>
</tr>
<tr>
<td>1. Anaesthetic given</td>
<td>[Yes No]</td>
</tr>
<tr>
<td>3. Venepuncture Time start :</td>
<td></td>
</tr>
<tr>
<td>4. Sample Taken Time stop :</td>
<td></td>
</tr>
<tr>
<td>5. No. of Barcodes remainder</td>
<td></td>
</tr>
</tbody>
</table>

Transfusion Practice Guidelines for Clinical and Laboratory Personnel 3rd edition March 2008
55
CRITERIA FOR SETTING UP A TRANSFUSION TRANSMITTED INFECTION LABORATORY FOR SCREENING OF DONATED BLOOD

THE LABORATORY SHALL HAVE

(a) Comprehensive and effective quality management system with all elements of GMP in place

(b) A annual workload of at least 20,000 sample per year for donors to be screened for HIV, hepatitis B & C and syphilis.

(c) Infrastructure, resources and equipment that are appropriate for the function:
   - proper facility for screening transfusion transmitted infection with compliance to GMP or other quality system
   - partial or full automation system;
   - adequate budget
   - adequate number of personnel of at least 2 Microbiologist and 4 Medical Laboratory Technologist dedicated for the laboratory.

(d) Should be headed by a trained Microbiologist with a sound knowledge of virology and have a working experience of at least 3 months under supervision in a Transfusion transmitted Infection laboratory.

(e) Participation in external quality assessment programmee at national or international level.

(f) A written approval from Kementerian Kesihatan Malaysia
APPENDIX 5

BLOOD SCREENING/BLOOD RELEASE FLOW-CHART

TRANSFUSION MICROBIOLOGY LAB.

Testing of Pilot Tubes for syphilis, HIV 1 & 2, HCV, HBV

Quarantine till results are ready

List down all Initial reactive

Inform INVENTORY to identify tainted blood bag by designated staff

Send +ve bags with segment for retesting to Transfusion Microbiology Lab.

Segment Discrepant Result NR

- Quarantine and recheck the batch of blood bags with similar blood group.
- Recall all donors of the same blood group for re-screening if the problem still occurs.

Component Lab designated staff is to remove WB/PRBC/Platelets/Plasma products of the +ve sample from the quarantine fridge/freezers. All tainted components must be labelled with a “BIOHAZARD” sticker. Check the segments to tally with each positive blood bag. Denote the type of component on the Discard File copy & the Component Copy against correct Barcode.

Send the above said components to Transfusion Microbiology Lab for safe disposal.

Segment +ve RR

Release rest of negative bags for use once the results of +ve segment correspond with pilot tube of the same donation

Official Report to:-
( containing list of screened blood for a particular collection batch)
:INVENTORY
:COMPONENT
:COUNSELLING i. HBV
ii. HCV
iii. Syphilis
iv. HIV 1 & 2

Negative blood to be labelled with stickers “SCREENED”. Check number against Negative List (Official Report) given by Transfusion Microbiology Lab.

Check component bag numbers against the Notification File copy and the Discard File copy. Dispose the bags (Concession company). All involved persons must indicate their part by a signature on Discard Copy.
APPENDIX 6

CONSENT FORM FOR BLOOD OR
BLOOD COMPONENT TRANSFUSION

Date :

Patient’s Name :   Age :
Identity Card No. : Sex : Male/Female*
Address :

Attending Medical Practitioner : Dr.
Identity Card No. :

I, the above-named/parent/guardian/spouse/next of kin of the above-named*, have been informed of the need for a blood transfusion of the patient. The attending medical practitioner has explained to me the risk and benefits involved in the transfusion as well as answering all my inquiries satisfactorily. I understand that despite testing and screening on the blood/blood components for HIV, Hepatitis B, Hepatitis C and Syphilis according to established standard, there are still risks of developing the disease. I also understand that unavoidable complications of transfusion may also occur.

I fully understood the above and hereby agree to the blood/blood component transfusion.

.................................................  ...............................................  
Signature of the patient/ parent/guardian/spouse/next of kin*  Signature of Attending Medical Practitioner

Name of parent/guardian/spouse/next of kin** :
Identity Card No. of the above :

I was present while the above matter was explained to the patient/ parent/ guardian/ spouse/ next of kin* whose signature appears above. In my opinion, the person referred to has understood the contents of this form and agreed to the transfusion willingly.

.................................................  
Signature of witness  
Name of witness :
Identity Card No. :

* delete appropriately
** if necessary
BORANG PERSETUJUAN PEMINDAHAN DARAH
ATAU KOMPONEN DARAH

Tarikh:
Nama Pesakit: Umur:
No. Kad Pengenalan: Jantina: Lelaki/ Perempuan*
Alamat:

Pengamal Perubatan Yang Merawat: Dr.
No. Kad Pengenalan:

Saya, seperti nama tersebut di atas / ibu bapa / penjaga / suami/ isteri / saudara kepada pesakit seperti nama di atas*, telah dimaklumkan bahawa pesakit memerlukan pemindahan darah atau komponen darah. Pengamal Perubatan yang merawat telah memberi penjelasan kepada saya tentang risiko dan kebaikan pemindahan darah dan saya berpuas hati dengan semua jawapan yang diberikan kepada soalan-soalan yang saya kemukakan. Saya faham dan sedar, meskipun darah atau komponen darah itu telah menjalani ujian saringan untuk HIV, Hepatitis B, Hepatitis C dan Siflis mengikut standard yang telah ditetapkan, namun risiko jangkitan penyakit menerusi pemindahan darah masih boleh berlaku. Saya juga faham dan sedar bahawa komplikasi pemindahan darah yang lain yang tidak dapat dielakkan juga mungkin berlaku.

Saya benar-benar faham kenyataan diatas dan saya bersetuju untuk menerima pemindahan darah atau komponen darah.

.................................................. ..................................................
Tanda tangan pesakit / ibu bapa/penjaga / isteri / saudara terdekat.* Tandatangan Pengamal suami / Perubatan yang merawat.

Nama Ibu bapa/penjaga/suami/isteri/saudara terdekat**:
No. Kad Penenalan:

Saya memperakui makluman di atas telah diterangkan kepada pesakit/ibu bapa/penjaga/suami/isteri/ saudara terdekat yang tanda tangannya tertera diatas.

Pada hemah saya penama yang dirujuk telah memahami kandungan borang ini dan telah bersetuju untuk menerima pemindahan darah atau komponen darahsecara sukarela.

........................................
Tanda tangan saksi
Nama saksi:
No. Kad Pengenalan saksi:

* potong yang tidak berkaitan
** jika perlu
CHECKLIST FOR TAKING BLOOD FOR GROUP AND CROSSMATCH

1. Confirm the patient’s
   • Name:
   • Identification no:

      by: asking the patient/relatives
      checking patient’s notes

2. Confirm patient’s name and identification before labelling the sample

3. Labelling must be done immediately at the bedside
   by the person taking the blood

      Never label samples from 2 or more patients at the same time.
BORANG PERMOHONAN TRANSFUSI DARAH

(Mesti dipenuhi dalam dua salinan oleh Pegawai Perubatan. Tulis dengan pen mata bulat dan sila tandakan √ dalam petak yang sesuai.)

<table>
<thead>
<tr>
<th>Nama (Tulis huruf besar)</th>
<th>No. Kad Pengenalan</th>
<th>No. Daftar</th>
</tr>
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<tbody>
<tr>
<td>Hospital</td>
<td>Unit</td>
<td>Wad</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bangsa</td>
</tr>
<tr>
<td>Pegawai Kerajaan</td>
<td>Kelas</td>
<td>Bayaran/Percuma</td>
</tr>
<tr>
<td>Ya/Tidak</td>
<td></td>
<td>Pakar Perunding</td>
</tr>
<tr>
<td>Diagnosa</td>
<td></td>
<td>Kumpulan Darah</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ada/Tiada</td>
</tr>
<tr>
<td>Transfusi darah masa lalu?</td>
<td></td>
<td>Jika 'ya' sebutkan tarikh transfusi darah yang terakhir</td>
</tr>
<tr>
<td>Ya/Tidak</td>
<td></td>
<td>Komplikasi?</td>
</tr>
<tr>
<td>Sekiranya pesakit seorang wanita, nyatakan --&gt;</td>
<td>Bil. kehamilan</td>
<td>Bil. Lahir Matl</td>
</tr>
</tbody>
</table>
|                         |                     | Tanda-tanda "Haemolytic Disease of Newborn"
| Contoh darah diambil oleh | Units/mls | Unit/mls |
|                         |                     |                     |
| Contoh darah dilabel oleh |                     |                     |
|                         |                     |                     |
| Pada ________ jam ________ pagi/petang |                     |                     |
|                         |                     |                     |
| Nota:-
(1) Sila hantarkan 5ml contoh darah dalam tiub tanpa antibekuan.
(2) Dalam keadaan kecemasan, sila talipon makmal transfusi darah. Ujian Keserasian darah memerlukan masa 2 jam. Bila darah diperlukan dengan segera, ujian keserasian darah boleh dipercuba, tetapi tahap keselamatan penggunaan darah adalah berkuranan dan Pegawai Perubatan yang menggunakan darah tersebut bertanggungjawab diatas segala masalah yang timbul sekiranya ada. Untuk kes-kes yang tidak memerlukan darah dengan segera, hantarkan contoh darah 24 jam lebih awal.
(3) Darah yang tidak digunakan pada waktu yang ditetapkan dalam tempoh 24 jam akan dibatalkan kecuali Pegawai Perubatan meminta diperpanjang tempoh simpanannya.
(4) MUSTAHAK- Sila beritahu PPD dengan segera sekiranya darah yang diminta tidak diperlukan.
(5) AMARAN: Setiap transfusi darah boleh mengakibatkan risiko kecil infeksi.
WARNING Every blood transfusion carries a small risk of infection.

KHAS UNTUK KEGUNAAN KAKITANGAN MAKMAL PUSAT PERKHIDMATAN DARAH

Permintaan diterima
Pada ____________ jam ____________ pg/ptg
(Tandatangan)

Serum pesakit diserasikan dengan Beg Darah No.

<table>
<thead>
<tr>
<th>R.T.</th>
<th>37ºC</th>
<th>AHG</th>
<th>T.T.</th>
<th>Tarih &amp; masa</th>
</tr>
</thead>
</table>

UJIAN KESERASIAN DARAH

<table>
<thead>
<tr>
<th>R.T.</th>
<th>37ºC</th>
<th>AHG</th>
<th>T.T.</th>
<th>Tarih &amp; masa</th>
</tr>
</thead>
</table>

Tandatangan

Catatan

Bekalan diperlukan
(a) Serta merta, tanpa ujian keserasian darah (untuk menyelamatkan nyawa)
(b) Segera (lihat Nota 2)
(c) Pada __________ jam __________ pg/ptg (Lihat Nota 3)
(d) Disimpan selama 24 jam.

Tandatangan: __________

Cop dan Nama Pegawai Perubatan __________

(Huruf besar)
APPENDIX 9

GUIDELINES ON THE TRANSFUSION OF BLOOD AND BLOOD COMPONENTS IN Rh D-NEGATIVE PATIENTS

Introduction

The Rh blood group system is extremely complex, and certain aspects of its genetics, nomenclature, and antigenic interactions are not fully understood. After the A and B antigens of the ABO system, the D antigen of the Rh system has the most significant implications for transfusion practice. The Rh antigens are well developed at birth and they have not been demonstrated in secretions or in any other tissues other than red cells.

In Malaysia, the frequencies of the Rh D-negative phenotypes based on ethnic groups are as follow: Malay 2-3%, Chinese < 1% and Indians 15%. In general less than 2% of the population in Malaysia is of Rh D-negative phenotype.

Clinical significance

The clinical importance of the Rh blood group system stems from the fact that the D antigen has greater immunogenicity than virtually all other red cell antigens. About 90% of D-negative individuals will make anti-D after the transfusion of large volume of D-positive cells, and 70% will respond to repeated small volumes.

Anti-D can cause haemolytic transfusion reaction that can lead to disseminated intravascular coagulation and renal failure. Moreover, since they are of IgG subclass, anti-D can cross the placenta and cause severe haemolytic disease of the newborn. The Rh system is also involved in the specificity of some of the warm autoantibodies of autoimmune haemolytic anaemia.

Immune response to D-antigen

Following the transfusion of D-positive red cell to D-negative patients, anti-D can be detected in the plasma of 90% of the recipient within 2-5 months. Primary immunization still occurs in about half of those D-negative subjects that do not have serologically detectable anti-D. Studies have been shown that as little as 0.03 ml red cells in cumulative dose are capable of inducing primary Rh D immunization. The earliest reported time at which anti-D can be detected in primary immunization is 4 weeks.

Immunization to D-antigen persists indefinitely; therefore D-negative blood should always be given to women, even after menopause. Anti-D can sometimes be detected in the serum a very long time after the last known stimulus. In cases where anti-D can no longer be demonstrated serologically, a transfusion of D-positive blood may evoke a powerful secondary response leading to a delayed haemolytic transfusion reaction. This secondary immune response can occur within few days following transfusion with D-positive red cells, which can shorten the survival of red cells already transfused.

RECOMMENDATION

1. It is the current practice in KKM blood banks that all blood is routinely screened for D-antigen prior to transfusion in donors and recipients. As far as possible, all Rh D-negative patients must receive D-negative whole blood or packed red cells except in certain situation as stated in recommendation no.4.

2. All blood banks should have a few Rh D-negative units in their stock based on their requirement. It is also recommended that the blood bank should keep a list of their Rh D-negative donors that can be called in an emergency.
3. Physician in-charge of known Rh D-negative patient must alert the blood bank of their patient’s blood need at least a week prior to the requirement date such as planned operation or expected date of delivery so that the blood bank can recruit appropriate number of donors in time.

4. In the event of life threatening bleed/ when D-negative blood is not available, effort should be made to try and find D-negative blood. Please refer to the flow chart on the management of Rh D-negative patient with life threatening bleed. In the event that blood may not be made available in time, the treating physician may decide to allow Rh D-positive blood be given instead. This is safe provided the patient does not have preformed anti-D.

5. **Rh D immunoprophylaxis (Anti-D Immunoglobin)**

In any D-negative woman in childbearing age who is not already immunized to RhD, the inadvertent transfusion of D-positive blood should be treated by giving a suitable dose of anti-D. However, in D-negative post-menopausal women or in men who have been transfused with D-positive blood, consideration of immuno-prophylaxis should be given although the consequences to the subject of becoming immunized are not likely to be serious and because treatment with large amounts of anti-D is wasteful and can produce unpleasant effect.

Anti-D immunoglobin is prepared from plasma collected from donors who have high levels of anti-D. Two types of preparation are available- intramuscular and intravenous, however the later is currently not available in Malaysia. As a rule of thumb, 20-25μg anti-D (100-125iu) given intramuscularly is capable of suppressing primary immunization by 1 ml Rh D positive red cells if given within 72 hours of a sensitizing event. When it is possible to give intravenously, a lesser dose will suffice, i.e. 10-15 μg/ml red cells.

When more than 2 units of Rh D-positive blood have been transfused, an exchange transfusion with Rh D-negative blood (once available) should be considered to reduce the load of Rh D-positive RBCs in circulation and thus reducing the dose of anti-D immunoglobin required to suppress primary immunization.

Following exchange transfusion, the residual volume of Rh D-positive RBCs should be estimated using flow cytometry or resetting. Follow-up tests for Rh D-positive RBCs should be undertaken every 48 hours and further anti-D Ig given until all Rh D-positive RBCs have been cleared from the circulation.

6. As it is quite difficult to have D-negative platelet concentrates and plasma, D-negative patients who require them can be safely given D-positive blood components. However, the blood bank supplying the components should select the product with the least red cells contamination. It is also advisable to give the patient anti-D immunoglobulins to suppress primary Rh D immunization in women of childbearing age. 50 μg (250iu) anti-D should be given following every three adult doses of platelets.

7. **Side effects of Anti-D immunoglobulins**

Skin: Local erythema, swelling and tenderness at the injection site

General: Transient rise in temperature, chills, general malaise. Rarely, can cause shock, hypotension, tachycardia and dyspnoea.

When large doses of anti-D are given, it can also cause rapid red cell destruction/ haemolysis with haemoglobinuria.
Transfusion of Rh D–negative patient in life-threatening situation

1. Life threatening bleed, to estimate blood requirement
2. To liaise with Blood Bank MO/Specialist
3. Transfuse ABO group specific Rh D negative blood
   - Not available
   - To transfuse group O Rh D negative packed cell
   - Not available

**Blood Bank**
- To contact nearest/ other blood bank for Rh negative blood.
- To call donor and relatives /siblings for urgent Rh D–ve blood.
- To do antibody screen to exclude the presence of anti-D in patient

- If no anti-D is detected Blood Bank Dr to discuss with the Physician in charge regarding transfusion of Rh D positive blood. Patient’s consent should be sought with the explanation of risks involved.
- For women in childbearing age, need to give Anti-D IgG within 72 hours.
- For others, Anti-D IgG should be given.
- To monitor anti D level weekly x 4/52, then monthly x 6/12.
- KIV exchange transfusion once Rh D-negative blood is available.

- If anti-D is detected, Rh D negative blood must be given

* Any queries to contact Pusat Darah Negara directly at 03-26933888. After office hours please contact 03-26955564
APPENDIX 10

GUIDELINES ON ESTABLISHING MAXIMUM BLOOD ORDERING SCHEDULE FOR KKM HOSPITALS

Introduction

Many blood banks are facing increasing workloads without corresponding increase in trained staff. To improve the efficiency and reduce unnecessary workload the group screen and hold policy was introduced some years ago. To implement this, hospitals must develop their own maximum surgical blood order schedule.

The Maximum Surgical Blood Order Schedule (MSBOS) is a table of elective surgical procedures, which lists the number of units of blood routinely requested, and crossmatched for them pre-operatively. The schedule is base on retrospective analysis of actual blood usage associated with the individual surgical procedure. An important factor in the establishment of an MSBOS is the identification of those procedures that can be accommodated by the group, antibody screen and hold (GSH) procedure. For cases where blood is not likely to be transfused group screen and hold is performed. Where blood is likely to be transfused a full crossmatch is done. However when antibody is screen is positive, compatible blood must be made available in all cases before surgery.

Developing MSBOS

Data on Blood request for all procedure for 6 months is analysed. For each procedure indicate the number of units crossmatched and the number of units transfused. Calculate the percentage of blood usage:

\[
\text{Total No of units transfused} \times 100 = \% \\
\text{Total No of units crossmatched}
\]

Procedures where blood usage is less than 30% GSH is performed. Other procedures are allotted a tariff based on the average number of units transfused.

Example:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. of Operation</th>
<th>Units of bld crossmatch</th>
<th>Units of bld Transfused</th>
<th>% of units transfused</th>
<th>C : T Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caesarian Section</td>
<td>60</td>
<td>120</td>
<td>8</td>
<td>6.6%</td>
<td>15</td>
</tr>
<tr>
<td>Total Hip Replacement</td>
<td>20</td>
<td>60</td>
<td>40</td>
<td>66%</td>
<td>1.5</td>
</tr>
</tbody>
</table>

In the above example for caesarian section GSH is performed while in total hip replacement a full crossmatch is performed. The number of units crossmatched is base on the average number of units transfused.

In drawing up the schedule local factors such as expertise available in the hospital and the speed of provision of compatible blood has to be taken into account.
Implementation

MSBOS should be explained to all doctors in the hospitals or at least the heads of the department. The best way to do this is through the hospital transfusion committee. Once the draft schedule has been constructed, it should be circulated and discussed. Flexibility should be allowed for individual cases e.g. placenta previa. When urgent blood is required this should be made available in time. All heads of department must agree on the schedule.

Once agreed, the schedule is circulated. Regular monitoring is necessary to detect any problems in the implementation and ‘fine turning’ of the schedule may be necessary. An example of the schedule is in Appendix I.

Confidence in the operation of MSBOS and compliance by users depends on the laboratory being able to provide compatible blood whenever it is required, including urgent requests. This is dependent on the following five factors.

1. Pre-operative blood samples must be obtained from all patients whether the ‘GSH’ and cross-matching categories. The laboratory will normally set its own time limits for the receipt of blood for grouping and antibody screening before operation. If an irregular antibody is detected, this may delay the provision of compatible blood and the consultant must be informed.

2. Serum saved for cross-matching must be accurately labeled and readily accessible.

3. Procedures must be clearly defined to enable blood transfusion staff to provide compatible blood safely should an emergency occur during a ‘GSH’ operation.

4. Communication between the operating theatre and the blood transfusion laboratory must be clearly defined. An urgent need for blood during an operation must be promptly reported to the laboratory by the anaesthetist, or his/her deputy. The request must be received by a responsible person in the blood transfusion laboratory (usually a technologist) and acted upon immediately. Adequate details to identify the patient are essential and the degree of urgency must be clearly indicated so that the most appropriate compatibility tests can be carried out in the time available.

5. Portering of blood between the laboratory and the operating theatre must have an established priority.

Serological Techniques

- Blood sample from all patients must have a full ABO & Rh D grouping and antibody screening done.

- For GSH category, the serum is kept for 48 hours.

- Where antibody screen is positive antibody identification must be performed and compatible blood crossmatched before surgery is performed

- If blood is urgently required, blood of the same ABO and RhD can be given after an appropriate ‘quick method’. After the blood has been issued the laboratory would continue to do a full crossmatch. If any incompatibility is detected, the patient’s doctor must be informed immediately.
Advantages

The introduction of an MSBOS has the following advantages.

1. A reduction in crossmatching workload of the blood transfusion Laboratory (in some cases in excess of 25%) which allows more time to respond to emergency requests, and also to investigate complex serological problems.

2. A reduction in the level of stress.

3. More efficient use of blood stocks and a reduction in wastage due to out-dating.

4. Improve the quality of the blood in stock as blood is not removed from the blood bank unless it is almost certain to be transfused.

MAXIMUM SURGICAL BLOOD ORDER SCHEDULE (MSBOS)

**GENERAL SURGERY**

- Abdominal-perineal resection 4
- Cholecystectomy GSH
- Gastrectomy 2
- Hemicolecction, Small bowel resection GSH
- Hiatus hernia repair
  - abdominal GSH
  - transthoracic 2
- Inguinal hernia repair GSH
- Laparotomy GSH
  - Perforated viscus 2
- Mastectomy 4
- Oesophagectomy 4
- Pancreatectomy 4
- Portocaval shunt 4
- Splenectomy 2
- Thyroidectomy , GSH
- Parathyroidectomy GSH
- Varicose veins GSH
- Vagotomy GSH
- Whipple’s procedure 4

**GYNAECOLOGY**

- Hysterectomy
  - abdominal, vaginal GSH
  - Wertheim 2
- Myomectomy 2
- Ovarian Cystectomy GSH
- Termination, D & C GSH
- Vaginal Repair GSH
- Vulvectomy 2
UROLOGY

Cystectomy 4
Nephrectomy GSH
Percutaneous nephrolithotomy GSH
Pyelolithotomy
  - simple GSH
  - complicated or large calculus 2
Renal transplant GSH
Retropubic prostatectomy 2
TUR prostate GSH
Ureterolithotomy GSH

ORTHOPAEDIC

Femoral osteotomy 2
Fractured humerus GSH
Fractures neck of femur GSH
Laminectomy, spinal fusion 2
Harrington rods 4
Putti-Platt shoulder repair GSH
Total hip replacement 3
Total knee replacement 2
Total shoulder replacement GSH

MISCELLANEOUS

Cardiac catheterisation GSH
Coronary angiogram GSH
Liver, renal biopsy GSH
Pacemaker insertion GSH
CHECKLIST FOR THE ISSUE OF
BLOOD PLASMA/PLASMA & BLOOD COMPONENT

BEFORE YOU ISSUE BLOOD OR BLOOD COMPONENT

1. Check that the person collecting the blood or blood component has brought documentation to identify the patient.

2. Check the patient’s:
   - Name
   - Hospital reference number
   - Ward
   - Blood group
   
   With
   - The blood request form
   - The compatibility label
   - The compatibility register

3. Check that all other tests, including anti-HIV, Hepatitis B, Hepatitis C and Syphilis, have been performed and are negative

4. Confirm that the blood or blood component is compatible by checking the blood group on:
   - The blood request form
   - The compatibility label
   - The compatibility register.

5. Check the expiry date of the blood or blood component.

6. Inspect the blood or blood component for any signs of deterioration.

7. Enter the date and time of issue in the compatibility register.

8. Obtain a signature in the compatibility register from the person collecting the blood.
## INSTRUCTIONS ON PROPER HANDLING OF BLOOD AND BLOOD COMPONENTS IN THE WARD

<table>
<thead>
<tr>
<th></th>
<th>Whole blood/RBC.</th>
<th>Platelet Conc.</th>
<th>Cryo/LP/FFP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Supply</strong></td>
<td>- After Crossmatch</td>
<td>- Group Specific/Compatible</td>
<td>- Group Specific</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No Crossmatching Required</td>
<td>- No Crossmatching Required</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Should be thawed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>REQUEST ONLY WHEN REQUIRED</td>
</tr>
<tr>
<td><strong>Collection</strong></td>
<td>- Blood Box WITH Ice</td>
<td>- Blood Box WITHOUT Ice</td>
<td>Blood Box WITH Ice</td>
</tr>
<tr>
<td><strong>Use</strong></td>
<td>- As Soon As Possible (After Reaching The Ward)</td>
<td>- Transfuse Immediately</td>
<td>- Transfuse Immediately</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>+2°C to +6°C</td>
<td>Room Temperature + 20°C to +24°C on agitator</td>
<td>SHOULD NOT BE STORED OR KEPT IN THE WARDS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DO NOT STORE IN FRIDGE</td>
<td></td>
</tr>
<tr>
<td><strong>Return</strong></td>
<td>- Return Immediately If Not Used</td>
<td>- Return Immediately If Not Used</td>
<td>- Return Immediately If Not Used</td>
</tr>
<tr>
<td></td>
<td>SHOULD NOT BE KEPT &gt; 4 HOURS IN THE WARDS</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>After Used</strong></td>
<td>Fill Up Blood Tag (PPDK 1) And Return Together With Empty Bag to Blood Bank As Soon As Possible</td>
<td>Fill Up Blood Comp. Tag (PPDK 1) And Return Together With Empty Bag to Blood Bank As Soon As Possible</td>
<td>Fill Up Blood Comp. Tag (PPDK 1) And Return Together With Empty Bag to Blood Bank As Soon As Possible</td>
</tr>
</tbody>
</table>
APENDIX 13

CHECKLIST FOR GIVING BLOOD OR BLOOD COMPONENT TO A PATIENT

BEFORE YOU GIVE BLOOD OR BLOOD COMPONENT TO A PATIENT

1. Confirm the patient’s:
   * name
   * hospital reference number
   * ward

   by asking the patient or relative to confirm the patient’s name and by checking:
   * the patient’s note
   * the compatibility label
   * the blood request form

2. Confirm that the blood or blood component plasma is compatible by checking the blood group on:
   * the patient’s notes
   * the compatibility label
   * the blood request form

3. Check for any change in colour, expiry date, leakage, etc of the blood or blood component.

4. In the patient’s notes, record:
   * the date of transfusion
   * the time of transfusion
   * the number of units of blood or blood components given
   * the blood or blood component unit numbers

5. Sign the patient’s note
1. IMMUNE HAEMOLYTIC TRANSFUSION REACTION

This is defined as the destruction of red cells in the recipient of a transfusion caused by red cells immune alloantibodies.

**Acute haemolytic transfusion reaction:** immediate intravascular haemolysis occur with ABO-incompatibility while immediate extravascular haemolysis occur with anti- Rhesus, Kell or S antibodies. In a conscious patient, even a few mls of ABO incompatible blood may cause symptoms within 1 or 2 minutes.

The symptoms include feeling of doom, agitation, flushing, restlessness, dyspnoea, pain in abdominal, flank or chest, vomiting and diarrhoea. The signs are fever, hypotension, unexpected bleeding, dark coloured urine and renal shutdown. In an unconscious/anaesthesised patient, only the signs will be evident.

**Delayed haemolytic transfusion (DHTR) reaction:** due to extravascular destruction of red cells caused by alloantibodies not detectable at the time of compatibility testing. However, patient experiences haemolysis of the transfused red cells after an interval of 24 hours up to one week during which an anamnestic response occurs.

The findings are: fall in haemoglobin level after transfusion, jaundice, progressive anaemia, fever, arthralgia, myalgia and serum-sickness like illness.

**The Management Of Haemolytic Transfusion Reaction**

For suspected acute transfusion reaction, the blood transfusion must be STOP immediately and resuscitation measures taken depending on the situation and at the same time, this transfusion reaction investigations begin simultaneously.

**Investigation**

a) The compatibility label of the blood unit should be checked again to ensure that it corresponds with patient’s name, registration number/I.C., request form and case note.

b) If a mistake is found, the blood bank should be informed immediately since the unit of blood intended for that patient could be transfused to another patient.

c) Blood should be taken for the following:
   - 10 mls of clotted blood to Blood Bank and label as post transfusion sample 1
     - for repeat ABO and Rhesus grouping
     - for repeat compatibility testing
     - Antibody screening and Direct Coomb's Test
   - Send another sample 24 hours later and label as post transfusion sample 2
   - Send FBC/FBP in EDTA tube.
   - Send blood sample to biochemistry laboratory for:
     - Serum electrolytes and renal profile
     - Serum Bilirubin
   - Send blood for Disseminated Intravascular Coagulopathy (DIVC) screening.

d) All blood bags including unused bags and giving set should be returned to the blood bank for microbiological study.

e) Urine output should be monitored and presence of haemoglobinuria noted.

f) An ECG should be done to check for evidence of hyperkalaemia.

g) Urine should be sent to confirm the presence of haemoglobinuria.
Treatment of Hemolytic Transfusion Reaction

a) The transfusion must be stopped immediately and the doctor in-charge of the patient must be informed for further management.

b) The blood administration set should be changed and venous access maintained using normal saline.

c) The patient’s vital signs should be monitored and urine output should be maintained at >1.5 ml/kg/hr.

d) If urine output <1.5 ml/kg/hr, fluid challenges should be given with CVP monitoring.

e) If urine output still <1.5ml/kg/hr and CVP adequate then I.V. frusemide 40-80 mg should be given and to be repeated when necessary.

f) If no diuresis follows frusemide, then 100mls of 20% mannitol should be given intravenously.

g) If the urine output, 2 hours after 20% mannitol and frusemide, is < 1.5ml/kg/hr, obtain expert advice as acute renal failure is likely.

h) If bacterial contamination is suspected, treatment with broad-spectrum intravenous antibiotics should be instituted immediately.

i) If disseminated intravascular coagulation (DIC) develops, blood components replacement should be guided by clinical state and coagulation screen results.

j) If the patient needs further transfusions use rematched blood. There is no increased risk of a second haemolytic reaction.

k) In critically emergency situation, time factor is the main concern, the use of emergency group ( packed cell group O rhesus positive or group O rhesus negative should be use to maintain optimal oxygen delivery to the vital organ until the investigation is completed and the compatible blood units are ready.

2. FEVERIL NONHAEMOLYTIC TRANSFUSION REACTIONS (FNHTR)

FNTHR is defined as a temperature increased of more or equal to 1°C associated with transfusion and without any other explanation. It is due to anti-leukocyte antibodies in those previously immunised by pregnancy or previous transfusion. The temperature rise may begin early in the transfusion or be delayed in onset for up to several hours after completion. In severe cases, the symptoms include shivering, flushing, palpitations and tachycardia, followed by headache and rigors. The diagnosis of FNHTR is by exclusion of other causes of transfusion reaction as the fever could be due to an acute haemolytic transfusion reaction or by bacterially contaminated blood.

Recommendations:

a) If FNHTR occurs during transfusion, it can be managed by giving an antipyretic e.g. paracetamol and by slowing the transfusion rate.
b) If patient has experienced two or more FNHTR try:
   - Paracetamol 1g orally 1 hour before transfusion.
   - Slow transfusion and keep patient warm.
   - Leukocyte–depleted blood components.

3. **BACTERIAL CONTAMINATION**

Contamination of blood at source (during collection) or due to faulty storage can lead to the development of septic shock with high mortality rate in the recipient. Bacteria associated with red cells transfusion are usually cold-growing strains such as Psuedomonas or Yersinia. Skin contaminant such as staphylococci may proliferate in platelet concentrates stored at 20º-22ºC.

The signs and symptoms include high fever, shock, haemoglobinuria and renal failure. Gram stain and culture should be sent for diagnosis and vigorous treatment of septic shock and hypotension should be instituted immediately.

4. **URTICARIA**

The typical urticarial reaction consists of circumscribed areas of cutaneous oedema and itching. It usually occurs within minutes of transfusion without fever or other adverse findings. It is caused by the degranulation of the mast cells in the skin and subsequent release of histamine.

Recommendations:

a) The transfusion may be temporarily interrupted while an antihistamine (Chlorpheniramine 10 mg by slow intravenous injection) is administered. If urticaria is the only symptom noted, the transfusion may then be resumed.

b) In a patient who developed extensive urticaria or a confluent total body rash during transfusion, it would be prudent to discontinue the transfusion even if symptoms have responded to treatment.

c) Recipient who have had a severe or frequent minor urticaria following transfusion, administering oral antihistamine (Chlorpheniramine 8 mg) 30 minutes before transfusion may be helpful.

5. **ANAPHYLACTIC REACTION**

An anaphylactic reaction is defined as an immediate generalized hypersensitivity reaction due to activity of Ig E antibodies or the presence of anti-Ig A in patients with congenital deficiency of Ig A. It is a rare but life-threatening complication.

The clinical manifestations include generalized flushing, urticaria, cough, bronchospasm, dyspnoea, respiratory distress, vomiting, diarrhoea, abdominal pain, arrhythmias, hypotension, syncope and can progress to loss of consciousness, shock and in rare cases, death.
Recommendations

a) Treatment of anaphylaxis
   - Stop the transfusion immediately.
   - Maintain venous access with 0.9% saline.
   - Maintain airway and give oxygen, Salbutamol nebuliser can also be given.
   - Give Adrenaline 0.5-1.0 mg i.m. repeated every 10 minutes according to blood pressure and pulse until improvement occurs.
   - Give Chlorpheniramine 10-20 mg by slow intravenous injection.

b) In an IgA deficient recipient requiring transfusion, do not transfuse until after expert advice by the transfusion medicine department.

6. TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

A very severe type of transfusion reaction is the acute, sometimes fatal, pulmonary reaction termed as TRALI. This condition should be suspected in a patient with fever, nonproductive cough, hypotension, tachypnoea, dyspnoea and non-cardiogenic pulmonary oedema within 6 hours of initiating the transfusion with majority within the first 1-2 hour following transfusion. Chest x-ray reveals diffuse pulmonary infiltrates. The pathophysiology is unclear but it is thought that leukocytes antibody in the donor that react with the recipient white blood cell.

Recommendations:

a) Patient suspected to have TRALI should be managed in ICU setting in which oxygen therapy and assisted ventilation are often required. Intravenous steroids may be helpful.

b) The blood bank must be informed so that the implicated donor can be deferred.

7. POST TRANSFUSION PURPUR (PTP)

PTP is rare but potentially lethal complication of transfusion, most often seen in multiparous women with platelet-specific alloantibody due to immune mediated thrombocytopenia. PTP should be suspected in a patient who developed precipitous fall in platelet count and generalized purpura occurring 5-9 days after red cells or platelet transfusion.

Recommendations

- Get expert advice from the transfusion medicine department.
- Treatment is with high dose corticosteroids combined with high dose intravenous immunoglobulin.
- If platelet transfusion is unavoidable, platelets that are compatible with patient’s antibody is needed in managing PTP.
8. **TRANSFUSION ASSOCIATED GRAFT-VS-HOST DISEASE (TA-GVHD)**

TA-GVHD is a rare complication of transfusion, may be acute or chronic. It results from viable lymphocytes from cellular blood component engrafting in an immuno-incompetent patient or in immunologically normal patient after transfusion of a relative's blood. This condition should be suspected in a patient who developed fever, skin rash, diarrhoea, elevated liver enzymes and pancytopenia 1-6 weeks following transfusion. Diagnosis of TA-GVHD could be made by skin biopsy or cytogenetic/HLA analysis to establish presence of third party lymphocytes.

**Recommendations:**

a) Directed donation from a relative to a recipient should be avoided in view of the possibility of shared HLA haplotype.

b) TA-GVHD is prevented in immuno-incompetent recipient by gamma irradiation of cellular blood components at the recommended dose of 25-30 Gy.

9. **OTHER TRANSFUSION REACTION**

Other adverse transfusion reactions include:-

- Fluid overload
- Metabolic disturbances e.g. hyperkalaemia and hypocalcaemia.
- Hypothermia
- Embolism
- Iron overload
- Alloimmunisation to red cell, white cell or platelet antigen.
- Immunosuppression and immunomodulation
- Transmission of viral infection

These should be managed accordingly.
APPENDIX 15

LAPORAN REAKSI KEPADA DARAH ATAU PLASMA
REPORT OF REACTION TO BLOOD OR PLASMA

Hospital ......................... Ward/Clinic ............... Patient’s name ..............................
Reg. Number..........................Age ............... Sex...............Race............................
Diagnosis.................................................................
1. Date and Time transfusion started.................................................................
2. Date and Time of onset of reaction.................................................................
3. Blood/Plasma Serial No.................................................................
4. Volume Blood/Plasma transfused.................................................................
5. Temperature: Before transfusion ................................................................. After transfusion.................................
6. Nature of Reaction : Tick off (✓) the positive symptoms/signs.
   Chills    ☐ Shock    ☐ Haematuria  ☐
   Blood Pressure ☐ Rigors  ☐ Jaundice ☐
   Urticaria ☐ Dyspnoea ☐ Haemoglobinuria ☐
   Pain & Location ................. Elevated ............... Date noticed .................
7. Solution use for starting drip:- N.Saline/5% Dextrose/Other...........................................
8. History of previous transfusion: Yes/No.
   Date of last transfusion ..........................................................................................
9. History of previous reaction:
   ..................................................................................................................................
10. Additional Information ..........................................................................................
11. In the case of females:
   History of pregnancy Yes/No................. No. of pregnancies.........................
   History of abortion Yes/No ................. No. of abortions.........................

Tandatangan ................................
Tarikh : ...................... Nama.................................
1. When a patient has a reaction to blood plasma, inform the doctor immediately.
2. Report all reactions. Use the following directions for febrile or suspected haeboictic reactions.
3. Preserve the blood bag and giving set with all attached labels, closing it securely so that cultures can be taken.
   SEND IMMEDIATELY TO BLOOD BANK.
4. Send 10ml of blood to the Blood Bank for investigation.
5. Send the next urine specimen 20 c.c. to the Pathology Laboratory to examine for haemoglobinuria.
6. Send at least 10 c.c. of clotted blood to the Blood Bank 24 hours after the reaction labelled ‘Post-transfusion 2’. These will be used for further compatibility tests and for bilirubin determinations. An additional 2.5 c.c. for Full Blood Picture is also advisable. Similarly a urine specimen should be sent to the Pathology Laboratory.

RETURN THIS REPORT AT ONCE TO THE BLOOD BANK
## Investigation of a Reported Transfusion Reaction

**Patient's name ________________________ Reg. No. ____________ Ward ________**

No. of returned blood packs ____________ Date reaction was noted _______________

Date blood was returned ________________

### I. Recheck of Blood Grouping

<table>
<thead>
<tr>
<th>ANTI SERA</th>
<th>CELL</th>
<th>ANTI SERA</th>
<th>GROUP</th>
<th>RH</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>AB</td>
<td>AC</td>
<td>A</td>
</tr>
</tbody>
</table>

**Patient**:  
1. Pre Transfusion Sample  
2. Post Transfusion Sample I  
3. Post Transfusion Sample II

**Donor**:  
1. Blood from Segment

### II. Check for Sensitization and Atypical Antibody

**Patient**:  
1. Pre Transfusion Sample  
2. Post Transfusion Sample I  
3. Post Transfusion Sample II

**Donor**:  

**Direct Coombs Test on Cells**

<table>
<thead>
<tr>
<th>RT</th>
<th>37°C / LISS / ALBUMIN</th>
<th>AHG</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>II</td>
<td>III</td>
</tr>
</tbody>
</table>

**Antibody Screening Using Screening Cells**

<table>
<thead>
<tr>
<th>RT</th>
<th>37°C/ LISS / ALBUMIN</th>
<th>AHG</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>II</td>
<td>III</td>
</tr>
</tbody>
</table>

### III. Recheck of Crossmatchings:

1. Pre Transfusion Sample with Donor Blood  
2. Post Transfusion Sample I with Donor Blood  
3. Post Transfusion Sample II with Donor Blood

### IV. Urine:

1. Post Transfusion Sample I  
2. Post Transfusion Sample II

### V. Blood Culture:

1. From Blood Bag

<table>
<thead>
<tr>
<th>DATE SENT</th>
<th>BACTERIOLOGICAL REPORT</th>
</tr>
</thead>
</table>

### Conclusion

**Tandatangan ________________________**

**Nama ______________________________**

**Tarikh ______________________________**

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Transfusion Practice Guidelines for Clinical and Laboratory Personnel 3rd edition March 2008
### APPENDIX 17

**Reporting format for ADVERSE TRANSFUSION EVENT**

Report ALL adverse events related to transfusion of blood or blood component using this form. Completed form should be sent to your blood bank for compilation. Where appropriate, treatment of reactions and investigations of event should be carried out using existing protocol.

**Patient’s particulars:**

Name: ........................................ I/C no: ........................................

Age: .............................. Race: .............................. Gender: ..............................

Ward:.............................. Hospital:..............................................................

**Components implicated in the adverse event: (please tick)**

- Whole blood
- Packed red cells
- Plasma (FFP)
- Platelets
- Cryoprecipitate
- Others

**Date of transfusion:** ......................... **Time:** .........................

**Onset of incident:**

- Pre-transfusion*
- Immediate (within 24 hours of transfusion)
- Delayed (after 24 hours of transfusion)

**Reactions seen / experienced:**

- Fever
- Nausea
- Hypertension
- Chill & rigors
- Vomiting
- Hypotension
- Rash
- Headache
- Diarrhoea
- Itchiness
- Dyspnoea
- Chest pain
- Flushing
- Bronchospasm
- Others ............
- Urticaria
- Pulmonary oedema

**Other clinical / laboratory findings:**

- Raised bilirubin / jaundice
- Haemoglobinuria
- Unexplained fall in haemoglobin
- Thrombocytopenia (5-12 days post transfusion)
- Deranged liver enzyme
- Reduced urine output
- None
Type of adverse event:

*Near misses / pre-transfusion incident – errors detected before transfusion took place eg. wrong sample, wrong label, wrong blood issued, clerical errors.

Reported by:
Name: ........................................ Designation: ........................................
Hospital: ........................................ Tel no: ........................................
Date: ........................................

PLEASE SEND REPORT TO
National Coordinator on Surveillance of Adverse events in Transfusion.
National Blood Center, Kuala Lumpur, Jalan Tun Razak, 50400, Kuala Lumpur
Telephone No: 03- 26955555/26955554 Confidential Fax No: 26925826
Main clinical features of adverse events:

<table>
<thead>
<tr>
<th></th>
<th>Adverse Events</th>
<th>Common clinical features</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Incorrect blood or component transfused</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a) ABO compatible</td>
<td>Maybe none or as in acute haemolytic transfusion reaction if patient has antibodies against transfused red cells</td>
</tr>
<tr>
<td></td>
<td>b) ABO incompatible</td>
<td>Maybe none or major collapse as in acute haemolytic transfusion reaction</td>
</tr>
<tr>
<td>2</td>
<td>Acute transfusion reaction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a) Haemolytic</td>
<td>Fever, chills, dyspnoea, chest pain, hypotension, oliguria, DIC</td>
</tr>
<tr>
<td></td>
<td>b) Non-haemolytic</td>
<td>Chills, itchiness, rash, urticaria, flushing</td>
</tr>
<tr>
<td></td>
<td>c) Anaphylaxis</td>
<td>Urticaria, dyspnoea, hypotension, bronchospasm</td>
</tr>
<tr>
<td>3</td>
<td>Delayed haemolytic transfusion reaction</td>
<td>Unexplained fall in Hb, jaundice, dark coloured urine</td>
</tr>
<tr>
<td>4</td>
<td>Bacterial contamination</td>
<td>Fever, rapid onset of shock</td>
</tr>
<tr>
<td>5</td>
<td>Post-transfusion viral infection</td>
<td>May take weeks or months to manifest, depending on the virus Jaundice, malaise, rash, fever</td>
</tr>
<tr>
<td>6</td>
<td>Post-transfusion purpura (PTP)</td>
<td>Purpura, bleeding, thrombocytopenia 5-12 days post transfusion</td>
</tr>
<tr>
<td>7</td>
<td>Transfusion Associated Graft Versus Host Disease (TA-GVHD)</td>
<td>Fever, rash, raised liver enzymes, diarrhoea, nausea, vomiting, pancytopenia (1-6 weeks post transfusion)</td>
</tr>
<tr>
<td>8</td>
<td>Transfusion Related Acute Lung Injury (TRALI)</td>
<td>Acute respiratory distress (non-cardiogenic), chill, fever, cyanosis, hypoxia, hypotension, bilateral pulmonary infiltrate</td>
</tr>
</tbody>
</table>

FOR BLOOD BANK USE

Report No: ………………………………..
Date received: ………………………………..
Date sent to PDN: ………………………………..
Date received by PDN: ………………………………..
Flowchart for reporting of adverse transfusion events

Note:
1. Every case of adverse reaction must be reported.
2. If the case of adverse reaction involved a seropositive donor, a look back and recall procedure must be carried out.
3. Identity card number (I/C), donation date must be submitted to Surveillance Unit, National Blood Centre.
LOOK BACK AND RECALL

Introduction

Look back is a procedure for identifying previously untested or tested negative donation from individuals whose subsequent donation test positive for a particular microbial marker. The donations are traced to individual’s recipients for counseling and testing. Any blood component that has not been transfused would be recalled. At the same time the donor is contacted for further counseling and testing.

Rationale

The decision to implement the look back procedure is to inform recipients based on the well established principle that whatever a person has information that is of potential benefit to others he or she is obliged to give it to them. The recipient needed to be informed so that he or she has access to counseling and treatment as well as taken steps to prevent further transmission. The right to know is inherent to the broad ethical proposition that all persons who have undergone a medical procedure have the right to know all the details of their medical condition. It is also an ethical and moral obligation of doctor to inform them.

Responsibilities

Blood Transfusion Service
Treating clinician
Infectious disease physician

The responsibility of BTS once it become aware that infected blood has been dispatched top a hospital, was to alert the hospital concerned. It is the duty of the hospital to identify the recipient for the treating doctor to arranged subsequent counseling, testing, treatment and referral to infectious disease physician if necessary. The BTS is also responsible for counseling the donor and determine the point and source of infection.

Counseling

1. First counseling session (Pretest counseling): What to say?
   1. State reason for consultation.
   2. Inform and explain the situation of seroconverting donor to the patient as part of the precautionary measures.
   3. Assess the risk factors of the recipient. (Question recipient on risk behaviour other than blood transfusion eg: Sexual promiscuity, multiple sexual partners or sharing of sharps and needles).
   4. Facts on the disease, mode of transmission and complication.
   5. Tests availability and their interpretation.
   6. Reassure after a sample of blood is taken for transfusion transmitted diseases.
   7. Discuss possibility of disease transmission through blood.
   8. Treatment option.
   9. Inform on the precautions to be taken while waiting for the results, thus preventing transmission.
   10. Explore with the patient what he would do if the test is positive.
   11. Explain the window period and the need for a repeat test after 6 month if the test result is negative.
Second counseling session (Post-test counseling):

This counseling is done after the results of the test (Anti-HIV, Anti-HCV, HBsAg) has been done depending on the hospital. This may vary from 2 days to 2 weeks.

1. If test result is positive.
   a. Inform the recipient of his result and explain what it means.
   b. Explore other risk factors than blood transfusion, if absent and the only possible cause is blood transfusion, inform the recipient that the blood he/she received was tested negative at the time of donation. It is not a laboratory error.
   c. Explain about ‘window period’ and occult infection
   d. Reassure and offer treatment.
   e. Referral if necessary

2. If test result is negative
   a. Inform recipient of the result and reassure.
   b. If necessary to retest after 6 month.

Seroconverting recipient.

There maybe instances that recipient of blood transfusion becomes positive for transfusion transmitted infections. The treating doctor should ensure the following:

1. Inform patient of the result.
2. Determine risk factors other than blood transfusion.
3. If risk factor cannot be identified, explain to patient the possibility of “window period” donation. However transmission through transfusion can only be admitted if the donor can be identified and the status is known (positive in subsequent donation or test) or the patient was tested negative before transfusion.
5. Inform the blood bank or BTS.
   (The BTS should then trace the donors of the blood that was transfused. These donors would be contacted, counseled and retested. If a donor is implicated, other recipients would be traced and identified.)
SEROCONVERTING RECIPIENTS (ALGORITHM)

Recipient

Confirmed Positive

Counsel & Determine Risk Factor
Other than transfusion

Trace all Transfusion
No. and date

Inform BTS

Trace all donors &
Determine Donor Status

Sent letters for donor recall

Counseled and retest

Confirmed positive

Negative — Feedback to clinician

Reassure donor

Counsel and refer physician

1st. time donor

Regular donor

No subsequent donation

Trace and determine previous & subsequent donation

Product recall

NOTE:

Patient/recipient is confirmed free of the disease marker prior to blood transfusion and exclude the other possible exposure to the implicated donor beside transfusion. Preferably patients/recipient has baseline negative of any disease marker(s) than can be transmitted by blood transfusion.
SEROCONVERTING DONORS (ALGORITHM)

Regular Donor

Preliminary results: Reactive

Confirmed positive

Trace all present donated Blood & Blood Component

send letter To call donor

Discard or (keep as QC sample)

Counsel Donor

Determine risk factor

Take repeat sample

Refer to physician for further management

List all type of blood and blood component

Determine status of last donation

Donation recall of blood and Blood component

Trace fractionated products

Trace recipient

Inform clinician & call recipient

Pretest counselling

Post test counselling

* Trace last seronegative donation and six months beyond
* The implicated donor is confirmed positive