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MINISTRY OF HEALTH MALAYSIA

NATIONAL POLICY FOR TRANSFUSION MEDICINE SERVICES IN MALAYSIA (2nd Edition)

CLINICAL SUPPORT SERVICES UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

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National Policy For Transfusion Medicine Services
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The document outlines optimal achievable standards in accordance with the best practices and guidelines.

Publication Notes: National Policy for Transfusion Medicine Services in Malaysia

This publication presents an outline of the comprehensive National Policy for Transfusion Medicine Service in Malaysia, aimed at establishing a uniform and secure framework for the safe and efficient delivery of blood and blood products for transfusions across the nation. The policy's development involved collaborative efforts among the Ministry of Health, healthcare institutions, medical experts, and other stakeholders, ensuring a well-rounded and holistic strategy for the field of transfusion medicine. A notable focal point of the policy is its strong emphasis on upholding rigorous standards of quality control and adherence to internationally recognized best practices throughout the entirety of processes involving blood collection, processing, testing, storage, and distribution. Additionally, the publication sheds light on the establishment of a centralized Transfusion Medicine Services, equipped with advanced facilities and technology to facilitate blood banking and transfusion services. Special emphasis is placed on vigilant haemovigilance and prompt adverse event reporting, underscoring the importance of robust surveillance systems to swiftly identify and manage any complications related to transfusion.

The policy underscores the significance of continuous training and professional development for healthcare personnel engaged in transfusion medicine, ensuring their competency and up-to-date knowledge. Collaborations with regulatory bodies are highlighted to ensure alignment with safety and quality standards, coupled with regular inspections and audits of Transfusion Medicine Services. The policy also highlights the importance of public education campaigns in promoting awareness about safe blood donation practices, transfusion safety, and the essential role of blood donors. Successful implementation of the policy necessitates close coordination among healthcare facilities, regulatory authorities, and stakeholders, integrating it effectively into the national healthcare system. Recognizing the dynamic nature of medical science, the publication commits to periodic reviews and updates of the policy to accommodate advancements in transfusion medicine practices. Ultimately, the overarching goal of the National Policy for Transfusion Medicine Service in Malaysia is to elevate patient care through standardized, safe, and efficient blood transfusion procedures, aligning with global best practices and guidelines.

Foreword By
DIRECTOR GENERAL OF HEALTH MALAYSIA

This publication unveils the comprehensive National Policy for Transfusion Medicine Services in Malaysia, a testament to our dedication to safe and effective blood transfusion across our diverse nation. Shaped collaboratively by the Ministry of Health, healthcare institutions, medical experts, and stakeholders, this policy establishes a robust framework for secure blood delivery. It places a strong emphasis on quality control, adhering to global best practices for blood collection, processing, testing, and distribution.

Delving into its essence, the policy highlights the establishment of a cutting-edge Transfusion Medicine Services and the imperative of vigilant haemovigilance for monitoring adverse events. It stresses the continuous professional development of healthcare personnel and collaborative compliance with regulatory standards, ensuring safe transfusion practices.

Beyond the medical sphere, the policy champions public education campaigns, to raise awareness about safe blood donation and transfusion safety. By harmonizing efforts, it calls for close coordination among healthcare entities, regulatory bodies, and stakeholders to integrate seamlessly into the national healthcare system. This policy encapsulates our commitment to standardized, safe and efficient blood transfusion practices, aligning with global standards for elevated patient care.

Datuk Dr Muhammad Radzi bin Abu Hassan

Foreword By
DIRECTOR NATIONAL BLOOD CENTRE

The National Transfusion Medicine Services (NTMS) is the main service provider for the Ministry of Health's hospitals in Malaysia. Its activities encompass all aspects of the transfusion from blood donation, transfusion microbiology, blood components preparation, immunohaematology, clinical transfusion practices, transfusion of plasma derived medicinal products, patient blood management, haemovigilance and the critical processes of lookback and recall. Additionally, NTMS is involved in stem cell collection, cellular therapy and transplant immunology, ensuring comprehensive care and safety in transfusion medicine.

Although the NTMS in Malaysia has evolved and major progress has been achieved, the main objective of the service still remains. The objective is to provide safe, adequate and equitable supply of blood, blood component and plasma derived medicinal products (PDMP) and other related services to meet the healthcare needs of the nation. It is important to establish an effective nationally coordinated blood program with an accepted quality system and national blood policy in order to sustain efficient and excellent service delivery all the time.

An appropriate blood transfusion legislation and regulations from vein to vein processes aim to safeguard the blood donors, recipients of blood and blood products and healthcare personnels. A structure of management with clearly defined responsibility and accountability, well accepted processes and procedures, adequate resources together with community participation are the key toward achieving a safe, adequate and sustainable blood supply at any time. There is a need to elaborate a comprehensive legislative framework to support our blood transfusion system that will be more vigilant, proactive and sustainable.

Safe Blood, Safe Life, Safe Nation.

Dr Mohammad Masrin bin Md Zahrin

ACKNOWLEDGEMENT

The Medical Development Division would like to acknowledge and appreciate Datuk Dr Muhammad Radzi bin Abu Hassan, Director General of Health Malaysia for the leadership and continuing support and ensuring that the policy materialized.

The Ministry of Health Malaysia recognizes the commitments and contributions from all parties involved; the public and private sectors, and all other related parties.

Thank you to all others who are directly or indirectly involved in formulating this policy.

ABBREVIATIONS

CUE	Confidential Unit Exclusion
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
HTC	Hospital Transfusion Committee
ISO	International Organization for Standardization
KPI	Key Performance Indicators
MOH	Ministry of Health
NAT	Nucleic Acid Amplification Technology
NBC	National Blood Centre
NHCC	National Haemovigilance Coordinating Centre
NTMS	National Transfusion Medicine Services
PBM	Patient Blood Management
TMS	Transfusion Medicine Specialist
TTI	Transfusion Transmissible Infection
TRALI	Transfusion Related Acute Lung Injury
VNRBD	Voluntary Non-Remunerated Blood Donation

CONTENT

1.0 INTRODUCTION

Transfusion Medicine is a broad multidisciplinary specialty of medicine that is concerned with the donation, collection, production, testing and transfusion of blood, its components and derivatives as well as its related complementary activities from the clinical and laboratory perspectives for the benefit of patients and the community.

The National Transfusion Medicine Services (NTMS) is one of the crucial components of the healthcare delivery system provided by the Ministry of Health (MOH) Malaysia. Additionally, the Ministry of Higher Education, Ministry of Defence and some private hospitals provide the service to a certain extent to complement the NTMS.

The NTMS, under the MOH, is guided by the relevant legislative bodies with various Acts[1] that govern professional codes of conduct. The Code of Ethics for Blood Donation and Transfusion[2] which defines the ethical principles and rules to be observed in the field of Transfusion Medicine, provides a framework for ethical policy making and service delivery.

Safe blood transfusion is a national priority. The main objective of the NTMS is to provide safe, adequate and equitable supply of blood, its component and plasma derived medicinal products (PDMP) (hereafter defined as 'blood') and other related services[3] to meet the healthcare needs of the nation.

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1 Medical Act 1971 (Act 50)
Nurses Act 1950 (Act 14) & Nurses Registration Regulations 1985
Registration of Pharmacists Act 1951 (Act 371) & Registration of Pharmacists Regulations 2004
Private Healthcare Facilities and Services Act 1998 (Act 586)
Private Healthcare facilities and Services (Private Hospitals & Other Private Healthcare Facilities)
Regulations 2006 , [P.U. (A) 138/2006];

2 The Code of Ethics for Blood Donation and Transfusion, Eleventh Schedule (Regulation 299); Page 1312 – 1314.

3 Reference Panduan Perkhidmatan Dan Polisi Operasi

To achieve these objectives, the NTMS must have a well-organised structure with clearly defined responsibility, accountability and authority. Community involvement, proper processes and procedures, and adequate resources are essential for a safe, adequate and sustainable blood supply.

All procedures are carried out by the NTMS shall adhere to the safety and universal precautions in accordance with MOH requirements. Promotion of appropriate use of blood and safe transfusion practices shall continuously be emphasized to ensure patient safety and the efficient use of this limited and precious resource.

2.0 OBJECTIVES OF POLICY

2.1 General Objective

To provide quality, safe, adequate and equitable blood and govern transfusion medicine related services to meet the healthcare needs of the nation.

2.2 Specific Objectives

2.2.1 To provide care and education for donors and the public.

2.2.2 To establish a pool of safe donors among members of the public.

2.2.3 To establish and maintain proper donation, collection, production and screening procedures.

2.2.4 To promote safe transfusion practices, appropriate use of blood and Patient Blood Management (PBM).

2.2.5 To incorporate quality assurance in all procedures and processes within the NTMS.

2.2.6 To provide recruitment, training, career development, education, research and development in keeping with current practices and technologies in transfusion medicine.

2.2.7 To strive for a sustainable system with the aim of self-sufficiency in providing safe blood to meet the demands of the healthcare system.

3.0 SCOPE

This policy applies to all personnel of the Ministry of Health, Ministry of Higher Education, Ministry of Defence and private facilities who are involved in the Transfusion Medicine Services.

4.0 POLICY STATEMENT

The MOH Malaysia is committed towards an excellent and sustainable National Blood System that meets the healthcare needs of the nation. This policy document provides guiding principles for the NTMS in Malaysia, ensuring maximum protection of the health and safety of blood donors, blood recipients and healthcare personnel.

The following policies and strategies are formulated to realize the policy objectives:

Policy 1:	Voluntary Non-Remunerated Blood Donation (VNRBD) Program
Policy 2:	Safe Donation Process & Donor Care
Policy 3:	Safe and Adequate Blood Supply
Policy 4:	Blood Component Production
Policy 5:	Patient Blood Management & Safe Transfusion Practice
Policy 6:	Quality Management System
Policy 7:	Human Resource
Policy 8:	Sustainability and Strategic Independence
Policy 9:	Organization of the NTMS
Policy 10:	Disaster Preparedness and Management
Policy 11:	Legislative and Regulatory Control
Policy 12:	Haemovigilance
Policy 13:	Lookback and Recall

Policy 1 VOLUNTARY NON-REMUNERATED BLOOD DONATION (VNRBD) PROGRAM

The NTMS, MOH is committed to maintain 100% voluntary and non-remunerated blood donation for blood and its component based on the recommendations by the World Health Assembly, Resolution (WHA) 28.72 in 1975 and WH70 in 2017 A 70/19.

Strategies:

1. Voluntary non-remunerated blood donation (VNRBD)[€] should be the basis for donation of blood, blood components and other medical products of human origin.
2. Fostering voluntary blood donation culture by increasing public awareness of the need for voluntary blood donation as a foundation for universal access to safe blood transfusion.
3. Engaging with the community through effective communication, providing information and education to create awareness of voluntary and regular blood donation.
4. Building networks within the community and strengthening ties with strategic partners to ensure greater community participation.
5. Establishing an effective blood donor recruitment and retention program to create and maintain sustainable VNRBDs.
6. Engaging the youth as the new generation of VNRBD.

€ Voluntary Non-Remunerated Blood Donation (VNRBD) is when a donor gives blood or cellular components of his or her own free will and receives no payment 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 reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.

7. Profiteering from donated blood and its components is prohibited.

8. Payment to blood donors shall not be allowed.[∞]

9. Directed donation of blood and its components is not recommended except in special circumstances e.g. rare blood groups.

10. Equity in donation should be promoted by engaging all segments of society in efforts to meet the need for medical products of human origin. Opportunity to donate should not be denied to individuals and groups and at the same time this does not equate with the right to donate.

11. Anonymity between donor and recipient should be ensured except when both donor and recipient freely and expressly consent otherwise.

12. Blood donor selection should be based on current, accepted and regularly reviewed scientific data and guidelines.

∞ Code of Ethics Relating to Transfusion Medicine General Assembly Copenhagen 2017

Policy 2

SAFE DONATION PROCESS & DONOR CARE

The NTMS, MOH ensures the highest safety and quality of care for the donors.

Strategies

1. Donors are given information on the nature of the procedures involved and the associated risks.
2. All donors shall answer the pre-donation questionnaire as truthfully as possible.
3. All donors shall undergo a pre-donation interview and basic health assessment by trained and competent medical personnel to ensure donation eligibility and a safe blood donation process.
4. All information provided by donors shall be kept confidential.
5. A registry or database of all blood donors including Rh(D) Negative and rare blood group donors is maintained to provide accurate and current information.
6. Apheresis donors are assessed for eligibility and recruited from a pool of regular blood donors.
7. Staff shall be trained on communication, clinical and recruitment skills to provide quality donor care before, during and after blood donation.
8. Staff shall be trained to recognise and manage adverse donor events in a timely manner.

9. Donor haemovigilance shall be reported by the hospital collection centre to the National Haemovigilance Coordinating Centre (NHCC) to improve donor safety through the detection, reporting, analysis of information on unexpected or undesirable effects for implementation of corrective and preventive actions.

10. Management of seroconverted donors shall be conducted with utmost care, including counselling, deferral and appropriate follow-up to ensure donor health and safety, as well as the safety of the blood supply.

Policy
3

SAFE AND ADEQUATE BLOOD SUPPLY

The NTMS, MOH is committed towards a safe and adequate blood supply throughout the country based on the healthcare service requirements to meet the full range of clinical needs.

Strategies

1. Safe blood comes from safe donors. The NTMS ensures adequate and safe blood through the establishment of effective blood donor recruitment and retention programs from low-risk population groups.
2. All donors shall answer a pre-donation questionnaire and undergo a pre-donation interview and basic health assessment conducted by trained and competent medical personnel to ensure that they are safe donors.
3. An established national donor eligibility and deferral criteria shall be followed to ensure only safe donors are allowed to donate blood. These criteria are reviewed in a timely manner.
4. Donors are responsible for providing relevant and correct information pertaining to their health and lifestyle.
5. Blood donors involved in high-risk lifestyle which may have exposed them to Transfusion Transmissible Infections (TTI) shall not be allowed to donate blood.[£]

£ Screening Donated Blood for Transfusion-Transmissible Infections, WHO 2009

6. Blood donors found to have made false declarations pertaining to their infectious status and /or high-risk lifestyle are liable for further action under Act 342 Prevention and Control of Infectious Disease Act 1988-Incorporating latest amendment-P.U.(A)374/2006. [Part IV-Control of Spread of Infectious Disease, Section 10 Para (6)]

7. Each blood collection centre shall have an up-to-date data of confirmed TTI-reactive and permanently deferred donors.

8. Each blood collection centre shall have a mechanism for blood donors to immediately inform the centre after donation if they believe their blood may be unsafe for transfusion.

9. Mandatory screening tests shall be performed on all donated blood by implementing and employing the appropriate tests and procedures as well as the suitable methodology which are reviewed periodically. The mandatory screening tests are:

   a) Serology screening for HIV, HBV, HCV and Syphilis

   b) Molecular screening for HIV, HBV and HCV

10. Surveillance and screening of other TTIs that may affect the safety of the blood supply are carried out whenever necessary.

11. TTI screening of donated blood shall be performed only at designated and quality-assured screening centres specifically for transfusion microbiology testing.

12. Physical segregation of screened and unscreened blood shall be maintained at all times to prevent unintended release of unscreened blood.

13. Only screened and TTI non-reactive blood can be released for clinical or manufacturing use.

14. Maintain optimal blood inventory levels and encourage blood mobilization nationwide while avoiding over collection of blood to prevent blood wastage.

15. Effective blood supply management shall be established, including annual assessment of blood usage and contingency plans for blood shortages or disasters.

16. There shall be a bidirectional traceability mechanism of donated blood from donors to recipients and from recipients back to donors using a unique identification system.

17. Blood cold chain shall be maintained at all times to preserve the characteristics, integrity and quality of blood throughout blood collection, transportation, processing and transfusion at clinical areas.

18. Information management system, either manual or computerised, shall be established to ensure safe blood supply.[£]

19. Clinical waste management procedures in transfusion medicine service shall be established to ensure a safe environment and prevent untoward incidents.

Policy
4

BLOOD COMPONENT PRODUCTION

The NTMS, MOH advocates the use of specific blood components for specific clinical conditions, in order to maximise efficacy, and to prevent unnecessary and possible adverse effects of transfusing excessive constituents of blood. Transfusion is made safe by implementing and employing Good Manufacturing Practices (GMP) throughout the processing of the donated blood.

Strategies

1. Processing of donated blood should be carried out in facilities that are suitable for the purpose.
2. Donated whole blood shall be processed into specific blood components for specific clinical use.
3. All processes involved in blood component production shall be clearly defined in accordance with national guidelines and GMP.
4. All equipment used in blood component production shall be qualified and adequately maintained.
5. Regular in-process and product quality control (QC) shall be carried out to ensure quality and consistency of blood components as per requirements and standards.
6. Regular quality reviews should be conducted to verify the consistency of the existing processes and the appropriateness of current specifications.

Policy 5

PATIENT BLOOD MANAGEMENT & SAFE TRANSFUSION PRACTICE

Safe transfusion practice ensures patient safety.

The NTMS, MOH is committed to strengthen the national capacity for the implementation of best transfusion practices and access to safe transfusion processes.

Strategies

1. National transfusion guideline[4] on adequate and safe blood transfusion practice and patient blood management shall be made available, reviewed and updated regularly as determined by MOH.
2. Principles of clinical governance shall be are applied to ensure optimum transfusion outcomes and patient safety.
3. Sustainable quality system shall be in place for the clinical transfusion process including standardised procedures, blood request forms, labels and records.
4. Clinical and laboratory personnel shall be trained and competent in the clinical transfusion process.
5. Advocacy of Patient Blood Management® shall be advocated at all levels.

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4 Guidelines For the Rational Use of Blood and Blood Products.
Transfusion Practice Guidelines for Clinical and Laboratory Personnel.

® Patient Blood Management (PBM) is an evidence-based, individualised, multidisciplinary approach to optimise the care of patients who might need blood transfusion by optimising the patient's red cell mass, minimizing blood loss and harnessing the physiological reserve of anaemia.

6. Prescription of blood is the responsibility of a qualified, registered and competent medical practitioner.

7. Blood shall be appropriately prescribed when clinical benefits outweigh the potential risks and clinical indication for transfusion shall be clearly documented.

8. Informed consent from the patient for blood transfusion shall be obtained by the registered medical practitioner following communication and discussion about indications, potential risks, benefits and possible alternatives[5].

9. Systems, processes and procedures for compatibility testing and issue of blood, rational use of blood, safe transfusion practice at bedside, patient monitoring and follow up shall be maintained and reviewed periodically.

10. A system shall be in place to ensure that staff is trained to recognise and manage adverse transfusion reactions in a timely manner.

11. Patient haemovigilance shall be implemented to improve patient safety through the detection, reporting, analysis of information on unexpected or undesirable effects of transfusion and implementation of corrective and preventive actions.

12. A lookback and recall procedure shall be established and followed rigorously when a patient receiving blood is suspected of acquiring a transfusion-transmissible infection (TTI), ensuring timely investigation, management, and reporting to safeguard both patient and donor safety.

5 Consent shall be obtained from parents or legal guardians if patients are below 18 years old. In emergency situations or where the patient has no capacity to consent, the patient's next of kin can give consent on behalf of the patient. Where this is not possible, the decision to transfuse shall be made by 2 medical practitioners and documented.

Policy **6**

QUALITY MANAGEMENT SYSTEM

The NTMS, MOH has established a quality management system (QMS) covering all the processes throughout the blood transfusion chain to ensure high quality, safety and efficacy of its services and products in order to maintain public confidence.

Strategies

1. Establish and implement an effective Quality Management System (QMS) with continuous improvement for its operations covering all aspects of its activities carried out in all its facilities.
2. The QMS is guided by the requirements of established practices, standards and guidelines as follows:
    a) National guidelines
    b) National standards
    c) Good Manufacturing Practices (GMP)
    d) National and International Organization for Standardization (ISO)
    e) Malaysian Society for Quality in Health (MSQH)
    f) Good Distribution Practices (GDP)
3. Establish a Quality Manual or an equivalent document that contains a description of the Quality Management System.
4. Clearly defined organizational structure that defines accountability, authority and responsibility.

5. Ensure appropriate, adequate and sustainable infrastructure and resources are provided for its purposes.

6. Qualified personnel equipped with the necessary skills and expertise is appointed as the Quality Manager to coordinate all quality activities.

7. Continuous education, training and competency assessment of personnel are carried out at regular intervals to maintain and improve quality of services and products.

8. A quality risk management framework should be developed to address and control potential safety and quality risks.

9. Develop an effective documentation system. Procedures are documented, controlled, updated and accessible to all personnel.

10. All records shall be maintained and protected to ensure traceability and to prevent inadvertent removal or destruction[6].

11. An effective national blood banking information system is developed for the collection and management of data throughout the transfusion chain.

12. Premises are appropriately designed and properly maintained to ensure that operational needs are met and the work environment is safe and clean.

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6 Jadual Pelupusan Rekod Perubatan 2016, and Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil 13/2001: Garis Panduan Penyimpanan Rekod Penderma dan Penerima Darah

All donor and patient records, in the form of hard copy or soft copies or both, shall be kept for 20 years. The following requirements shall be fulfilled when an IT system is used:
i. active records shall be maintained online for not less than three years.
ii. database shall be archived for the legally designated period of retention
iii. a mechanism for maintaining and protecting records from loss or unintentional removal or destruction shall be put in place.

13. Qualification of equipment, reagents and materials and validation of processes, systems and methods that have an influence on the quality and safety of blood and blood components shall be performed before introduction.

14. Conduct regular internal audits and management reviews to ensure compliance with the QMS and identify opportunities for improvement.

15. Implement corrective and preventive actions based on audit findings and review outcomes.

Policy
7

HUMAN RESOURCE

The NTMS, MOH strives for a prioritized and sustainable development of the National Blood Program to ensure self-sufficiency in provision of safe blood. This is achieved by strengthening the manpower through human resource development.

Strategies

1. Transfusion Medicine has been recognized by the MOH and the Malaysian Medical Council as a specialty under the Medical (Amendment) Act 2012.
2. Blood transfusion is deemed a medical procedure and shall therefore be placed under constant supervision by a qualified medical practitioner.
3. All hospital transfusion services shall be headed by a suitably qualified medical practitioner who is competent and experienced in Transfusion Medicine.
4. All hospital transfusion services shall have a sufficient number of competent staff with appropriate skills and knowledge to carry out their functions. **(Refer APPENDIX I)**
5. Encourage and provide human resource capacity building via career pathway development with opportunity for promotion and training for various categories of NTMS personnel.
6. Continuing professional development and post-graduate training programs are developed to strengthen the organisation, management and coordination in order to ensure a sustainable NTMS.

Training programs to cater to the specific needs:

a) Master of Medicine in Transfusion Medicine for Medical Officers.

b) Master of Science in Transfusion Medicine for Scientific Officers.

c) Advanced Diploma in Transfusion Medicine for Medical Laboratory Technologists.

d) Post-Basic Training Course in Transfusion Medicine for Nurses.

7. Appropriate in-service training modules and continuous education for all categories of personnel shall be conducted periodically to meet the specific demands within the NTMS.

Policy
8

SUSTAINABILITY AND STRATEGIC INDEPENDENCE

To strive for optimal availability of blood and blood components.

Strategies

1. MOH should establish a sustainable national blood system which is recognised through a national blood policy, strategic plan and appropriate legal instruments.
2. Strengthening the operational budget and developing a cost-recovery mechanism for blood and the services provided.
3. Establish effective and efficient national and regional mechanisms for the consolidation, clusterization, and regionalization of the services.
4. Maintain flexibility and ability to respond to changing circumstances and needs in a timely manner.
5. Continuously strive to improve efficiency and reduce waste through implementation of Lean Management.
6. Research and development in the field of Transfusion Medicine shall be encouraged and comply with national guidelines and research ethics to protect safety of blood donors, patients, and staff.
7. Continuous advocacy of Patient Blood Management to ensure patient safety and adequate blood supply.

Policy 9

ORGANISATION OF NTMS

The key to an efficient and effective NTMS is an appropriately planned organisation and management.

Ministry of Health, MOH shall be responsible for providing the resources required, including facilities, equipments and human resources in MOH organisations.

Strategies

1. The MOH shall coordinate the national blood programme that is fully integrated into the healthcare system.
2. MOH shall be responsible for financial sustainability, providing resources including facilities, equipment, human resources in MOH organizations.
3. National Blood Centre (NBC), regional blood centres and hospital transfusion services are entities under MOH.
4. The establishment of a national blood authority shall be the way forward for the national blood system to effectively coordinate and collaborate with the complex blood system which involves multiple stakeholders from government and non-government institutions and agencies. The national blood system shall be organised in a manner that ensures the most efficient and cost-effective use of all resources. The National Blood Centre (NBC) shall be responsible as the head of National Transfusion Medicine Services (NTMS) in providing:

a) Leadership across the field of transfusion medicine

b) Coordination of strategic and operational plans nationwide to ensure an adequate supply of blood products and safe clinical transfusion.

c) Policy, standards, and guidelines development and periodical review to achieve uniformity, consistency in the quality and safety of blood and best transfusion practices.

d) National surveillance programme through National Haemovigilance Coordinating Centre.

e) Assessment and monitoring of Key Performance Indicators (KPI) in transfusion service.

f) Technical oversight through external audit and supervisory visit on quality systems focusing on Good Manufacturing Practices (GMP).

5. The National Transfusion Committee, whereby the members are appointed by the Director General of Health, shall be appointed to advise on policy matters.

6. State Transfusion Committee and Hospital Transfusion Committee (HTC) shall be formed to ensure the effective implementation of the transfusion policies and to ensure the smooth operation of the service.

7. Blood transfusion services operating under the Ministry of Higher Education (University Hospitals), Ministry of Defence, and private healthcare facilities shall have an appropriate organisational structure and comply with this policy.

Policy
10
DISASTER PREPAREDNESS AND MANAGEMENT

A systematic and comprehensive plan of disaster management is very important as a preparedness to ensure sufficient and quality blood supply during a disaster (National Blood Contingency Plan).

Strategies

1. The Transfusion Medicine Services shall have a comprehensive standard operating procedure (SOP) for disaster management. This SOP shall be periodically reviewed and updated. Regular training shall be provided to all staff.
2. A risk assessment to identify the potential impact of disasters on blood supply shall be done before developing a contingency plan.
3. Establish a clear chain of command with defined lines of authority, decision-making, and communication responsibilities for staff shall be included in the emergency communication plan. For stage 3 disasters, NTMS should consider establishing MOH-CPRC communication to facilitate the coordination of response and recovery efforts.
4. Establish and maintain relationships and collaboration with other agencies and stakeholders (e.g. local, state and territory emergency management and public health agencies).
5. Inform the public about medical needs related to blood through media communications, providing accurate and concise messages.
6. The disaster management preparedness plan shall be tested through tabletop exercises. If any weakness or gap is identified, the corrective actions shall be performed.

7. The Transfusion Medicine Services shall take steps to ensure the safety and security of staff, volunteers, and donors both onsite and during mobile operations (e.g. transporting blood to affected hospitals).

8. Conduct a risk assessment of all information and records management systems to identify areas needing redundancy.

9. Develop an early warning system to enable prediction and notification about potential disasters for appropriate timely action.

10. The Transfusion Medicine Services shall have a plan for transition to recovery phase with the goal to reinstate the affected service to the normal capacity.

11. Conduct a comprehensive review and debriefing after each disaster event to assess the impact on the transfusion service.

12. Upon request and availability, blood and blood components shall be provided to other countries on humanitarian grounds in accordance with national and international policies and procedures.

13. Develop a volunteer and donor management plan, including a database of emergency donors who can be quickly mobilized during a disaster.

14. Develop an educational program to ensure the general public is aware of their role in disaster preparedness and response.

15. Ensure psychological support for staff, volunteers and donors post-disaster to manage trauma and stress effectively.

Policy
11

LEGISLATIVE AND REGULATORY CONTROL

Blood banks shall be governed by relevant legislation and registered with MOH.

Strategies:

1. Governments are responsible for ensuring ethical and effective procurement, distribution and use of medical products of human origin. This includes developing legislation, policies, systems, and services to ensure access to blood products and enforce regulations for safety, quality, and efficacy, both domestically and internationally.
2. Providing free healthcare services for a certain period following donation to ensure health security and protection for donors in relation to their donations.
3. Equity in donation should be promoted by engaging all segments of society in efforts to meet the need for medical products of human origin, ensuring a diverse and adequate donor pool.
4. Opportunity to donate should not be denied to individuals and groups and at the same time this does not equate with the right to donate.
5. Medical products of human origin should be used only in situations of clinical utility and in the absence of alternative and affordable therapies with a comparable or more favourable balance of risks and benefits. Other non-clinical use should be based on donor consent and in line with national laws and policies.

6. Ensure transparency and scrutiny in the organization and delivery of activities related to medical products of human origin, while protecting the confidentiality of donors and recipients in accordance with national laws.

7. Protecting the interests of the public and local practitioners, the National Blood Centre (NBC) does not agree with foreign equity participation.

8. Implement continuous monitoring and evaluation of blood bank activities to ensure compliance with regulations and to maintain high standards of safety and quality.

9. Conduct public awareness campaigns to educate the public about the importance of blood donation and the regulatory framework governing it, encouraging informed and voluntary donations.

10. Enhance reporting mechanisms to ensure transparency in the procurement, distribution, and use of blood products, fostering trust and accountability.

Policy
12
HAEMOVIGILANCE

Haemovigilance is a critical component of transfusion medicine, aimed at monitoring, reporting, and analysing adverse events related to blood donation and transfusion to improve safety and outcomes.

Strategies:

1. Establish a national haemovigilance system to systematically collect, analyse, and report data on adverse events and reactions related to blood donation and transfusion.
2. Implement mandatory reporting of all adverse transfusion reactions and donation-related incidents by hospitals and blood banks.
3. Regularly analyse haemovigilance data to identify trends, root causes, and areas for improvement, and take corrective actions to enhance safety.
4. Provide training and education to healthcare professionals and blood bank staff on the importance of haemovigilance, proper reporting procedures, and preventive measures.
5. Develop a feedback mechanism to communicate findings and recommendations from haemovigilance data analysis to all relevant stakeholders, including healthcare providers, blood banks, and policymakers.

Policy
13

LOOKBACK AND RECALL

Lookback and recall procedures are essential for identifying and notifying recipients of potentially unsafe blood products to prevent harm and ensure patient safety.

Strategies:

1. Develop and implement lookback procedures to trace and notify recipients of blood products from donors who later test positive for Transfusion Transmissible Infections (TTI) or other significant health concerns.
2. Establish recall protocols to quickly identify, retrieve, and quarantine blood products that are found to be potentially unsafe or defective.
3. Ensure clear and effective communication channels for notifying affected patients and hospitals promptly and providing necessary information and support.
4. Maintain thorough documentation and records of all lookback and recall activities, including identification, notification, and outcomes, to ensure accountability and facilitate future audits and improvements.
5. Conduct regular reviews and evaluations of lookback and recall procedures to assess their effectiveness and make improvements as needed to enhance patient safety.

5.0 LOOKING TO THE FUTURE

It is the vision of the NTMS to be a premier Blood Transfusion Services of excellence which provides safe and quality blood as well as comprehensive services that meet the healthcare needs of the country.

Transfusion Medicine is a medical discipline undergoing continuous change with enormous advances in all areas of Transfusion Medicine Services. This leads to the expansion of its services to include cellular therapy, tissue banking and stem cell transplantation.

The global trends in technological advances will present a paradigm shift to the way Transfusion Medicine is practised to overcome the challenges of the future, ensuring sustainability of the NTMS.

Glossary

ABO	A blood group system that has an antigen commonly carried on human red cells and platelets.
Adverse event	Any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to an adverse reaction in blood recipients or blood donors.
Apheresis	Method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.
Blood	Human blood that is collected, including whole blood and blood components collected by apheresis, either for direct transfusion or for use in the preparation of medicinal products for human use.
Blood Transfusion Services / blood establishment	Any structure or body that is responsible for any aspect of the recruitment of donors, collection and testing of blood, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion.
Blood product	Any therapeutic product derived from human blood or plasma.
Blood component	Therapeutic components of blood (red cell, white cell, platelets, plasma) that can be prepared by centrifugation, filtration and freezing using conventional blood bank methodology.

Blood cold chain	A system for storing and transporting blood and blood products, within the correct temperature range and conditions, from the point of collection from blood donors to the point of transfusion to the patient.
Document	All the written instructions, records and actions involved in providing a product of service, information and its support medium.
Donor	A person who voluntarily donates blood or blood components.
First time donor	Someone who has never donated either blood or plasma.
Good Manufacturing Practices (GMP)	A part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use and legal requirements.
Haemovigilance	A set of surveillance procedures covering the whole transfusion chain intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of blood and blood products and to prevent the occurrence or recurrence of such incidents.
Lapsed donor	A donor who has not donated in the last 24 months.

Lookback	Lookback is a systematic procedure used to identify and trace recipients of blood or blood products from a donor who is later found to have had a Transfusion Transmissible Infection (TTI) at the time of donation, or when a recipient is suspected of TTI through clinical symptoms, routine screening, or laboratory test results. The purpose of the lookback process is to notify recipients or donors of the potential risk, offer testing and counselling, investigate the source and distribution of the infection, and implement corrective actions to ensure the safety of the blood supply.
Process	A series of steps or actions that lead to a desired result or output.
Quality Manager	A qualified individual designated by the Director to establish methods to review, modify, approve and implement all procedures intended to maintain quality in the operation of the Blood Transfusion Service and to monitor compliance with these standards.
Quality	Ability of a set of inherent characteristics of a product, system or process to fulfil requirements of customers and other interested parties.
Recall	A procedure used to remove or correct blood or blood products that are discovered to be defective, contaminated, or otherwise not compliant with safety standards after they have been distributed. This process aims to prevent the use of potentially harmful blood products. Recalls are initiated when a risk to patient health is identified, and they involve notifying all entities in the distribution chain, retrieving the affected products, and ensuring proper disposal or reprocessing.

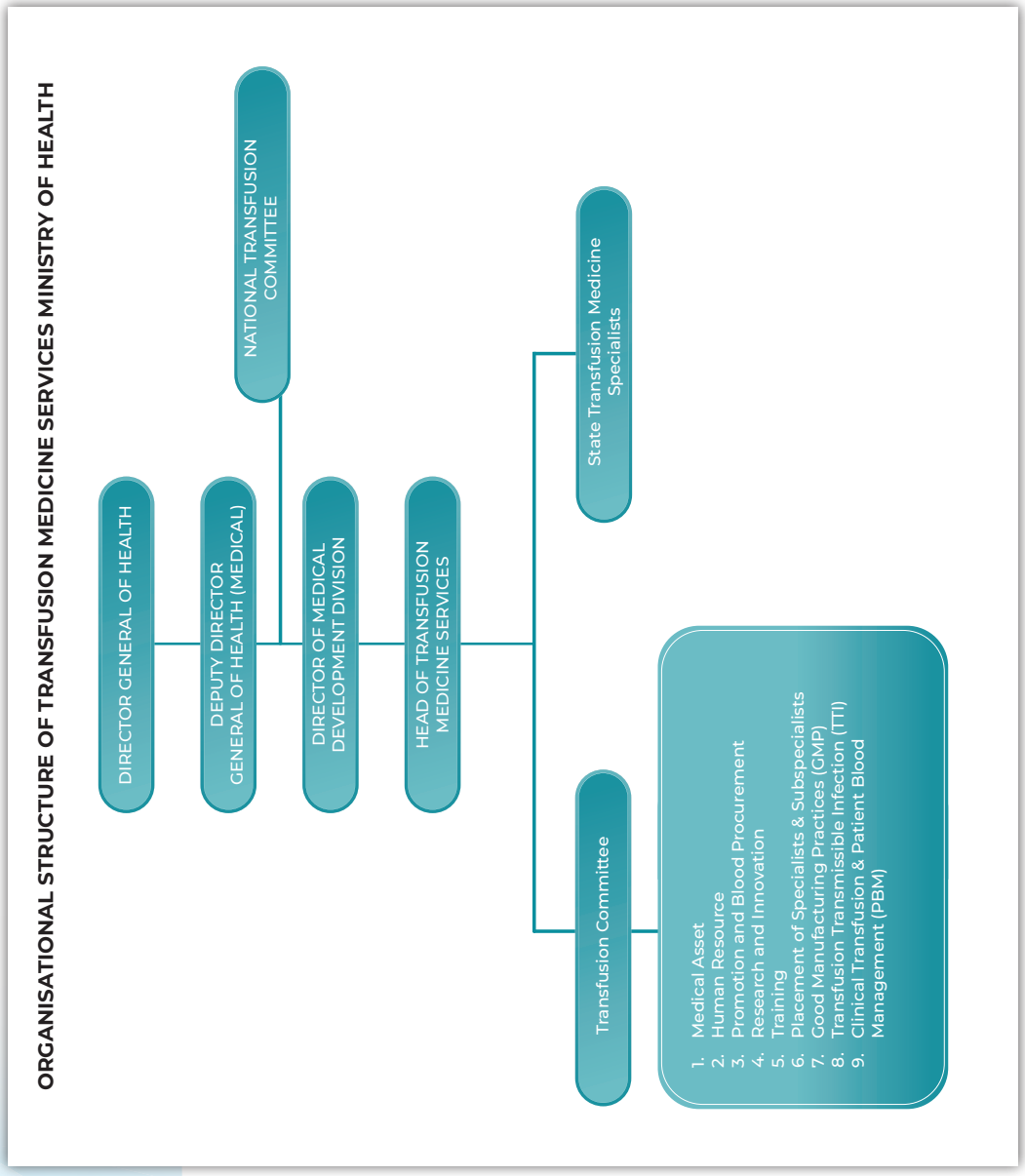
Record	Document stating results achieved or providing evidence of activities performed.
Regular donor	A person who donates blood within a period of 24 months from the date of last donation in Ministry of Health (MOH) facilities.
High risk behaviour	Behaviour that exposes a person to the risk of acquiring transfusion transmissible infections.
Rh(D)	An antigen found on the red blood cells of most people; those who have Rh(D) antigen are set to be Rh(D) positive while those who do not are Rh(D) negative.
Transfusion Transmissible Infection (TTI)	An infection that is potentially capable of being transmitted by blood transfusion.
Traceability	Ability to trace the history, application or location of that which is under consideration.
Voluntary Non-Remunerated Blood Donor	A donor who gives blood, plasma or other blood components freely and voluntarily, without receiving payment in the form of money or a substitute for money.

Reference:

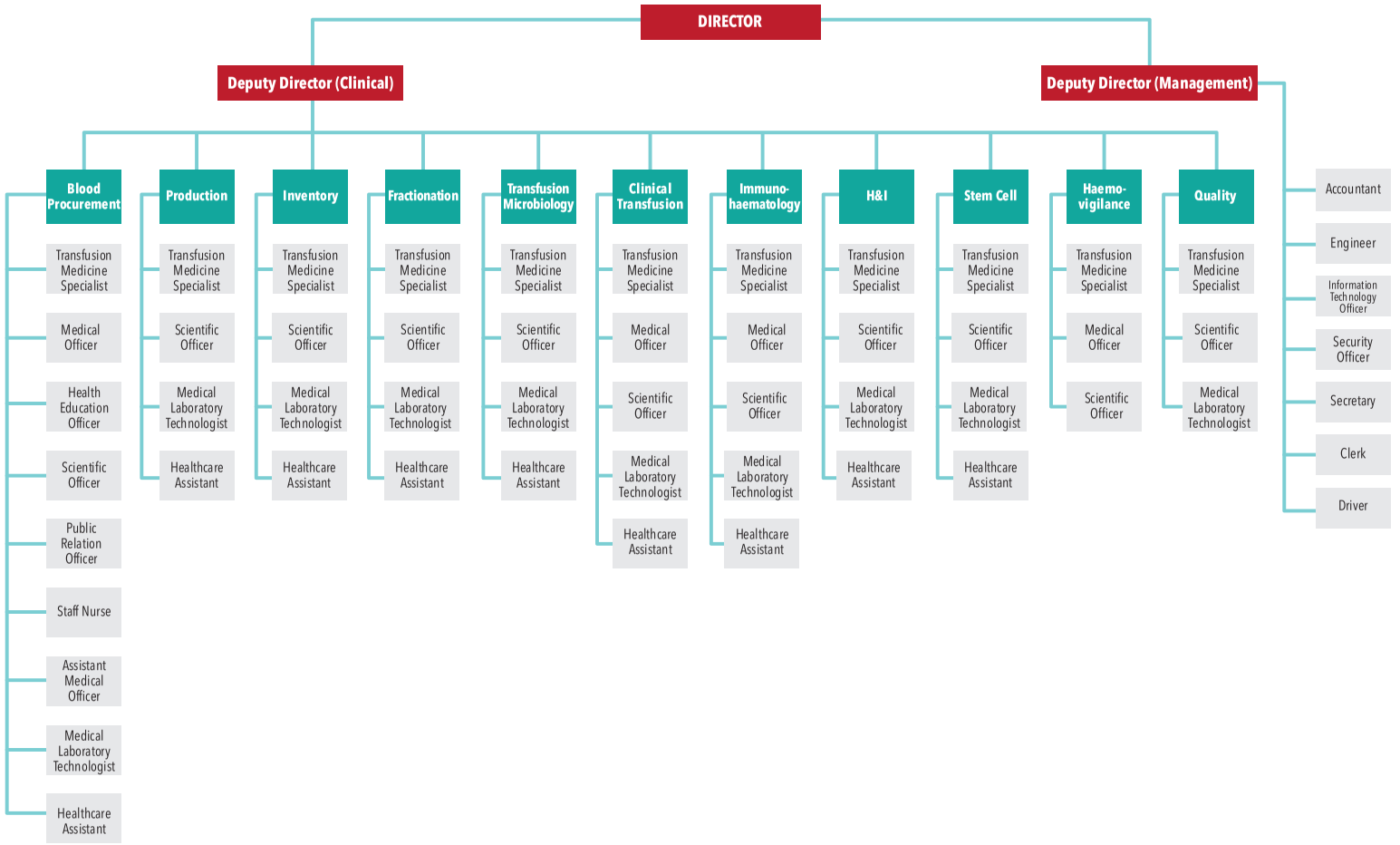
National Policy for Blood Transfusion Services in Malaysia, 2008

APPENDIX I:

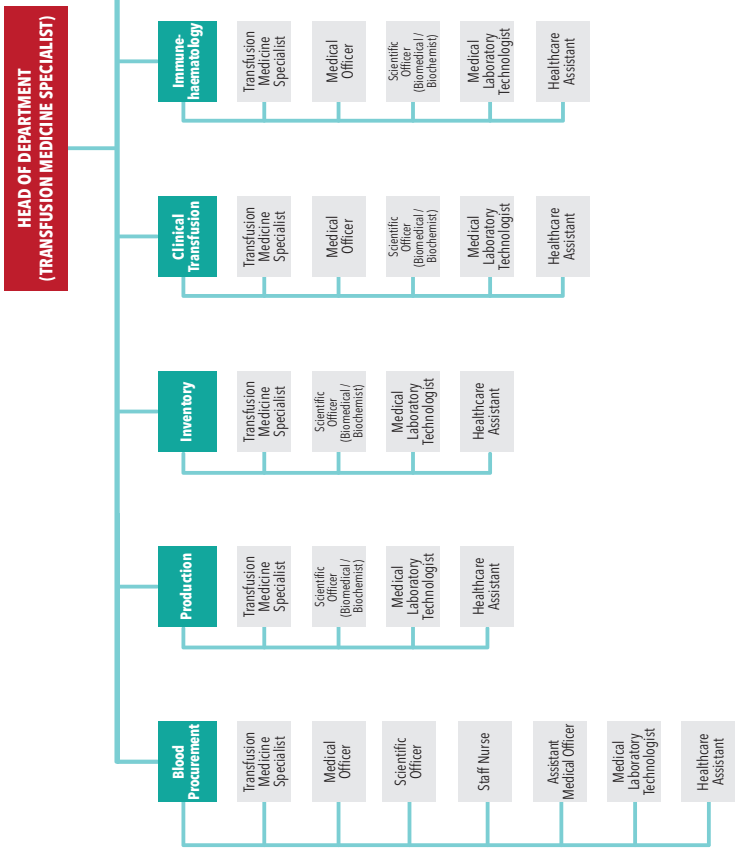
TRANSFUSION MEDICINE STAFFING STRUCTURE ACCORDING TO POSITION AND HEALTH CARE LEVEL



TRANSFUSION MEDICINE DEPARTMENT ORGANISATIONAL CHART
(NATIONAL BLOOD CENTRE / PUSAT DARAH WILAYAH)



TRANSFUSION MEDICINE DEPARTMENT ORGANISATIONAL CHART (HOSPITAL TYPE 1)



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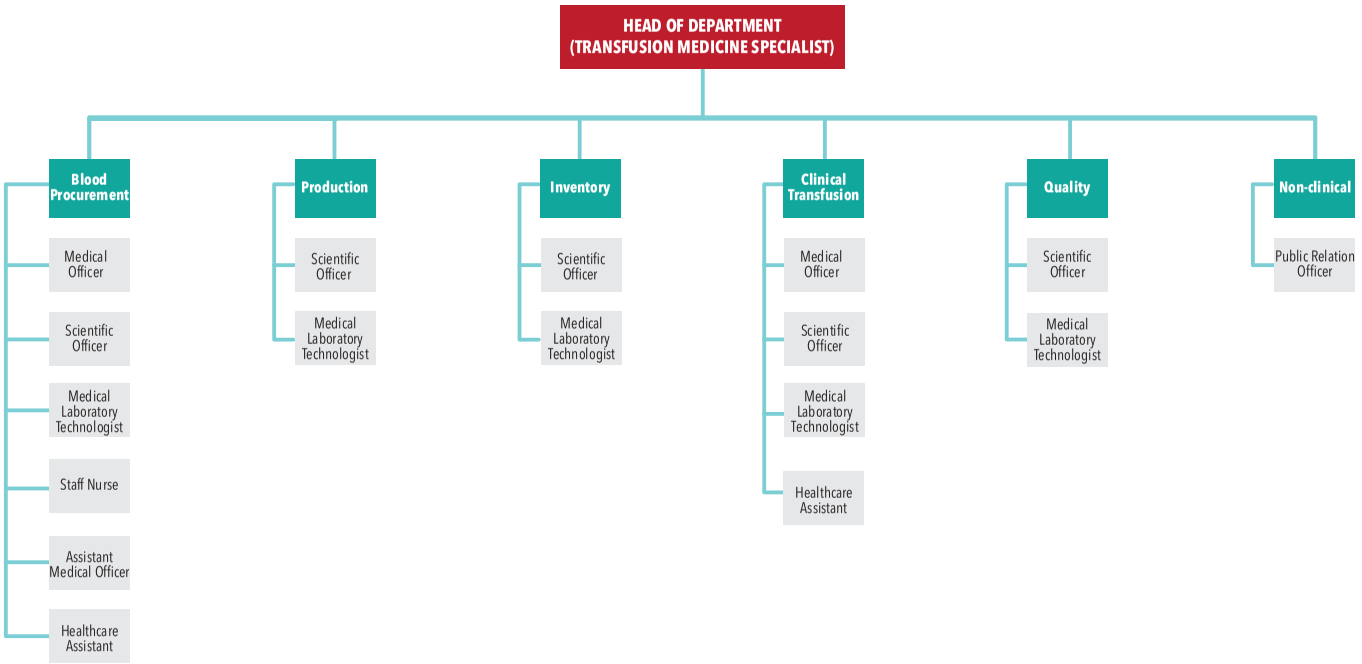
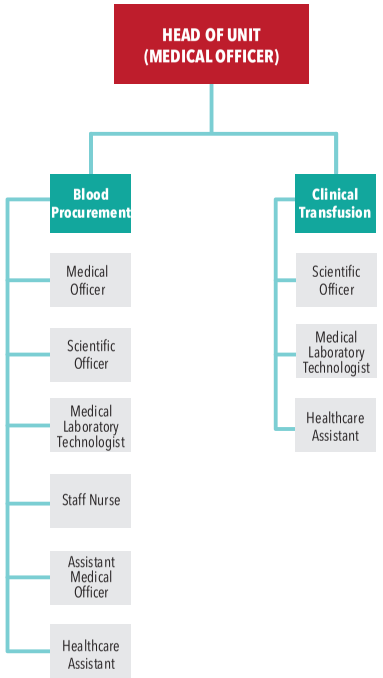


TRANSFUSION MEDICINE DEPARTMENT ORGANISATIONAL CHART (HOSPITAL TYPE 4)



Reference: Surat Pekeliling Ketua Pengarah Kesihatan Bil 5 / 2025: Struktur Organisasi Dan Tadbir Urus Klinikal (Clinical Governance) Bagi Hospital-Hospital Kementerian Kesihatan Malaysia

APPENDIX II:

LIST OF TESTS ACCORDING TO HEALTH CARE LEVEL

Divisions	Test	Categories				
		Regional / referral	Hospital Type 1	Hospital Type 2	Hospital Type 3	Hospital Type 4
Immunohaematology / Clinical Transfusion	ABO & Rh(D) Grouping	√	√	√	√	√
	Antibody screening	√	√	√	√	√
	Antibody identification	√	√	√		
	Crossmatching	√	√	√	√	√
	Antihuman Globulin Test (AHG)	√	√	√	√	√
	Red Cell Phenotyping	√	√	√		
	Elution Technique	√	√	√		
	Cold Agglutinin Titre	√	√	√		
	Secretor study	√				
	Haemolysin Test (selection of Emergency O blood)	√	√			
	Anti-D titre	√	√	√		
	Anti-A, Anti-B titre	√	√	√		
	Adsorption test	√	√	√		
	Platelet Antibody	√				
	Genotyping for Red Cell and Platelet	√				
	Urinalysis (blood) - patient's sample	√	√	√	√	√

Divisions	Test	Categories				
		Regional / referral	Hospital Type 1	Hospital Type 2	Hospital Type 3	Hospital Type 4
Quality	Plasma Hb	√	√			
	pH	√	√			
	Osmolality Testing	√	√			
	Sterility (screening only)	√	√			
	Full Blood Count (FBC)	√	√			
Transfusion Microbiology	Nucleic Acid Testing	√	√			
	Nucleic Acid Testing- discriminatory	√	√			
	Donor Screening for TTI	√	√			
	HIV Ag/Ab	√	√			
	HIV Confirmatory Test	√	√			
	Hepatitis B Surface Antigen	√	√			
	Hepatitis B Surface Antibody	√	√			
	Hepatitis B Confirmatory test (Neutralization)	√	√			
	Anti Hepatitis B core	√	√			
	Anti Hepatitis C virus	√	√			
	Anti Hepatitis C virus confirmatory test	√	√			
	Rapid plasma reagin	√	√			
	Treponema pallidum particle agglutination	√	√			

Divisions	Test	Categories				
		Regional / referral	Hospital Type 1	Hospital Type 2	Hospital Type 3	Hospital Type 4
Histocompatibility & Immunogenetics	HLA Typing	√				
	HLA Antibody (Solid Organ Transplant)	√				
	HLA Antibody (TRALI investigations)	√				
	HLA crossmatch (CDC)-living related donor	√				
	HLA crossmatch (Flow)-living related donor	√				
	HLA crossmatch (CDC)-deceased donor	√				
	HLA crossmatch (Flow)-deceased donor	√				

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