Institution Name: Directorate General of Specialize Medical Care, Department of Blood Banks Services (DBBS)

Document Title: National Policy for Blood Banks and Transfusion Medicine Services

Approval Process

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Acronyms:

WHO	World Health Organization
MOH	Ministry of Health
NBTC	National Blood Transfusion Committee
ISBT	International Society of Blood Transfusion
DBBS	Department of Blood Banks Services

National Policy for Blood Banks and Transfusion Medicine Services

1. Introduction

Blood services are crucial part of any Health care system. Each government must ensure that blood and blood components are available, equally accessible, safe and adequate for all patients. A strategy was formulated during the WHO Assembly Resolution 28.72 and adopted in 1975. The principles of this strategy emphasize government's commitment towards establishing a national blood program which is capable; through appropriate organization, infrastructure and supported management; of ensuring sustainable blood supply collected from non-remunerated voluntary blood donors who have been appropriately tested. Furthermore, it mandates appropriate use of blood and blood components to avoid unnecessary transfusions.

2. Scope

This policy is applicable to all blood banks and clinical transfusion services in the Sultanate of Oman

3. Purpose

3.1 To ensure sustainability and accessibility of safe and efficacious blood supply to all patients equally

3.2 To ensure that total quality management system which covers all aspects of blood donation, testing, processing, storage, transport and transfusion, is established and maintained

3.3 To ensure appropriate use of blood and blood components and prevent unnecessary transfusions

3.4 To ensure donation and blood transfusion safety through active national monitoring system (Haemovigilance)

4. Definitions

4.1 Blood Policy: Formal statement of intent that addresses the key organizational, financial, technical and legal issues for the establishment and development of the national blood system

4.2 National Blood System: constellation of blood donation policies pertaining to leadership and governance, coordination and collaboration, provision of safe blood components through a national blood program and clinical transfusion in patient management.

4.3 Blood Program: All procedures that ensure consistent blood and blood components collection from non-remunerated blood donors, testing, processing, storage and distribution.

4.4 Confidentiality: Obligation of health-care professionals and healthcare institutions not to disclose personal and sensitive information about their patients or blood donors to third parties

4.5 Blood Bank: Where blood donation is collected, tested, processed, stored and distributed for clinical use

4.6 Clinical Transfusion Service: Where blood and blood components are stored and compatibility testing is performed prior to issue for transfusion.

4.7 Governorate blood bank: Ministry of Health blood Banks located outside the Governorate of Muscat

4.8 Recall: The act of tracing a blood component after issuing and returning it to the blood bank for further investigation and/or discard

4.9 Look Back: The act of investigating the consequence of transfusing a specific blood or blood component to a recipient

4.10 Patient blood Management: A set of clinical therapies and procedures that optimize the blood circulation, reduce blood loss, ensure appropriate use and transfusion of the right blood component in the right volume/dose to the right patient at the right time

4.11 Haemovigilance: A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of the recipients), intended to collect and assess information on unexpected or undesirable

effects resulting from the use of labile blood components, and to prevent their future occurrence or recurrence

4.12 Blood Donor Haemovigilance: A systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, to improve the quality and safety of blood donation for the blood donors

4.13 External quality testing: An international testing scheme that compares the technical performance of blood banks.

5. Policy

5.1 Governance:

5.1.1 Directorate General of Specialized Medical Care (DGSMC) is committed to establish a national blood system that ensures a sustainable safe supply of blood and blood components

5.1.2 DGSMC is committed for the strategic planning of the blood bank and transfusion services and the provision of a national blood policy and legal frame work that govern all aspects related to the function of the national blood system

5.1.3 DGSMC is committed to ensure its leadership and governance through the establishment of the Department of Blood Banks Services, with overall responsibility of the national blood system

5.1.4 DGSMC is responsible for establishing and updating all national policies and guidelines including: National blood donor Form, blood donor selection and deferral criteria, technical standards on testing of blood donors and blood components and for processing, blood donor counseling, investigation of donation and blood transfusion related adverse events and patient blood management programs.

5.1.5 DGSMC is responsible for establishing a national Haemovigilance program

5.1.6 DGSMC is responsible for auditing and inspecting blood banks and clinical transfusion services until the “National Committee for Accrediting Health Care Institutions” is developed.

5.1.7 Directorate General of Private Establishement license the blood banks in private sector hospitals for clinical transfusion services only. A separate license

is required for the use of blood and blood components for non-transfusion purposes.

5.1.8 Hospitals (both governorate and private) comply with the national blood policy and adopt the related guidelines including those pertaining to the investigation of blood transfusion related adverse events and patient blood management

5.1.9 Hospitals (both governorate and private) report all transfusion related adverse events to the MOH through the National Haemovigilance program

5.2 Ethics:

5.2.1 The ISBT code of Ethics pertaining to blood donors and blood donation is adopted by all blood banks (Refer to Appendix 1)

5.2.2 The ISBT Code of Ethic pertaining to recipients of blood and blood components is maintained by the Hospitals (Refer to Appendix 1)

5.3 National Blood Program:

5.3.1 A national Blood Program is established to ensure sustainable supply of blood and blood components that meet the demands

5.3.2 The National Blood Program promotes collection of blood from voluntary non-remunerated blood donors with the aim to gradually phase out replacement blood donations

5.3.3 All blood banks recruit and retain voluntary non-remunerated blood donors through education and marketing programs in collaboration with other governmental institutions, private sector, social media and community based voluntary groups

5.3.4 All blood banks adhere consistently and strictly to the National Blood Donor selection criteria

5.3.5 All blood banks establish a confidential blood donor registry and promote for a linked unified national blood donor registry.

5.3.6 All blood banks must have a donor recruitment officer responsible for recruiting blood donors and organizing blood donation campaigns to promote 100% voluntary non-remunerated blood donations.

5.3.7 All blood banks have a counselor for pre and post donation counseling.

5.3.8 All blood banks provide adequate resources to ensure reliable, private and consistent counseling.

5.3.9 All blood banks follow the Policy and Procedure of Blood Donor Counselling (Pre-donation)

5.3.10 All blood banks maintain the confidentiality of the blood donor during counseling and the donor test results.

5.4 All blood banks adhere to the regulatory laws on disclosure of donor test results. This disclosure only take place to other health-care providers who are, or will be, directly involved in the subsequent care of the blood donor or to DBBS if this was related to a look back investigation.

5.5 Total Quality Management System:

5.5.1 Establishing a total quality management system that oversee the blood donation process, testing of blood donors, processing, storage, transport and distribution of blood and blood components is promoted

5.5.2 Efforts are made to provide the infrastructure, resources, funding and training to ensure and sustain the total quality management system in the blood banks and clinical transfusion services

5.5.3 All blood banks and transfusion services have a staff trained in Quality to ensure that all processes and procedures are monitored and maintained according to the requirements of the total quality management system

5.5.4 All blood banks have standard operating procedures for blood donation collection, testing of donations, processing, storage, transportation and distribution of blood and blood components.

5.5.5 All clinical transfusion services have standard operating procedures for recipient pre-transfusion testing and processes pertaining to handling of blood components including: storage, issuing, transportation and traceability.

5.5.6 All blood banks and clinical transfusion services check, monitor and maintain quality control parameters.

5.5.7 All blood banks and clinical transfusion services participate in external quality testing programs.

5.5.8 All blood banks and clinical transfusion services maintain traceability of all blood and blood components.

5.5.9 All blood banks and transfusion services have Policy and Procedure of National Look Back and Trace Back Procedure

5.6 Appropriate use of blood components:

5.6.1 Blood Banks should ensure appropriate utilization of blood components and reduce wastage.

5.6.2 All healthcare institutions promote patient blood management that is evidence or best practice based.

5.6.3 All healthcare institutions have policy and standard operating procedure for administration of blood and blood components.

5.6.4 Qualified physician only prescribes blood and blood components for patients

5.6.5 Policy and Procedure of Consent for transfusion of blood components is mandatory.

5.6.6 All healthcare institutions promote education and training of all medical staff involved in the prescription, handling of blood and blood components products and its administration to patients

5.6.7 All healthcare institutions have a Hospital Transfusion Committee to guide, monitor and audit the clinical use of blood and blood components

5.6.8 All healthcare institutions promote alternatives to blood and blood components transfusion

5.7 Haemovigilance:

5.7.1 A National Haemovigilance Program that covers both blood donor and recipient vigilance is promoted. All blood banks and clinical transfusion services have sufficient fund, efficient reporting system and adequate human resources to sustain it

5.7.2 All blood banks train phlebotomists and/or blood bank nurses to identify, report and manage blood donation-related adverse events.

5.7.3 All healthcare institutions train nurses and physicians to detect, investigate report and manage transfusion related adverse events

5.7.4 All healthcare institutions follow guidelines for the management of both blood donation and transfusion related adverse events.

5.7.5 All healthcare institutions have standard operating procedure, for investigating transfusion related adverse events.

5.7.6 All transfusion related adverse events and look-back investigations must be reported to DBBS for analysis.

5.7.7 Healthcare institutions (both government and private) assist DBBS in carrying out and completing look-back investigations related to blood components transfused, when indicated, in their respective institutions. This may include disclosing recipient clinical information, result of investigations, retesting and counseling. Confidentiality is maintained throughout the process of the investigation

5.8 Education and Training

5.8.1 All healthcare institutions have in-service training programs that are organized for all personnel working in blood banks and clinical transfusion services

5.8.2 All healthcare institutions have a Continuous Medical Educational Program for all personnel in all the blood banks and clinical transfusion services.

5.8.3 Post graduate training in transfusion medicine is promoted whether within the Country or overseas

5.8.4 Research in the area of blood bank and clinical transfusion is promoted

5.9 Contingency Planning:

5.9.1 All healthcare institutions follow the national contingency and disaster plan for provision and management of blood supply as a results of daily blood shortage, infrastructure related emergencies, natural disasters &/or in case of pandemics

6. Responsibilities

6.1. National Blood Transfusion Committee is responsible for:

6.1.1. Promote, Maintain and update the National Blood Policy

6.1.2. Establish and update the national policies and guidelines pertaining to both blood donation and clinical transfusion

6.1.3. Audit and monitor blood banks and transfusion services compliance to the National Blood Policy

6.1.4. Provide recommendations following lookback investigations

6.1.5. Oversee the effectiveness of the contingency plans as per the national contingency and disaster plans.

6.2. Department of Blood Banks Services is responsible for:

6.2.1. Provide technical advice to all blood banks and transfusion services.

6.2.2. Oversee the national blood program

6.2.3. Oversee the national Haemovigilance program and lookback investigations

6.2.4. Establish and maintain the National Haemovigilance Program

6.3. All blood banks and transfusion services is responsible for:

6.3.1 Adhere to the National Blood Policy

7. Document History and Version Control

Document History and Version Control			
Version	**Description of Amendment**	**Author**	**Review Date**
01	Initial Release	Dr. Sabria Al-Hashami	November/ 2024
02			
03			
04			
05			

Written by	**Reviewed by**	**Approved by**
Dr. Sabria Al-Hashami	National Blood Transfusion committee	Dr.Kadhim Jaffar Sulaiman

8. Related Documents:

8.1 Policy and Procedure of National Look Back and Trace Back Procedure (MoH/DGSMC/P&P/006/Vers.01)

8.2 Policy and Procedure of Blood Donor Counselling (Pre-donation) (MoH/DGSMC/P&P/005/Vers.01)

8.3 Policy and Procedure of Consent for transfusion of blood components (MoH/DGSMC/P&P/003/Vers.01)

9. References:

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
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Aide-Memoire for National Health Programmed. The Clinical Use of Blood. WHO/EHT/04.07	WHO	2004	
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WHO in collaboration with international federation of Red Cross and Red Crescent societies. Blood donor counselling: implementation guidelines	WHO	2014	
Basic components of a national blood system. Pan Am J Public Health 13(2/3),	Cruz J.	2003	
Haemovigilance – An effective tool for improving transfusion safety	Rene RP De Vries MD Jean-Claude Faber	2012	

10. **Appendix1**: **ISBT Code of Ethics: Adopted by General Assembly of ISBT, July 12, 2000**

Amended by the General Assembly of ISBT, September 5, 2006.The Code has been elaborated with the technical support and adopted by the WHO.

A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

The objective of this code is to define the ethical principles and rules to be observed in the field of Transfusion Medicine.

Blood Centers: donors and donation

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.

   A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.

   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. A profit motive should not be the basis for the establishment and running of a blood service.
3. 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 standards.
4. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
5. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.

6. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.
7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
8. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Hospitals: patients

12. 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 directive should be respected.
13. 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.
14. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.
15. Genuine clinical need should be the only basis for transfusion therapy.
16. There should be no financial incentive to prescribe a blood transfusion.
17. 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.
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.