

CODE



MINISTRY OF HEALTH MALAYSIA

MOH/P/PAK/131.07 (BP)

NATIONAL ORGAN, TISSUE AND CELL TRANSPLANTATION POLICY

JUNE 2007

Surgical and Emergency Services Unit,
Medical Services Development Section,
Medical Development Division



Organ and Tissue Donation is
a Gift of Life



NATIONAL ORGAN, TISSUE AND CELL
TRANSPLANTATION POLICY

Medical Development Division, Ministry of Health Malaysia

The National Organ, Tissue and Cell Transplantation Policy was written by Surgical and Emergency Services Unit of the Medical Services Development Section, Medical Development Division, Ministry of Health Malaysia, in collaboration with the Special Committee for Development of National Organ, Tissue and Cell Transplantation Policy

Published in June 2007

A catalogue record of this document is available from the Library and Resource Unit of the Institute of Medical Research, Ministry of Health;

MOH/P/PAK/131.07 (BP)

More about transplantation in Malaysia on the following websites;

www.ntrc.gov.my

(National Transplant Resource Centre Kuala Lumpur Hospital),

www.mst.org.my

(Malaysia Society of Transplantation),

www.msn.org.my

(Malaysia Society of Nephrology),

www.crc.gov.my

(Clinical Research Centre, Ministry of Health)

The National Organ, Tissue and Cell Transplantation Policy was approved by the Secretary General of the Ministry of Health, the Director General of Health Malaysia and the Members of the Policy and Planning Committee, Ministry of Health Malaysia

3 April 2007

Acknowledgements

Surgical and Emergency Services Unit would like to acknowledge Dato' Dr Noorimi Hj Morad, the Deputy Director General of Health (Medical) whose special interest and commitment in developing transplantation service in Malaysia has been the main driving force in the development of this document.

Special gratitude to Dato' Dr Zaki Morad Mohamad Zaher, the former Head of Nephrology Department, Kuala Lumpur Hospital who later joined the International Medical University of Malaysia as a professor of internal medicine. Despite his retirement from public service, he continues to offer his dedication, leadership and expertise to the Ministry of Health towards the publication of this document.

The Ministry of Health also appreciates the contributions by the members of the Special Committee for Development of National Organ, Tissue and Cell Transplantation Policy whose great commitment and continuing enthusiasm are strongly admired.

Surgical and Emergency Services Unit also acknowledges the contributions and cooperation by the Legal Advisors to the Ministry of Health, the Working Group for the Development of Cell Transplantation Policy, the Obstetrics, Gynaecology and Paediatric Services Unit and the Clinical Support Services Unit of Medical Development Division.

The Ministry recognises the commitment and support by the private sectors, the universities and other religious and government agencies who have submitted their feedbacks on the draft documents. They are namely; Tan Sri Dato' Dr Abu Bakar Suleiman, the President of the International University Malaysia, Tan Sri Dato' Dr Yahya Awang, Senior Consultant Cardiothoracic Surgeon of Damansara Specialist Hospital, Ahmad Yusuf Ngah, the Secretary of the Human Rights Commission Malaysia, Elaine PY Cheong, the Chief Executive Officer of Subang Jaya Medical Centre, Dr Syed Ali Tawfik Al-Attas, the Director General of the Institute of Islamic Understanding Malaysia and Dr T.Mahadevan, a Board member of the Association of Private Hospitals Malaysia.

To all other parties who have directly or may indirectly involved in the publication of this document.

FOREWORD



THE DIRECTOR GENERAL OF HEALTH MALAYSIA



In the last few decades the country has witnessed rapid socioeconomic development and this has led to changes in the healthcare needs and expectations of the population. The Ministry of Health, as the principal agency tasked with the development and monitoring of healthcare services, takes cognisance of these changes and continues to be responsive to the needs of the population. We have dealt successfully with major public health concerns and indicators such as the maternal mortality rate, infant mortality rate and life expectancy at birth are testimony to the progress we have made in these areas. We now have to face the challenges of new public health problems - chronic diseases like diabetes mellitus, hypertension, kidney diseases, cardiovascular diseases and cancers. While the emphasis is still on health promotion and primary prevention, we cannot but acknowledge that more resources are now needed to meet the sequelae of these diseases including organ failure states.

The management of these organ failure states requires costly technology-dependant interventions such as organ transplantation. In many situations such as end stage liver failure and end-stage heart failure, transplantation is the only treatment for long term survival of the affected patients. In end-stage renal failure there is the alternative of dialysis. The Ministry supports these programmes although they consume a disproportionate share of the healthcare budget. It is important that those involved in these programmes realise the importance of ensuring the cost effectiveness of the therapeutic interventions they perform.

A National Organ, Tissue and Cell Transplantation Policy document such as this will guide all those involved in working towards attaining the highest professional and ethical standards in the field of transplantation. In addition it addresses the needs for adequate resources, properly trained and credentialed personnel and the organisational structure needed to run a national programme effectively and efficiently.

I believe that with the adoption of this policy, organ and tissue transplantation will develop further and those in need of such treatment will benefit from a comprehensive and efficient service that is comparable to that found in the best centres in the world.



Tan Sri Datuk Dr Hj Mohd Ismail Merican

THE DEPUTY DIRECTOR GENERAL OF HEALTH (MEDICAL)



Organ transplantation is one of the many specialised, tertiary medical care available in the country for many years now. It is provided by a few hospitals although the demand for the treatment has been increasing over the years. There have been a number of constraints to the further development of organ transplantation, including the lack of organ donors, specialised laboratory services and trained personnel. The Ministry of Health has taken a number of initiatives to improve the service in the last few years. These initiatives have come at an opportune moment as the World Health Organisation (WHO) is similarly taking steps to assist countries to improve their transplantation programme. The WHO, at the invitation of The Transplantation Society, has joined the latter to form the Global Alliance for Transplantation (GAT) to promote organ and tissue transplantation the world over.

There are a number of areas that the Medical Programme of the Ministry is addressing in the development of organ/tissue transplantation services. The Ministry is concerned about the lack of cadaveric donors despite the high number of deaths in circumstances that could lead to organ donations. In this respect it has developed more intensive care facilities, established organ procurement teams and intensified public education on organ donation in collaboration with various professional bodies. The lack of donors both live related and cadaveric in the country has led many patients to go overseas where they purchase organs especially kidneys for transplantation.

There is also a need for better laboratory facilities to do tissue typing. The diagnosis of complications, especially viral infections, calls for specialised laboratory services. The high cost of immunosuppressive drugs is always a factor in any organ transplantation service. The Ministry will continue to subsidise the use of the most appropriate immunosuppressive agents to achieve the optimum results.

Training of personnel involved in transplantation will continue to be given priority in our programme. We will continue to send personnel to centres of excellence overseas to ensure that they obtain the best training and exposure in this field. The development of new transplantation centres will be properly planned, taking into account the availability of resources and trained personnel. Only accredited centres with credentialed personnel will be allowed to do transplantation.

The National Organ, Tissue and Cell Transplantation Policy will serve as a guide for the future expansion and development of transplantation services. It also addresses issues relating to ethical practice in transplantation. It is important that we also abide by guidelines of The Transplantation Society and WHO in contentious areas such as the sale of organs and the use of prisoners as donors.



Dato' Dr. Noorimi Hj Morad

THE CHAIRMAN OF THE SPECIAL COMMITTEE

For Development of National Organ, Tissue and Cell Transplantation Policy



Organ transplantation started more than half a century ago with the first successful kidney transplantation performed in Boston USA. Since then other organs, tissues and cells have been transplanted successfully and transplantation has been one of the most significant therapeutic advancement in the history of medicine. The current interest in the therapeutic potential of stem cell therapy has overshadowed the achievements of organ and tissue transplantation in rescuing patients from near death in daily human stories of hope, determination, sacrifice and grit.

In Malaysia we had our first organ transplantation when kidney transplantation was carried out in December 1975. The recipient who received a kidney from his brother survived for thirty years before succumbing to a major infection.

Since then we have had liver, heart and lung transplantation. Corneal transplantation was carried out even before kidney transplantation, with corneas brought in from other countries.

The major issue with organ transplantation in the country is, as in all other countries, the lack of organs. Cadaveric organ donation rate has been minimal (about one per million population) despite public education and publicity campaigns. In kidney transplantation, living related donors are the main source of kidneys for transplantation especially in the early years of the development of kidney transplantation in the country. In liver transplantation, live donors are still the main source of organs. In fact, in liver transplantation there had been several donors who were not biologically related to the recipients. In End Stage Renal Disease, the lack of kidneys from both cadaveric and live related donors has led to two major developments: 1) the rapid development of dialysis facilities - there are now about 15,000 patients on this treatment 2) Malaysian patients going overseas to purchase either live donor or cadaveric kidneys. The latter development has led to a number of ethical and moral issues which are continually being debated across the world.

The outcome of organ transplantation has seen major improvements in graft and patient survival over the last two decades. In a large part this is due to the better immunosuppressive drugs but prevention, early diagnosis and effective management of complications such as infection and cardiovascular disease have also contributed significantly.

The care of transplantation recipients continues to require specialized skills and knowledge and thus only credentialed personnel practicing in accredited centres should be allowed to perform organ transplantation and post transplantation care.

This National Organ, Tissue and Cell Transplantation policy is developed to guide practitioners in the field and all other stakeholders to further develop this therapeutic option to treat end stage organ failure states. It has taken into consideration the development of transplantation in this country so far, issues and concerns, resources required and their shortfall.

Above all the policy hopes to guide all involved to practice transplantation to the highest professional and ethical standard.



Dato' Dr Zaki Morad Mohamad Zaher

THE ARTICLES



1. INTRODUCTION

- 1.1. The government will continue to shoulder responsibility in delivering optimal healthcare to the population, with emphasis on maintaining health status, preventing diseases and providing appropriate medical treatment. Changes in demography including an increase in the elderly population and greater incidence of lifestyle-related diseases, have led to an increase in the incidence of end stage organ failures. The Ministry of Health has taken initiatives to address these new challenges through health promotion and prevention by developing comprehensive healthcare policies and strategies, one of which is a comprehensive National Transplantation Programme.
- 1.2. Organ transplantation is a successful therapy for end stage organ failures of kidney, liver, heart, lung, pancreas and intestine.

- 1.3. Transplantations of stem cells and tissues have widened the therapeutic options of many human diseases, and cord blood is an important alternative source of haematopoietic progenitor cells.
- 1.4. Organ and patient survival rates continue to improve as a result of advances in donor-recipient selection, better surgical techniques, judicious use of immunosuppressant and better management of post-transplantation infections and other complications.
- 1.5. Organs and tissues are obtained from suitable living or cadaveric donors. Historically there has always been a shortfall in the supply of organs and tissues. The success of transplantation has increased demand, thus increasing the gap even more. The shortage of organs for transplantation has led to greater use of organs from living donors. It has also led to unhealthy and unethical practices such as the use of organs from executed prisoners and rampant commercialisation in transplantation.

- 1.6. Stem cells of haematopoietic origin are now being successfully transplanted for the treatment of haematopoietic malignancies, marrow failures and some genetic diseases. Presently cell therapy remains unproven and shall be subjected to research protocols.
- 1.7. This Policy serves to guide the practice of organ, tissue and cell transplantation in Malaysia. It has been developed after taking into account the prevailing practices in this country, and also the relevant legislations, practices and guidelines in other countries. The policy promotes organ and tissue transplantation as a preferred treatment in end-stage organ failure states.
- 1.8. The Ministry of Health together with other relevant government agencies and non-governmental organisations shall take active measures to promote organ, tissue, cord blood and bone marrow donations in this country

1.9. This Policy shall be implemented and enforced through various existing mechanisms.

1.10. This Policy shall be reviewed every three years or as the need arises and necessary amendments shall be made accordingly.

2. AIM OF THE POLICY

- 2.1. To promote organ, tissue and cell transplantation in the country.
- 2.2. To promote cadaveric organ and tissue donation in the country.
- 2.3. To ensure transparent and equitable access to organ, tissue and cell transplantation for those in need.
- 2.4. To ensure that organ, tissue and cell transplantation is carried out to the highest ethical and professional standards.
- 2.5. To ensure that the rights and welfare of living donors are looked after, in cases where live donations are necessary.
- 2.6. To promote the highest quality of care including proper documentation and maintenance of registries.

3. GENERAL STATEMENT OF THE POLICY

- 3.1. Organ transplantation shall be promoted as the preferred treatment for end-stage organ failure because it is cost-effective and it provides good quality of life. Similarly tissue and cell transplantation shall be promoted for the treatment of appropriate diseases where evidence of effectiveness exists.
- 3.2. The commercialisation of organ, tissue and cell transplantation and any act that may indirectly promote or lead to commercial transaction are prohibited.
- 3.3. Organ, tissue and cell transplantation recipients shall receive appropriate assistance from the Government.
- 3.4. All living organ donors shall be followed up for life.

- 3.5. The cost incurred by the family of a cadaveric donor related to the organ and/or tissue procurement process shall be reimbursable by an authorised body or organisation recognised by the Ministry of Health. Direct payment by the recipient to the family of the donor is prohibited.
- 3.6. Confidentiality regarding the identity and personal details of donors and recipients shall be ensured.
- 3.7. All clinicians involved in the procurement and transplantation process shall ensure the highest standards of safety and quality.
- 3.8. There shall be a dedicated budget for the implementation of transplantation activities in the country.

4. ORGANISATION OF NATIONAL TRANSPLANTATION PROGRAMME¹

4.1. The main governing body of the National Transplantation Programme shall be the **National Transplantation Council (NTC)**. The Council shall consist of the following:

- 4.1.1. The Director General of Health Malaysia as Chairperson.
- 4.1.2. The Deputy Director General of Health (Medical)
- 4.1.3. The Director of Medical Development Division.
- 4.1.4. The Director of Medical Practice Division.
- 4.1.5. Three clinicians from the Ministry of Health.
- 4.1.6. One representative from the Malaysian Society of Transplantation.
- 4.1.7. Two representatives from the Universities (to be nominated by the Deans' council).
- 4.1.8. One representative from the Association of Private Hospitals Malaysia.

¹ Refer to appendix II

- 4.1.9. One representative from the Malaysian Medical Association.
- 4.1.10. One representative from the Academy of Medicine Malaysia.
- 4.1.11. One representative from JAKIM/IKIM².
- 4.1.12. One representative from the organisation representing all other religious bodies.
- 4.1.13. One representative from a patient support group.
- 4.1.14. One representative from a non-medical lay organisation.

² JAKIM – Jabatan Kemajuan Islam Malaysia (Department of Islamic Development Malaysia)
IKIM – Institut Kefahaman Islam Malaysia (Institute of Islamic Understanding Malaysia)

4.2. The Minister of Health shall appoint all members of the Council. Members may be nominated by the respective organisations represented on the Council, but will be selected based on their interest, expertise and experience in the field of transplantation.

4.3. The NTC shall:

4.3.1. Recommend policies on organ, tissue and cell transplantation in the country.

4.3.2. Promote and monitor the progress of the organ, tissue and cell transplantation programme in the country.

4.3.3. Play a major role in the advocacy of organ, tissue and cell transplantation in the country.

4.3.4. Ensure the highest ethical and professional standards in the practice of transplantation in the country.

4.4. There shall be a **National Transplantation Technical Committee (NTTC)** appointed by the Director General of Health. The NTTC shall be headed by the Deputy Director General of Health (Medical) and consist of four other persons with relevant expertise in the field of transplantation. The responsibilities of the NTTC are:

- 4.4.1. To promote the objectives of the Council (NTC).
- 4.4.2. To advise the NTC on matters related to policy.
- 4.4.3. To advise the National Transplantation Unit (NTU) on matters related to implementation.
- 4.4.4. To consider reports from the Expert Committees.
- 4.4.5. To consult with other relevant experts when necessary.

- 4.5. The NTTC shall establish Expert Committees with specific responsibilities and scopes as follow:
 - 4.5.1. Training, standards and accreditation.
 - 4.5.2. Law and ethics.
 - 4.5.3. Public education.
 - 4.5.4. Planning and development.
 - 4.5.5. Registry of organ, tissue and cell recipients and donors.
 - 4.5.6. Any other scope as, and when necessary.

- 4.6. The implementation of the organ, tissue and cell transplantation programme shall be coordinated by the **National Transplantation Unit (NTU)** within the Medical Development Division of the Ministry of Health.

- 4.7. The NTU shall have the following responsibilities;
- 4.7.1. Secretariat for NTC and NTTC.
 - 4.7.2. Establish organ and tissue procurement units in hospitals.
 - 4.7.3. Establish a system for organ and tissue allocation and national transplantation waiting lists for potential organ and tissue recipients.
 - 4.7.4. Develop and support organ, tissue and cell transplantation units in designated hospitals.
 - 4.7.5. Facilitate and support the development of a national transplantation recipients, donors and donor pledgers registries.
 - 4.7.6. Implement training programmes for all personnel involved in organ, tissue and cell procurement and transplantation.
 - 4.7.7. Work with relevant agencies to ensure the implementation of processes of the accreditation for organ, tissue and cell procurement and transplantation.
 - 4.7.8. Ensure that all practitioners in organ, tissue and cell transplantation are properly credentialed.

- 4.7.9. Monitor standards of practice in organ, tissue and cell procurement and transplantation.
- 4.7.10. Promote public education activities.
- 4.7.11. Facilitate necessary/required amendments to existing legislation and/or enactment of new legislation on transplantation, according to the recommendations of the Law and Ethics Expert Committee and as approved by the NTC and NTTC.

5. ACCREDITATION, CREDENTIALING AND STANDARDS

- 5.1. Organ, tissue and cell transplantations shall only be performed in accredited centres which meet the standards established by the Ministry of Health.
- 5.2. Transplantation shall be performed by credentialed personnel.
- 5.3. The follow up care of patients who have undergone transplantations shall be provided by trained personnel.
- 5.4. Transplantation centres shall maintain high standards of practice. This can be achieved by the regular monitoring of patient and graft survivals and other indices of quality care using internationally accepted criteria.

5.5. Criteria for accreditation, credentialing and standards shall be determined and reviewed by the appropriate professional bodies or societies appointed / recognised by the Ministry of Health.

6. ORGAN AND TISSUE PROCUREMENT

- 6.1. Organs and tissues shall be procured preferably from cadaveric donors. However, where appropriate organs and tissues from living donors may be used.
- 6.2. Organ and tissue procurement from living donors:
 - 6.2.1. Competent adult living persons can donate organ and/or tissue but they shall preferably be related to the recipients and donor consent must be given freely and altruistically without coercion or any commercial inducement.
 - 6.2.2. No organ and/or tissue shall be removed from the body of a living minor for the purpose of transplantation except in the case of regenerative tissues.

- 6.2.3. Prior authorisation from the Unrelated Transplant Approval Committee (UTAC) shall be obtained before any unrelated live organ donation. Such donation must fulfil the following criteria except in the case of regenerative tissues;
- 6.2.3.1. No available cadaveric donor;
 - 6.2.3.2. No compatible donor from genetically-related or emotionally related family members and
 - 6.2.3.3. No other alternative treatment.
- 6.2.4. In the case of organ donation, all living donors shall be counselled by donor advocates regarding the risks, benefits and possible consequences. Donor advocates shall be independent of the organ procurement and transplantation team.
- 6.2.5. Prisoners awaiting execution and mentally disabled person shall be prohibited from live donation.

- 6.2.6. Under life saving circumstances, live donation of organs from prisoners may be considered for immediate relatives subjected to approval from relevant authorities.
- 6.2.7. Organ and tissue procurement and transplantation from living donors shall only be performed in accredited centres by credentialed personnel.
- 6.2.8. Accredited centres performing organ procurement from related and unrelated living donors shall have written guidelines and standard operating procedures. These shall include the following:
 - 6.2.8.1. Criteria for eligibility to be a donor.
 - 6.2.8.2. Detailed donor evaluation including psychosocial and medical assessment.
 - 6.2.8.3. Plan for life-long donor follow-up.

6.3. Organ and tissue procurement from cadaveric donor:

6.3.1. Organisation of cadaveric donation activity;

6.3.1.1. There shall be a dedicated unit at the national level to manage and coordinate all aspects of organ and tissue procurement from cadaveric donors. This unit shall be known as **Transplantation Procurement Management Unit (TPMU)**. The responsibilities of this unit include;

- a To coordinate organ and tissue procurement in any part of the country with the local hospital unit managing the donor;
- b To liaise with organ and tissue transplantation teams;
- c To organise efficient and safe transport of organ and tissue from donor hospital to recipient hospital;

- d To develop guidelines, standard operating procedures and standard criteria for donor referral, donor management, organ and tissue procurement, storage and transport as well as disposal of any unused organ and tissue;
- e To conduct public education and promotion of organ and tissue donation and
- f To provide regular data on organ and tissue donation activities.

6.3.1.2. At each identified hospital there shall be a **Tissue Organ Procurement (TOP) Team** consisting of trained personnel who shall be responsible for the identification and management of the potential donor including getting consent from the next of kin, evaluation for donation, organising the procurement, storage and transport of the organs and tissues and speedy return of the donor's remains to the next of kin.

- 6.3.2. All potential cases for cadaveric donations shall be made known to the local Tissue Organ Procurement (TOP) Team.
- 6.3.3. All deaths shall be considered for possible tissue donations.
- 6.3.4. The TOP Team shall provide support and follow-up care to the family of the donor for an appropriate duration.
- 6.3.5. Death certification for potential cadaveric donors shall be carried out by registered medical practitioners who are independent of the organs and/or tissues transplantation teams.

- 6.3.6. In cases where potential cadaveric donors' remains are being held under the Criminal Procedure Code for post-mortem or coronal inquest, prior written consent from the magistrate has to be obtained before any organ and/or tissue procurement is carried out, in accordance with the existing legislation.
- 6.3.7. Consent for donation can be obtained either from the deceased's expressed wish made through the organ and/or tissue donor pledge card and/or from the next of kin.

6.4. Unused Organs and Tissues;

- 6.4.1. The next of kin shall be informed by the TOP Team if the organs and/or tissues are not used and the next of kin shall be consulted on the method of disposal.
- 6.4.2. It is mandatory to obtain consent from the next of kin if the organs and/or tissues are to be used for purposes other than transplantation.
- 6.4.3. Any incidence of unused organ and/or tissue shall be investigated and reported to the NTTC.
- 6.4.4. Any unused organ and/or tissue which are not claimed by the next of kin shall be disposed with dignity in accordance with the guidelines on disposal of human materials.

7. ORGAN AND TISSUE ALLOCATION AND TRANSPLANTATION WAITING LIST

- 7.1. Organs and tissues donated by cadaveric donors shall be transplanted into potential recipients who are on the national transplantation waiting list. All organs and tissues donated for transplantation are regarded as national resources and are to be allocated in a fair, equitable and transparent manner based on agreed criteria.
- 7.2. The National Transplantation Waiting List is a list of patients eligible to receive organs and/or tissues based on an agreed set of criteria. There is a separate list for each organ and tissue transplantation service.
 - 7.2.1. All potential transplantation recipients shall be listed in the National Transplantation Waiting List.

- 7.2.2. Only credentialed specialists shall be privileged to place, review or remove patients on the list. This shall be done according to agreed criteria.
- 7.2.3. Criteria for the particular organ and/or tissue transplantation waiting list shall be developed by each organ and/or tissues specific transplantation group and shall be evidence-based, with clear inclusion and exclusion criteria.
- 7.2.4. There shall be only one national cadaveric waiting list for each organ and tissue transplantation service.

7.3. Urgent Status Candidate Waiting List:

- 7.3.1. There shall be a separate waiting list for urgent status candidates.
- 7.3.2. Placement of such candidates shall be based on individual organ and/or tissue specific allocation guidelines.

7.4. Organ and tissue allocation guidelines:

7.4.1. Each organ and tissue transplantation service shall have clear allocation guidelines. The guidelines shall take into consideration:

7.4.1.1. Donor-Recipient matching criteria.

7.4.1.2. Priority according to clinical urgency and status.

7.4.1.3. Duration of waiting time.

7.4.1.4. Special cases, e.g. highly sensitised patients and logistic factors.

7.4.1.5. The presence of co-morbid conditions.

7.4.2. There shall be clearly defined criteria for allocating organs in cases of paired organs or split organ transplantation.

7.4.3. The organ and/or tissue transplantation teams shall have the final decision to use or reject the allocated organ and/or tissue.

7.4.4. An individual patient has the right to refuse the organ and/or tissue allocated through the national allocation system. However, he/she will then be de-listed from the waiting list except in special circumstances. The patient may then apply to be re-listed.

8. ACCEPTANCE CRITERIA

- 8.1. Each organ and tissue transplantation service shall develop criteria or guidelines for the acceptance of individual organ and/or tissue for the purpose of transplantation.

9. CELL TRANSPLANTATION

- 9.1. Cell transplantation holds the promise of treating many human diseases. To safeguard public interests and patients' safety, emerging technologies and therapy shall be regulated.
- 9.2. New, innovative and investigational cell therapy approaches shall be subjected to approval by the Ministry of Health.
- 9.3. A National Stem Cell Committee shall be one of the expert committees established under the NTTC.
- 9.4. Stem cells of haematopoietic origin are now being successfully transplanted for treatment of certain diseases. Cord blood is an important alternative source of haematopoietic progenitor cell.
 - 9.4.1. The Ministry of Health shall establish a National Cord Blood and Stem Cell Transplantation Programme which shall

include a coordinating centre for cord blood and marrow donation.

9.4.2. The National Cord Blood Banking Programme which includes both public and private sectors shall be coordinated and regulated by the Ministry of Health.

9.4.3. The establishment of public and private cord blood banks shall be in accordance with national standards and guidelines and subjected to Ministry of Health approval.

9.4.4. Only when there are established clinical indications, shall there be provision for directed cord blood donation.

9.5. The practice of haematopoietic stem cell transplantation in the country shall be in accordance with the National Standards for Stem Cell Transplantation.

9.6. No embryonic stem cell therapy shall be permitted.

10. TRANSPLANTATION LABORATORY SERVICE

- 10.1. Organ, tissue and cell transplantation programmes require services from various clinical specialties. As such, pathology and laboratory services shall be established in parallel with other clinical specialties in the development of organ, tissue and cell transplantation.
- 10.2. A National Pathology Committee for Transplantation Programme shall be established as one of the expert committees under the NTTC.
- 10.3. There shall be a National Reference Laboratory for tissue typing and immunological services.
- 10.4. Specialised services including immunology, mycology, virology, bacteriology and therapeutic drug monitoring to support transplantation shall be available in identified laboratories in the country.

- 10.5. Pathology and laboratory services to support routine tests for transplantation services shall be made available in identified centres in the country.
- 10.6. All pathology services and laboratories that support transplantation shall participate in Quality Assurance Programs and should be accredited.
- 10.7. Each centre shall have a local network to store clinical and laboratory data of all donors and recipients of that centre.
- 10.8. A shared database of all recipients and donors (from all centres) shall be made available.

11. INTERNATIONAL SHARING OF ORGAN, TISSUE AND CELL

- 11.1. Organs and/or tissues procured from donors in Malaysia shall not be allocated to recipients in another country unless there is no suitable recipient locally and there is a prior agreement on organ and/or tissue sharing between such country and Malaysia.

- 11.2. Importation of tissues from other countries shall be made through institutions recognised by the Ministry of Health and in accordance with the Guidelines on Importation and Exportation of Human Tissues and/or any Body Part.

12. REGISTRY

- 12.1. All centres performing transplantation shall report to the **National Transplant Registry**. The report shall include appropriate details on the centre, the surgery and short and long term outcomes. The National Transplant Registry shall report annually on all transplantations in the country.
- 12.2. A registry of organ, tissue and cell donors shall be maintained. All centres participating in organ and tissue procurement shall report to the registry. The registry shall record short and long term outcomes of living donors.
- 12.3. A National Marrow Donor Registry and a National Cord Blood Registry shall be maintained. They shall serve to provide potential donors for those requiring transplantations where related donors are not available /suitable.

13. IMMUNOSUPPRESSIVE DRUGS

- 13.1. All organ recipients require life long immunosuppressive drugs.
- 13.2. Clinical practice guidelines on the use of these drugs shall be evidence-based.
- 13.3. Generic immunosuppressive agents may be as effective as propriety drugs. However, there should be adequate bioequivalence and/or therapeutic equivalence studies prior to their use.

14. INFORMATION AND COMMUNICATION TECHNOLOGY

14.1. There shall be adequate provision for a comprehensive information and communication technology infrastructure and personnel to ensure efficient data management, record keeping, analysis, auditing, monitoring of outcome measures and research purposes.

15. RESEARCH IN TRANSPLANTATION

- 15.1. Research in all aspects of organ, tissue and cell transplantation is encouraged. This includes laboratory based research, clinical trials, outcome and health economic studies.
- 15.2. All research activities must abide by the existing International/National guidelines on ethical conduct of research. Any study involving human subjects must receive prior approval from Institutional Review Board or Ethics Committee of the particular institution and/or the Ministry of Health.
- 15.3. Research findings shall be made available at appropriate forums (publications etc) in order to benefit the care of transplantation patients.

APPENDIX



REFERENCE

Consensus of Convention of Human Rights and Biomedicine, Council of Europe, April 1997

Directive 2004/23/EC of The European Parliament and of the council on setting standards of quality and safety for the donation, processing, testing, processing, preservation, storage and distribution of human tissues and cells, Official Journal of the European Union, 31 March 2004

Ethics, Access and Safety in Tissue and Organ Transplantation; Issues of Global Concern, World Health Organization, Madrid Spain, 6-9 October 2003

Guidance on the Microbiological Safety of Human Organs, Tissues and Cells Used in Transplantation, Department of Health United Kingdom, August 2000

Guidelines on Importation and Exportation of Human Tissues and/or any Body Part (Garispanduan Pengimporan dan Pengeksportan Tisu

Manusia atau Mana-mana Bahagiannya), Disease Control Division,
Ministry of Health Malaysia, August 2006

*Guidelines on Living Donation (Garis panduan Mengenai Pendermaan
Hidup)*, Medical Development Division, Ministry of Health
Malaysia, 2000

Guidelines on Stem Cell Research, Medical Development Division,
Ministry of Health Malaysia, June 2006

Guiding Principles on Human Organ Transplantation, World Health
Organisation, www.who.int

Human Organ and Tissue Transplantation, Report by Secretariat,
World Health Organization, EB113/14, November 2003

Human Tissue Act (1974), Malaysia

Liver Transplantation – Guidelines in Clinical Practice, Malaysian
Liver Foundation, 2000

National Liver Transplant Standard, United Kingdom Department of Health, August 2005

Policies on Organ/Tissue Donation and Transplantation, United Network for Organ Sharing (UNOS)/ Organ Procurement and Transplantation Networking (OPTN), 2004

Report of Consultation Meeting on Transplantation with National Health, Authorities in the Western Pacific Region, World Health Organization, November 2005

Resolutions and Decision of Fifty Seventh World Health Assembly; Human Organ and Tissue Transplantation, World Health Organisation, WHA57.18, May 2004

The Bellagio Task Force Report on Transplantation, Bodily Integrity and International Traffic in Organ, International Committee of the Red Cross, January 1997

The Donor Family Care Policy, Department of Health United Kingdom, October 2004

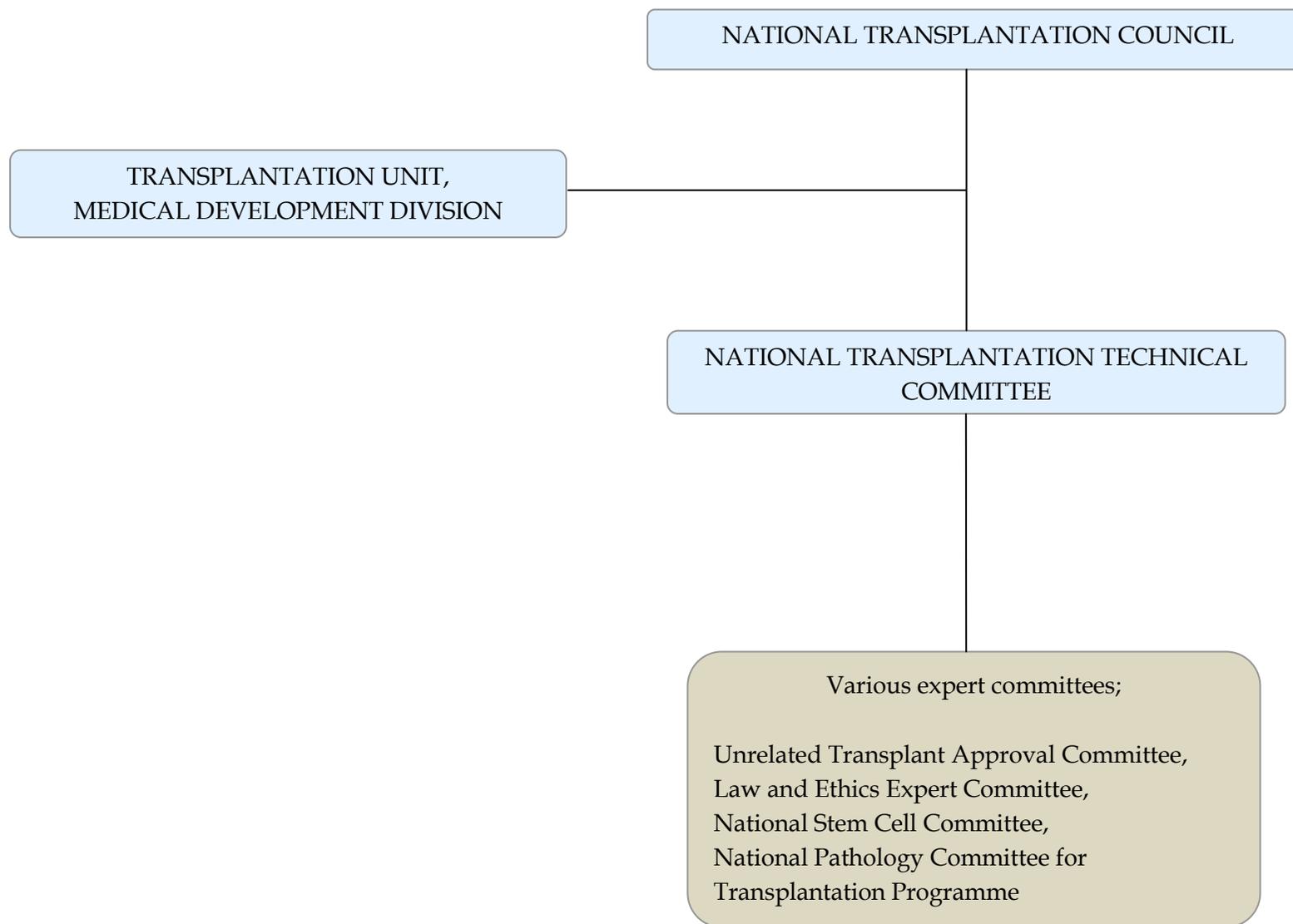
The Global Alliance for Transplantation, The Transplantation Society, 2005 www.transplantation-soc.org

United Kingdom Guidelines for Living Donor Kidney Transplantation, the British Transplantation Society and the Renal Association United Kingdom, January 2000

United Kingdom Hospital Policy for Organ and Tissue Donation, UK Transplant, United Kingdom National Health Service, April 2004

Unrelated Live Transplant Regulatory Authority; Guidance to Clinicians, Department of Health United Kingdom, May 2004

ORGANISATIONAL STRUCTURE OF NATIONAL TRANSPLANTATION PROGRAMME



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56. Professor Dr Che Muhaya Hj Mohamad
Malaysian Society of Ophthalmology
57. Dr Mary Suma Cardosa
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58. Mr Harjit Singh
Malaysian Society of Transplantation
59. Mr Harjit Singh
Malaysian Liver Foundation
60. Balachantar Subramaniam
President of Green Ribbon Support Association
61. Dato' Dr Zaki Morad Mohammad Zaher
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This Policy was approved by the Secretary General, the Director General of Health Malaysia and the Members of the Policy and Planning Committee, Ministry of Health, 3 April 2007

More about transplantation in Malaysia;

www.ntrc.gov.my

(National Transplant Resource Centre, Kuala Lumpur Hospital)

www.mst.org.my

(Malaysia Society of Transplantation)

www.msn.org.my

(Malaysia Society of Nephrology)

www.crc.gov.my

(Clinical Research Centre Ministry of Health)

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