STANDARDS FOR HEART AND LUNG TRANSPLANT SERVICES

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Health Policies and Standards Department

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ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with United Network for Organ Sharing (UNOS) and Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

The Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld
- Governing the use of narcotics, controlled and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health and promoting innovation.

The DHA Standards for Heart and Lung Transplant Services aims to fulfill the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

EXECUTIVE SUMMARY

Heart transplantation is the removal of a heart from a deceased donor and transferring it into a patient with end-stage heart failure. Lung transplantation is the removal of a single or bilateral lungs from a deceased donor and transferring the lung(s) into a patient with end-stage lung disease.

This document is developed to ensure that heart and lung transplant services provided in Dubai Health Authority (DHA) licensed health facilities are of the highest standards and aligned with current international best practices.

The document elaborates the licensing requirements of a health facility aiming to provide heart and lung transplant service, the health facility requirements, the healthcare professional requirements, the consent for organ transplant, medication requirements, criteria for continuity of the heart and lung transplant service, and pre-operative assessment and evaluation of recipient candidate. This standard is aligned with all the applicable United Arab Emirates (UAE) laws and legislations related to the subject.

This Standards shall align with the following:

- Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.
- Federal Decree Law (18) of 2023 concerning the Medical Liability.
- Federal Law no. (8) of 2023 amending some provisions of Federal Law no (4) of 2015 concerning the Private Health Facilities.
- Ministerial Decision no. (19) of 2022 concerning the Standards of Death Determination.

- Cabinet Decision No. (25) of 2020 concerning Federal Decree No. (5) of 2016 concerning regulating the transfusion and transplantation of human organs and tissues.
- DHA Standards for Human Organ and Tissue Donation Services (Deceased donor).
- DHA Guidelines for Organ and Tissue Donation Registry and KPIs.

DEFINITIONS

Critical Care Support Unit (CCSU) is a 24/7 operating unit within the hospital ICU responsible for all end-of-life care patient matters, run by the Critical Care Support Unit director and coordinator(s). It was earlier referred to as the Organ Donation Unit (ODU).

Critical Care Support Unit Coordinator (CCSUC): ICU nurse, Intensivist or other trained clinical staff assigned by the health facility management, responsible for ensuring that all families of patients experiencing end-of-life care pathways receive the required support, as well as the ability to exercise their right for organ donation. This individual ensures that, if consented, that all organ and tissue donation processes occur as per protocol and all communications between the CCSU, DHA and the National Center for Donation and Transplant (NCDT) are done on timely manner to facilitate organ donation and transplant.

Donation is a legal act indicating that a living individual has legally accepted to donate, during his/her lifetime or after death when formally documented either by the notary public, through Emirates identify card, under a legal will left for his/her heirs or permitted successors, or through consent from next of kin in accordance with published DHA standards, to donate with no compensation one or more of his/her body organs or part thereof or tissues to someone by way of transplant operation.

Donor is a human being, living or deceased, who is a source of organs, tissues or cells which are to be used for the purpose of transplantation.

Health Facility is a facility licensed by DHA to provide medical services to individuals, including

areas of prevention, treatment, and convalescence owned and managed by natural or corporate body.

Healthcare Professional are healthcare personnel working in health care facilities and required to be licensed as per the applicable laws in United Arab Emirates (UAE).

Heart or Lung Transplant Coordinator serves as a facilitator, educator and point of contact as well as assisting patients with all details of care involved in preparing for transplantation.

Informed Consent refers to an agreement or permission accompanied by full information on the nature, risks, and alternatives of a surgical or interventional procedure before the physician begins the procedure/treatment. Accordingly, the patient either consents to or refuses treatment.

National Center for Donation and Transplantation (The National Center) is the federal center under the Ministry of Health and Prevention responsible to regulate and coordinate organ and tissue donation and transplantation in UAE.

Next of kin refers to a person who is authorized to make decision on behalf of the patient (in case the patient is not competent). Next of kin may include husband and wife and relatives up to the fourth degree. In case relatives up to the fourth degree are not available, then relatives available from the same origin of the spouse's side will be considered as a next of kin.

Organ Transplant Unit (OTU) is an area in the hospital dedicated to Organ Transplant with privileged healthcare professionals and administrative staff like the Transplant Coordinator to ensure a seamless and efficient provision of Organ Transplant Services.

Transplant Candidate is a person registered on the organ transplant wait list awaiting a transplant. When an organ is offered on behalf of the candidate, they are then called a Potential Transplant Recipient.

Transplant Coordinator serves as a facilitator, educator and point of contact as well as assisting patients with all details of care involved in preparing for transplantation.

Workup is a thorough potential donor or recipient review, which may include diagnostic assessments such as laboratory tests, imaging, cancer screening, psychosocial assessment, and other evaluations for the purpose of ensuring successful transplant outcomes.

ABBREVIATIONS

ABG	:	Arterial Blood Gases
Ag/Ab	:	Antigen/Antibody
ALG	:	Antilymphocyte Globulin
ALP	:	Alkaline Phosphatase
ALT	:	Alanine Transaminase
ASLOT	:	Antistreptolysin O Titer
AST	:	Aspartate Aminotransferase
ATG	:	Anti-Thymocyte Globulin
AZA	:	Azathioprine
BID	:	Bis in Die (Twice per Day)
BODE	:	Body Mass Index, Airflow Obstruction, Dyspnea, Exercise Capacity Index
BOS	:	Bronchiolitis Obliterans Syndrome
BMD	:	Bone Marrow Density
BMI	:	Body Mass Index
BUN	:	Blood Urea Nitrogen
CAD	:	Chronic Allograft Dysfunction
CBC	:	Complete Blood Count
CCSU	:	Critical Care Support Unit
CCSUC	:	Critical Care Support Unit Coordinator
CLAD	:	Chronic Lung Allograft Dysfunction
CMP	:	Complete Metabolic Panel

CMV	:	Cytomegalovirus
CNI	:	Calcineurin Inhibitors
COVID	:	Coronavirus Disease
CPK	:	Creatine Phosphokinase
CPK-MB	:	Creatine Phosphokinase-Myocardial Band
CT	:	Computer Tomography
CTX	:	C-Terminal Telopeptides
DEXA	:	Dual X-Ray Absorptiometry
DHA	:	Dubai Health Authority
DLCO	:	Diffusing Capacity of Lungs for Carbon Monoxide (Transfer Factor)
DNC	:	Death by Neurological Criteria
DSA	:	Donor-Specific Alloantibody
EBV	:	Epstein-Barr Virus
ECG	:	Electrocardiogram
EGDS	:	Esophagogastroduodenoscopy
ESR	:	Erythrocyte Sedimentation Rate
FEV	:	Forced Expiratory Volume
FVC	:	Forced Vital Capacity
GDMT	:	Guideline-Directed Medical Therapy
GFR	:	Glomerular Filtration Rate
GGT	:	Gamma Glutamyl Transpeptidase

GI	:	Gastrointestinal
HA	:	Hepatitis A
HBV	:	Hepatitis B Virus
HCV	:	Hepatitis C Virus
HDL	:	High Density Lipoprotein
HFG	:	Health Facility Guidelines
HHV8	:	Human Herpesvirus-8
HIV	:	Human Immunodeficiency Virus
HLA	:	Human Leukocyte Antigens
HPV	:	Human Papillomavirus
HRS	:	Health Regulation Sector
HTK	:	Histidine-Tryptophan-Ketoglutarate
HTLV	:	Human T-Lymphocyte Virus
ICU	:	Intensive Care Unit
IgG	:	Immunoglobulin G
IgM	:	Immunoglobulin M
IL2	:	Interleukin-2
INR	:	International Normalized Ratio
IPAH	:	Idiopathic Arterial Hypertension
LDL	:	Low Density Lipoproteins
LV	:	Left Ventricular

MCS	:	Mechanical Circulatory Support
MMF	:	Mycophenolate Mofetil
MMR	:	Measles, Mumps, Rubella
MNA	:	Mini Nutritional Assessment
MOCA	:	Montreal Cognitive Assessment
MOHAP	:	Ministry of Health and Prevention
m-TOR	:	Mammalian Target of Rapamycin
MWT	:	Minute Walk Test
NAT	:	Nucleic Acid Testing
NCDT	:	National Center for Donation and Transplantation
NYHA	:	New York Heart Association
OD	:	Once Daily
OKT3	:	Orthoclone
OT	:	Operating Theatre
OTU	:	Organ Transplant Unit
PAP	:	Papanicolaou Test
PEEP	:	Positive End-Expiratory Pressure
PO	:	Per Os (By Mouth)
PH	:	Pulmonary Hypertension
POD	:	Postoperative Day

PRA	:	Panel Reactive Antibodies
PSA	:	Prostate-Specific Antigen
PT	:	Prothrombin Time
PTT	:	Partial Thromboplastin Time
PVR	:	Pulmonary Vascular Resistance
RAS	:	Restrictive Allograft Syndrome
RN	:	Registered Nurse
RNA	:	Ribonucleic Acid
SARS	:	Severe Acute Respiratory Syndrome
SOP	:	Standard Operating Procedure
STAT	:	Statim (Immediately)
TDM	:	Therapeutic Drug Monitoring
TLC	:	Total Lung Capacity
TPHA	:	Treponema Palladium Hemagglutination
TTR	:	Transthyretin Related
UAE	:	United Arab Emirates
US	:	Ultrasound
UW	:	University of Wisconsin
VDRL	:	Venereal Disease Research Laboratory
VLDL	:	Very Low-Density Lipoproteins
WHO	:	World Health Organization

1. BACKGROUND

In 2016 the United Arab Emirates (UAE) issued a law to allow transplantation of human organs and tissues from both living donors and the deceased. In 2023 this law was replaced as the Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.

In September 2020, the National Center to Regulate Human Organs and Tissues Transplantation[1] was established. The National Center aims to unify the national efforts in the field of transplantation of human organs and tissues, regulate and coordinate organ transplant surgeries across the country.

This standard is developed to regulate heart and lung transplant services, with an aim to assure the provision of the highest levels of safety and quality for providing heart and lung transplant services in Dubai Health Authority (DHA) licensed hospitals.

Heart or lung transplant surgery is done to place a healthy heart or lung from a donor into a recipient whose heart or lungs no longer function well enough to support independent existence.

A donor heart or lung typically comes from a deceased donor.

2. SCOPE

2.1. Heart transplant services in DHA licensed health facilities.

2.2. Lung transplant services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality heart transplant services in DHA licensed health facilities.

3.2. To assure provision of the highest levels of safety and quality lung transplant services in DHA licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing heart transplant services.

4.2. DHA licensed healthcare professionals and health facilities providing lung transplant services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing heart or lung transplant services shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities opting to provide heart or lung transplant services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.3. Licensed health facilities opting to add heart or lung transplant services shall inform Health Regulation Sector (HRS) and submit an application to HRS to obtain permission to provide the required service.

5.4. Accreditation

5.4.1. The hospital shall be accredited as per the DHA Hospital accreditation policy before the commencement of heart or lung transplant service.

5.4.2. The hospital laboratory must be accredited as per the DHA Clinical Laboratory accreditation policy before the commencement of heart or lung transplant service.

5.5. The hospital shall employ trained and experienced healthcare professionals as identify and described in this document.

5.6. The health facility shall have Standard Operating Procedures (SOPs) related to Heart Transplant Service and/or Lung Transplant Service. The relevant staff shall be trained to abide by these SOPs. The SOPs shall be made available to HRS upon request.

5.7. The health facility shall develop the following policies and procedures at minimum and provide documented evidence to HRS upon request:

5.7.1. Patient Continuity of Care.

5.7.2. Patient acceptance criteria for heart and lung organ transplant waitlist; patient exclusion criteria for these procedures.

5.7.3. Candidate blood type determination, which must include the requirements listed in **Appendix 1**.

5.7.4. Process to inform patients when they have been selected and added to the waitlist or removed from the waitlist for reasons other than death or transplant.

5.7.5. Patient education and informed consent, including the provision of donor

risk criteria present.

5.7.6. Patient assessment for transplant candidate work up, as elaborated in **Appendix 1**. Indications and contraindications/criteria for rejection for heart or lung transplant are included in **Appendix 2**.

5.7.7. Hospital policy for deceased organ donation as per DHA Standards for Human Organs and Tissues Donation Services (Deceased Donor), DHA Guidelines for Reporting Human Organ and Tissue Donation Services Registry and Key Performance Indicators, and including the requirements listed in **Appendix 3** specific to heart and lung deceased donor assessment and evaluation.

5.7.8. ABO Compatibility verification and documentation for organ transplantation, conducted by the transplant surgeon and another healthcare professional, in accordance with the requirements listed in **Appendix 3** and **Appendix 4.**

5.7.9. Pre-transplant assessment immediately prior to transplant surgery, including the requirements listed in **Appendix 4**.

5.7.10. Post-transplant follow-up protocol, including the requirements listed in **Appendix 5**.

5.7.11. Incident reporting to the DHA in accordance with the requirements detailed in **Appendix 5.**

5.7.12. Patient health record must be maintained and demonstrate that all

policies and procedures were followed.

5.7.13. Infection control measures, including post-transplant surveillance testing detailed in **Appendix 6**, and hazardous waste management.

5.7.14. Patient privacy.

5.7.15. Medication management.

5.7.16. Emergency action plan.

5.7.17. Patient discharge/transfer.

5.8. The health facility shall provide documented evidence of the following:

5.8.1. Transfer of critical/complicated cases when required.

5.8.2. Patient discharge.

5.8.3. Clinical laboratory services.

5.8.4. Equipment maintenance services.

5.8.5. Laundry services.

5.8.6. Medical waste management as per Dubai Municipality (DM) requirements.

5.8.7. Housekeeping services.

5.9. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).

5.10. The health facility shall have in place a written plan for monitoring equipment for electrical and mechanical safety, with monthly visual inspections for apparent defects. This written plan shall be provided upon request.

5.11. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets, and communications.

5.12. The health facility shall allocate sufficient operating and recovery room resources, intensive care resources, surgical beds, and personnel to the heart and/or lung transplant services.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. Heart and/or lung transplant services shall only be performed in DHA licensed Hospitals with Role Delineation Level 5 to 6, or general hospitals with more than 100 beds.

6.2. The hospital shall have a Critical Care Support Unit (CCSU) to ensure proper support to all families with patients on end-of-life care pathways. The CCSU director should ensure that families can exercise the right to organ donation after death.

6.3. The hospital shall have an Organ Transplant Unit (OTU) to ensure integrated and seamless transplant services, including the heart transplant service and/or lung transplant service.

6.4. The hospital providing heart or lung transplant services shall have the following services:

6.4.1. Cardiology.

6.4.2. Pulmonology with bronchoscopy.

6.4.3. Radiology.

6.4.4. Hematology.

6.4.5. Infectious Disease.

6.4.6. Pathology Laboratory:

a. All routine investigations necessary for the patients either before or after the transplantation must be available.

b. Facilities to do tissue typing, cytotoxic antibodies and blood levels of drugs including cyclosporine or similar drugs shall be available.

6.4.7. Biochemistry Laboratory.

6.4.8. Intensive Care Unit (ICU) and Cardiac Intensive Care Unit (CCU).

6.4.9. Quality Management.

6.4.10. Blood banking services.

6.4.11. Microbiology services.

6.4.12. Histocompatibility testing.

6.4.13. Necessary resources to monitor treatment with immunosuppressive medications.

6.5. The hospital providing paediatric heart or lung transplant services shall also have the following:

6.5.1. A facility which performs regular paediatric cardiac surgery, including surgery for complex congenital heart disease and the necessary OT, intensive care, and recovery infrastructure.

6.6. The hospital shall provide the following:

6.6.1. Minimum of two (2) Operating Theatres (OT).

6.6.2. Minimum of two (2) rooms for the management of post-transplant patients.

6.7. The health facility shall install and operate equipment required for provision of the proposed services in accordance with the manufacturer's specifications.

6.8. The health facility shall ensure easy access to the health facility and treatment areas for all patient groups.

6.9. The health facility shall provide assurance of patients and staff safety.

6.10. The health facility shall have appropriate emergency medications as defined in the published DHA Policy for Emergency Medications, equipment, and trained healthcare professionals to manage critical and emergency cases.

6.11. The health facility's design shall align with the health facility requirement as per the DHA Health Facility Guidelines (HFG) 2019, Part B – Health Facility Briefing & Design, for all the above-mentioned categories of services.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS FOR HEART TRANSPLANT SERVICES

7.1. A DHA licensed hospital providing heart transplant services shall have a team of healthcare professionals to ensure the smooth functioning of the service to ensure patient continuity of care.

7.2. There must be DHA licensed consultant Cardiac Surgeons/Cardio-Thoracic Surgeons/Cardiovascular Surgeons/Thoracic Surgeons with training and experience in heart transplant and privileged to do so aligned with the DHA Privileging Policy.

7.3. There must be a DHA licensed consultant Cardiologist to ensure pre and post-surgical care is provided.

7.4. The consultant transplant surgeons and consultant transplant physicians (mentioned above) are responsible for ensuring the operation and compliance of liver transplant services align with requirements set forth in this standard.

7.5. A surgeon can meet requirements for consultant heart transplant surgeon if all the following conditions are met:

7.5.1. The surgeon must have performed:

a. Twenty (20) or more heart or heart/lung transplants within the last ten (10) years at a hospital designated to perform heart transplants and participated in pre-operative assessment of heart transplant candidates and post-operative care of these recipients.

b. At least one (1) heart or heart/lung transplant within the last two (2) years as primary surgeon, co-surgeon or first assistant.

c. At least ten (10) heart or heart/lung procurements.

(i) These procedures must be documented in a log that includes the date of procedure, the role of the surgeon, and medical record number or other unique identifier. This log must be

signed by an individual in a supervisory position from the hospital where the experience was gained.

7.6. A physician can meet requirements for consultant transplant cardiologist if all the following conditions are met:

7.6.1. The physician must have:

a. Been directly involved in the primary care of twenty (20) or more newly transplanted heart or heart/lung recipients within the last ten (10) years at a hospital designated to perform heart transplants.

b. Been directly involved in the primary care of at least one (1) newly transplanted heart or heart/lung recipient within the last two (2) years.

c. Continued to follow these recipients for a minimum of three (3) months from transplant.

d. Observed at least three (3) heart transplants.

(i) This care must be documented in a log that includes the date of transplant and medical record number or another unique identifier that can be verified. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

7.7. A DHA licensed health facility providing paediatric heart transplant services shall employ a DHA licensed consultant pediatric Cardiac Surgeon with training and

experience in heart transplant and a DHA licensed consultant pediatric Critical Care Medicine/consultant pediatrician with training and experience in heart transplant, as described below:

7.7.1. In addition to the requirements described in above the surgeon must have:

a. Performed at least eight (8) heart transplants in recipients less than eighteen (18) years old at the time of transplant. At least four (4) of these heart transplants must have been in recipients less than six (6) years old or weighing less than twenty-five (25) kilograms at the time of transplant.

b. Maintained a current working knowledge of paediatric heart transplantation, defined as performing a paediatric transplant within the last two (2) years.

c. A current, active practice performing regular cardiac surgery in paediatric patients, including repair of complex congenital heart disease.

d. To verify this experience, a log documenting procedure date, role of surgeon, and medical record number or other unique identifier must be maintained and signed by an individual in a supervisory capacity from the hospital where the experience was gained.

7.7.2. In addition to all the requirements described in above the physician must

have:

a. Been directly involved in the primary care of five (5) or more newly transplanted paediatric heart recipients and followed ten (10) newly transplanted heart recipients for a minimum of six (6) months from the time of transplant.

b. Been directly involved the pre-operative, peri-operative, and post-operative care of ten (10) or more paediatric heart transplant recipients.

c. Maintained a current working knowledge of paediatric heart transplantation, defined as direct involvement in paediatric heart transplant care within the last two (2) years.

d. To verify this transplant experience, a log documenting transplant date, and medical record number of the recipient must be maintained and signed by an individual in a supervisory capacity from the hospital where the experience was gained.

7.8. A DHA licensed health facility providing heart transplant services shall have the following DHA licensed healthcare professionals to support the above mentioned physicians:

7.8.1. **Anesthesiologist** with experience in intra-operative management of heart transplant recipients.

7.8.2. **Registered Nurses (RNs)** experienced and trained to care for patients

during and after heart transplants.

7.8.3. **Heart Transplant Coordinator** to work with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation. The coordinator shall be a registered nurse or other licensed clinician with minimum of three years of acute care experience required. Experience relevant to cardiology transplant subspecialty is preferred.

7.8.4. **Financial Coordinator** to coordinate the financial resources required for care, beginning with the transplantation evaluation, and continuing after transplantation to ensure continuity of care.

7.8.5. **Clinical Pharmacist** to provide comprehensive medication management to transplant candidates, recipients.

7.8.6. **Clinical Social Worker** to coordinate psychosocial needs of transplant candidates, recipients, and their families.

7.8.7. **Clinical Dietician** to provide nutritional services to transplant candidates, recipients, and living donors.

7.8.8. **Head of the Critical Care Support Unit and Donor Coordinator** who is responsible for defining hospital deceased organ donation policy, assessing deceased organ donor potential, and measuring KPIs for organ donation as defined by published DHA standards and reporting them to DHA on a monthly basis.

7.9. Heart transplant services shall collaborate with medical experts in these fields; including but not limited to:

7.9.1. Anesthesiology.

7.9.2. Cardiology.

7.9.3. Histocompatibility and immunogenetics.

7.9.4. Immunology.

7.9.5. Infectious disease.

7.9.6. Interventionalist skilled in stenting and other areas.

7.9.7. Pathology.

7.9.8. Physical therapy and rehabilitation medicine.

7.9.9. Radiology.

7.9.10. Medical nutrition therapy.

7.9.11. Pulmonary medicine, including respiratory therapy support, as appropriate.

7.9.12. Hepatology, as appropriate.

7.9.13. Nephrology, including dialysis capability, as appropriate.

7.9.14. Paediatric specialists, if applicable.

7.10. Heart Transplant Coordinators shall be assigned in each OTU providing heart transplant services, with the following responsibilities:

7.10.1. Act as liaison between the Organ Donation and Transplantation team of DHA, National Center and the hospital OTU.

7.10.2. Work closely with the coordinator(s) of the National Center and the Critical Care Support Unit Coordinator (CCSUC) of the donor facilities to facilitate donation and subsequent transplant.

7.10.3. Ensure that all potential transplant recipients and donors meet transplant or donation criteria and maintain documentation to support that these requirements are met.

7.10.4. Ensure that all policies and procedures for the OTU are up to date and aligned with current international best practices.

7.10.5. Ensure that all activities of the OTU adhere to policy and procedures for transplant and donation and assume responsibility for maintaining all supportive documentation in patients' medical records.

7.10.6. Explain policies and procedures for transplant and donation to patients and their families to support them and coordinate their care.

7.10.7. Prepare for the hospital OTU a sequentially prioritized list of candidates waiting for transplant (the waitlist).

7.10.8. Provide to The National Center the names of all patients determined to be suitable for heart transplant following a completed transplant workup. These shall be included on the national waitlist.

7.10.9. Inform The National Center when a suitable patient for transplantation is not available in the local waiting list.

7.10.10. Send and update all information related to patients with end-stage heart

disease fit for transplantation to the National Center.

7.10.11. Oversee implementing the post-transplant care of the patient and act as a conduit between patient care teams and the recipient.

7.10.12. Report all relevant information regarding transplant program activity in accordance with the National Registry for Organ Donation and Transplant to HRS and the National Center.

7.11. A DHA licensed health facility providing heart transplant services shall have a Heart Transplant Committee to ensure efficiency and safe heart transplant services. The Heart Transplant Committee shall consist of:

7.11.1. Consultant Surgeon for Heart Transplant (lead).

7.11.2. Consultant Transplant Cardiologist

7.11.3. Heart Transplant Coordinator.

7.11.4. Registered Nurse Representative.

7.11.5. Quality Coordinator.

7.11.6. Anaesthesiologist.

7.11.7. Clinical Social Worker.

7.11.8. Pulmonologist (optional).

7.11.9. Nephrologist (optional).

7.11.10. Hepatologist (optional).

7.11.11. Psychiatrist (optional).

7.11.12. Legal Representative (optional).

7.12. A DHA licensed health facility providing paediatric heart transplant services shall have a Heart Transplant Committee to ensure efficiency and safe heart transplant services. The Heart Transplant Committee shall consist of the same members as the adult Heart Transplant Committee, except the following positions must have paediatric specializations:

7.12.1. Consultant Pediatric Transplant Cardiologist (could be the lead).

7.12.2. Anaesthesiologist with paediatric experience.

7.13. The Heart Transplant Committee that shall meet on a regular basis to ensure smooth operation of the OTU. The responsibilities of the Heart Transplant Committee are as follows:

7.13.1. Ensure that each potential candidate has access and fair opportunity to be assessed for transplant and/or donation.

7.13.2. Review the health records of patients to undergo pre-transplant evaluation as elaborated in **Appendix 1**.

7.13.3. Create a process of transplant wait-listing that is efficient, effective, and transparent.

7.13.4. Make clinical decisions as to which potential candidates are suitable for wait listing and which candidates should be rejected, based on criteria set forth by The National Center.

7.13.5. Review the patients on a routine basis to ensure that they continue to meet program requirements for transplant and wait-listing.

7.13.6. Review post-transplant follow-up every 6 months to monitor patient

outcomes and track observed one-year graft and survival rate.

7.13.7. Ensure that transplant and donation activities abide to the highest ethical and legal standards.

7.13.8. Ensure all practices of the OTU are aligned with current international best practices.

7.13.9. Facilitate multidisciplinary decision-making to provide the best possible care for potential transplant candidates.

7.13.10. Develop and regularly update Policies and Procedures related to Heart Transplant Service to ensure efficient and safe provision of services.

7.14. The Privileging Committee and/or Medical Director of the health facility must privilege the physicians listed above aligned with her/her education, training, experience, and competencies. The privilege shall be reviewed and revised on regular intervals aligned with the DHA Clinical Privileging Policy.

7.15. It is strictly prohibited for transplant Healthcare Professionals or surgeons to take part in diagnosing Death by Neurological Criteria (DNC) or obtaining the consent for deceased donation.

8. **STANDARD FOUR:** HEALTHCARE PROFESSIONALS REQUIREMENTS FOR LUNG TRANSPLANT SERVICES

8.1. A DHA licensed hospital providing lung transplant services shall have a team of healthcare professionals to ensure the smooth functioning of the service to ensure patient continuity of care.

8.2. There must be DHA licensed Consultant Cardiac Surgeons/Cardio-Thoracic Surgeons/Cardiovascular Surgeons/Thoracic Surgeons with training and experience in heart transplant and privileged to do so aligned with the DHA Privileging Policy.

8.3. There must be a DHA licensed consultant Cardiologist/Pulmonologist to ensure pre and post-surgical care is provided.

8.4. The consultant transplant surgeons and consultant transplant physicians (mentioned above) are responsible for ensuring the operation and compliance of lung transplant services align with requirements set forth in this standard.

8.4.1. A surgeon can meet requirements for consultant lung transplant surgeon if all the following conditions are met:

a. The surgeon must have:

(i) Performed fifteen (15) or more lung or heart/lung transplants within the last ten (10) years at a hospital designated to perform lung transplants.

(ii) Performed at least one (1) lung or heart/lung transplant within the last two (2) years.

(iii) Participated in pre-operative assessment of lung transplant candidates and post-operative care of these recipients.

(iv) Performed at least ten (10) lung or heart/lung procurements.

(v) This experience must be documented in a log that includes the date of procedure, the role of the surgeon in the procedure,

and medical record number or another unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

8.4.2. A physician can meet requirements for consultant transplant pulmonologist if all the following conditions are met:

a. The physician must have:

(i) Been directly involved in the primary care of fifteen (15) or more newly transplanted lung or heart/lung recipients within the last ten (10) years at a hospital designated to perform lung transplants.

(ii) Been directly involved in the primary care of at least one (1) newly transplanted lung or heart/lung recipient within the last two (2) years.

(iii) Continued to follow these recipients for a minimum of three (3) months from transplant.

(iv) Observed at least three (3) lung transplants.

(v) This care must be documented in a log that includes the date of procedure and medical record number or another unique identifier. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

8.5. A DHA licensed health facility providing paediatric lung transplant services shall employ a DHA licensed consultant pediatric surgeon with training and experience in lung transplant and a qualified consultant pediatric physician with training and experience in lung transplant, and privileged by the health facility aligned with the DHA Privileging Policy.

8.5.1. The surgeon meets all the requirements described in above.

8.5.2. The physician meets all the requirements described in above.

8.6. A DHA licensed health facility providing lung transplant services shall have the following DHA licensed healthcare professionals:

8.6.1. **Anaesthesiologist** with experience in intra-operative management of lung transplant recipients.

8.6.2. **Registered Nurses (RNs)** experienced and trained to care for patients during and after lung transplants.

8.6.3. **Transplant Coordinator** to work with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation. The coordinator shall be a registered nurse or other licensed clinician with a minimum of three years of acute care experience required. Experience relevant to pulmonology transplant subspecialty is preferred.

8.6.4. **Financial Coordinator** to coordinate the financial resources required for care, beginning with the transplantation evaluation, and continuing after

transplantation to ensure continuity of care.

8.6.5. **Clinical Pharmacist** to provide comprehensive medication management to transplant candidates, recipients, and living donors.

8.6.6. **Clinical Social Worker** to coordinate psychosocial needs of transplant candidates, recipients, living donors, and their families.

8.6.7. **Clinical Dietician** to provide nutritional services to transplant candidates, recipients, and living donors.

8.6.8. **Head of the Critical Care Support Unit and Donor Coordinator** who is responsible for defining hospital deceased organ donation policy, assessing deceased organ donor potential, and measuring KPIs for organ donation as defined by published DHA standards and reporting them to DHA on a monthly basis.

8.7. Lung transplant services shall collaborate with medical experts in these fields; including but not limited to:

8.7.1. Pulmonary medicine, including respiratory therapy and bronchoscopy support.

8.7.2. Anesthesiology.

8.7.3. Histocompatibility and immunogenetics.

8.7.4. Immunology.

8.7.5. Infectious disease.

8.7.6. Interventionalist skilled in stenting and other areas.

8.7.7. Pathology.

8.7.8. Physical therapy and rehabilitation medicine.

8.7.9. Radiology.

8.7.10. Cardiology, as appropriate.

8.7.11. Hepatology, as appropriate.

8.7.12. Nephrology, including dialysis capability, as appropriate.

8.7.13. Pediatrics, if applicable.

8.8. Lung Transplant Coordinators shall be assigned in each OTU providing lung transplant services, with the following responsibilities:

8.8.1. Act as liaison between the Organ Donation and Transplant Team in DHA (where applicable), The National Center and the hospital OTU.

8.8.2. Work closely with the coordinator(s) of the National Center and the Critical Care Support Unit Coordinator (CCSUC) of the donor facilities to facilitate donation and subsequent transplant.

8.8.3. Ensure that all potential transplant recipients and donors meet transplant or donation criteria and maintain documentation to support that these requirements are met.

8.8.4. Ensure that all policies and procedures for the OTU are up to date and aligned with current international best practices.

8.8.5. Explain policies and procedures for transplant and donation to patients and their families to support them and coordinate their care.

8.8.6. Ensure that all activities of the OTU adhere to policy and procedures for transplant and assume responsibility for maintaining all supportive documentation in patients' medical records.

8.8.7. Prepare for the hospital OTU a sequentially prioritized list of candidates waiting for transplant (the waitlist) and coordinate the list with the National Center.

8.8.8. Provide to The National Center the names of all patients determined to be suitable for lung transplant following a completed transplant workup. These shall be included on the national waitlist.

8.8.9. Inform The National Center when a suitable patient for transplantation is not available in the local waiting list.

8.8.10. Send and update all information related to patients with end-stage lung disease fit for transplantation.

8.8.11. Oversee implementing the posttransplant care of the patient and act as a conduit between patient care teams and the recipient.

8.8.12. Report all relevant information regarding transplant program activity in accordance with the National Registry for Organ Donation and Transplant to HRS and the National Center.

8.9. A DHA licensed health facility providing lung transplant services shall have a Lung Transplant Committee to ensure efficiency and safe lung transplant services., which shall consist of the following members:

8.9.1. Consultant Surgeon with training and experience in Lung Transplant (could be the lead).

8.9.2. Consultant Pulmonologist with training and experience in Lung Transplant (could be the lead).

8.9.3. Lung Transplant Coordinator.

8.9.4. Registered Nurse Representative.

8.9.5. Quality Coordinator.

8.9.6. Clinical Social Worker.

8.9.7. Anaesthesiologist.

8.9.8. Psychiatrist (optional).

8.9.9. Cardiologist (optional).

8.9.10. Legal Representative (optional).

8.10. A DHA licensed health facility providing paediatric lung transplant services shall have a Lung Transplant Committee to ensure efficiency and safe heart transplant services. The Lung Transplant Committee shall consist of the same members as the adult Lung Transplant Committee, except the following positions must have paediatric specializations:

8.10.1. Consultant Pediatric Pulmonologist with training and experience in lung Transplant (could be the lead).

8.10.2. Anaesthesiologist with paediatric experience.

8.11. The Lung Transplant Committee that shall meet on a regular basis to ensure

smooth operation of the OTU. The responsibilities of the Lung Transplant Committee are as follows:

8.11.1. Ensure that each potential candidate has access and fair opportunity to be assessed for transplant and/or donation.

8.11.2. Make clinical decisions on eligibility of patients to waitlist and who are rejected based on criteria set forth by the National Center for Organ Donation and Transplantation.

8.11.3. Create a process of transplant wait-listing that is efficient, effective, and transparent.

8.11.4. Review the health records of patients to undergo pre-transplant evaluation as elaborated in **Appendix 1.** Review the patients on a routine basis to ensure that they continue to meet program requirements for transplant and wait-listing.

8.11.5. Ensure that transplant and donation activities abide to the highest ethical and legal standards.

8.11.6. Review post-transplant follow-up every 6 months to monitor patient outcomes and track observed one-year graft and survival rate.

8.11.7. Ensure all practices of the OTU are aligned with current international best practices.

8.11.8. Facilitate multidisciplinary decision-making to provide the best possible care for potential transplant candidates.

8.11.9. Develop and regularly update Policies and Procedures related to Lung Transplant Service to ensure efficient and safe provision of services.

8.12. The Privileging Committee and/or Medical Director of the health facility must privilege the physicians listed above aligned with her/her education, training, experience, and competencies. The privilege shall be reviewed and revised on regular intervals aligned with the DHA Clinical Privileging Policy.

8.13. It is strictly prohibited for transplant Healthcare Professionals or surgeons to take part in diagnosing Death by Neurological Criteria (DNC) or obtaining the consent for deceased donation.

9. **STANDARD FIVE:** INFORMED CONSENT FOR ORGAN TRANSPLANT

9.1. For potential transplant recipients who are on the waitlist for a deceased donor heart or lung, the consent shall be signed before the procedure and maintained in the medical record.

9.2. Heart or Lung Transplant Surgery Consent shall include the following:

9.2.1. Potential psychosocial risks post-transplant.

9.2.2. OTU's observed and expected one-year survival rate, beginning one year after the hospital's first Heart or Lung transplant.

9.2.3. Alternative treatments for the prospective transplant candidate.

9.2.4. Organ donor risk factors that could affect the success of the graft of the candidate's health as a recipient.

9.2.5. If the organ donor has lifestyle-based risk factors present that could

increase the risk of disease transmission, that the information was disclosed to the potential recipient prior to transplant and documented in the recipient's medical record.

9.3. Before performing deceased donor organ removal and transplantation, the following conditions should be fulfilled:

9.3.1. It is not permissible to remove an organ unless the donor's wish is conclusively confirmed and documented on the deceased donation consent form, signed by the deceased donor's relatives in accordance with Federal Decree Law No. (25) of 2023.

9.3.2. When brain death is confirmed and consent is obtained from the family for organ donation, organ placement and transplantation shall be carried out as per the Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation. Brain death confirmation must be documented in the donor's medical record as well as documentation of the consent for donation obtained.

9.3.3. For further information refer to the DHA Standards for Human Organs & Tissues Donation Services (Deceased Donor).

9.4. Always ensure donor and recipient confidentiality.

9.5. The health facility shall design and implement an action plan to educate and raise awareness regarding prevention of organ-related chronic diseases, as well as organ donation.

10. STANDARD SIX: MEDICATION REQUIREMENTS

10.1. Health facilities providing heart or lung transplant services shall ensure the in-house availability of the following drugs, but not limited to:

10.1.1. Immunosuppressive drugs:

a. Cyclosporine.

b. Tacrolimus (FK 506).

c. Azathioprine.

d. Mycophenolate Mofetil.

e. Prednisolone.

f. Sirolimus (Rapamycin).

g. Other similar drugs categories.

10.1.2. Drugs for treating rejection episodes:

a. Methylprednisolone.

b. Anti-lymphocyte Globulin (ALG) or Anti-Thymocyte Globulin (ATG).

c. Basiliximab, Rituximab.

d. Eculizumab if there is an anticipated intent or need to transplant with positive crossmatch.

10.1.3. Solution for perfusing the organs such as Eurocollins solution, University of Wisconsin (UW) solution, or HTK solution.

10.1.4. Drugs for treating bacterial, viral, fungal, or parasitic infections.

11. STANDARD SEVEN: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DONOR & CANDIDATE

11.1. The pre-operative assessment and evaluation of Donor Candidate is elaborated in **Appendix 3**.

11.2. The pre-operative assessment and evaluation of Recipient Candidate is elaborated in **Appendix 4**.

12. STANDARD EIGHT: POST-OPERATIVE MANAGEMENT OF TRANSPLANT RECIPIENT

12.1. During the post-operative management of a heart or lung transplant recipient, the parameters for monitoring graft function recovery and clinical surveillance for early surgical complications are elaborated in **Appendix 5**.

12.2. The surveillance for heart or lung transplant complications after hospital discharge are elaborated in **Appendix 6**.

12.3. The immunosuppressive therapy for heart or lung transplant recipients is elaborated in **Appendix 7.**

12.4. In case of rapid worsening of heart or lung function, the Protocol of Acute Rejection therapy is elaborated in Appendix 8.

12.5. The protocols of Chronic Allograft Dysfunction (CAD) management are elaborated in **Appendix 9**.

13. STANDARD NINE: KEY PERFORMANCE INDICATORS

13.1. The Key Performance Indicators (KPIs) are elaborated in **Appendix 10**.

13.2. The health facility shall report the KPIs (quarterly) and all donation related information defined by the National Center to the National Center at ncdt@mohap.gov.ae and HRS at MonitoringKPIs@dha.gov.ae

13.3. The information shall be as follows, but not limited to:

13.3.1. Donor- full name, date of birth, emirates ID, nationality, country of residence, date of donation, visa number and passport number

13.3.2. Transplant Recipient- full name, date of the transplant, nationality of the recipient, if related describe the type of relation (parent, siblings, etc), visa number and passport number.

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APPENDICES

APPENDIX 1: CHECK-LIST FOR WORKUP OF POTENTIAL HEART AND LUNG TRANSPLANT CANDIDATES

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the checklist were followed.

CHECK-LIST FOR HEART AND LUNG TRANSPLANT CANDIDATE WORKUP		CHECK
PRELIMINARY EVALUATION	Patient medical history, including history of cardiovascular disease and surgical history.	
	Patient social history (including smoking, alcohol, and drug use).	
	Family medical history.	
	Psychosocial evaluation to identify and modify factors that may impact adherence and self-care, including social support networks.	
	Physical examination, including weight/BMI and blood pressure (BP).	
	Detailed evaluation of the underlying cardiac or pulmonary disease	
	Surgical evaluation confirming the need for transplant and identifying technical challenges.	
	Anesthesiology consult to identify any challenges related to high operative risk.	
	Frailty assessment using modified Fried's Frailty Criteria (3 of 5 symptoms, including fatigue, hand grip strength, gait speed, unintended weight loss, physical activity).	
	Cognitive assessment using the Montreal Cognitive Assessment (MoCA) tool.	
	Nutritional status assessment using either the Mini Nutritional Assessment (MNA), MNA-short form, Nutritional Risk Index, or Geriatric Nutritional Risk Index.	
LABORATORY TESTS	ABO blood typing (tested on two separate occasions, with different collection times, prior to addition to wait-list).	
	Anti-HLA antibody testing for Class 1 and Class 2 antigens by single antigen bead methodology (i.e., Flow or Luminex method).	
	Complete blood count (CBC).	
	Blood gas test.	

	Complete Metabolic Panel (CMP) (including electrolytes, renal panel, Na, K, Cl, CO2, Cr, BUN, Ca, PO4).	
	Bone disease evaluation: • Bone marrow density (BMD) test. • Parameters of bone mineral metabolism.	
	Full urine test with urine sediment examination (if residual diuresis present).	
	Creatinine clearance or similar, such as iothalamate clearance test.	
	Complete liver enzyme panel, including AST, ALT, GGT, alkaline phosphatase, total bilirubin, direct bilirubin.	
	Full Lipid panel (including LDL, HDL, VLDL, triglycerides, total cholesterol).	
	Complete coagulation function panel (PT/INR, PTT, Fibrinogen).	
	Plasma protein levels and protein electrophoresis.	
	CPK, CPK-MB.	
	ESR, ASLOT.	
	Fecal occult blood test.	
MICROBIOLOGY ASSESSMENT AND INFECTIOUS DISEASE TESTING	Hepatitis Panel: • Hepatitis A antibody (HAAb). • Hepatitis B core antibody (HBcAb). • Hepatitis B e-antibody (HBeAb). • Hepatitis B e-antigen (HBeAg). • Hepatitis B surface antibody (HbsAb). • Hepatitis B surface antigen (HbsAg). • Hepatitis C antibody.	
	HCV Testing: • HCV-RNA. • HCV Ag/Ab.	
	HIV Testing • HIV RNA. • HIV Ag/Ab.	
	Syphilis Antibody Testing • VDRL. • TPHA.	

	Serologies • CMV (IgM, IgG). • EBV (IgM, IgG). • Toxoplasmosis (IgM, IgG). • HTLV I – II (IgM, IgG).	
	MANTOUX (if required), blood testing if history of infection.	
	Infectious Disease Consultant Evaluation (if indicated).	
CARDIOVASCULAR ASSESSMENT	ECG.	
	Echocardiogram.	
	Exercise cardiac stress test. • Exercise/treadmill. • Chemical (Dobutamine/persantine, adenosine) if cannot tolerate exercise.	
	Chest X-Ray.	
	Chest CT Scan.	
	Right heart catheterization.	
	Pulse volume recordings of leg arteries.	
	Doppler studies, if indicated.	
	Pulmonary function test.	
	Evaluation for short-term mechanical circulatory support (MCS) for patients: • In cardiogenic shock refractory to medical therapy, until hemodynamic parameters and end organ function stabilize. • Who are at a high risk for mortality with medical management alone.	
	Evaluation for long-term MCS in patients who are potential heart transplant candidates and: • When ventricular function is unlikely to recover, or unrecoverable. • Who are inotrope dependent. Who have elevated pulmonary vascular resistance that is considered reversible with left ventricular (LV) decompression. • Who have contraindications requiring substantial time to reverse, i.e., drug or alcohol dependence, obesity, cancer, etc.	

	Administer a vasodilator challenge when the pulmonary artery systolic pressure is >=50mmHg, and either: • The transpulmonary gradient is >=15; or • The pulmonary vascular resistance (PVR) is > 3Wood units while maintaining a systolic arterial blood pressure >85mmHg.	
	If patient has congenital heart disease: • CT with contrast of the chest.	
	If patient has had multiple previous cardiac surgeries: • Assessment of peripheral arteries and veins for cannulation via US or CT with contrast.	
	Myocardial Perfusion scintigraphy (if indicated).	
IMMUNOLOGIC ASSESSMENT	Protein electrophoresis.	
	Lymphocyte subset counts (CD3, CD4, CD8, CD19).	
	Immunization Records Review or Catch-up. All patients should receive the following vaccinations prior to transplant: • Td or Tdap. • HPV. • Hepatitis A. • Hepatitis B. • Meningococcal (conjugate). • Pneumococcal (conjugate and/or polysaccharide). • Hib. • Influenza (administered annually). • MMR (live). • Varicella (live). • Attenuated zoster (live) or recombinant subunit zoster. • Rotavirus (live). *Live vaccines administered before the transplant must be completed at least four to six weeks before transplantation.*	
GENDER- AND AGE-	For females: • PAP cervical screening test. • Mammogram (if indicated or >40 years old).	

APPROPRIATE ONCOLOGICAL STUDIES	For males: • Digital Prostate Exam. • PSA Testing.	
	• Colonoscopy, if indicated or if >50 years old.	
OTHERS	Carotid ultrasound.	
	Dental examination with orthopantomogram.	
	Fundus oculi.	
	Dermatologic examination.	
	Psychological evaluation.	
	Anesthesiologist evaluation.	
	For lung transplant candidates: • Sputum culture. • Ventilation/perfusion scan.	

APPENDIX 2: INDICATIONS AND CONTRAINDICATIONS FOR HEART AND LUNG TRANSPLANT

1. Indications and contraindications for heart transplant.

1.1. The following are **indications for heart transplant evaluation and listing.** Timely referral for transplant evaluation is key to enhancing patient survival on inotropes or mechanical support until an appropriate heart becomes available.

INDICATIONS FOR HEART TRANSPLANT EVALUATION AND LISTING	
Chronic Heart Failure In an outpatient setting, the following category of patients should be referred for heart transplant:	Patients on guideline-directed medical therapy (GDMT) who still have limiting symptoms on exertion. (New York heart association class 3 or 4 or American College of Cardiology stage D patients).
	Patients with frequent readmissions for heart failure exacerbation despite adherence to GDMT (two or more in 12 months).
	Worsening renal function attributed to the cardiorenal syndrome.
	Dose-limiting side effects like hypotension or contraindications like renal failure preventing the use of GDMT.
	Progressively worsening right ventricular function (cor pulmonale) or rising pulmonary artery pressure from left heart failure.
	Frequent episodes of ventricular arrhythmias despite optimal drug and electrophysiological therapy.
	Other features like anaemia, weight loss, hyponatremia, or liver dysfunction that are attributable to heart failure.
Acute Heart Failure In inpatient settings, patients that require urgent referral for heart transplant include:	Refractory cardiogenic shock despite maximum dose inotropic treatment.
	Refractory cardiogenic shock despite percutaneous mechanical circulatory support and inability to wean the MCS.
	Refractory pulmonary edema not responding to diuretics and requiring ventilation and positive pulmonary pressure.
	Refractory ventricular arrhythmia not responding to medical therapy or electrophysiological procedures.
End-Stage Cardiac Disease Patients with the following (but not	Cardiomyopathy (with class III or IV congestive heart failure).
	Class IV angina (on medical therapy not amenable to revascularization despite evidence of ischemia on stress test).
	Non-obstructive hypertrophic heart disease.
	Severe decompensated inoperable valvular heart disease.

limited to) diagnoses shall be considered for heart transplant evaluation:	Transthyretin related (TTR) amyloidosis involving the heart (with no other end organ damage).
	Congenital heart disease with heart failure (without irreversible pulmonary hypertension).
	Any other cardiac abnormalities that severely limit normal function and/or have a mortality risk of greater than 50% at two years.
In addition to the above, there are some indications for heart transplant unique to paediatrics:	
Paediatric Chronic Heart Failure	Failure to thrive/grow, due to heart disease, plastic bronchitis, or protein-losing enteropathy.
	Infants or very young children with single ventricle physiology and significant valvular disease, severe coronary anomalies or systemic ventricular dysfunction.
	Hypoplastic left heart syndrome may be treated with heart transplant as primary therapy.
	Previously palliated congenital heart disease (CHD) with severe valvular disease.
	Restrictive cardiomyopathy with reactive pulmonary hypertension.

1.2. Patients with advanced heart failure may not be appropriate for the waitlist if the following **contraindications to heart transplantation** exist. However, durable mechanical circulatory support may serve as a bridge to candidacy for transplant list in some instances.

CONTRAINDICATIONS TO HEART TRANSPLANTATION
Active infection: Acute infections should be treated first prior to consideration. Patients with well-controlled chronic infections like HIV, hepatitis C, and B with undetectable titers and no end-organ damage can be considered for a transplant.
Chronic liver disease (cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant)
Advanced kidney disease (glomerular filtration rate of less than 30 ml/min/1.73m^2) - unless being evaluated for multi-organ transplant.
Recent stroke or symptomatic, untreated peripheral vascular disease.
Uncontrolled diabetes mellitus with end-organ damage.
Active malignancy (other than neoplasms from skin) or malignancy with high rate of recurrence or

death, in which case the discussion should involve oncologists in shared decision-making to decide if a transplant is feasible or not.
Severe lung disease with a forced expiratory volume (FEV1) and forced vital capacity (FVC) less than 50% predicted or evidence of parenchymal lung disease.
Recent pulmonary embolism requiring anticoagulation (within the last 3 to 6 months), resulting in a significant pulmonary infarction.
Severe pulmonary hypertension (PH) with pulmonary artery systolic pressure greater than 60 mmHg and pulmonary vascular resistance (PVR) greater than 4 Wood units (if PH is refractory to medical therapy, then it is an absolute contraindication to heart transplant).
BMI > 35 kg/m2.
Multisystem disease requiring other transplant procedures (like renal, hepatic, or lung transplant).
Clinically severe symptomatic cerebrovascular disease.
Septic shock.
Lack of patient willingness or acceptance of transplant.
Psychosocial factors including: • lack of social support. • disabling psychiatric illness. • non-compliance with previous medical management. • active smoking or drug use (including alcohol, tobacco, and marijuana use), and not willing to quit.
Age greater than 70
In addition to the above, there are some contraindications for heart transplant unique to paediatrics:
Non-repairable venous structures such as situs inversus (relative).
Hypoplastic pulmonary arteries.
Severe pulmonary arteriovenous malformations.
Severe systemic-pulmonary arterial collaterals.
Severe cyanosis due to systemic pulmonary venous collaterals (relative).

2. Indications and contraindications for lung transplant.

2.1. The following are primary **indications for lung transplant evaluation and listing.**

Timely referral for transplant evaluation is key to enhancing patient survival on inotropes or mechanical support until an appropriate heart becomes available.

INDICATIONS FOR LUNG TRANSPLANT EVALUATION AND LISTING	
Chronic Obstructive Pulmonary Disease At time of listing, presence of one criterion is sufficient.	BODE index ≥7.
	FEV <15% to 20% predicted.
	Three or more severe exacerbations during the preceding year.
	One severe exacerbation with acute hypercapnic respiratory failure.
Cystic Fibrosis At time of listing.	Chronic respiratory failure.
	With hypoxia alone (partial pressure of oxygen [PaO] <8 kPa or <60 mm Hg).
	With hypercapnia (partial pressure of carbon dioxide [PaCO2] >6.6 kPa or >50 mm Hg).
	Long-term non-invasive ventilation therapy.
	Pulmonary hypertension.
	Frequent hospitalization.
	Rapid lung function decline.
	World Health Organization Functional Class IV
Interstitial Lung Disease At time of listing.	Decline in FVC ≥10% during 6 months of follow-up (note: a 5% decline is associated with a poorer prognosis and may warrant listing).
	A decline in DLCO ≥15% during 6 months of follow-up.
	Desaturation to <88% or distance <250 m on 6-minute-walk test or >50 m decline in 6-minute-walk distance over a 6-month period.
	Pulmonary hypertension on right heart catheterization or 2-dimensional echocardiography.
	Hospitalization because of respiratory decline, pneumothorax, or acute exacerbation.
Pulmonary Vascular Disease/Idiopathic Arterial Hypertension (IPAH) At time of listing.	NYHA Functional Class III or IV despite a trial of at least 3 months of combination therapy including prostanoids.
	Cardiac index of <2 liters/min/m2.
	Mean right atrial pressure of >15 mm Hg.
	6-minute walk test of <350 m.
	Development of significant haemoptysis, pericardial effusion, or signs of progressive right heart failure (renal insufficiency, increasing bilirubin, brain natriuretic peptide, or recurrent ascites).
Bronchiectasis and	Other indications include constrictive bronchiolitis, connective tissue

Sarcoidosis	diseases, pulmonary hypertension secondary to congenital cardiac conditions, and others.

2.2. Patients with end stage lung disease may not be appropriate for the waitlist if the following **contraindications to lung transplantation** exist.

ABSOLUTE CONTRAINDICATIONS TO LUNG TRANSPLANTATION	**RELATIVE CONTRAINDICATIONS TO LUNG TRANSPLANTATION** Individual patient cases should be carefully discussed by the Lung Transplant Committee to evaluate risk versus benefit before listing is considered.
Recent history of malignancy.	Age > 65 years and low physiologic reserve.
Significant dysfunction of another major organ system (such as the heart, liver, kidney, or brain) refractory to therapy.	Class I obesity (BMI ≥ 30 but < 35 kg/m2) particularly central.
Severe atherosclerotic disease with suspected or confirmed end-organ ischemia or dysfunction and/or coronary artery disease, not amenable to revascularization.	Severe malnutrition.
Acute medical instability, such as acute sepsis, myocardial infarction, and liver failure.	Severe osteoporosis.
Stroke within the last 30 days.	Prior extensive chest surgery with lung resection.
Uncontrollable bleeding disorder.	Infection with highly resistant or highly virulent pathogens.
Chronic infection with highly virulent and/or multidrug-resistant pathogens.	
Active Mycobacterium tuberculosis infection.	
Significant chest wall or spinal deformity likely to result in severe restriction after transplant.	
Class II or III obesity (BMI ≥ 32 kg/m2).	
HIV.	
Lack of willingness or acceptance of transplantation.	

Noncompliance with medical therapy.	
Lack of patient willingness or acceptance of transplant.	
Limited functional status (e.g. non-ambulatory, 6MWT result under 200 meters) with poor potential for post-transplant rehabilitation.	
Psychosocial factors including: • lack of social support. • disabling psychiatric illness. • non-compliance with previous medical management.	
Active smoking or drug use (including alcohol, tobacco, and marijuana use), and not willing to quit.	

APPENDIX 3: ORGAN DONOR PRE-OPERATIVE ASSESSMENT AND EVALUATION

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.

CHECKLIST FOR DECEASED DONOR EVALUATION		CHECK
PRELIMINARY EVALUATION	Physiologic and medical history of potential donor, including comorbidities, previous surgeries, and treatments, with special attention to chronic diseases, history of cancer, and infectious diseases.	
	Family Medical History.	
	Structural brain damage and cause of Death by Neurological Criteria.	
	Full physical examination (systems).	
	Measures, including height, weight, BMI, thoracic circumference.	
	Vital signs, including blood pressure, temperature, heart rate, FiO_2 and O_2 saturation.	
	Inotrope support, including drug, dose, and trend if possible.	
	Donor behavioural and social history, including alcohol and ither drug abuse (type, frequency, type of administration).	
	Donor management information to date.	
	Demographic information, including age, sex, ethnicity, nationality.	
	Organ Anatomy, biopsy (if necessary), and recovery information.	
	Performance status and nutritional status.	
DEATH INVESTIGATION (MEDICAL EXAMINER)	Verify documentation that the donor is not a death under investigation by the legal authorities OR that the authorities have released the donor for organ recovery.	
	Verify that all requests for testing, imaging, photographs, biopsies, or other items have been noted and are performed.	
LABORATORY TESTS	ABG results and ventilator settings. • For lung donors, need ABGs on FiO_2 100%, PEEP 5mmHg.	
	Blood group: • Sample 1 collection date, time, and result. • Sample 2 collection date, time, and result.	

	Must be separate collections.	
	Complete blood count.	
	Complete liver enzyme panel, including AST, ALT, GGT, alkaline phosphatase, total bilirubin, direct bilirubin.	
	Serum Creatinine, blood urea nitrogen (BUN), sodium, potassium, calcium, chloride, glucose, Cystatin C, HbA1c.	
	Full urine test with urine sediment examination, proteinuria in 24 hours.	
	Serum total and direct bilirubin.	
	Serum HDL and non-HDL Cholesterol, Triglyceride.	
	Coagulation test: PT, PTT Fibrinogen.	
	For women of childbearing age, perform hCG.	
MICROBIOLOGY AND INFECTIOUS DISEASE TESTS	Cultures:	
	Blood. • Result 1 (day/time collected). • Result 2 (day/time collected).	
	Sputum. • Result 1 (day/time collected). • Result 2 (day/time collected).	
	Urine culture test (2 times): • Result 1 (day/time collected). • Result 2 (day/time collected).	
	If cause of death was meningitis/meningoencephalitis, the CSF culture is mandatory.	
	Serologies:	
	Note: it is highly recommended to calculate haemodilution for all potential donors before obtaining blood samples for serology. The tests must have been carried out a maximum of 36 hours before organ retrieval.	
	HBV-RNA, HBV-NAT, and HBV markers: HBsAg, HBsAb, HBcAb, from donor samples obtained within 96 hours prior to organ procurement.	
	HCV Ab and HBV NAT from donor samples obtained within 96 hours prior to organ procurement.	

	HIV (1&2), HIV NAT, and HIV Ab from donor samples obtained within 96 hours prior to organ procurement.	
	Serology test for Cytomegalovirus (CMV) IgG - IgM, Toxoplasma, Epstein Barr, HTLV I-II, screening for syphilis (VDRL, TPHA).	
	SARS-CoV-2 (COVID-19) testing status (If testing is performed, include date, time, type of specimen, testing method, and results).	
	Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) pre-transplant of lungs.	
	MANTOUX.	
	Additional testing may be considered in selected cases where clinically indicated such as endemic or geographic risks, including PCR investigation as needed	
OTHER PRELIMINARY THORACIC EXAMINATIONS	Chest x-ray.	
	FOR LUNG DONOR CANDIDATES: Bronchoscopy.	
	FOR HEART DONOR CANDIDATES: ECG, echocardiogram (off inotropes or very low dose), cardiologic examination, including 12-lead electrocardiogram interpretation if available, information on dose of inotropes and trend if applicable and possible.	
SECOND-LEVEL INVESTIGATIONS	Specific examinations for previously suspected or diagnosed pathologies (e.g. chest CT scan, mammogram, and US).	
	Angio-CT scan or Angio-MR imaging.	
	Left heart catheterization, if requested.	
	Right heart catheterization, if requested.	
	Coronary angiogram, if requested.	
	Sputum gram stain, with description of sputum.	
ACCEPTABLE HEART DONOR CRITERIA	Echocardiogram results: • Ejection fraction 55-65%. • Posterior left ventricular wall thickness <11mm. • Septal wall thickness <11mm. • Absence of any valvular disease, damage, and/or vegetations. No wall motion abnormalities.	
	Age, left heart catheterization (if assessed), and donor-recipient weight match will be evaluated on a donor-candidate basis.	

ACCEPTABLE LUNG DONOR CRITERIA	Donor PAO_2/FIO_2 ratio >400 (FiO_2 = 1.0, PEEP = 5-8 cm H_2O).	
	Smoking history <20 pack-year.	
	Normal chest x-ray without infiltrate.	
	Normal bronchoscopy without significant secretions.	
	Absence of organisms on sputum gram stain.	
EVALUATION OF DONOR HEART AND/OR LUNGS AT THE PROCUREMENT OPERATING THEATRE	Verification of Death by Neurological Criteria.	
	Verification of consent for donation.	
	Verification of ABO and crossmatch compatibility to the recipient.	
	Run repeat HBV, HCV, and HIV tests, if requested.	
	Review serologies: • CMV (IgM, IgG). • EBV (IgM, IgG). • Toxoplasmosis (IgM, IgG). • HTLV I – II.	
	Review supplies: • Tubing for preservation solutions. • Sternal saw. • Surgical equipment. • Bronchoscope. • Saline. • Sterile bags or container for organs, ice bucket and ice, or other preservation device.	
	• Review any new information about the donor history since organ acceptance or any changes in the donor since acceptance to arrival at the procurement centre.	

APPENDIX 4: PRE-OPERATIVE HEART OR LUNG TRANSPLANT CHECK-LIST

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the checklist were followed.

PRE-HEART OR LUNG TRANSPLANT CHECK-LIST	
RECIPIENT CANDIDATE CHECKLIST	**CHECK**
Select an appropriate recipient candidate according to: • Donor/recipient ABO compatibility. • Donor/recipient clinical match. • Donor demographics (e.g. size) appropriate for recipient. • Medical urgency, time on waiting list.	
Call the selected recipient candidate and admit to hospital.	
Stop intended recipient's anticoagulation and anti-arrhythmic medications if possible. Stop ACE inhibitors if possible.	
Confirm recipient identity and basic medical information, including: • Recipient unique identifier (i.e., Medical Record Number). • Recipient blood type.	
Review pre-transplant workup (see Appendix 1) and any subsequent serial results, re-ordering tests as necessary to confirm fitness for procedure.	
Order chest x-ray (urgent).	
Order ECG (urgent).	
• Order Labs (urgent) - Complete blood count (CBC), renal function panel, arterial blood gas test, coagulation studies (PT, PTT, aPTT, platelets), Anti-HLA Ab testing (single antigen bead).	
Update Serologies: • SARS-CoV-2 (COVID-19) (nasal swab). • CMV (IgM, IgG). • EBV (IgM, IgG). • Toxoplasmosis (IgM, IgG). • HTLV I – II.	
Request for Anesthesiologist re-evaluation.	
Alert ICU of pending post-operative admission.	
Order 4 units packed red blood cells (PRBC) and 4 units fresh frozen plasma (FFP).	

Activate the operating teams and alert staff of OT times.	
Review informed consent for heart or lung transplant procedure *(obtained at completion of successful work up and listing).*	
Obtain separate written informed consent for heart or lung transplant surgery.	
Perform patient preoperative surgical preparation.	
Administer induction immunosuppression (including premedications).	
Prescribe antibiotic prophylaxis.	
If donor/recipient CMV mismatch, prescribe postoperative CMV prophylaxis.	
HEART OR LUNG GRAFT CHECKLIST	**CHECK**
Confirm donor consent, identity, and donor/recipient matching, including blood type and ABO compatibility.	
Review documentation of Death by Neurological Criteria.	
Review donor demographic and clinical characteristics, including any new information about donor history or changes in the donor since acceptance of the organ.	
Evaluate graft anatomy and quality prior to procurement.	
Prepare the graft for implantation at back-table.	
Perfuse the organ: • FOR LUNGS: 4L cool preservation solution. • FOR HEARTS: 2L cool preservation solution.	
Place graft either in static cold storage in sterile bags on ice, or on a machine perfusion pump.	
Monitor machine perfusion activity, if applicable.	
HEART OR LUNG TRANSPLANT CHECKLIST	**CHECK**
Prior to induction of anesthesia, confirm with the patient their identity, planned procedure, informed consent, any reported allergy.	
Review: • FOR LUNGS: pre-transplant ABG + CXR • FOR HEARTS: pre-transplant echocardiogram.	
Confirm machine perfusion data, if applicable.	
Check availability of required specific surgical instruments and devices.	
Fill in the WHO Surgical Safety Checklist.	
Place CVC and arterial line (after induction of anesthesia).	
Place three-way Foley catheter (after induction of anesthesia).	
Prepare the surgical field.	

Before skin incision, call for Timeout for WHO Surgical Safety Checklist.	
Conduct verification required upon organ receipt, prior to anastomosis, with the intended recipient in the room, of: • Donor and recipient identification. • Organ type. • Blood type of donor and recipient. • ABO compatibility or intended incompatibility. • The correct organ has been identified for the correct recipient.	

APPENDIX 5: PARAMETERS FOR MONITORING GRAFT FUNCTION RECOVERY AND CLINICAL SURVEILLANCE FOR EARLY SURGICAL COMPLICATIONS

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. The health facility shall report to DHA, within seventy-two (72) hours of the health facility being made aware, if any of the following may have occurred:
    2.1. A transplant of an incorrect organ into an organ recipient.
    2.2. A transplant of an organ into the incorrect recipient.
3. Heart Graft Function
    3.1. Heart primary graft dysfunction presents as ventricular dysfunction occurring within 24 hours post-transplant where there is no identifiable secondary cause such as hyperacute rejection, pulmonary hypertension, or known surgical complications.

Treatment of heart PGD	• Medical management with inotropic support:
	  ○ Consider the use of levosimendan.
	  ○ For right ventricle primary graft dysfunction, consider use of nitric oxide and phosphodiesterase inhibitor (sildenafil).
	• Mechanical circulatory support is indicated when medical management is not sufficient to support the newly transplanted graft.

Body temperature	In presence of fever, the following investigations are indicated: • Full blood count. • Hemoculture. • Urine and sputum cultures. • Chest x-ray. • Wound inspection.

Laboratory tests	• Full blood count, glucose, BUN, creatinine, sodium, potassium, venous blood gas test; if indicated total and pancreatic amylases, calcium; frequency: TID on POD 1, 2, 3 --> BID from POD 4 to POD 6 --> OD from POD 6 to POD 10. • Liver function panel, frequency: on POD 1 --> thereafter once a week. • CMV-DNA in blood: after 1-2 weeks post-transplant or earlier in presence of signs of gastroenteritis, fever, leucopiastrinopenia, liver transaminases serum level increase --> once a month for the first 4 months after transplant --> thereafter when clinically indicated. ○ In presence of Donor+/Recipient-, ganciclovir is indicated right after transplant and continued until conversion to oral valganciclovir prophylaxis is possible. CMV-DNA determination performed every 15 days. • Immunosuppressant trough levels: Once drug is started after transplant, OD for the first two weeks --> twice weekly for the next 2 weeks --> weekly for the next 8 weeks --> thereafter once a month. • Single antigen bead flow test for donor specific antibodies: once weekly for the first 2 weeks --> at 1 month post-transplant --> at 3 months post-transplant --> at 1-year post-transplant.
Graft US scan with Color Doppler	Three times a week until POD 10 or when clinically indicated.

4. Lung Graft Function

4.1. The goals for treating primary lung graft dysfunction are to avoid excessive fluid administration while providing adequate perfusion of vital organs and the bronchial anastomoses.

4.2. Some renal dysfunction should be tolerated, with a low threshold for temporary ultrafiltration or dialysis support.

4.3. For fluid management:

4.3.1. Keep the haematocrit in the range of 25% to 30%.

4.3.2. Correct coagulopathy with fresh-frozen plasma or specific coagulation factor replacement.

4.4. Ventilatory management:

4.4.1. Provide protective ventilation using smaller tidal volumes (6 to 8 ml per kilogram of body weight).

4.4.2. Emphysema patients with PGD after single-lung transplant may require independent lung ventilation.

4.4.3. Consider providing nitric oxide in the event of hypoxemia and/or elevated pulmonary arterial pressure.

4.4.4. Consider low-dose prostaglandin E1 infusion for treating severe PGD.

4.4.5. Consider exogenous surfactant therapy.

4.4.6. Consider ECMO as a back-up in the event of severe, life-threatening PGD.

APPENDIX 6: SURVEILLANCE FOR HEART OR LUNG TRANSPLANT COMPLICATIONS AFTER HOSPITAL DISCHARGE

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.

2. Heart Follow-Up Visits and Test Schedule:

   2.1. The purpose of the follow-up visits is to monitor for rejection and screen for adverse events.

   2.2. The frequency of follow-up visits for heart transplant recipients will depend on the time from heart transplant and the post-operative clinical course.

      2.2.1. The frequency of follow-up should be increased if complications occur, particularly in patients with challenging medical or psychosocial conditions.

      2.2.2. The frequency of follow-up visits and schedule presented in the table below serve merely as an example and should be tailored to each center.

      2.2.3. As non-invasive modalities (e.g. Gene Expression Profiling) improve, it is likely that the need for biopsies and serial conventional angiography will be reduced accordingly.

Heart Follow-Up Visits and Testing Schedule

Month				**1**				**2**		**3**	**4**	**5**	**6**
Week	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**10**	**12**	**16**	**20**	**24**
Clinic visit			X	X		X		X		X	X	X	X
Lab tests			X	X		X		X		X	X	X	X
ECG			X			X		X		X			X
Echo	X	X	X	X		X		X		X			X
Biopsy[1]	X	X	X	X				X		X	X		X
Single antigen bead flow test for DSAs	X	X		X						X			

Right heart study	X			X						X			X
CMV DNA	X			X				X		X	X	X	X
EBV PCR				X				X		X	X	X	X
EBV Serology										X			X
PRA (DSA)				X						X			X
CPET													X
Skin cancer screening													X
Endocrinology clinic													X
Dental exam													X

Year						**1**				**2-5**	**>5**
Month	**7**	**8**	**9**	**10**	**11**	**12**	**15**	**18**	**21**	**>24**	**>60**
Clinic visit	X	X	X	X	X	X	X	X	X	X	
Lab tests	X	X	X	X	X	X	X	X	X	X	X
ECG		X				X		X		X	X
Echo		X				X		X		X	X
Biopsy[2]			X			X		X		X	X
Single antigen bead flow test for DSAs						X					
Right heart study						X				X	X
Dobutamine echo/ SPECT/CTA	Starting in the fifth year – to be done every other year alternating with coronary angiography										
CMV DNA	X	X	X	X	X	X				X	X
EBV PCR	X	X	X	X	X	X		X		X	X
EBV Serology			X			X				X	X
Coronary angiography						X				4X	
Urine 24h protein						X				X	X
Malignancy screening						X					
Chest X-ray						X				X	X
PSA						X				X	X

[1] Other non-invasive methods may be used as appropriate
[2] Other non-invasive methods may be used as appropriate

PRA (DSA)						X				X	X
Bone density						X				X	X
CPET						X				X	X
Skin cancer screening						X		X		X	X
Endocrinology clinic						X				X	X
Dental exam						X				X	X

3. Lung Transplant Follow-Up Visits and Test Schedule:

Cardiovascular diseases	• Follow up cardiologic examination and tests as appropriate.
Infectious complications	• HIV/HCV/HBV NAT: between 4-8 weeks post-transplant. • CMV-DNA: once a month for the first 4 months after transplant and thereafter when clinically indicated. • HBV and HCV: once a year in serum negative recipients, according to hepatologic indications in serum positive recipients. • HHV8 –HPV, if clinically indicated. • EBV Serology: every three months post-transplant for the first year, then annually or when clinically indicated.
Oncologic complications	• Standard clinical screening for prostate cancer (PSA, urologic examination), breast cancer (mammography, US), cervix cancer (PAP test), GI cancer (fecal occult blood test, EGDS, colonoscopy), according to local guidelines. • Dermatologic examination: every year. • Abdomen US: every year.
Bone complications	• Serum calcium, phosphates, ALP, magnesium, albumin, complete urine test, PTH: every 6 months. • 25OHD3 e CTX, lumbar spine x-ray, DEXA, endocrinologic examination, if clinically indicated.

APPENDIX 7: IMMUNOSUPPRESSIVE THERAPY FOR HEART AND LUNG TRANSPLANT RECIPIENTS

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.

2. For all doses below, paediatric patients should be dosed according to body size.

POD 0	Induction therapy: • Basiliximab (IL2 receptor antagonist): 20mg i.v., 2 hours before Transplant. Maintenance therapy: • Methylprednisolone 500 mg i.v. in the operating room at the vessels declamping time. • MMF 1g per os BID.
POD 1-2	• Methylprednisolone 250 mg i.v. OD. • MMF 1g per os BID. • Tacrolimus 0.0375mg/kg per os BID (in rapid steroid descaling protocol).
POD 3 -->	Rapid steroid descaling protocol: • Methylprednisolone 20 mg per os OD. • MMF 1g per os BID. • Tacrolimus 0.0375mg/kg per os BID.
	Gradual steroid descaling protocol: • Methylprednisolone 150mg (POD3) --> 100mg (POD4) --> 75mg (POD5) --> 50mg (POD6) --> 20mg (POD7). • MMF 1g per os BID. • Tacrolimus is initiated when the renal function trend is normalizing, within POD7.

3. In recipients with high immunologic risk, a double induction therapy may be indicated:

    3.1. Either:

        3.1.1. Antithymocyte globulin (ATG) 1.5 mg/Kg i.v OD from POD 0 --> POD 7.

            a. Lymphocyte subset counts should be monitored and ATG is only re-

dosed if CD4 and CD8 counts rise to or above 15.

3.1.2. Basiliximab 20 mg i.v OD 2 hrs before transplant and re-dose on POD 4.

3.2. Methylprednisolone 500mg at declamping time, followed by progressive descaling protocol.

3.3. MMF 750 mg per os BID.

APPENDIX 8: PROTOCOLS OF ACUTE REJECTION THERAPY

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. For all doses below, paediatric patients should be dosed according to body size.
3. Exclusion of other potential cause of graft dysfunction, endomyocardial biopsy proven:

Acute cell-mediated rejection	• Methylprednisolone 1g (1000mg) i.v OD x 3 days. • In presence of no responsive rejection or rapidly relapsing rejection: ATG 1.5 mg / Kg OD x 7-14 days.
Acute antibody mediated C4d positive rejection (BANFF grade I, II)	Methylprednisolone 10 mg / Kg i.v. x 3 days, thereafter 20 mg OD. • DAY 1: High dose Immunoglobulins (2g / Kg) or CMV specific Immunoglobulins (100mg / Kg), STAT. • DAY 2: Rituximab 375 mg / m2.
Severe Acute antibody mediated positive rejection (BANFF grade III), thromboitic microangiopathy	Same protocol as for Grade II. + Plasmapheresis on DAY 1, 2, 3, 5 and 7, and in cases of severe AMR or high risk for AMR, Eculizumab 600 – 1200mg per day. DAY 7, after plasmapheresis: High dose Immunoglobulins (2g / Kg) or CMV specific Immunoglobulins (100mg / Kg). DAY 8: Rituximab 375mg / m2. Monitoring of DSA: on DAY 1 before therapy initiation, DAY 3 after plasmapheresis, DAY 8 after Rituximab and Eculizumab administration.

4. Tacrolimus therapy is maintained with target trough levels 10-15 ng/ml, and MMF 1g BID.
5. Antibiotic prophylaxis must be instituted:
   - 5.1. Ganciclovir at dosage adjusted to renal function within 10 days of transplant for 3-6 months, for CMV.
   - 5.2. Fluconazole 100mg OD x 1 month, Nistamine per os x 1 month.
   - 5.3. Trimethoprim Sulfamethoxazole 80 mg OD x 6-12 months, for Pneumocystis jiroveci.

APPENDIX 9: PROTOCOLS OF CHRONIC ALLOGRAFT DYSFUNCTIONS (CAD) MANAGEMENT

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.

2. Heart Protocols for CAD Management:

   2.1. Heart chronic dysfunction is generally related to coronary artery disease, though some patients may develop a restrictive disease.

Treatment of non-immunologic factors	• Angioplasty or other procedures to improve blood flow. • Mechanical circulatory support is indicated when medical management is not sufficient to support the newly transplanted graft. • Prescribe corticosteroid such as prednisone, possibly alongside ATG.
Treatment of immunologic factors	• Plasmapheresis followed by CMV specific Immunoglobulins (100mg / Kg) on DAY 1, 3, 5, 7. • A course of steroids to augment immunosuppression.

   2.2. CNI therapy conversion to m-Tor inhibitors:

Indications	• Recipient who develops neoplasia. • Recipient who develops chronic allograft vasculopathy. • The occurrence of severe CNI related side effects. • GFR <40 ml/min.
Contraindications	• Proteinuria > 800mg/die. • Hyperlipemia despite adequate therapy with statin.
Scheme	• Progressive imbrication. • "Stop and Go".

2.3. CMV Infection Therapy

Prophylaxis	Receptive recipient (D+/R-)	• Valganciclovir 450 mg OD (then according TDM) x 6-9 months. • Viremia control every 2 weeks (check for viremia with CMV PCR or CMV DNA testing).
	Patient under acute-rejection therapy or ATG	• Ganciclovir i.v. x 6 weeks. • Viremia control every week.
Preemptive therapy	Patients with CMV-DNA positivity but no clinical manifestation	• Valganciclovir 450 mg per os BID (then according TDM). • Viremia control every week. • Therapy withdrawal after 3 consecutive negative CMV-DNA.
Therapy	Patients with CMV-DNA positivity and clinical manifestation	• Ganciclovir i.v. according to renal function and body weight (then according TDM). • Viremia control every week. • Therapy withdrawal after 3 consecutive negative CMV-DNA.

3. Lung Protocols for CLAD Management:

3.1. Chronic lung allograft dysfunction (CLAD) is a substantial and persistent decline (≥20%) in measured FEV_1 value from reference (baseline) value, after adequate treatment of infection or rejection.

3.1.1. The baseline value is computed as the mean of the best two post-operative FEV_1 measurements (taken >3 weeks apart).

3.2. CLAD can present either as a predominantly obstructive pattern, a restrictive pattern, or a mixed obstructive and restrictive pattern that is not explained by other conditions that may lead to chronic loss of allograft function.

3.3. Basic phenotypes of CLAD:

	Obstruction (FEV_1/FVC <0.7)	Restriction (TLC decline ≥10% from baseline)	CT Opacities
Bronchiolitis obliterans syndrome (BOS)	Yes	No	No
Restrictive allograft syndrome (RAS)	No	Yes	Yes
Mixed	Yes	Yes	Yes
Undefined	Yes	No	Yes
	Yes	Yes	No

3.4. Tools for diagnosis of CLAD phenotype and suggested follow-up:

3.4.1. Investigate patients with a first drop in FEV_1 of ≥10% and reassess within 4 to 6 weeks, especially if a new treatment has been initiated.

a. Conduct transbronchial biopsy and bronchoalveolar lavage.

3.4.2. Assess spirometry at every clinic visit.

a. If bronchodilator response is performed, use post-bronchodilator FEV_1 values to exclude other aetiologies for obstruction.

b. In stable CLAD patients with stable FEV_1 or a very slow decline in FEV_1, measure lung function at least every 3-4 months.

3.4.3. Measure TLC at 3 and 6 months after transplant and annually thereafter, and if FEV1 changes ≥10% from previous values.

3.4.4. Conduct CT scans without contrast media in all lung transplant recipients at 6-month follow-up.

a. Repeat CT scans when CLAD is diagnosed and if there are opacities on the chest x-ray that are not explained by other causes (e.g. infection, drug toxicity, rejection, malignancy).

3.5. Treatment options for CLAD are limited, and re-transplantation may be the only therapeutic option for advanced CLAD in well-selected patients.

3.5.1. For BOS, avoid sustained administration of high-dose corticosteroids.

3.5.2. Other potential treatment options include:

BOS	• Conversion of cyclosporine to tacrolimus. • Trial of azithromycin for ≥8 weeks. • Fundoplication for documented gastroesophageal reflux in selected cases. • Total lymphoid irradiation. • Extracorporeal photopheresis.
RAS	• Consider use of pirfenidone, nintedanib, or alemtuzumab.

3.6. CMV Infection Therapy

Prophylaxis	Receptive recipient (D+/R-)	• Valganciclovir 450 mg OD (then according TDM) x 6-9 months. • Viremia control every 2 weeks. • Consider reducing immunosuppression.
	Patient under acute-rejection therapy or ATG	• Ganciclovir i.v. x 6 weeks. • Viremia control every week.
Preemptive therapy	Patients with CMV-DNA positivity but no clinical manifestation	• Valganciclovir 450 mg per os BID (then according TDM). • Viremia control every week. • Therapy withdrawal after 3 consecutive negative CMV-DNA.
Therapy	Patients with CMV-DNA positivity and clinical manifestation	• Ganciclovir i.v. according to renal function and body weight (then according TDM). • Viremia control every week. • Therapy withdrawal after 3 consecutive negative CMV-DNA.

3.7. EBV Infection Therapy

Prophylaxis	Receptive recipient (D+/R-)	• Ganciclovir i.v. x 12 weeks according to body weight • Monitor for lymphoproliferative disease. • Consider reducing immunosuppression.

APPENDIX 10: KEY PERFORMANCE INDICATORS (KPIs)

1. Process.

1.1. Referral To Listing.

Referral to Listing	
Main Domain:	Process.
Subdomain:	Efficiency.
Indicator Definition:	Median number of days from the date the patient was referred to the transplant unit, to the date upon which the patient was listed for transplant.
Calculation:	Arrange the data points from smallest to largest. If the number of data points is odd, the median is the middle data point in the list. If the number of data points is even, the median is the average of the two middle data points in the list.
Target:	30
Methodology:	Median calculation.
Measuring Unit:	Number of days between referral and listing.
Reporting Frequency:	Annually.
Desired Direction:	Lower is better.
Rationale:	Metric of access to transplant.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.

1.2. Observed Pre-Transplant Mortality Rate.

Observed Pre-Transplant Mortality Rate	
Main Domain:	Process.
Subdomain:	Effectiveness.
Indicator Definition:	The rate at which patients expire due to complications from organ failure or are removed from the waiting list for being too sick to transplant. The denominator is calculated as person-years, i.e. the cumulative number of years all waitlisted heart or lung transplant patients at a hospital have been on the waitlist, within the last year.
Calculation:	Numerator: Total number of deaths of patients waiting for either a heart or lung transplant due to complications from organ failure or are removed from the waiting list for being too sick to transplant, within the last year. Denominator: The total number of person-years individuals are on the waiting list for a heart or lung transplant within the last year.
Target:	<=10%
Methodology:	Numerator/Denominator.
Measuring Unit:	Percentage of patients who expire while waiting for a transplant or are removed from the waiting list for being too sick for transplant.
Reporting Frequency:	Annually.
Desired Direction:	Lower is better.
Rationale:	Metric of access to transplant.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.

1.3. Transplant Rate.

Transplant Rate	
Main Domain:	Process.
Subdomain:	Effectiveness.
Indicator Definition:	The rate at which patients receive a transplant. The denominator is calculated as person-years, i.e. the cumulative number of years all waitlisted heart or lung transplant patients at a hospital have been on the waitlist, within the last year.
Calculation:	Numerator: Total number of heart or lung transplants within the last year. Denominator: The total number of person-years individuals are on the waiting list for a heart or lung transplant within the last year.
Target:	>50%
Methodology:	Numerator/Denominator x 100.
Measuring Unit:	Percentage of patients who receive a transplant per 100 person-years waiting for a transplant.
Reporting Frequency:	Annually.
Desired Direction:	Higher is better.
Rationale:	Metric of access to transplant.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.

2. Outcomes

2.1. ICU Length of Stay.

ICU Length of Stay	
Main Domain:	Outcomes.
Subdomain:	Effectiveness and efficiency.
Indicator Definition:	Median number of days in the ICU after transplant surgery.
Calculation:	Arrange the data points from smallest to largest. If the number of data points is odd, the median is the middle data point in the list. If the number of data points is even, the median is the average of the two middle data points in the list.
Target:	< 10
Methodology:	Median calculation.
Measuring Unit:	Calendar days.
Reporting Frequency:	Monthly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and effectiveness.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.

2.2. Early Hospital Readmission

Early Hospital Readmission	
Main Domain:	Outcomes.
Subdomain:	Patient safety.
Indicator Definition:	Percentage of patients readmitted to the hospital within 14 days post-transplant.
Calculation:	Numerator: Total number of heart or lung patients readmitted to the hospital within 14 days after discharging post-transplant. Denominator: The number of patients who received a heart or lung transplant.
Target:	< 20%
Methodology:	Numerator/Denominator x 100.
Measuring Unit:	Percentage of early hospital readmissions.
Reporting Frequency:	Quarterly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and patient safety.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.

2.3. Ninety (90) Day Patient Survival Rate.

Ninety (90) Day Patient Survival Rate	
Main Domain:	Outcomes.
Subdomain:	Effectiveness.
Indicator Definition:	The percentage of transplanted hearts and lungs where the patient survives 90-days post-transplant.
Calculation:	Numerator: The total number of patients alive at ninety (90) days post-transplant. Denominator: The total number of patients transplanted with hearts or lungs.
Target:	>85% for heart transplant. >80% for lung transplant.
Methodology:	Numerator/Denominator x 100.
Measuring Unit:	Percentage of ninety (90) day patient survival post-transplant.
Reporting Frequency:	Quarterly.
Desired Direction:	Higher is better.
Rationale:	Metric of success with surgical outcomes and effectiveness.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.

2.4. One-Year Patient Survival Rate.

One-Year Patient Survival Rate	
Main Domain:	Outcomes.
Subdomain:	Effectiveness.
Indicator Definition:	The percentage of transplanted hearts and lungs where the patient survives one-year post-transplant.
Calculation:	Numerator: The total number of patients alive at one-year post-transplant. Denominator: The total number of patients transplanted with hearts or lungs.
Target:	>83% for heart transplant. >80% for lung transplant.
Methodology:	Numerator/Denominator x 100.
Measuring Unit:	Percentage of one-year patient survival post-transplant.
Reporting Frequency:	Quarterly.
Desired Direction:	Higher is better.
Rationale:	Metric of success with surgical outcomes and effectiveness.
KPI Source:	DHA Standards for Heart and Lung Transplant Services.