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MINISTRY OF HEALTH
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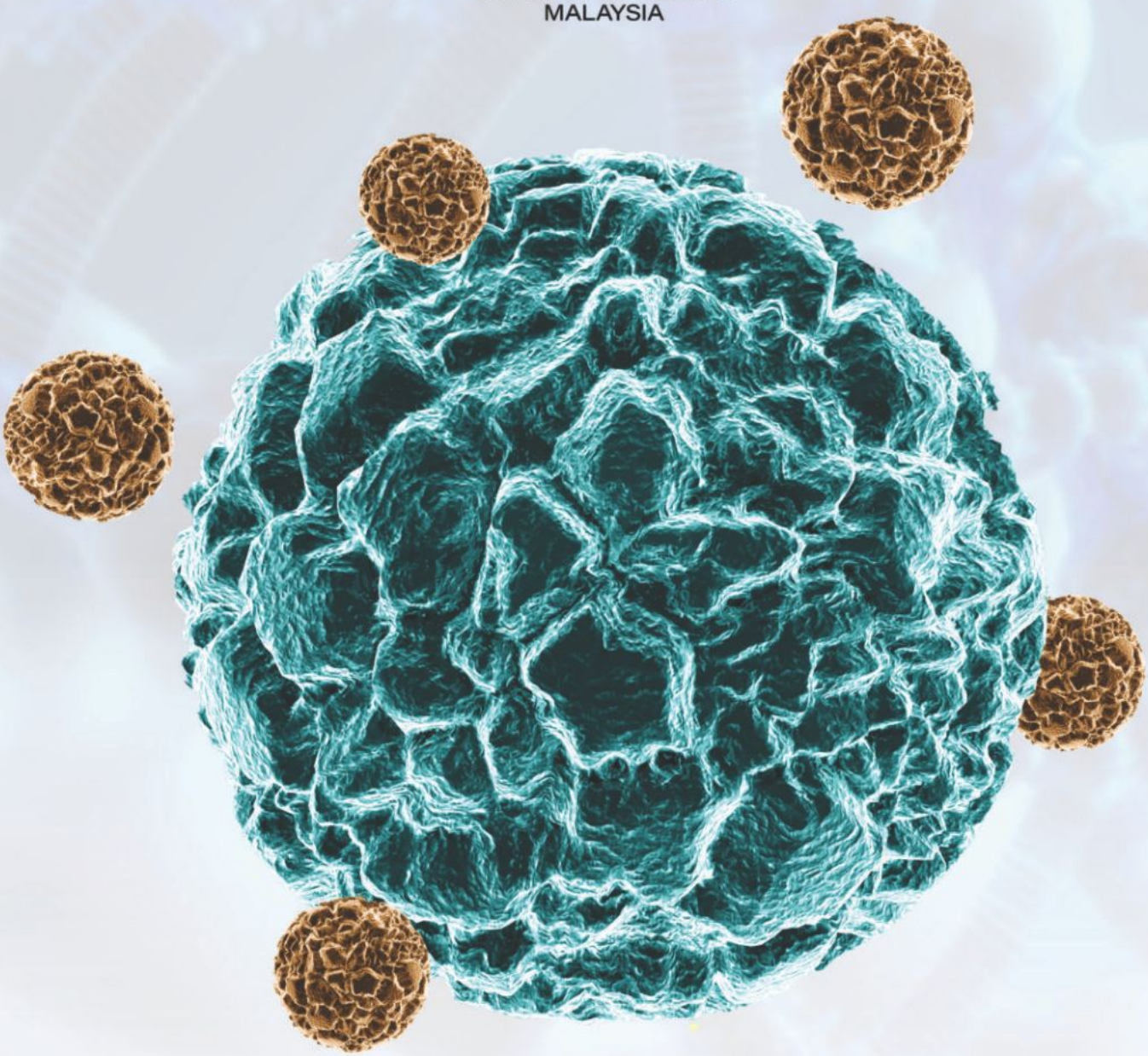

NATIONAL GUIDELINES FOR HAEMOPOIETIC STEM CELL THERAPY

- 2ND EDITION -

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

NATIONAL GUIDELINES FOR HAEMOPOIETIC STEM CELL THERAPY

- 2ND EDITION -

The National Guidelines For Haemopoietic Stem Cell Therapy 2nd Edition was prepared by Obstetric & Gynaecological and Paediatric Services Unit of the Medical Services Development Section, Medical Development Division, Ministry of Health Malaysia, in collaboration with the Stem Cell Therapy Subcommittee

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FOREWORD

by Director-General of Health Malaysia

Haemopoietic stem cell transplant is a highly specialised and potentially life-saving medical procedure for a wide variety of life threatening malignant as well as benign disorders. Indications for haemopoietic stem cell transplant have evolved and expanded over time with the introduction of novel therapies and tests. Therefore, it is timely that the National Guidelines For Haemopoietic Stem Cell Therapy are reviewed and updated.

With its potential risks and unique complications, qualified and well-trained personnel in facilities with the expertise and support of multidisciplinary teams should perform haemopoietic stem cell transplant. Suitable donors for haemopoietic stem cell transplant is no longer limited to HLA-matched sibling or matched unrelated donor. Haploidentical transplant using a partially matched donor from a first-degree relative has recently gained popularity due to the ease of donor availability and equal success rate.

Ministry of Health feels the need to strengthen the criteria for the accreditation of transplant centres in this updated guideline due to the increasing number of transplant centres in both the public and private sectors and the more complex procedures being performed. In addition, this guideline will not be complete without including CART-cell therapy, an innovative cellular therapy using genetically engineered T cells to target cancer cells. CAR T-cell therapy is now increasingly being recognised as an emerging therapeutic option and has shown promising results for relapsed refractory lymphoma, acute lymphoblastic leukaemia and multiple myeloma.

To date, at least six CART-cell therapies have been internationally approved although at a high cost. Thus, improving access to more affordable CART-cell therapies should be a priority. The importance of transplant databases and involvement in national or international registries is again emphasized. Finally, I would like to thank the Medical Development Division of the Ministry of Health (MOH) and the Working Committee consisting of haematologists and paediatric oncologists from MOH, universities and private centres for their effort in updating this guideline, which will serve as a reference for all stakeholders including healthcare professionals, health insurers and policymakers.

DATUK DR. MUHAMMAD RADZI BIN ABU HASSAN
Director-General of Health Malaysia

FOREWORD

by Deputy Director-General of Health Malaysia

The National Guidelines For Haemopoietic Stem Cell Therapy 2nd Edition, prepared by the Medical Development Division of the Ministry of Health, has comprehensively revised the first edition to facilitate researchers and clinicians involved in stem cell research and therapy.

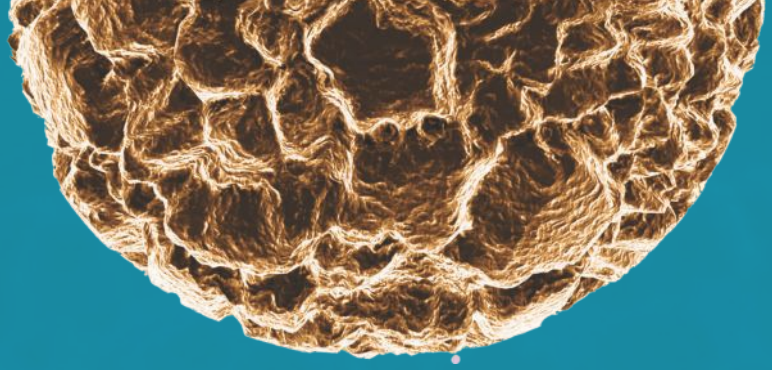
Stem cells have gained popularity not only among scientists, but also among the public in recent years. Stem cell have a tremendous potential in terms of therapy and are capable of restoring organ functions via regeneration and functional repair of damaged tissues. It is possible that off-the-shelf stem cell products could be made available for therapy in the future. In the realm of medical advancements, few discoveries have captivated the imagination and offered hope as much as haemopoietic stem cell therapy. This groundbreaking field of medicine has opened doors to revolutionary treatments and transformative possibilities for countless individuals facing life-threatening diseases and conditions.

The impact of haemopoietic stem cell therapy extends across diverse medical domains. It has become a beacon of hope for patients diagnosed with conditions such as leukemia, lymphoma, aplastic anaemia and genetic blood disorders. Through transplantation of healthy stem cells, damages or malfunctioning cells can be replenishes, rejuvenating the body's ability to fight disease, restore vitality and offer a renewed lease on life.

In Malaysia, haemopoietic stem cell transplant started in the early 1990s. Since then the number of healthcare facilities and institutions performing haemopoietic stem cell transplants have increased, both in the public and private sectors. It is thus timely that the Ministry of Health (MOH), Malaysia establish the National Guidelines for Haemopoietic Stem Cell Therapy 2nd Edition to serve as a guide to all personnel involved in haemopoeitic stem cell transplant to ensure safe and effective procedures are carried out and the quality of the stem cell transplantation in the country would further improve and patients would be assured of getting the best option possible.

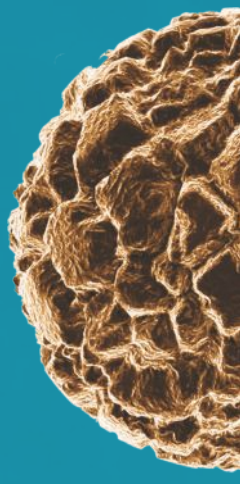
I would like to congratulate and acknowledge the effort of the working committee especially the Medical Development Division of MOH and and members from all other disciplines for this great initiative in preparing this edition.

DATO' DR. ASMAYANI KHALIB
Deputy Director-General of Health (Medical) Malaysia



1.0

INTRODUCTION

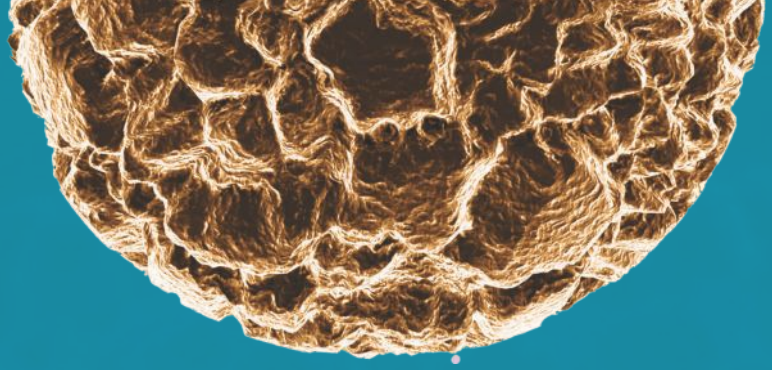


INTRODUCTION

Stem cells are a population of undifferentiated cells characterized by three main properties – the ability to divide indefinitely, to self-renew and to generate a progeny of specialised cells. Stem cell sources include the fertilized egg, embryonic stem cells and adult somatic stem cells found in the blood and marrow, brain, neural and other tissues. Currently, haemopoietic stem cell transplants are the most established form of therapy.

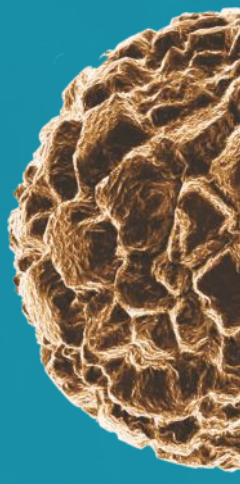
Haemopoietic stem cell transplants treat a variety of life threatening malignant and non-malignant disorders. With the continued advancement in the transplantation procedure, the development of new conditioning regimes – myeloablative and non-myeloablative as well as the use of new haemopoietic stem cell sources – peripheral blood and cord blood, the list of indications will continue to increase. It is a requirement that the harvesting, procurement and transplantation procedures are done in accredited centres with experienced personnel and good support facilities.

The purpose of this document is to establish National Standards for all centres in Malaysia performing haemopoietic stem cell transplantations.Another promising cellular therapy is chimeric antigen receptor (CAR-T) T-cell therapy, which will be covered in a special chapter within this guideline.



2.0

GENERAL



GENERAL

2.1 A Clinical Haemopoietic Stem Cell Transplant Programme shall comprise a core team of personnel who are trained in the field of Haemopoietic Stem Cell Therapy (HSCT) and the management of haematological diseases. There shall be a Programme Head and a team of trained personnel, a transplantation ward and access to an accredited stem cell laboratory.

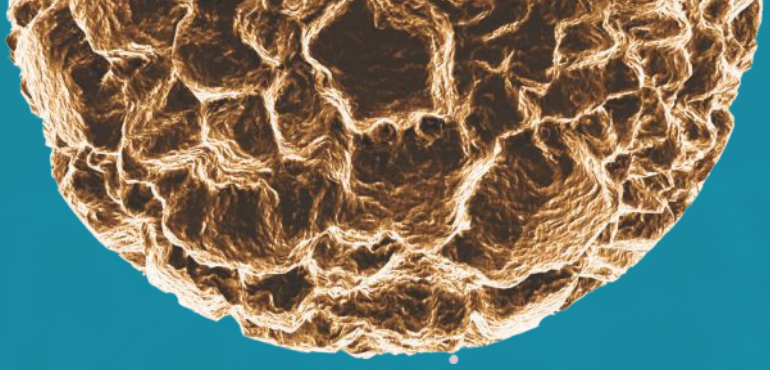
2.2 All policies, procedures, and protocols, as well as quality management systems shall be established and documented.

2.3 All centres performing HSCT shall seek accreditation.

2.4 It is recommended to perform a minimum of 10 transplants yearly to attain sufficient proficiency.

2.5 To achieve accreditation as an allogeneic centre, a minimum of 10 allogeneic transplants shall be performed each year. Centres performing transplants for both paediatric and adult patients shall perform transplants on at least five adults and five paediatric patients each year. Centres performing autologous transplants only shall perform a minimum of 10 transplants each year. Centres performing both shall meet the requirements of an allogeneic transplant centre. New transplant centres may attain this target within 5 years of initiation of service.

2.6 In order to be recognized as an international matched unrelated donor (MUD) transplant centre, it is mandatory for the centre to fulfil the criteria, which is set by the relevant international donor registry, e.g. Bone Marrow Donor Programme (BMDP) Singapore.



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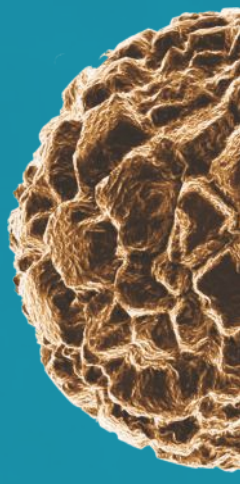
TRANSPLANT UNIT



TRANSPLANT UNIT

The transplant unit shall have:

3.1 CLINICAL UNIT

3.1.1 A designated inpatient unit that minimizes airborne microbial contamination ideally HEPA filtration with positive pressure or laminar airflow for allogeneic transplants.

3.1.2 Autologous-HSCT patients and hospitalized HSCT patients can be nursed in isolation rooms.

3.1.3 A designated outpatient day care unit.

3.1.4 Provisions shall be made for prompt evaluation and treatment of patients with complications on a 24-hour basis.

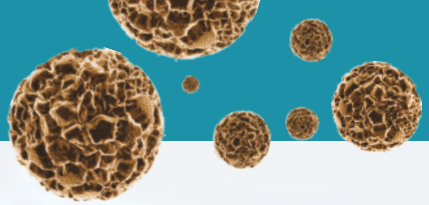
3.2 LABORATORY UNIT

3.2.1 A stem cell laboratory that is capable for stem cell harvest, enumeration, processing, and cryopreservation shall be available. The stem cell laboratory shall conform to the National Standards of Stem Cell Procurement, Storage and Allocation.

3.2.2 Stem cell laboratory should perform a stem cell viability test within one week prior to initiation of conditioning chemotherapy, with an acceptable post-thawing CD34 (+) cells viability (≥ 70%).

3.2.3 Centres performing allogeneic haemopoietic stem cell transplants shall have access to an HLA-testing laboratory with the capability to carry out DNA-based HLA-typing. This HLA laboratory shall seek local as well as international accreditation.

3.2.4 A good laboratory support with availability of microbiological tests, monitoring of drug levels, chimerism study and histopathology services are important. The pathologist shall have experience and knowledge about complications of HSCT in particular the histological interpretation of graft-versus-host-disease.



3.3 SUPPORTIVE SERVICES

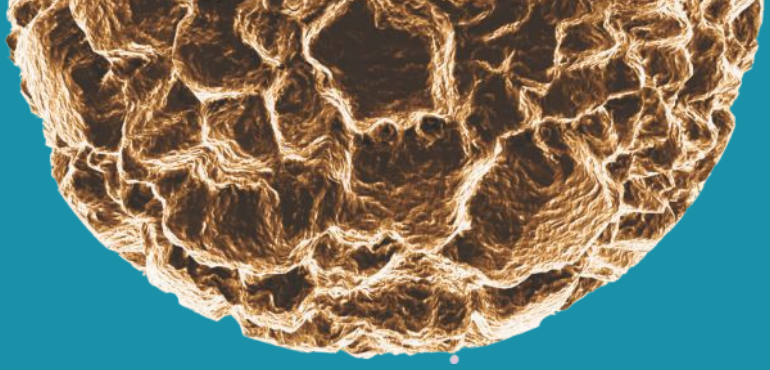
3.2.1 A transfusion service shall be available to provide irradiated blood products on a 24-hour basis.

3.3.2 A pharmacy shall be available to provide essential medications on a 24-hour basis.

3.3.3 A radiotherapy service shall be available if the particular transplant centre is planning for a radiotherapy-based conditioning regimen.

3.3.4 Radiology services (including imaging and interventional radiology) shall be available.

3.3.5 Supportive services including specialists in the field of intensive care, neurology, nephrology, respiratory medicine, gastroenterology, cardiology, infectious disease, psychology, dietetics, social welfare, physiotherapy, and occupational therapy shall be available for consultations.



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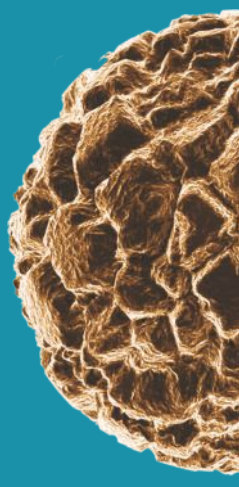
PERSONNEL



PERSONNEL

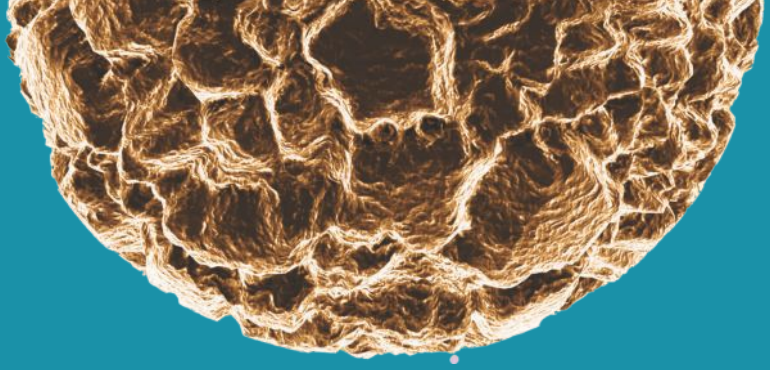
4.1 The Head of Clinical Transplant Services shall be a clinical haematologist or paediatric hemato-oncologist who has at least one year specific training in haemopoietic stem cell transplantation. Proof of training is required.

4.2 The adult transplant physician shall be certified in Internal Medicine, accredited in Clinical Haematology and has at least one year of specific training in haemopoietic stem cell transplantation. He/she shall be a licensed medical practitioner registered with the Malaysian Medical Council.

4.3 The paediatric transplant specialist shall be certified in Paediatrics, accredited in Haematology & Oncology or Immunology and has at least one year of specific training in haemopoeitic stem cell transplantation. He/she shall be a licensed medical practitioner registered with the Malaysian Medical Council.

4.4 The transplant nurses shall be formally trained at a recognised transplant centre. Training shall include haematology/oncology patient care, administration of high-dose chemotherapy, growth factor and immunosuppressive medications, management and handling of central venous access, management of infectious complications associated with immunocompromised host, administration of blood products and some degree of intensive care. A minimum nurse-to-patient ratio of 1:2 is recommended. The transplant nurses shall be privileged for haematology/oncology core procedures and for stem cell transplant.

4.5 Other supportive staff members shall include a transplant coordinator, pharmacist, dietician, social worker, physiotherapist and data manager. They shall be given appropriate training in transplant-related ancillary care.



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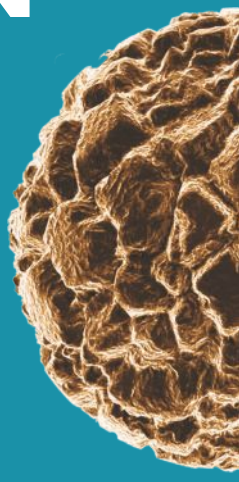
INDICATIONS FOR HAEMOPOIETIC STEM CELL TRANSPLANTATION



INDICATIONS FOR HAEMOPOIETIC STEM CELL TRANSPLANTATION

5.1 There are two main types of HSCT

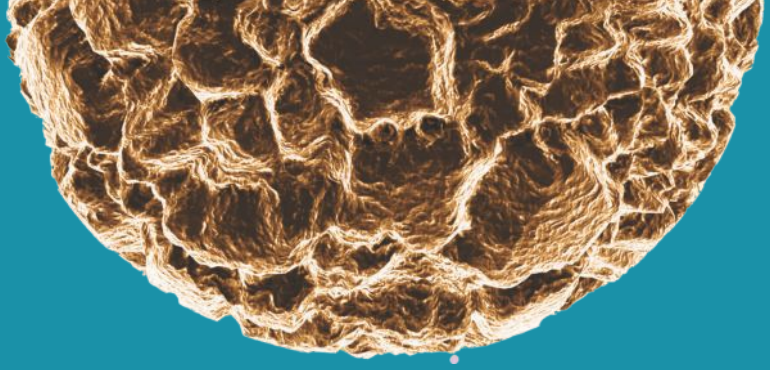
a. Autologous
b. Allogeneic

5.2 Allogeneic HSCT is further divided into several types, based on the source of donor

a. Matched related donor
b. Matched unrelated donor
c. Haploidentical donor
d. Mismatched related/unrelated donor
e. Umbilical cord blood

5.3 HSCT is currently performed for patients with malignant and non-malignant haematological conditions, solid organ tumours, inherited metabolic and primary immunodeficiency diseases. The list of standard indications is not exhaustive and will continue to expand.
** Refer to Appendix 1 and 2 for the proposed classification of transplant indications*

5.4 Indications which are experimental e.g. tissue repair, angiogenesis and revascularization shall be studied as clinical trials until more evidence is obtained. Ethics review and approval shall be obtained from the relevant local institutions. This shall conform to the National Guidelines for Stem Cell Research and Therapy.



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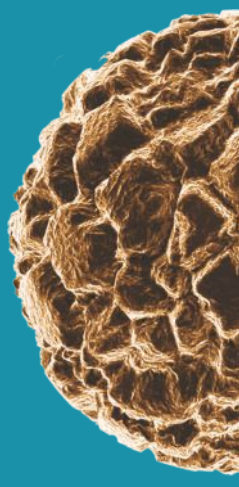
PATIENT EVALUATION



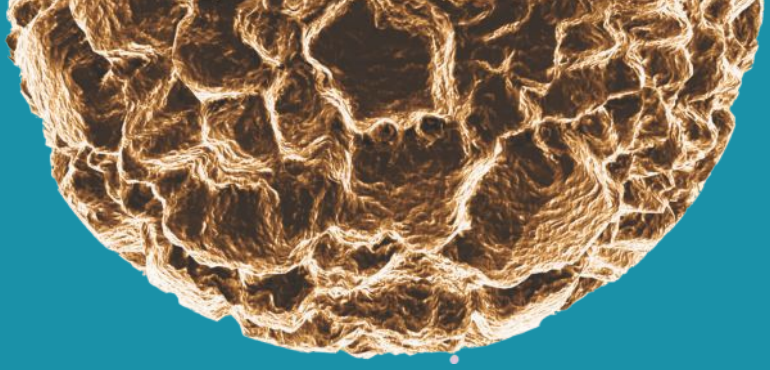
PATIENT EVALUATION

6.1 The centre shall be well-versed in the selection of appropriate patients and the selection of condition regimens.

6.2 Assessment of patient eligibility shall include medical fitness, medical history, physical examination, and psychosocial evaluation.

6.3 Patient and/or legal guardian shall have documented detailed counselling.

6.4 Signed informed consent shall be obtained from the patient/legal guardian after a thorough discussion of the HSCT procedure and its risks. Permission to be included in the transplant database/registry shall be written in the informed consent.



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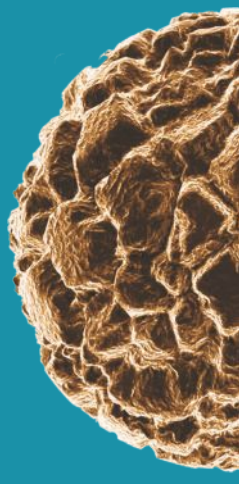
DONOR EVALUATION AND MANAGEMENT



DONOR EVALUATION AND MANAGEMENT

7.1 The safety and welfare of the donor shall be prioritized.

7.2 Donor medical history, physical examination, psychosocial evaluation and laboratory test results shall be performed and its suitability shall be documented before initiation of the recipient's conditioning regimen. This includes history of vaccination and blood transfusion. Any abnormal findings shall be informed to the prospective donor with proper documentation and recommendations made for follow-up care.

7.3 Rationale and reason for selection of donor out of standard criteria must be fully documented and informed consent must be obtained.

7.4 Pregnancy tests for donors of childbearing potential shall be performed.

7.5 Donor screening shall include questions to identify persons at high risk of blood borne virus infections.

7.6 Laboratory tests required for donor selection shall be done by an accredited laboratory and include at least the following:

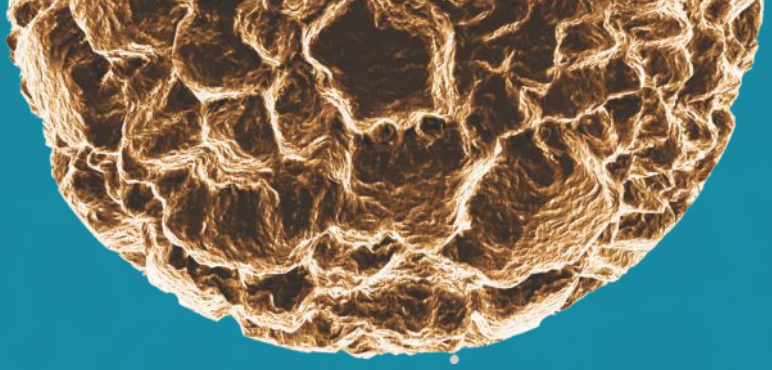
i. Appropriate initial HLA typing, with repeated confirmatory HLA typing prior to HSCT.
ii. For alternative donor HSCT, at least one of the HLA typing must be of a high resolution typing
iii. ABO group and Rh type
iv. Appropriate infectious disease screening including: HIV-1, HIV-2, HBsAg, Hep B core Ab (Total), HCV, CMV, toxoplasmosis, syphilis, EBV, VZV, HSV-1, HSV-2, etc.

7.7 Validity of the tests listed in 7.6 (iv) is 90 days. These tests shall be repeated for the donor if the collection of the stem cell is performed more than 90 days from the previous results.

7.8 For adult donors, a full blood count, including platelet count shall be performed within 72 hours prior to the first PBSC collection and within 24 hours before each subsequent apheresis.

7.9 In accordance to the National Organ, Tissue and Cell Transplantation Policy, donors shall not be offered any compensation or any form of reward.

7.10 Donors shall be followed-up with regards to their well-being according to the institution's practice.



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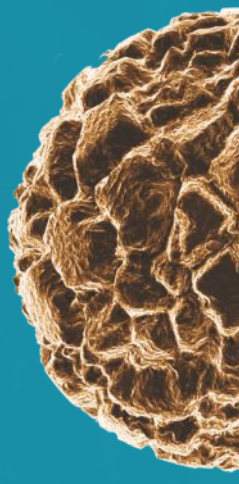
DONOR CONSENT



DONOR CONSENT

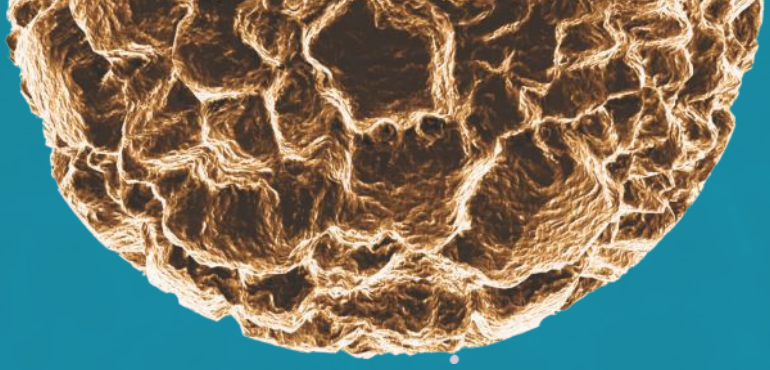
8.2 Informed consent from the donor shall be obtained.

8.2 The donor shall be informed about the significant risks and benefits of the procedure, tests performed to protect the health of the donor and recipient, and the rights of the donor to review the results of their tests.

8.3 The donor shall be given the opportunity to ask questions and the right to refuse to donate. Assessment by a counsellor/social worker/psychologist is encouraged.

8.4 In the case of a donor less than 18 years old, informed consent shall be obtained from the donor's parents or legal guardian in accordance with the relevant law.

8.5 A separate informed consent shall be obtained if the donor's name is to be added to an HSC donor registry.



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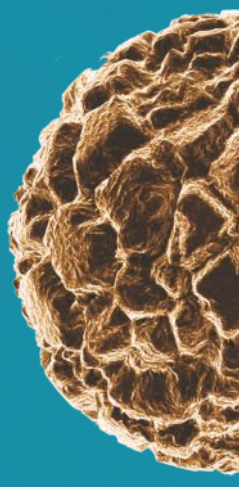
CORD BLOOD UNIT (CBU)

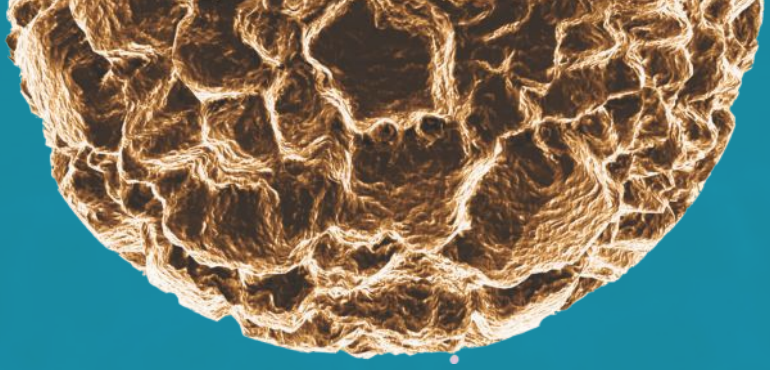


CORD BLOOD UNIT (CBU)

9.2 Procurement of CBU shall be made from accredited Cord Blood Banks.

9.2 Adequate infectious screening shall be performed on both mothers and CBUs.

9.3 Selection of CBU shall consider the degree of HLA match, nucleated cell dose or CD34+ cell dose and viability assay.



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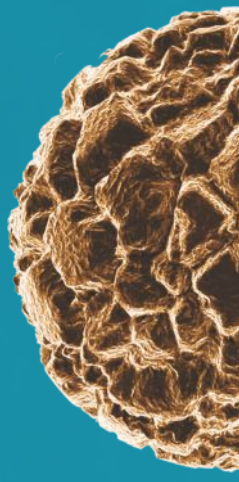
PROFICIENCY OF THE TRANSPLANT PHYSICIAN/ TEAM



PROFICIENCY OF THE TRANSPLANT PHYSICIAN/TEAM

The transplant team shall be proficient in the following procedures

10.1 SELECTION OF STEM CELL SOURCE

10.1.1 10.1.1 Identification and selection of haemopoietic stem cell source, including use of local and international matched unrelated donor registries.

10.1.2 Knowledge in methodology and implications of HLA-typing.

10.1.3 Knowledge in selecting the most appropriate donor.

10.2 TRANSPLANT RELATED/TRANSPLANT SPECIFIC PROCEDURES

10.2.1 Bone marrow harvest and apheresis procedures.

10.2.2 Selection and handling of central venous access.

10.2.3 Administration of conditioning regimen chemotherapy.

10.2.4 Haemopoietic stem cell products thawing and infusion.

10.2.5 Management of patients receiving ABO incompatible haemopoietic stem cell products

10.2.6 Diagnosis and management of haemopoietic stem cell engraftment failure.

10.3 PREVENTING AND MANAGING HSCT RELATED COMPLICATIONS

10.3.1 CONDITIONING REGIMEN RELATED TOXICITIES

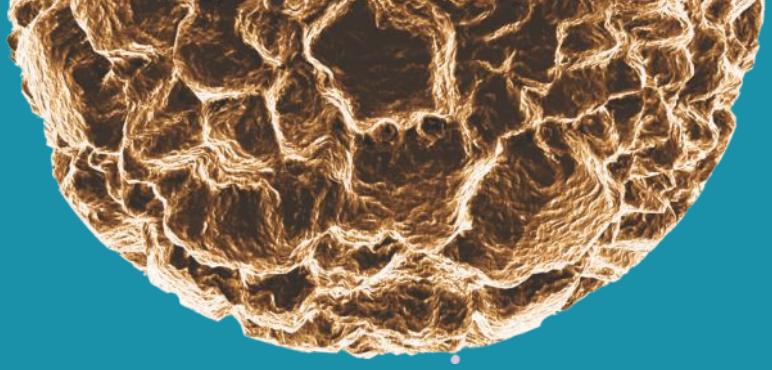
i. Management of conditioning regimen related organ toxicities
ii. Diagnosis and management of sinusoidal obstruction syndrome (SOS)
iii. Management transplant-associated thrombotic microangiopathy (TA-TMA)
iv. Management of haemorrhagic cystitis
v. Management of mucositis, pain, nausea and vomiting

10.3.2 INFECTIOUS COMPLICATIONS

i. Management of neutropenic fever
ii. Diagnosis and management of fungal infections
iii. Diagnosis and management of CMV infections and other viral infections in the post - transplant setting
iv. Diagnosis and management of other opportunistic and emerging infections

10.3.3 POST TRANSPLANT ISSUES

i. Diagnosis and management of acute and chronic graft versus host disease (GVHD)
ii. Management of primary and secondary graft failure
iii. Diagnosis and management of pure red cell aplasia (PRCA)
iv. Management of immunosuppressive therapy
v. Monitoring of chimerism, minimal residual disease, and utilization of donor lymphocytes infusion
vi. Diagnosis and management of post-transplant immunodeficiency and vaccination
vii. Monitoring and treatment for long term complications and palliative care



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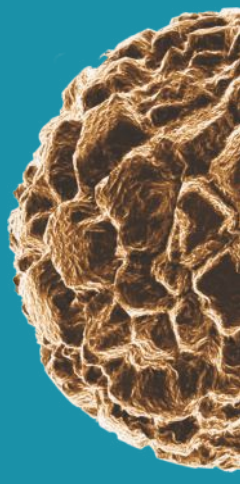
PROTOCOLS FOR CONDITIONING



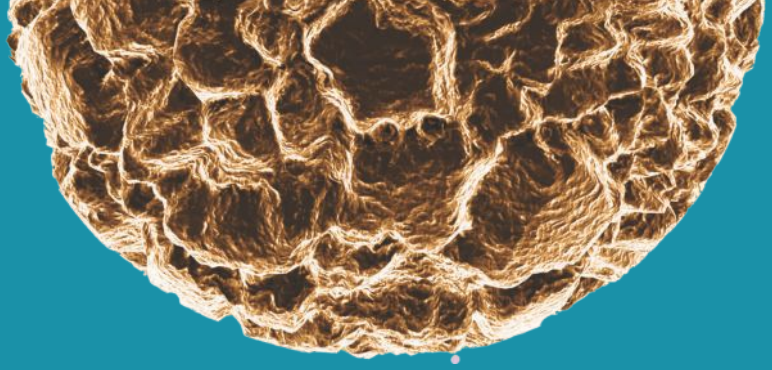
PROTOCOLS FOR CONDITIONING

11.1 There shall be pre-printed protocols to ensure that conditioning regimens are administered safely.

11.2 The treatment prescription shall include the patient's height and weight, specific dates, daily doses and route of administration of each agent, with the complete name of the drug. There should be at least two identifiers for the patient's identity in the treatment orders (e.g., Name, IC, hospital registration number). Any changes out of standard protocol shall be done with caution and with adequate clinical evidence.

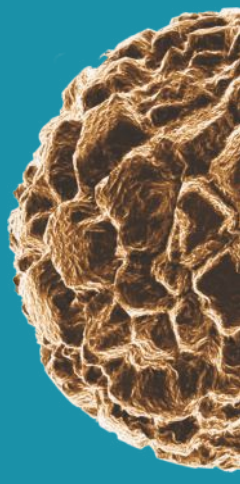
11.3 The pharmacist preparing the chemotherapy shall verify the doses against the protocol or standardized regimen listed on the orders.

11.4 Two persons qualified to administer chemotherapy shall verify the drug and dose in the bag and the identity of the patient before administration.



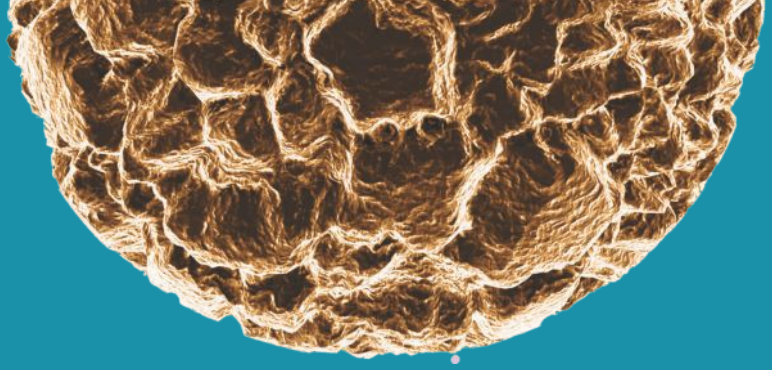
12.0

POLICIES AND PROCEDURES



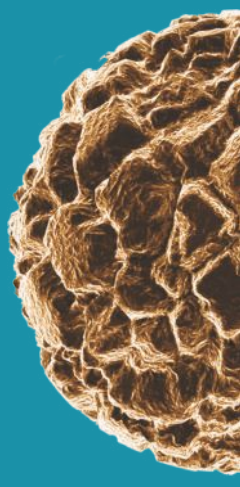
POLICIES AND PROCEDURES

The Clinical Transplant Programme shall have written policies and procedures addressing all appropriate aspects of the transplant including donor and patient evaluation, admission procedures, conditioning regimens and administration of chemotherapeutic agents, infusion of stem cells, blood products and immunosuppressive agents, GVHD prophylaxis and management, nutritional requirements as well as management of neutropenic sepsis and transplant-related complications.



13.0

QUALITY MANAGEMENT



QUALITY MANAGEMENT

13.1 The Clinical Transplant Programme shall have a written Quality Management Plan that includes incident reporting of errors, accidents, significant outcome parameters and adverse reactions.

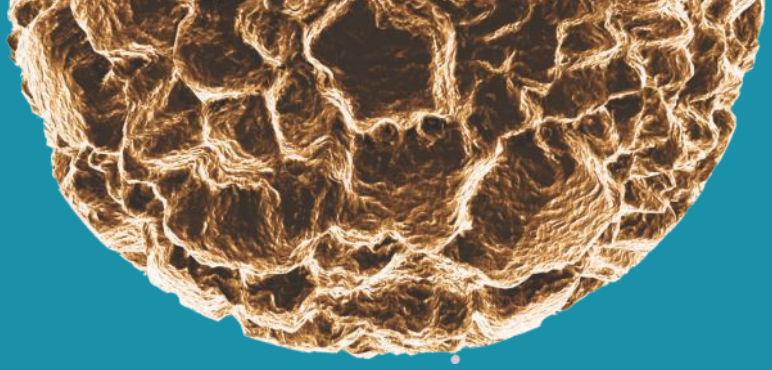
13.2 Regular meetings shall be held for review, documentation, corrective actions, and reporting.

13.3 Transplant centres are encouraged to have their own transplant database and participate in national and/or international registries.

13.4 Physicians-in-training and transplant nurses should be credentialed and priviledged to practise within the jurisdiction of the Transplant Programme.

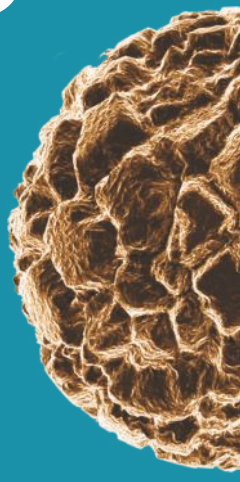
13.5 Audits (either internal or external) shall be conducted by individuals with sufficient expertise to identify problems and corrective and preventive actions shall be implemented in a timely manner.

13.6 The Clinical Transplant Director shall evaluate the effectiveness of the overall Quality Management Programme annually.



14.0

CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR-T) AND OTHER CELL-BASED THERAPY



CHIMERIC ANTIGEN RECEPTOR-T CELL (CAR-T) AND OTHER CELL BASED THERAPY

14.1 Introduction

Chimeric antigen receptor T-cell (CAR-T) therapeutics are widely gaining attention for the treatment of relapsed/refractory haematological malignancy. Globally, several CAR-T products have been available in the market and many more are still in the clinical trial phase. CAR-T are also under evaluation in acute myeloid leukaemia and solid tumours.

In general, for CAR-T and cell-based therapy clinical trials, healthcare teams shall follow relevant trial protocols. However, in the setting where commercialized CAR-T therapies are available, this guideline shall apply.

14.2 CAR-T and other cell-based therapy centers

14.2.1 CAR-T and other cellular therapies shall be performed in recognised haemopoietic stem cell transplant centres with experience in handling leukapheresis, administration of conditioning regimen and infusion of cellular products.

14.2.2 These centres shall have 24-hour facilities for prompt evaluation and treatment of related complications. The centres shall also have timely access to critical care services, in case of life-threatening complications.

14.2.3 Immediate access to interleukin-6 inhibitors is mandatory for rapid treatment of cytokine release syndrome (CRS).

14.2.4 These centres shall have access to determine lymphocyte subsets, immunoglobulin level and CAR-T cell persistence.

14.3 Personnel for CART

14.3.1 The centres shall have experienced physicians/ paediatricians who are trained in patient selection, planning of appropriate bridging and lymphodepletion conditioning regimen, thawing and/or infusion of the cellular products and management of ensuing CAR-T-related complications such as CRS and neurotoxicities.

14.3.2 The centres shall have a multi-disciplinary team, which consists of trained medical, nursing and pharmacy personnel. Access to other support personnel such as clinical psychologists, social workers, data managers and clinical trial staff is desirable.

14.3.3 Informed consent shall be obtained for cell collection, cell infusion and data collection.

14.4 Leukapheresis and cell processing facilities

14.4.1 Mononuclear cell collection shall be performed at an accredited apheresis centre.

14.4.2 Generation of CAR-T cells shall be performed in ISO5 clean room/ Grade B cGMP facilities to ensure high quality and safe products.

14.4.3 The facilities shall have skilled cell culture technologists and relevant supportive staff. An established body shall regulate the cell processing facilities.

14.4.4 This process requires significant coordination with manufacturers, including site inspection, transportation and sample tracking.

14.5 Indications

Currently approved indications for CAR-T therapy include:

1. Relapsed/Refractory B-Acute Lymphoblastic Leukaemia
2. Relapsed/Refractory Diffuse Large B cell Lymphoma
3. Relapsed/Refractory Mantle Cell Lymphoma
4. Relapsed/Refractory Multiple Myeloma

Nevertheless, this is an evolving field, and the list of approved indications will continue to expand.

14.6 Quality management

14.6.1 CAR-T centres are encouraged to participate in national /or international registries to ensure ongoing evaluation of safety and efficacy as well as long-term outcomes. CAR-T centres shall have policies for long-term follow-up and surveillance, in view of the lack of long-term safety data now.

14.7 Compassionate/off-label use

14.7.1 The committee recognizes that this is a rapidly evolving field. Hence, there should be a provision for compassionate or off-label usage within the institution in cases of life-threatening malignancies where there is no satisfactory or readily available alternative therapy and where access to or eligibility for clinical trials is not possible. These shall be performed with appropriate institutional approval.

15.0

APPENDIX

Appendix 1 : Proposed classification of transplant indications for adults

Disease	Disease status	Matched sibling donor (MSD)	Matched unrelated donor (MUD#)	Mismatched alternative donors (MMAD+)	Auto
Acute myeloid leukaemia (AML)	CR1 (low risk) [a]	CO/II	D/II	GNR/II	CO/I
	CR1 (intermediate) [a]	S/II	CO/II	D/II	S/II
	CR1 (high risk) [a]	S/II	S/II	CO/II	CO/I
	CR 2	S/II	S/II	CO/II	CO/II
	CR 3, incipient relapse	S/III	CO/III	D/III	GNR/III
	M3 Molecular persistence	S/II	CO/II	GNR/III	GNR/II
	M3 Molecular CR2	S/II	CO/II	GNR/III	S/II
	Relapsed or refractory	CO/II	CO/II	D/II	GNR/III
Acute lymphoblastic leukaemia (ALL) [b]	Ph (–), CR1 (standard risk and MRD–) [a]	GNR/II	GNR/II	GNR/III	CO/III
	Ph (–), CR1 (standard risk and MRD+) [a]	S/II	CO/II	CO/II	GNR/II
	Ph (–), CR1 (high risk) a	S/II	S/II	CO/II	GNR/III
	Ph (+), CR1 (MRD–)	S/II	S/II	CO/II	CO/III
	Ph (+), CR1 (MRD+)	S/II	S/II	S/II	GNR/II
	CR2	S/II	S/II	S/II	GNR/II
	Relapse or refractory	CO/II	CO/II	CO/II	GNR/III
Chronic myeloid leukaemia (CML)	1st CP, failing 2nd or 3rd line TKI	S/II	S/II	CO/III	GNR/II
	Accelerated phase, blast crisis or >1st CP	S/II	S/II	CO/II	GNR/III
Myelofibrosis	Primary or secondary with an intermediate-2 or high DIPSS score	S/II	S/II	S/III	GNR/III
Myelodysplastic syndrome (MDS)	Very low and low-risk (IPSS-R)	CO/II	CO/II	CO/II	GNR/III
	Intermediate-risk without additional factors c (IPSS-R)	CO/II	CO/II	CO/II	CO/II
	Intermediate-risk with additional factors c (IPSS-R)	S/II	S/II	S/II	GNR/III
	High-, very high-risk (IPSS-R)	S/II	S/II	S/II	
	sAML in CR1 or CR2	S/II	S/II		
Chronic myelomonocytic leukaemia (CMML)	CMML-2 or MP- CMML	S/II	S/II	S/II	GNR/III

Disease	Disease status	Matched sibling donor (MSD)	Matched unrelated donor (MUD#)	Mismatched alternative donors (MMAD+)	Auto
Chronic lymphocytic leukaemia (CLL)	Poor risk disease refractory or relapsing after at one line of prior therapy (Richter's transformation excluded)	CO/II	CO/II	GNR/III	GNR/III
	Richter transformation	S/II	S/II	S/II	GNR/III
Large B cell lymphoma (LBCL)	CR1 (intermediate/high IPI at diagnosis)	GNR/III	GNR/III	GNR/III	CO/I
	Untested relapse	GNR	GNR	GNR	GNR
	Chemosensitive early relapse, ≥CR2	CO/II	CO/II	D/III	CO/I
	Chemosensitive late relapse, ≥CR2	CO/II	CO/II	D/III	S/II
	Refractory disease	CO/II	CO/II	CO/III	GNR/I
	Primary CNS lymphoma	GNR/III	GNR/III	GNR/III	S/II
Follicular lymphoma (FL)	CR1, untransformed	GNR/III	GNR/III	GNR/III	GNR/II
	CR1, transformed into high-grade lymphoma	GNR/III	GNR/III	GNR/III	CO/III
	Chemosensitive relapse, ≥CR2	CO/III	CO/III	GNR/III	S/II
	≥CR2 after auto-HSCT failure	S/II	S/II	D/III	GNR/III
	Refractory	CO/II	CO/II	CO/III	GNR/III
Mantle cell lymphoma (MCL)	CR1	GNRIII	GNR/III	GNR/III	S/II
	CR/PR >1, no prior auto-HCT	CO/III	CO/III	D/III	CO/II
	CR/PR >1, after prior auto-HCT	CO/II	CO/II	CO/III	GNR/II
	Refractory	CO/II	CO/II	CO/III	GNR/II
Waldenström macroglobulinemia (WM)	CR1	GNR/III	GNR/III	GNR/III	GNR/III
	Chemosensitive relapse, ≥CR2	GNR/III	GNR/III	GNR/III	CO/II
	Poor risk disease	CO/II	CO/II	D/III	GNR/III
Peripheral T cell lymphoma (PTCL)	CR1	CO/II	CO/II	GNR/III	CO/II
	Chemosensitive relapse, ≥CR2	S/II	S/II	CO/III	CO/II
	Refractory	CO/II	CO/II	CO/III	GNR/II
Primary Cutaneous T cell lymphoma (CTCL)	EORTC/ISCL Stages I–IIA (early)	GNR/III	GNR/III	GNR/III	GNR/III
	EORTC/ISCL Stages IIB–IV (advanced)	CO/III	CO/III	D/III	GNR/III
Amyloidosis		CO/III	CO/III	GNR/III	CO/II
Hodgkin Lymphoma (HL)	CR1	GNR/III	GNR/III	GNR/III	GNR/I
	Chemosensitive relapse, no prior auto-HCT	D/III	D/III	GNR/III	S/I
	Chemosensitive relapse, after prior auto-HCT	S/II	S/II	S/II	CO/III

Disease	Disease status	Matched sibling donor (MSD)	Matched unrelated donor (MUD#)	Mismatched alternative donors (MMAD+)	Auto
Multiple myeloma (MM)	Upfront standard risk	CO/II	CO/II	GNR/III	S/I
	Upfront high risk	S/III	S/III	CO/II	S/I
	Chemosensitive relapse, prior auto-HCT	CO/II	CO/II	CO/II	S/II
Acquired severe aplastic anaemia (SAA) and aplastic anaemia/ paroxysmal nocturnal haemoglobinuria (PNH)	Newly diagnosed	S/II	CO/II	GNR/III	NA
	Relapsed/refractory	S/II	S/II	CO/II	NA
Haemolytic PNH		GNR/II	GNR/II	GNR/II	NA
Constitutional bone marrow failure syndromes / SAA e		S/II	S/II	CO/II	NA
Germ cell tumours	Second line, high risk	GNR/III	NA	NA	CO/II
	Primary refractory, second and further relapse	GNR/III	NA	NA	S/II
Medulloblastoma	Post-surgery, high risk/ recurrent disease	NA	NA	NA	CO/III
Ewing's Sarcoma	Locally advanced/metastatic, chemosensitive	D/III	NA	NA	CO/II
Multiple sclerosis	Highly active RR-MS failing DMT	D/III	GNR/III	GNR/III	S/I
	Progressive MS with AIC, and Aggressive MS f	D/III	GNR/III	GNR/III	CO/II
	Progressive MS without AIC	GNR/III	GNR/III	GNR/III	GNR/III
Systemic sclerosis		D/III	GNR/III	GNR/III	S/I
Systemic lupus erythematosus		D/III	GNR/III	GNR/III	CO/II
Crohn's disease		D/III	D/III	D/III	CO/II
Rheumatoid arthritis		D/III	GNR/III	GNR/III	CO/II
Juvenile idiopathic arthritis		CO/II	CO/II	CO/III	CO/II
Autoimmune cytopaenias		CO/II	CO/II	CO/III	CO/II
Primary Immunodeficiency		CO/II	CO/II	CO/II	NA

This classification does not cover patients for whom a syngeneic donor is available.
#MUD well-matched unrelated donor (8/8, 10/10, or 9/10 if mismatched is in DQB1)
+MMAD mismatched alternative donors (cord blood, haploidentical and mismatched unrelated donors)
NA not applicable

AIC active inflammatory component, APL acute promyelocytic leukaemia, CP chronic phase, CR1, 2, 3 first, second, third complete remission, DIPSS dynamic international prognostic score system, DMT disease-modifying treatments, IPI international prognostic index, IPSS-R revised International Scoring System, MP-CMML myeloproliferative CMML, MRD minimal residual disease, PR partial remission, RA refractory anaemia, RAEB refractory anaemia with excess blasts, RCD refractory coeliac disease, RCMD refractory cytopenia with multilineage dysplasia, RR-MS relapsing-remitting multiple sclerosis, sAML secondary acute myeloid leukaemia, TKI tyrosine kinase inhibitors.

[a] Categories are based on number of white blood cells, cytogenetics and molecular markers at diagnosis and time to achieve remission.
[b] Some centres consider older age (e.g., >60 years) as a criterion for high-risk disease in decision making for allogeneic HSCT for AML or ALL. Beyond transplant indications, maintenance therapy after transplant is being increasingly used with the aim of improving survival outcomes (e.g., FLT3 inhibitors in FLT3-ITD AML).
[c] Additional factors include >5% marrow blasts, poor karyotype, profound cytopaenias (i.e., Hb <80 g/L, ANC <0.8 × 109/L, platelets <50 × 109/L), or severe BM fibrosis.
[d] Additional high-risk gene mutations (ASXL1, RUNX1, SETBP1, N-RAS), severe cytopenia or transfusion dependency, excessive proliferative features or extramedullary involvement.
[e] Constitutional SAA includes Fanconi anaemia, dyskeratosis congenita, Blackfan–Diamond anaemia and other inborn bone marrow failure syndromes (see also the section and table for paediatric indications).
[f] Aggressive MS as per Menon et al.

Type of indication for transplant procedures and strength of evidence

Categories	Settings where HCT ought to be performed
Standard of care (S)	Indicated and considered as standard of care in the suitable candidate with access to facilities
Clinical option (CO)	Clinical option, discussion between the attending physician, patient and clinician with experience in the related clinical condition with careful consideration of the benefits versus risks is recommended
Developmental (D)	Developmental, shall be conducted in well-designed clinical trials with ethics review and approval.
Generally not recommended (GNR)	Not recommended
Grade	*Strength of the evidence supporting the assignment of a particular category*
Grade I	Evidence from at least one well-executed randomised trial.
Grade II	Evidence from at least one well-designed clinical trial without randomisation; cohort or case-controlled analytic studies (preferably from more than one centre); multiple time-series studies; or dramatic results from uncontrolled experiments.
Grade III	Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports from expert committees.

Modified from:

1. Indications for allo and auto SCT for haematological diseases, solid tumours and immune disorders:current practice in Europe, 2015.
2. Indications for haematopoietic cell transplantation for haematological diseases, solid tumours and immune disorders: current practice in Europe, 2022

Appendix 2: Proposed classification of transplant indications for children

DISEASE	STATUS	MSD	MUD	*MMAD	Auto
BONE MARROW FAILURE SYNDROMES					
Severe Aplastic Anaemia (Acquired)		S	S	CO	NO
Inherited Bone Marrow Failure Syndrome • Fanconi Anaemia • Dyskeratosis Congenita • Severe Congenital Neutropaenia • Congenital Amegakaryocytic Thrombocytopaenia		S	S	CO	NO
Diamond Blackfan Anaemia		S	S	**NO	NO
THALASSAEMIAS & HAEMOGLOBINOPATHIES					
Transfusion Dependent Thalassaemia		S	S	CO	NO
Sickle Cell Disease		S	S	**NO	NO
INBORN ERRORS OF IMMUNITY					
SCID		S	S	CO	NO
Wiskott Aldrich Syndrome		S	S	CO	NO
Chronic Granulomatous Disease		S	S	CO	NO
Haemophagocytic Lymphohistiocytosis	Primary Familial	S	S	CO	NO
Other Inborn Errors of Immunity		S	S	CO	NO
METABOLIC DISEASES					
Mucopolysacharidosis I- Hurler		S	S	NO	NO
Other Mucopolysaccridoses		CO	CO	NO	NO
Metachromatic Leukodystrophy		S	S	NO	NO
X-Linked Adrenaleukodystrophy		S	S	NO	NO
Osteopetrosis		S	S	CO	NO
HAEMATOLOGICAL MALIGNANCIES					
Acute Myeloid Leukaemia	High Risk/ Relapse	S	S	CO	NO
Acute Lymphoblastic Leukaemia	High Risk/ Relapse	S	S	S	NO
Chronic Myeloid Leukaemia		S	S	NO	NO
Juvenile Myelomonocytic Leukaemia		S	S	CO	NO
Myelodysplastic Syndromes		S	S	CO	NO
Hodgkin's Lymphoma	Relapse	NO	NO	NO	S
Non-Hodgkin's Lymphoma	High Risk/ Relapse	S	S	NO	CO
SOLID TUMOURS					
Neuroblastoma	High Risk	NO	NO	NO	S
Ewing's Sarcoma		NO	NO	NO	CO
Brain Tumours	Selected	NO	NO	NO	CO

Modified from:

1. The EMBT handbook: Hematopoietic Stem Cell Transplantation and Cellular Therapies (2019)
2. EBMT/ESID Guidelines For Haemopoeitic Stem Cell Transplantation For Primary Immunodeficiencies (2017)
3. Indications for haematopoietic cell transplantation for haematological diseases, solid tumours and immune disorders: current practice in Europe, 2022.

***MMAD**: mismatched alternative donors (haploidentical and mismatched unrelated donors) Depending on the degree of HLA match, cord blood may be matched sibling or matched unrelated

** Applicable for centres in the Ministry of Health. It may differ in the university or private medical centres.

Type of indication for transplant procedures

Categories	Settings where HCT ought to be performed
Standard of care (S)	Indicated and considered as standard of care in the suitable candidate with access to facilities
Clinical option (CO)	Clinical option, discussion between the attending physician, patient and clinician with experience in the related clinical condition with careful consideration of the benefits versus risks is recommended
Not offered (NO)	Not offered in Ministry of Health Institutions

Appendix 3: Post HSCT Vaccination Schedule (Adult)

No	Vaccine		Time Post HSCT	Doses	Interval between doses
1	*COVID-19 (prefer mRNA vaccine)		3- 6 months	2 + 1 booster	Depends on vaccine
2	Influenza		6 months onwards	2 + yearly booster	1 month
	Diphtheria, Tetanus, Pertussis (DTaP)		6-12 months	3	1-2 months
3	Polio (inactivated vaccine only - IPV)		6-12 months	3	1-2 month
4	Haemophilus influenzae (Hib)		6-12 months	3	1 month
5	[a]Hepatitis B		6-12 months	3 + booster	1 month
4	[b]Pneumococcal	PCV 13	6 months	3	1 month
		PCV 23	6 months after the last dose of Prevenar 13	1	5 years
5	Meningococcal (Conjugate A,C,W,Y)		6 months	2	2 months
6	MMR		Not recommended, may consider after 24 months post in a seronegative patient, no longer on immunosuppressants, no chronic GVHD and no evidence of relapse	1	-
7	Varicella and zoster		Not recommended	-	-
9	Typhoid (IM, polysaccharide vaccine)		6 months onwards	1	3 yearly
10	HPV		6-12 months	3	2 months, 6 months

Adapted from Guidelines of Adult Immunisation, 3rd Edition, 2020

For HSCT patients who wish to travel abroad, immunisation may be necessary. Vaccines that should be safe for blood and marrow transplant patients intending to travel include:

- Typhoid – The oral form is contraindicated,
- Cholera – Not recommended because of low protective efficacy,
- Hepatitis A – Both active and passive are safe.
- Contraindicated: Yellow fever, Japanese encephalitis, oral polio vaccines

*COVID-19 vaccine recommendations may change from time to time depending on the nationwide and worldwide situation, including the predominant strain affecting the population. Please refer to the most current guideline on COVID-19 vaccination published by the Ministry of Health (MOH).

a. Before allogeneic HSCT, patients who are negative for all HBV markers that are transplanted with a graft from an anti-HBc positive donor should be vaccinated if possible (B III) and could additionally receive anti-HBV immunoglobulins. After 6-12 months of HSCT, the Hep B vaccine may be given to seronegative patients before HSCT with an antiHBc positive donor, or previously infected patients with anti-HBs < 10mIU/ml.

b. Pneumococcal vaccine: There are 2 types of the pneumococcal vaccine – conjugate vaccine (PCV13) and polysaccharide vaccine (PPV23). PCV13 is used for the primary series because the immunological response to conjugate vaccines is generally more immunogenic than polysaccharide vaccines but, the spectrum of protection is narrower and therefore the subsequent dose of PPV23 is given to broadening the immune response. The PPV23 covers 23 strains but is less immunogenic and may elicit an inadequate response. It may be beneficial to use PPV23 as the fourth dose to broaden the immune response.

Appendix 4: Post HSCT Vaccination Schedule (Children)

All patients post stem cell transplant **SHOULD NOT** be immunized unless they fulfil the following criteria :-

- At least 12 months off immunosuppressives (eg CSA, MMF, tacrolimus, prednisolone)
- No active GVHD

INTERVAL POST TRANSPLANT	VACCINES		Details
1st Visit	*Pneumococcal Polysaccharide (PPSV 23)		at least 6 months post cessation of IST
2nd visit	Hep B DTaP Hib IPV	1st dose	at least 12 months post transplant
3rd visit	Hep B DTaP Hib IPV	2nd dose	1 month after 2nd visit
4th visit	¥Pneumococcal Conjugate (PCV13)	1st dose	1 month after 3rd visit)- *If not given PPSV23*
5th visit	Hep B DTaP Hib IPV	3rd dose	1 month after 4th visit
6th visit	¥Pneumococcal Conjugate (PCV13)	2nd dose	1 month after 5th visit) *If not given PPSV23*
7th visit	¥Pneumococcal Conjugate (PCV13)	3rd dose	1 month after 6th visit) *If not given PPSV23*
24 months post transplant	MMR	1st dose	
3-6 months after previous dose	MMR	2nd dose	
24 months post transplant	Chicken pox		

Prepared by Dr Quah and Dr Ida Shahnaz Othman (HTA, 2020)

Note

1. Choose either:
    - Pneumococcal Polysaccharide (PPSV 23) – for more than 2 years old, single dose
    - Pneumoccal Conjugate (PCV13) – recommended in less than 2 years-old, total 3 doses, at least 4 weeks apart. The last dose (booster dose) should be at least 12 months of age or older
2. BCG reimmunisation is NOT required
3. Chicken Pox vaccine is optional (not available at MOH hospitals

16.0

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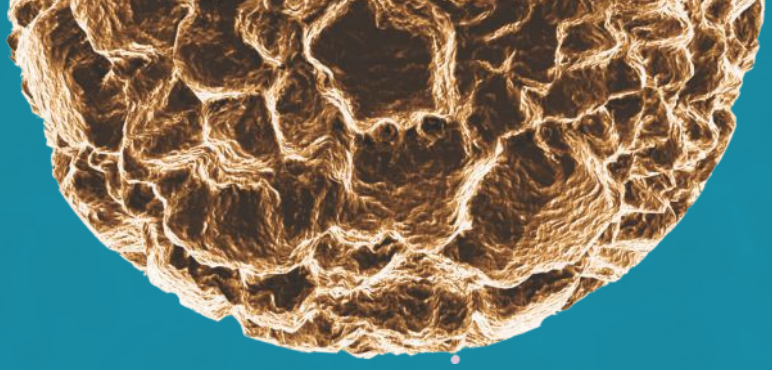

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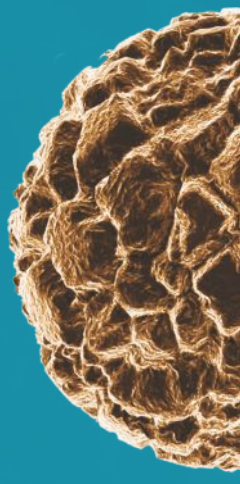

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