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STANDARDS FOR LIVER AND PANCREAS TRANSPLANT SERVICES

Version (1)

Issue date: 27/05/2024

Effective date: 27/07/2024

Health Policies and Standards Department

Health Regulation Sector (2024)



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 Liver and Pancreas Transplant Service 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

Liver transplantation is the removal of a whole liver or a segment of a liver from a deceased or living donor and transfer into a patient with end-stage liver disease. Pancreas transplantation is the removal of a pancreas from a deceased donor and transfer into a patient with insulin-dependent diabetes. This document is developed to ensure that liver and pancreas 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 liver or pancreas transplant services, the health facility requirements, the healthcare professional requirements, the consent for organ transplant, medication requirements, criteria for continuity of the liver transplant service and the pancreas transplant service, assessment and evaluation of donor candidates and pre-operative assessment and evaluation of recipient candidates. This standard is aligned with all the applicable United Arab Emirates (UAE) laws and legislations related to the subject.

These 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.



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- 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 transplantation 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 UAE.

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.

Living Donor is a living human being from whom organs tissues or cells have been retrieved for the purpose of transplantation and who has one of the following possible relationships with the recipient:

- Genetic Relative up to fourth degree of kinship;
- Emotionally Related: Spouse up to fourth degree of kinship;
- Reciprocal donor in accordance with Federal Decree No. (25) of 2023; or
- Unrelated or Non-Related: Not genetically or emotionally related, approved by special Committee as coordinated by the National Center.

Liver or Pancreas 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.

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 decisions 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 review of a potential donor or recipient, which includes diagnostic assessments such as laboratory tests, imaging, cancer screening and other evaluations for the purpose of ensuring successful transplant outcomes.



ABBREVIATIONS

Ab	:	Antibody
ABG	:	Arterial Blood Gas
ACE	:	Angiotensin-Converting Enzyme
Ag	:	Antigen
AIH	:	Autoimmune Hepatitis
ALF	:	Acute Liver Failure
ALG	:	Anti-Lymphocyte Globulin
ALP	:	Alkaline Phosphatase
ASA	:	Acetylsalicylic Acid (e.g. Aspirin)
ATG	:	Antithymocyte Globulin
AZA	:	Azathioprine
BID	:	Bis in Die (Twice Per Day)
BKV	:	B.K. Virus
BMD	:	Bone Mass Density
BMI	:	Body Mass Index
BSA	:	Body Surface Area
BUN	:	Blood Urea Nitrogen
CAD	:	Chronic Allograft Dysfunction
CBC	:	Complete Blood Count
CCSU	:	Critical Care Support Unit
CCSUC	:	Critical Care Support Unit Coordinator



CMP	:	Complete Metabolic Panel
CMV	:	Cytomegalovirus
CNI	:	Calcineurin Inhibitors
COVID	:	Coronavirus Disease
CPP	:	Cerebral Perfusion Pressure
CPSI	:	Carbaryl Phosphate Synthetase I
CT	:	Computed Tomography
CTX	:	C-Terminal Telopeptides
CVC	:	Central Venous Catheter
DEXA	:	Dual X-Ray Absorptiometry
DGF	:	Delayed Graft Function
DHA	:	Dubai Health Authority
DNA	:	Deoxyribonucleic Acid
DNC	:	Death by Neurological Criteria
EBV	:	Epstein Barr Virus
ECG	:	Electrocardiogram
EGDS	:	Esophagogastroduodenoscopy
ERCP	:	Endoscopic Retrograde Cholangiopancreatography
ESRD	:	End Stage Renal Disease



ESLD	:	End Stage Liver Disease
FAP	:	Familial Amyloid Polyneuropathy
FFP	:	Fresh Frozen Plasma
GFR	:	Glomerular Filtration Rate
GGT	:	Gamma Glutamyl Transpeptidase
GI	:	Gastrointestinal
GVHD	:	Graft-Versus-Host Disease
HAS	:	Hepatic Artery Stenosis
HAT	:	Hepatic Artery Thrombosis
HBV	:	Hepatitis B Virus
HCC	:	Hepatocellular Carcinoma
HCV	:	Hepatitis C Virus
HDL	:	High Density Lipoproteins
HFG	:	Health Facility Guidelines
HH	:	Hereditary Hemochromatosis
HHV8	:	Human Herpesvirus-8
HIV	:	Human Immunodeficiency Virus
HLA	:	Human Leukocyte Antigens
HPV	:	Human Papillomavirus



HRS	:	Health Regulation Sector
HSV	:	Herpes Simplex Virus
HTK	:	Histidine–Tryptophan–Ketoglutarate
IBW	:	Ideal Body Weight
ICP	:	Intracranial Pressure
ICU	:	Intensive Care Unit
IgG	:	Immunoglobulin G
IgM	:	Immunoglobulin M
IL2	:	Interleukin-2
INR	:	International Normalized Ratio
IPV	:	Inactivated Polio Vaccine
IVC	:	Inferior Vena Cava
KPI	:	Key Performance Indicator
LDH	:	Lactate Dehydrogenase
LDL	:	Low Density Lipoprotein
LFI	:	Liver Frailty Index
LFT	:	Liver Function Test
MELD	:	Model for End-stage Liver Disease
MMA	:	Methylmalonic Acidemia



MMF	:	Mycophenolate Mofetil
MMR	:	Measles, Mumps, Rubella
MOHAP	:	Ministry of Health and Prevention
MRCP	:	Magnetic Resonance Cholangiopancreatography
MRI	:	Magnetic Resonance Imaging
m-TOR	:	Mammalian Target of Rapamycin
NASH	:	Nonalcoholic Steatohepatitis
NAT	:	Nucleic Acid Test
NPO	:	Nil Per Os (Nothing by Mouth)
OD	:	Once Daily
OR	:	Operating Room
OS	:	Mouth (i.e. Per Mouth)
OT	:	Operating Theatre
OTC	:	Ornithine Transcarbamylase
OTU	:	Organ Transplant Unit
PAK	:	Pancreas After Kidney Transplant
PAP	:	Papanicolaou
PBC	:	Primary Biliary Cirrhosis
PFIC	:	Progressive Familial Intrahepatic Cholestasis



POD	:	Postoperative Day
PRBC	:	Packed Red Blood Cells
PSA	:	Prostate-Specific Antigen
PSC	:	Primary Sclerosing Cholangitis
PT	:	Prothrombin Time
PTA	:	Pancreas Transplant Alone
PTC	:	Percutaneous Transhepatic Cholangiography
PTH	:	Parathyroid Hormone
PTLD	:	Posttransplant Lymphoproliferative Disease
PTT	:	Partial Thromboplastin Time
QNAT	:	Quantitative Nucleic Acid Test
RAI	:	Rejection Activity Index
RI	:	Resistive Index
RN	:	Registered Nurse
RNA	:	Ribonucleic Acid
SARS	:	Severe Acute Respiratory Syndrome
SGA	:	Subjective Global Assessment
SOP	:	Standard Operating Procedure
SPK	:	Simultaneous Pancreas and Kidney Transplant
SPLK	:	Simultaneous Pancreas and Living Donor Kidney Transplant



STAT	:	Statim (Immediately)
TDM	:	Therapeutic Drug Monitoring
TID	:	Ter In Die (Twice Per Day)
TIPS	:	Transhepatic Intrajugular Portosystemic Shunt
TPHA	:	Treponema Pallidum Hemagglutination
UAE	:	United Arab Emirates
US	:	Ultrasound
UW	:	University of Wisconsin
VDRL	:	Venereal Disease Research Laboratory
VLDL	:	Very Low-Density Lipoproteins
WBC	:	White Blood Cell
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 Transplantation¹ 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 liver and pancreas transplant services, with an aim to assure the provision of the highest levels of safety and quality for providing liver and pancreas transplant services in Dubai Health Authority (DHA) licensed health facilities.

Liver transplant surgery places a healthy liver or liver segment from a donor into a recipient whose liver no longer functions well enough to support independent existence. Pancreas transplant surgery places a healthy pancreas from a suitable donor into a recipient having diabetes mellitus, to provide pancreatic endocrine function to the recipient.

The donor liver for a liver transplant can come from either a deceased donor or a living donor.

The donor pancreas for a pancreas transplant comes from a deceased donor.

2. SCOPE

2.1. Adult and pediatric liver transplant services in DHA licensed health facilities.

¹ Referred to as The National Center throughout this document.



2.2. Adult pancreas transplant services in DHA licensed health facilities.

3. PURPOSE

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

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

4. APPLICABILITY

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

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

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing liver or pancreas transplant services shall adhere to the UAE Laws and Dubai regulations.

5.2. Hospitals opting to provide liver or pancreas 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 liver or pancreas transplant services shall apply to the Health Regulation Sector (HRS) and comply with the DHA licensure and administrative requirements available on the DHA website 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 commencing with a liver or pancreas transplant service.

5.4.2. The hospital laboratory must be accredited as per the DHA Clinical Laboratory accreditation policy before commencing with a liver or pancreas transplant service.

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

5.6. The hospital shall have Standard Operating Procedures (SOPs) related to the Liver Transplant Service or Pancreas 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 as follows but not restricted to the following and provide documented evidence to HRS upon request:

5.7.1. Patient Continuity of Care

5.7.2. Patient acceptance criteria and exclusion criteria as elaborated in **Appendix 1** (liver) and **Appendix 2** (pancreas).

5.7.3. Patient assessment and workup, including the requirements listed in **Appendix 3** (liver), **Appendix 4** (paediatric liver) and **Appendix 5** (pancreas).

5.7.4. Blood type determination of the candidate, which must include the requirements listed in **Appendix 3** (liver) and **Appendix 5** (pancreas).

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



- 5.7.6. Recipient selection criteria.
- 5.7.7. 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.
- 5.7.8. 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 6** (liver) and **Appendix 7** (pancreas).
- 5.7.9. Pre-Transplant work up process, including the requirements listed in **Appendix 6** (liver) and **7** (pancreas).
- 5.7.10. 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 8** specific to liver and pancreas deceased donor assessment and evaluation.
- 5.7.11. Post-Transplant follow up protocol, including the requirements listed in **Appendices 9 through 15** (liver) and **16 through 20** (pancreas).
- 5.7.12. Patient health records must be maintained and demonstrate that all policies and procedures are followed.
- 5.7.13. Infection control measures, including post-transplant surveillance testing detailed in **Appendix 9** (liver) and **16** (pancreas), and hazardous waste management.



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- 5.7.14. Incident reporting to the DHA, in accordance with the requirements detailed in **Appendix 9** (liver) and **16** (pancreas).
- 5.7.15. Patient privacy.
- 5.7.16. Medication management.
- 5.7.17. Emergency action plan.
- 5.7.18. 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 premises 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. A DHA licensed health facility providing liver and/or pancreas transplant services shall have a detailed coverage plan, including:

5.12.1. How continuous medical and surgical coverage is provided by transplant surgeons and physicians who have been privileged by the hospital to independently manage the care of transplant patients.

5.12.2. The hospital must inform its patients if liver transplant services are staffed by a single surgeon or a single physician.

5.12.3. Acknowledgement of the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

5.12.4. The written coverage plan shall be provided to patients when placed on the waiting list and when there are any substantial changes to transplant services or personnel.

5.12.5. The coverage plan must be submitted to HRS upon request.

6. STANDARD TWO: HEALTH FACILITY REQUIREMENTS

6.1. Liver or pancreas 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)/Organ Donation Unit (ODU) 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 (OUT) to ensure integrated and



seamless organ transplant services, including the liver transplant service or pancreas transplant service.

6.4. The hospital providing liver or pancreas transplant services shall have the following services:

6.4.1. Cardiology.

6.4.2. Gastroenterology with endoscopy.

6.4.3. Pulmonology with bronchoscopy.

6.4.4. Radiology, with skills in interventional radiology.

6.4.5. Hematology.

6.4.6. Infectious Disease.

6.4.7. 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 should be available.

6.4.8. Biochemistry Laboratory.

6.4.9. Nephrology with hemodialysis unit preferably having both portable dialysis machines and continuous venovenous hemodiafiltration machine.

6.4.10. Intensive Care Unit (ICU).

6.4.11. Quality Management.

6.4.12. Blood banking services.

6.4.13. Microbiology services.



- 6.4.14. Histocompatibility testing.
- 6.4.15. Necessary resources to monitor treatment with immunosuppressive medications.
- 6.5. The hospital shall provide the following:
 - 6.5.1. Minimum of two (2) Operating Theatres (OTs).
 - 6.5.2. Minimum of two (2) rooms for the management of post-transplant patients.
- 6.6. The health facility shall install and operate equipment required for provision of the proposed services in accordance with the manufacturer's specifications.
- 6.7. The health facility shall ensure easy access to the health facility and treatment areas for all patient groups.
- 6.8. The health facility shall provide assurance of patient and staff health and safety.
- 6.9. 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.
- 6.10. The hospital's design shall align with the health facility requirement as per the DHA Health Facility Guidelines (HFG), Part B – Health Facility Briefing & Design, for all the above-mentioned categories of services.
- 6.11. 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.

7. STANDARD THREE: REQUIREMENTS OF HEALTHCARE PROFESSIONALS FOR LIVER TRANSPLANT SERVICES



- 7.1. A DHA licensed hospital providing liver 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 General Surgeons/Gastrointestinal Surgeon/Visceral Surgeon with training and experience in liver transplant and privileged to do so aligned with the DHA Privileging Policy.
- 7.3. There must be a DHA licensed consultant Transplant Hepatologist/consultant Gastroenterologist to ensure pre and post-surgical care is provided.
- 7.4. The consultant liver 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. The consultant General Surgeons/Gastrointestinal Surgeon/Visceral Surgeon must meet the following conditions:
 - 7.5.1. They must have:
 - a. Performed fifty (50) liver transplants as primary or consultant surgeon, co-surgeon or first assistant within the last five (5) years.
 - b. Performed at least ten (10) liver transplants as primary surgeon.
 - c. Performed at least fifteen (15) of these cases within the previous two years at a hospital designated to perform liver transplants.
 - d. Performed at least twenty (20) liver procurements as primary or consulting surgeon, co-surgeon, or first assistant under the supervision of a qualified liver transplant surgeon.



- e. Participated in preoperative assessments of liver candidates and postoperative care of these recipients.
- 7.6. A physician can meet requirements for consultant transplant hepatologist if all the following conditions are met:
- 7.6.1. The physician must have:
- a. Been directly involved in the primary care of thirty (30) or more recently transplanted liver recipients at a hospital designated to perform liver transplant.
 - b. Followed these recipients for a minimum of three (3) months post-transplant. At least fifteen (15) of these cases must be within the last two (2) years.
 - c. Observed at least three (3) complete liver transplant surgeries.
 - (i) 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.
- 7.7. A DHA licensed hospital providing pediatric liver transplant services shall employ a DHA licensed consultant pediatric General Surgeons/Gastrointestinal Surgeon/Visceral Surgeon and a DHA licensed consultant pediatric transplant hepatologist, as described below.
- 7.7.1. In addition to the requirements described above the surgeon must have:



- a. Performed at least fifteen (15) liver transplants as the primary or consultant surgeon in recipients less than eighteen (18) years old at the time of transplant. At least eight (8) of these liver 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 pediatric liver transplantation, defined as performing a pediatric transplant within the last two (2) years.
 - (i) 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 the requirements described above the physician must have:

- a. Been directly involved in the primary care of five (5) or more newly transplanted pediatric liver recipients and followed ten (10) newly transplanted liver recipients for a minimum of six (6) months from the time of transplant.
- b. Been directly involved in the pre-operative, peri-operative, and post-operative care of ten (10) or more pediatric liver transplant recipients.
- c. Maintained a current working knowledge of pediatric liver transplantation, defined as direct involvement in pediatric liver transplant patient care within the last two (2) years.



- 7.8. A DHA licensed hospital providing living donor liver transplant services shall identify a consultant General Surgeon/Visceral Surgeon/Gastroenterologist as elaborated in the published DHA Standards for Living Donation Services.
- 7.9. A DHA licensed hospital providing liver transplant services shall also have the following DHA licensed healthcare professionals:
- 7.9.1. **Registered Nurses (RNs)** experienced and trained to care for patients during and after liver transplant.
- 7.9.2. **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 hepatology and/or transplant subspecialty is preferred.
- 7.9.3. **Financial Coordinator** to coordinate the financial resources required for care, beginning with the transplantation evaluation, and continuing after transplantation to ensure continuity of care.
- 7.9.4. **Clinical Pharmacist** to provide comprehensive medication management to transplant candidates, recipients, and living donors.
- 7.9.5. **Clinical Social Worker** to coordinate psychosocial needs of transplant candidates, recipients, living donors, and their families.
- 7.9.6. **Clinical Dietician** to provide nutritional services to transplant candidates, recipients, and living donors.



7.9.7. **Director of Liver Transplant Anesthesia** responsible for establishing internal policies for anesthesiology participation in the intra-operative care of liver transplant patients. The director of liver transplant anesthesia shall be a designated member of the transplant team and must have experience in the intra-operative care of at least twenty (20) liver transplant recipients in the operating room, within the last five (5) years.

7.9.8. **Head of the Critical Care Support Unit and Organ Donation Unit 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.

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

7.10.1. Hepatology.

7.10.2. Anesthesiology.

7.10.3. Histocompatibility and immunogenetics.

7.10.4. Immunology.

7.10.5. Infectious Disease.

7.10.6. Pathology.

7.10.7. Physical therapy and rehabilitation medicine.

7.10.8. Radiology, with skills in interventional radiology.

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

7.10.10. Cardiology, as appropriate.



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- 7.10.11. Nephrology, including dialysis capability, as appropriate.
- 7.10.12. Pediatrics, if applicable.
- 7.11. Liver Transplant Coordinators shall be assigned in each OTU providing liver transplant services, with the following responsibilities:
- 7.11.1. Acts as liaison between the Organ Donation and Transplantation Team of DHA (if applicable), The National Center and the hospital OTU.
- 7.11.2. Work closely with coordinator(s) of The National Center and the Critical Care Support Unit Coordinator (CCSUC) of the donor hospital to facilitate donor organ recovery and subsequent transplant.
- 7.11.3. Ensure that all potential transplant recipients, as well as all deceased and living donors meet transplant or donation criteria and maintain documentation to support that these requirements are met.
- 7.11.4. Ensure that all policies and procedures for the OTU are up to date and aligned with current international best practices.
- 7.11.5. 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.
- 7.11.6. Explain policies and procedures for transplant and donation to patients and their families to support them and coordinate their care.
- 7.11.7. Prepare for the hospital OTU a sequentially prioritized list of candidates waiting for transplant (the waitlist) and coordinate the list with HRS and the National Center.



- 7.11.8. Provide to The National Center the names of all patients determined to be suitable for liver transplant following a completed transplant workup. These shall be included on the national waitlist.
- 7.11.9. Inform The National Center when a suitable patient for transplantation is not available in the local waiting list.
- 7.11.10. Continually update all relevant information with the National Center regarding a candidate's status on the waitlist.
- 7.11.11. 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.
- 7.11.12. Oversee implementing the post-transplant care of the patient and act as a conduit between patient care teams and the recipient.
- 7.12. A DHA licensed hospital providing liver transplant services shall have a Liver Transplant Committee to ensure efficient and safe liver transplant services. The Liver Transplant Committee shall consist of:
 - 7.12.1. Consultant General Surgeons/ Gastrointestinal Surgeon/ Visceral Surgeon (could lead the team).
 - 7.12.2. Consultant Transplant Hepatologist (could lead the team).
 - 7.12.3. Liver Transplant Coordinator.
 - 7.12.4. Registered Nurse Representative.
 - 7.12.5. Quality Coordinator.
 - 7.12.6. Anaesthesiologist.



- 7.12.7. Social Worker.
 - 7.12.8. Psychologist.
 - 7.12.9. Dietician.
 - 7.12.10. Geneticist (optional)
 - 7.12.11. Cardiologist (optional)
 - 7.12.12. Pulmonologist (optional)
 - 7.12.13. Nephrologist (optional)
 - 7.12.14. Urologist (optional)
 - 7.12.15. Psychiatrist (optional)
 - 7.12.16. Legal Representative (optional).
- 7.13. A DHA licensed health facility providing paediatric liver transplant services shall have a Liver Transplant Committee to ensure efficiency and safe liver transplant services. The paediatric Liver Transplant Committee shall consist of the same members as the adult Liver Transplant Committee, except the following positions must have paediatric specializations:
- 7.13.1. Clinical Child Psychologist or Child Development specialist.
 - 7.13.2. Anaesthesiologist with paediatric experience.
- 7.14. The Liver Transplant Committee shall meet on a regular basis to ensure smooth operation of the OTU. Responsibilities of the Liver Transplant Committee are as follows:
- 7.14.1. Ensure that each potential candidate has access and equitable opportunity to be assessed for transplant and/or donation.
 - 7.14.2. Review the health records of patients to undergo pre-transplant evaluation as elaborated in **Appendix 3, Appendix 4** (paediatric patients), and **Appendix 6**.



- 7.14.3. Create a process of transplant wait-listing that is efficient, effective, and transparent.
- 7.14.4. 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.
- 7.14.5. Review the patients on a routine basis to ensure that they continue to meet program requirements for transplant and wait-listing.
- 7.14.6. Review post-transplant follow-up every 6 months to monitor patient outcomes and track observed one-year graft and survival rate.
- 7.14.7. Ensure that transplant and donation activities abide to the highest ethical and legal standards.
- 7.14.8. Ensure all practices of the OTU are aligned with current international best practices.
- 7.14.9. Facilitate multidisciplinary decision-making to provide the best possible care for potential transplant candidates.
- 7.14.10. Develop and regularly update Policies and Procedures related to Liver Transplant Services to ensure efficient and safe provision of services.
- 7.15. 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.
- 7.16. 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: REQUIREMENTS OF HEALTHCARE PROFESSIONALS FOR PANCREAS TRANSPLANT SERVICES

- 8.1. A DHA licensed hospital providing pancreatic 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. A DHA licensed hospital providing pancreas transplant services shall have consultant General Surgeons/Gastrointestinal Surgeon/Visceral Surgeon Surgeons with training and experience in pancreas transplant surgery and privileged by the health facility in alignment with the DHA Privileging Policy.
- 8.3. Physician responsible for the pre and post care of the transplant patient shall be DHA licensed consultant Internal Medicine/Gastroenterologist and consultant Endocrinologist with training and experience in the subject and privileged by the health facility in alignment with the DHA Privileging Policy.
- 8.4. The consultant pancreas transplant surgeons (as mentioned above) and consultant pancreas transplant physicians (as mentioned above) are responsible for ensuring the operation and compliance of pancreas transplant services align with requirements set forth in this standard.
 - 8.4.1. The consultant General Surgeons/Gastrointestinal Surgeon/Visceral Surgeon must meet the following conditions:
 - a. The surgeon must have performed:



- (i) At least ten (10) pancreas transplants as primary or consultant surgeon, co-surgeon or first assistant within the last five (5) years at a hospital designated to perform pancreas transplants.
- (ii) At least five (5) of these must be as primary or co-surgeon.
- (iii) At least ten (10) back-table preparations of the pancreas allograft, including arterial vascular reconstruction.
- (iv) Participated in pre-operative assessment of pancreas transplant candidates and post-operative care of these recipients.

b. The surgeon's experience must include:

- (i) Substantive experience in the preoperative assessment of pancreas transplant candidates.
- (ii) The postoperative care of the transplant recipient, both in the immediate postoperative period, as well as in continued inpatient care.

8.4.2. A physician can meet requirements for consultant pancreas transplant physician 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 recent pancreas transplant recipients within the last ten (10) years.
- (ii) Continued to follow these recipients for a minimum of three (3) months from transplant.



- (iii) Been directly involved in the primary care of at least one (1) patient within the last two (2) years.
 - (iv) Observed at least two (2) complete pancreas transplant surgeries, including the back-table allograft reconstruction.
 - (v) Experience with interpreting histocompatibility typing, and the histological interpretation of pancreas biopsies.
- b. To verify this transplant experience, a log documenting transplant date, and medical record number or other unique identifier of the recipient, must be maintained and signed by an individual in a supervisory capacity from the hospital where the experience was gained.
- 8.5. A DHA licensed hospital providing pancreas transplant services shall have a detailed plan and procedures for continuity of patient care as also mentioned above.
- 8.6. A DHA licensed hospital providing pancreas transplant services shall also have the following DHA licensed healthcare professionals to support the above-mentioned physicians:
- 8.6.1. **Registered Nurses (RNs)** experienced and trained to care for patients during and after pancreas transplant.
 - 8.6.2. **Transplant Coordinator**, minimum of two (2), to work with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation. The coordinator(s) shall be a registered nurse or other licensed clinician.



- 8.6.3. **Financial Coordinator** to coordinate the financial resources required for care, beginning with the transplantation evaluation, and continuing after transplantation to ensure continuity of care.
- 8.6.4. **Clinical Pharmacist** to provide comprehensive medication management to transplant candidates, recipients, and living donors.
- 8.6.5. **Clinical Social Worker** to coordinate psychosocial needs of transplant candidates, recipients, living donors, and their families.
- 8.6.6. **Clinical Dietician** to provide nutritional services to transplant candidates, and recipients.
- 8.6.7. **Head of the Critical Care Support Unit and Organ Donation Unit 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 HRS.
- 8.7. Pancreas transplant services shall collaborate with medical experts in these fields; including but not limited to:
- 8.7.1. Anesthesiology.
- 8.7.2. Histocompatibility and immunogenetics.
- 8.7.3. Immunology.
- 8.7.4. Nephrology, including dialysis capability.
- 8.7.5. Infectious disease.
- 8.7.6. Pathology.



- 8.7.7. Physical therapy and rehabilitation medicine.
 - 8.7.8. Radiology, with skills in interventional radiology,
 - 8.7.9. Pulmonary medicine, including respiratory therapy support, as appropriate.
 - 8.7.10. Cardiology, as appropriate.
 - 8.7.11. Hepatology, as appropriate.
 - 8.7.12. Pediatrics, if applicable.
- 8.8. Pancreas Transplant Coordinators shall be assigned in each OTU providing pancreas transplant services, with the following responsibilities:
- 8.8.1. Acts as liaison between the Organ Donation and Transplantation Team of DHA, The National Center and the hospital OTU.
 - 8.8.2. Work closely with coordinator(s) of the National Center and the Organ Critical Care Support Unit Coordinator (CCSUC) of the donor facilities to facilitate donor organ recovery and subsequent transplant.
 - 8.8.3. Ensure that all potential transplant recipients meet transplant 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. 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.
 - 8.8.6. Explain policies and procedures for transplant and donation to patients and their families to support them and coordinate their care.



- 8.8.7. Prepare for the hospital OTU a sequentially prioritized list of candidates waiting for transplant (the waitlist).
- 8.8.8. Provide to HRS and The National Center the names of all patients determined to be suitable for pancreas transplant following a completed transplant workup. These shall be included on the national waitlist.
 - a. Each hospital and organ transplant center shall send a list of the names of potential recipients having diabetes mellitus who are suitable pancreas transplant candidates to The National Center which in turn establishes national and local waiting lists for each organ transplant in accordance with priority.
- 8.8.9. Coordinate with The National Center when there is Death by Neurological Criteria (DNC), in any of the hospitals and extend assistance, as needed.
- 8.8.10. Inform The National Center when there is not a suitable patient for transplantation on the local waiting list.
- 8.8.11. Send and update all information related to patients with insulin dependent diabetes mellitus that meet indications for transplantation to the National Center.
- 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.
- 8.8.13. Oversee implementing the posttransplant care of the patient and act as a conduit between patient care teams and the recipient.



8.9. A DHA licensed hospital providing Pancreas transplant services shall have a Pancreas Transplant Committee, which shall consist of the following members:

8.9.1. Consultant General Surgeons/Gastrointestinal Surgeon/Visceral Surgeon
(team lead)

8.9.2. Consultant Internal Medicine/Consultant Gastroenterologist and Consultant Endocrinologist.

8.9.3. Nephrologist.

8.9.4. Pancreas Transplant Coordinator.

8.9.5. Registered Nurse Representative.

8.9.6. Quality Coordinator.

8.9.7. Psychologist.

8.9.8. Social worker.

8.9.9. Anesthesiologist.

8.9.10. Cardiologist (optional).

8.9.11. Urologist (optional).

8.9.12. Pulmonologist (optional).

8.9.13. Psychiatrist (optional).

8.9.14. Legal Representative (optional).

8.10. The Pancreas Transplant Committee shall meet on a regular basis to ensure effective operation of the OTU. Responsibilities of the Pancreas Transplant Committee are as follows:

8.10.1. Ensure that each potential candidate has access and equitable opportunity to



- be assessed for transplant and/or donation.
- 8.10.2. Review the health records of patients to undergo pre-transplant evaluation as elaborated in **Appendix 5** and **Appendix 7**.
 - 8.10.3. Make the 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.
 - 8.10.4. Create a process of transplant wait-listing that is efficient, effective, and transparent.
 - 8.10.5. Review patients on a routine basis to ensure that they continue to meet program requirements for transplant and wait-listing.
 - 8.10.6. Review post-transplant follow-up every six (6) months to monitor patient outcomes and track observed one-year graft and survival rate.
 - 8.10.7. Ensure that transplant and donation activities abide to the highest ethical and legal standards.
 - 8.10.8. Ensure all practices of the OTU are aligned with current international best practices.
 - 8.10.9. Facilitate multidisciplinary decision-making to provide the best possible care for potential transplant candidates.
 - 8.10.10. Develop and regularly update Policies and Procedures related to Pancreas Transplant Services to ensure efficient and safe provision of services.
- 8.11. 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.

- 8.12. 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 liver or pancreas, the consent shall be signed before the procedure and maintained in the medical record.

9.1.1. Checklist for liver transplant candidate workup is elaborated in **Appendix 3**.

9.1.2. Checklist for pancreas transplant candidate's workup is elaborated in **Appendix 5**.

- 9.2. Liver Transplant Surgery Consent and Pancreas 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 liver or pancreas transplant.

9.2.3. Prospective transplant candidate of alternative treatments.

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

9.2.5. If the organ donor has risk factors present that could increase the risk of disease transmission, that this information was disclosed to the potential



recipient prior to transplant, and ensure those details are documented in the recipient's medical record.

- 9.3. Living donors shall sign the consent before the donor workup begins. Consent for living liver donation shall be in accordance with published DHA Standards for Human Organs and Tissues Donation Services (Living Donor).
- 9.4. The performance of transplantation from a living donor must meet all conditions set forth in published DHA Standards for Human Organs and Tissues Donation Services (Living Donor).
- 9.5. Before performing deceased donor procurement, the following conditions shall be fulfilled:
 - 9.5.1. 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.
 - 9.5.2. When brain death is confirmed and consent is obtained from the family for organ donation, organ placement and transplantation shall be carried out per the Federal Decree Law No. (25) of 2023 concerning Human Organ and Tissue Donation and Transplantation. Both the brain death confirmation, as well as the consent for donation, must be documented in the donor's medical record.
 - 9.5.3. For further information refer to the DHA Standards for Human Organs & Tissues Donation Services (Deceased Donor).
- 9.6. Always ensure donor and recipient confidentiality.



10. STANDARD SIX: MEDICATION REQUIREMENTS

10.1. Health facilities providing liver or pancreas 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. Prednisone.
- f. Sirolimus (Rapamycin).
- g. Other similar drugs categories.

10.1.2. Drugs for treating rejection episodes:

- a. Methylprednisolone.
- b. Anti-Thymocyte Globulin (Thymoglobulin).
- c. Monoclonal Antibodies.

10.1.3. Solution for perfusing the organs such as University of Wisconsin (UW) solution or Histidine-Tryptophan-Ketoglutarate (HTK) solution.

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

11. STANDARD SEVEN: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DONOR AND RECIPIENT CANDIDATES FOR LIVER TRANSPLANT

11.1. The pre-operative assessment and evaluation of the Liver Recipient Candidate is elaborated in **Appendix 6**.



11.2. The pre-operative assessment and evaluation of the Liver Donor Candidate is elaborated in **Appendix 8**.

12. STANDARD EIGHT: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DONOR AND RECIPIENT CANDIDATES FOR PANCREAS TRANSPLANT

12.1. The pre-operative assessment and evaluation of Pancreas Recipient Candidate is elaborated in **Appendix 7**.

12.2. The pre-operative assessment and evaluation of the Pancreas Donor Candidate is elaborated in **Appendix 8**.

13. STANDARD NINE: POST-OPERATIVE MANAGEMENT OF LIVER TRANSPLANT RECIPIENT

13.1. During the post-operative management of the liver transplant recipient, the parameters for monitoring graft function recovery and clinical surveillance for early surgical complications are elaborated in **Appendix 9**.

13.2. The surveillance for liver transplant complications after hospital discharge are elaborated in **Appendix 10**.

13.3. Immunosuppressive therapy for liver transplant recipients is elaborated in **Appendix 11** (adult) and **Appendix 12** (paediatric).

13.4. The Protocol of Acute Rejection therapy is elaborated in **Appendix 13** (adult) and **Appendix 14** (paediatric).

13.5. The protocols of Chronic Allograft Dysfunction (CAD) management are elaborated in **Appendix 15**.

14. STANDARD TEN: POST-OPERATIVE MANAGEMENT OF PANCREAS TRANSPLANT RECIPIENT



- 14.1. During the post-operative management of the pancreas transplant recipient, the parameters for monitoring graft function recovery and clinical surveillance for early surgical complications are elaborated in **Appendix 16**.
- 14.2. The surveillance for pancreas transplant complications after hospital discharge is elaborated in **Appendix 17**.
- 14.3. Immunosuppressive therapy for pancreas transplant recipients is elaborated in **Appendix 18**.
- 14.4. The Protocol of Acute Rejection therapy is elaborated in **Appendix 19**.
- 14.5. The protocols of Chronic Allograft Dysfunction (CAD) management are elaborated in **Appendix 20**.

15. STANDARD ELEVEN: KEY PERFORMANCE INDICATORS

- 15.1. The Key Performance Indicators (KPIs) are elaborated in **Appendix 21**.
- 15.2. 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
- 15.3. The information shall be as follows, but not limited to:
 - 15.3.1. Donor- full name, date of birth, emirates ID, nationality, country of residence, date of donation, visa number and passport number
 - 15.3.2. 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.



REFERENCES

- Bahar, S.G. and Devulapally, P. (2022). Pancreas Transplantation. [online] PubMed. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK562338/>.
- Dababneh, Y. and Mousa, O.Y. (2021). Liver Transplantation. [online] PubMed. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK559161/>.
- Lucey, M.R., Terrault, N., Ojo, L., Hay, J.E., Neuberger, J., Blumberg, E. and Teperman, L.W. (2012). Long-term management of the successful adult liver transplant: 2012 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. *Liver Transplantation*, 19(1), pp.3–26. doi: <https://doi.org/10.1002/lt.23566>.
- Martin, P., DiMartini, A., Feng, S., Brown, R. and Fallon, M. (2014). Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. *Hepatology*, 59(3), pp.1144–1165. doi: <https://doi.org/10.1002/hep.26972>.
- Miller, C.M., Durand, F., Heimbach, J.K., Kim-Schluger, L., Sung Gyu Lee, Lerut, J., Chung Mau Lo, Cristiano Quintini and Pomfret, E.A. (2016). The International Liver Transplant Society Guideline on Living Liver Donation. *Transplantation*, 100(6), pp.1238–1243. doi: <https://doi.org/10.1097/tp.0000000000001247>.
- Miller, C.C., Cristiano Quintini, Dhawan, A., Durand, F., Heimbach, J.K., H.L. Kim-Schluger, Eirini Kyrana, Lee, S.-G., Lerut, J., Chung Mau Lo and Pomfret, E.A. (2017). The International Liver Transplantation Society Living Donor Liver Transplant Recipient Guideline. *Transplantation*, 101(5), pp.938–944. doi



:<https://doi.org/10.1097/tp.0000000000001571>.

- Organ Procurement and Transplantation Network (2024). OPTN Policies. [online] Available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

APPENDICES

APPENDIX 1: INDICATIONS AND CONTRAINDICATIONS FOR LIVER TRANSPLANTATION FOR ADULT AND PAEDIATRIC PATIENTS

1. Below are indications and contraindications for adult liver transplantation.

INDICATIONS FOR ADULT LIVER TRANSPLANTATION	
Graft Failure	<ul style="list-style-type: none"> Primary non-function, a complete metabolic, synthetic, and excretory failure of the liver allograft in the immediate postoperative period. Early hepatic artery thrombosis, an arterial occlusion leading to parenchymal and biliary damage. Although re-transplantation can be done, the survival outcomes are significantly worse than a primary transplant.
Chronic Hepatitis C (<i>resulting in cirrhosis</i>)	<ul style="list-style-type: none"> Was the most common indication for liver transplantation until the year 2015. Novel direct antiviral agents allow for chronic hepatitis C therapy post-liver transplantation.
Hepatitis B	<ul style="list-style-type: none"> Treating and getting the infection under control is important to prevent re-infection after transplant. Hepatitis B can be complicated by hepatocellular carcinoma, which serves as an important indication for liver transplantation.
Autoimmune Hepatitis (AIH)	<ul style="list-style-type: none"> Liver transplantation is indicated in acute liver failure secondary to autoimmune hepatitis or cases of chronic decompensated cirrhosis due to autoimmune hepatitis. Poor outcomes and the need for liver transplantation can be predicted with the following observations: young age, MELD score higher than 12, multiple relapses, and delayed downward slope of aminotransferase after treatment.
Primary Biliary Cirrhosis (PBC)	<ul style="list-style-type: none"> Patients with decompensated cirrhosis or severe pruritis refractory to other medical interventions require liver transplantation.
Primary Sclerosing Cholangitis (PSC)	<ul style="list-style-type: none"> Liver transplantation is an effective treatment modality for patients with PSC or those who develop perihilar cholangiocarcinoma (within certain criteria) or recurrent bouts of bacterial cholangitis. PSC is associated with inflammatory bowel disease; therefore, frequent colonoscopy is necessary to screen for CRC before and after liver transplantation.



Alcohol-Related Liver Disease	<ul style="list-style-type: none"> • Patients with alcohol use disorder shall be referred for psychosocial and psychiatric support before liver transplantation to ensure at least six months of abstinence and prevent relapses. • In cases of acute alcoholic hepatitis who do not respond to medical therapy, liver transplantation may be required while less than six months of abstinence is achieved.
Acute Liver Failure (ALF)	<ul style="list-style-type: none"> • Patients rapidly deteriorate and develop severe liver dysfunction, elevated bilirubin, aminotransferases, encephalopathy, and coagulopathy (INR above 1.5). • ALF is a strong indication for liver transplantation as it supersedes all other etiologies of chronic liver disease.
Hepatocellular Carcinoma (HCC)	<p>Must meet the Milan criteria to be eligible for liver transplantation:</p> <ul style="list-style-type: none"> • One tumor less than 5 cm in diameter, or 3 tumors each having a diameter less than 3 cm that must be confirmed by CT or MRI • No metastasis documented by chest CT and bone scan. • Absence of major vessel involvement. • An unresectable tumor. • Patients with HCC usually have a normal liver function, and their MELD score is usually normal or low. Therefore, they require MELD exception to get a score that allows them to be prioritized on the waiting list for liver transplantation.
Cholangiocarcinoma	<ul style="list-style-type: none"> • Liver transplantation is considered in the management of patients with early-stage cholangiocarcinoma with nonresectable perihilar lesions (<3 cm in diameter) or underlying parenchymal liver disease such as PSC with cirrhosis. • Liver transplantation shall be done in combination with neoadjuvant chemotherapy regimens to ensure higher survival rates.
Nonalcoholic steatohepatitis (NASH)	<ul style="list-style-type: none"> • NASH is included in the spectrum of nonalcoholic fatty liver disease which has no other treatment than liver transplantation
Wilson Disease	<ul style="list-style-type: none"> • Liver transplantation is indicated in patients with acute liver failure due to Wilson disease or in cases of decompensated cirrhosis that failed all medical therapies. • Liver transplantation in Wilson disease has great outcomes, even in cases with metabolic complications like renal failure, which resolves after liver transplantation.



	<ul style="list-style-type: none"> Parents of patients who are heterozygous can contribute to living donor liver transplantation with success.
Other Cirrhosis-Related Complications	<ul style="list-style-type: none"> These can include complications such as hepatopulmonary syndrome and portopulmonary hypertension.
Alpha-1 Antitrypsin Deficiency	<ul style="list-style-type: none"> Usually diagnosed in adults with no history of liver disease. Liver transplantation is considered the only treatment modality for decompensated liver disease secondary to alpha-1 antitrypsin deficiency. There is no risk of recurrence due to the expression of the donor's alpha-1 antitrypsin gene after liver transplantation. Patients shall undergo screening for lung disease by chest imaging and pulmonary function testing.
Hereditary Hemochromatosis (HH)	<ul style="list-style-type: none"> Cirrhosis due to HH accounts for the highest risk of developing HCC among all other causes of cirrhosis. The use of iron reduction therapy through phlebotomy before transplant has resulted in improved outcomes post-liver transplantation.
Familial Amyloid Polyneuropathy (FAP)	<ul style="list-style-type: none"> Liver transplant is effective in FAP due to a mutation in the transthyretin gene. It is most effective in patients less than fifty (50) years because liver transplantation merely prevents disease progression. Patients with hereditary renal amyloidosis inherited as an autosomal dominant gene usually benefit from liver and renal transplantation, without affecting the ocular or cardiac effects of amyloidosis.
Primary Hyperoxaluria Type I	<ul style="list-style-type: none"> This usually leads to end-stage renal disease (ESRD) at twenty (20) to forty (40) years. Liver transplantation is effective in curing the disease.
Other metabolic liver diseases	<ul style="list-style-type: none"> Those having indications for liver transplantation include cystic fibrosis and glycogen storage diseases.

CONTRAINDICATIONS TO ADULT LIVER TRANSPLANTATION

Uncontrolled systemic infection

Uncontrolled extrahepatic or metastatic malignancy

Severe cardiopulmonary disease
Intracranial hypertension with sustained intracranial pressure (ICP) > 50 mmHg or cerebral perfusion pressure (CPP) < 40 mmHg for sustained period
Intrahepatic cholangiocarcinoma
HIV with CD4 count < 200 cells/mm ³
Active Alcohol Abuse / Substance Abuse
Lack of Social Support
Persistent Non-Compliance

2. Below are indications and contraindications for paediatric liver transplantation.

INDICATIONS FOR PAEDIATRIC LIVER TRANSPLANTATION	
Acute Liver Failure	<ul style="list-style-type: none"> Severe liver dysfunction within 8 weeks of onset of illness with coagulopathy (INR >1.5), encephalopathy, and elevated bilirubin. Complications include sepsis, hypoglycemia, acidosis, multiorgan failure, and cerebral edema. Causes include autoimmune, viral, Wilson's disease, drug-induced, and undetermined.
Metabolic Genetic Liver Diseases	
Alpha 1 antitrypsin	<ul style="list-style-type: none"> Associated with other forms of liver disease such as cirrhosis and HCC, and early onset pulmonary emphysema. No risk of recurrence due to the expression of the donor's alpha-1 antitrypsin after liver transplantation. Needs chest imaging and pulmonary function testing.
Wilson's Disease	<ul style="list-style-type: none"> A disorder of copper metabolism, causing a build-up in the body which damages the liver. Paediatric presentation includes dysarthria, anorexia, drooling, clumsiness, fatigue, joint pain. Classic finding is Kaiser-Fleischer rings (brown/green rings in the cornea).
Maple Syrup Urine Disease	<ul style="list-style-type: none"> A disorder of amino acid metabolism leads to accumulation of branched chain amino acids. Paediatric presentation is irritability, lethargy, dystonia, difficulty eating.
Tyrosinemia	<ul style="list-style-type: none"> A group of disorders that cause deficiencies for the enzymes that catabolize tyrosine and causes a buildup that damages the liver and kidneys.

	<ul style="list-style-type: none"> Paediatric presentation includes failure to thrive, loss of balance, mental retardation, and photophobia. Transplant is needed for those patients that fail medical treatment.
Glycogen Storage Disease	<ul style="list-style-type: none"> A disorder where an abnormal amount of glycogen becomes stored in the liver, which alters the liver's ability to metabolize glucose. Enzymatic deficiencies causing damage include liver glycogen synthase, glucose-6-phosphatase, glucose-6-phosphate transporter, glycogen debrancher.
Urea Cycle Defect	<ul style="list-style-type: none"> Disorders resulting from deficiencies in the enzymes of the urea cycle which excretes urea from the body and can lead to liver failure. The most common are carbamyl phosphate synthetase I (CPSI) and ornithine transcarbamylase (OTC). Transplant is needed in those with chronic hyperalbuminemia leading to neurologic damage.
Hyperoxaluria	<ul style="list-style-type: none"> Disrupted conversion of glyoxylate into oxalate and with subsequent oxalate excretion. In infants it causes renal failure without actual stone formation. However, in older children it causes kidney stones which damages kidneys. Transplant of the liver is needed to preserve renal function, although typically a combined liver-kidney transplant is needed.
Cystic Fibrosis	<ul style="list-style-type: none"> A mutation in a transmembrane conductor disrupts chloride ion transport and thickens the bile and blocks the intrahepatic ducts. This releases inflammatory proteins and growth factors that cause progressive fibrosis of the liver.
Methylmalonic Acidemia (MMA)	<ul style="list-style-type: none"> A metabolic disorder which disrupts amino acid metabolism and leads to a buildup of methylmalonic acid in the blood. It is typically diagnosed in the neonatal period and can cause failure to thrive, lethargy, encephalopathy, hypotonia, seizures, and strokes. Treatment requires a low protein diet and long-term monitoring of serum and urine MMA levels. Transplant is reserved for those that fail diet modification, and the transplant allograft resolves the enzyme deficiency.
Others	<ul style="list-style-type: none"> These include rare enzymatic deficiencies such as liver phosphorylase, glycogen branching enzyme and phosphorylase b kinase, where transplant replaces the enzymatic deficiency. Also includes iron storage disorders and mitochondrial function defects.

Cholestatic Liver Diseases

Extrahepatic Biliary Atresia	<ul style="list-style-type: none"> • A ductopenia and obliterative cholangiopathy seen in childhood leading to narrowed, blocked or absent bile ducts, either congenital or acquired. • Presents like harmless neonatal jaundice, but does not improve, and the child gets progressive jaundice, failure to thrive and malabsorption, and eventually portal hypertension and cirrhosis. • Treatment is a hepatoportoenterostomy (“Kasai procedure”) and liver transplantation is reserved for those who fail this operative therapy.
Primary Sclerosing Cholangitis	<ul style="list-style-type: none"> • A chronic inflammatory disease, causing stricture and destruction of the biliary tree with resultant episodes of cholangitis. • Liver transplantation is reserved for those progressing to cirrhosis and portal hypertension. • Transplant is also indicated for those children with chronic pruritis so debilitating as to negatively impact quality of life and school performance.
Progressive Familial Intrahepatic Cholestasis (PFIC)	<ul style="list-style-type: none"> • PFIC is a disease disrupting genes for bile formation. • Indications include severe pruritis, growth retardation, and cirrhosis. • Liver transplantation is the only effective treatment for PFIC and resolves symptoms, although in some variants of PFIC such as PFIC-1, an aggressive diarrhea can follow transplantation.

Tumours

Hepatoblastoma	<ul style="list-style-type: none"> • The most common liver tumour usually affecting children less than 3 years. • Often asymptomatic, it is associated with an elevation of alpha fetoprotein persisting past infancy. • Liver transplantation is reserved for those with unresectable hepatoblastoma, or advanced disease with poor chemosensitivity.
Hepatocellular Carcinoma (HCC)	<ul style="list-style-type: none"> • The second most common paediatric liver tumour which is found more commonly in Middle Eastern countries. • The biological behaviour of paediatric HCC differs from adults, and unlike adult HCC, only a small segment of paediatric HCC develops in a setting of cirrhosis. These tumours typically present at an advanced stage. • Transplantation is reserved for those patients with surgically unresectable HCC.
Other Tumours	<ul style="list-style-type: none"> • These include rare tumours such as sarcomas and hemangioendotheliomas.

Miscellaneous Diseases

Budd Chiari Disease	<ul style="list-style-type: none"> • Related to blockage in hepatic veins due to clotting in a hypercoagulable setting.
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	<ul style="list-style-type: none"> • These are typically managed by anticoagulation, balloon dilation of hepatic veins and placement of a TIPS shunt. • Treatment is reserved for those who fail therapy and having deteriorating liver function with development of cirrhosis
TPN Associated	<ul style="list-style-type: none"> • In cases of very long-term parenteral nutrition where cessation of therapy is not an option, it causes steatosis, cholestasis and fibrosis that progresses to cirrhosis. This cholestasis and liver dysfunction can often evolve more rapidly in children compared to adults and can lead to liver transplantation.

CONTRAINDICATIONS TO PAEDIATRIC LIVER TRANSPLANTATION	
Absolute	Relative
	<i>Individual cases should be carefully discussed by the Liver Transplant Committee to evaluate risk versus benefit before listing is considered</i>
Active sepsis.	Low weight <5kg.
Metastatic hepatoblastoma with disease found outside of lung or liver.	Metastatic hepatoblastoma with disease limited to liver and lungs.
Severe cardiac disease.	
Severe pulmonary hypertension.	

APPENDIX 2: INDICATIONS AND CONTRAINDICATIONS FOR PANCREAS TRANSPLANTATION

1. Pancreas transplantation should only be performed in patients 21 years of age or older.
2. Pancreas transplantation is a treatment strategy used to manage diabetes mellitus .
 - 2.1. This includes Type 1 diabetes that cannot be controlled with standard treatment, frequent insulin reactions, consistently poor blood sugar management, severe kidney damage.
 - 2.2. Increasingly, individuals with Type 2 diabetes associated with both low insulin resistance and production are benefiting from transplantation.
 - 2.3. Patients with ESRD and Type 1 diabetes may benefit from kidney alone or pancreas and kidney transplantation.
 - 2.4. Pancreas transplants are completed using several different methods:

Pancreas Transplant Alone (PTA)	Indications for this procedure include: <ul style="list-style-type: none"> • Severe complications of diabetes mellitus with frequent and severe hypoglycemia or keto acidosis (more than two severe hypoglycemic episodes within the last 24 months). • Poor quality of life despite insulin therapy (with adequate renal function and no uremia) as assessed by an endocrinologist. • Glomerular filtration rate (GFR) of 80 to 100 mL/min/1.73 m² are unlikely to need a kidney transplant.
Simultaneous Pancreas and Kidney Transplant (SPK)	Indications for this procedure include: <ul style="list-style-type: none"> • Type 1 diabetes with ESRD on dialysis or requiring dialysis within six months. • Insulin treated diabetics (Type 1 or Type 2) with ESRD and GFR < 20ml/min (not on dialysis).
Pancreas After Kidney Transplant (PAK)	Indications for this procedure include: <ul style="list-style-type: none"> • Patients who match the criteria for pancreas-alone transplant and have previously working kidney transplant(s). • Insulin-treated diabetes with stable function of previous renal allograft and who meet criteria for PTA.



<i>(from different living or deceased donors)</i>	<i>This procedure is noted as having reduced waiting time and lower mortality rate as compared to SPK patients.</i>
Simultaneous Deceased Donor Pancreas and Living Donor Kidney Transplant (SPLK)	Indication same as SPK (above). <i>Primary benefit is a lower rate of delayed graft function (DGF) than an SPK and significantly reduced waiting time, which often results in improved outcomes when compared to patients waiting for SPK.</i>

2.5. The following circumstances should be recognized and carefully considered by the Pancreas Transplant Committee when evaluating potential pancreas transplant candidates:

ABSOLUTE CONTRAINDICATIONS TO PANCREAS TRANSPLANT	RELATIVE CONTRAINDICATIONS TO PANCREAS TRANSPLANT
	Individual cases should be carefully discussed by the Pancreas Transplant Committee to evaluate risk versus benefit before listing is considered
Age less than 21 or greater than 65.	Cerebrovascular accident with long-term impairment.
Major cardiovascular risk defined as non-correctable significant coronary artery disease.	Active Hepatitis B or C infection.
Myocardial infarction within six (6) months.	BMI >30 kg/m.
Left ventricular ejection fraction <30%.	Insulin requirements >1.5 units/kg per day.
Pulmonary artery systolic pressure over 50mmHg.	Extensive aorta/iliac and/or peripheral vascular disease.
Incurable malignancy (exception is localized skin cancer).	Continued abuse of alcohol, tobacco, or drugs (including marijuana).
Low-grade prostate cancer.	
Active sepsis.	
Peptic ulcer disease.	
Immunosuppression.	



A major psychiatric history which can result in non-adherence to treatment.	
Inability to withstand surgery.	



APPENDIX 3: CHECK-LIST FOR LIVER TRANSPLANT CANDIDATE WORKUP

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 LIVER TRANSPLANT CANDIDATE WORKUP		CHECK
PRELIMINARY EVALUATION	Patient Medical history, including history of liver disease and surgical history.	
	Patient social history <ul style="list-style-type: none"> • FOR ADULT CANDIDATES: including smoking, alcohol, and drug use, and social support network. • FOR PAEDIATRIC CANDIDATES: including school, socialization, and support networks. 	
	Family medical history.	
	Physical examination, including weight/BMI.	
	Hepatology evaluation, including disease severity and prognosis, confirmation of diagnosis, and optimizing management until transplant (which may include treatments such as variceal banding, paracentesis, TIPS placement, etc.).	
	Surgical evaluation confirming the need for transplant and identifying technical challenges such as prior abdominal surgery, portal vein thrombosis, or prior spontaneous bacterial peritonitis.	
	Anesthesiology consult to identify any challenges related to high operative risk.	
	ADULT CANDIDATES ONLY: <ul style="list-style-type: none"> • Performance status (Karnofsky Score). • Nutritional status (Subjective Global Assessment). • Frailty (Liver Frailty Index). 	
	PAEDIATRIC CANDIDATES ONLY: <ul style="list-style-type: none"> • Child Developmental and Child Psychiatry Assessment, including size measurements (weight, height head circumference), growth charts, stature, physical developmental metrics (fine and gross motor skills and balance issues). • Neurological and cognitive developmental evaluation. • Nutritional evaluation. 	



	<ul style="list-style-type: none"> Genetic Consult (if necessary for specific metabolic diseases, storage diseases, and cholestatic disease). 	
LABORATORY TESTING	ABO blood typing (perform 2 separate tests at different times, prior to addition to wait-list).	
	Complete blood count (CBC).	
	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 Metabolic Panel (CMP) (including electrolytes, renal panel, Na, K, Cl, CO ₂ , Cr, BUN, Ca, PO ₄).	
	Urinalysis, including urine sediment examination.	
	Complete coagulation function panel (PT/INR, PTT, Fibrinogen).	
	Plasma proteins levels and protein electrophoresis.	
	PAEDIATRIC CANDIDATES ONLY: Specific urine tests as indicated by disease (including urine methylmalonic acid, urine organic acids, urine cooper, etc.)	
MICROBIOLOGY ASSESSMENT AND INFECTIOUS DISEASE TESTING	Hepatitis Panel: <ul style="list-style-type: none"> Hepatitis A antibody (HAAb). Hepatitis B core antibody (HBcAb). Hepatitis B surface antibody (HbsAb). Hepatitis B surface antigen (HbsAg). Hepatitis C antibody. 	
	Hepatitis Quantitative Testing: <ul style="list-style-type: none"> HBV – DNA. HCV – RNA. 	
	HIV Testing <ul style="list-style-type: none"> HIV RNA. HIV Ag/Ab. 	
	Syphilis Antibody Testing <ul style="list-style-type: none"> VDRL. TPHA. 	
	Serologies <ul style="list-style-type: none"> CMV (IgM, IgG). EBV (IgM, IgG). Toxoplasmosis (IgM, IgG). 	



	<ul style="list-style-type: none"> HTLV I – II (IgM, IgG). 	
	Tuberculosis Test <ul style="list-style-type: none"> Mantoux tuberculin skin test or QuantiFERON. 	
	Infectious Disease Consultant Evaluation (if indicated).	
CARDIOVASCULAR ASSESSMENT*	Cardiovascular examination.	
	ECG.	
	Echocardiogram.	
	Chest X-ray.	
	ADULT CANDIDATES ONLY: Exercise cardiac stress test. <ul style="list-style-type: none"> Exercise/treadmill. Chemical (Dobutamine/persantine, adenosine) if cannot tolerate exercise. 	
	ADULT CANDIDATES ONLY: Myocardial Perfusion scintigraphy (if indicated).	
	ADULT CANDIDATES ONLY: <i>*Patients with positive screening tests shall be referred to cardiologist for further evaluation by coronary angiography. Intervention may allow for future listing.</i>	
IMAGING	Cross Sectional Imaging <ul style="list-style-type: none"> CT scan of chest. CT scan (Abdomen/Pelvis) with triple-phase contrast. MRI of abdomen/pelvis with gadolinium (if contrast CT contraindicated). 	
	Duplex Ultrasound to evaluate flow dynamics of the liver vasculature.	
OTHER TESTING	ADULT CANDIDATES ONLY: Colonoscopy.	
	Esophagogastroduodenoscopy (including H Pylori test).	
	Ophthalmic exam, including fundoscopic evaluation.	
	Dermatologic exam.	
	Psychological exam.	
	Anesthesiologist evaluation.	
GENDER- AND AGE-APPROPRIATE ONCOLOGICAL STUDIES	For adult females: <ul style="list-style-type: none"> PAP cervical screening test Mammogram. 	
	For adult males: <ul style="list-style-type: none"> Digital Prostate Exam. 	



	<ul style="list-style-type: none"> PSA Testing. 	
DENTAL EXAM	Dental Examination, including orthopantomogram.	
IMMUNOLOGIC EVALUATION	<p>HLA Typing.</p> <p>For Adult Candidates: Immunization Records Review or Catch-up. All adult candidates shall receive the following vaccinations prior to transplant, and antibody levels are determined at time of referral. For information on paediatric immunizations, refer to Appendix 4.</p> <ul style="list-style-type: none"> Td or Tdap. IPV. Hepatitis A. Hepatitis B. Meningococcal (conjugate). Pneumococcal (conjugate and/or polysaccharide). Hib. Influenza (administered annually). MMR (live vaccine). Varicella (live vaccine). <p><i>Live vaccines (MMR and varicella) administered before the transplant must be completed at least six weeks before transplantation.</i></p>	

1. Below are additional notes for the evaluation of adult candidates for transplant:

- 1.1. Assessment of nutrition is vital for successful transplant outcomes, as malnutrition is common in patients with End Stage Liver Disease (ESLD), while poor outcomes have been associated with a low BMI<18.5.
- 1.2. The Subjective Global Assessment (SGA) is a reliable and valid tool which predicts morbidity and mortality associated with malnutrition.
- 1.3. The Liver Frailty Index (LFI) is a composite metric of three performance-based measures that have been shown to predict recovery after transplant, as frailty is a powerful predictor of clinical outcomes in patients with ESLD.



1.4. The cardiovascular assessment is important for adult transplant candidates, as they have an increased risk of coronary artery disease.

1.4.1. There are some high-risk subgroups which have the following elements, and will need extra care and evaluation:

- a. Prolonged duration of dialysis (>5 years).
- b. Smoking history.
- c. Dyslipidemia (HDL<0.9mmol/L, LDL>3.4mmol/L).
- d. Family history of coronary in first degree relative.
- e. Hypertension.
- f. Diabetes mellitus.



APPENDIX 4: PAEDIATRIC LIVER TRANSPLANT VACCINATION GOALS AND SCHEDULE

1. Vaccine-preventable infections are a significant cause of morbidity and mortality in paediatric liver transplantation. Pre-transplant vaccinations and post-transplant management of vaccinations are key to success in paediatric patients.
2. Pre-transplant vaccinations:
 - 2.1. The goal is to have the vaccine schedule as “appropriately complete” as possible prior to transplant, maintaining the regular schedule if possible.
 - 2.2. Give all vaccines, both inactivated and live vaccines, a minimum of 1 month prior to transplant.
 - 2.3. All vaccines should be either given on the same day or separate the dosing by at least 1 month.
 - 2.4. Vaccines:
 - 2.4.1. Routine Inactivated Vaccines
 - a. Diphtheria / Tetanus/ Pertussis.
 - b. Polio Vaccine.
 - c. Hepatitis A.
 - d. Hepatitis.
 - e. Hemophilus influenzae type b.
 - f. Pneumococcus.
 - 2.4.2. Routine Live-Attenuated Vaccines:
 - a. Measles, Mumps, Rubella (MMR).
 - b. Varicella.



2.4.3. Other Recommended Vaccines:

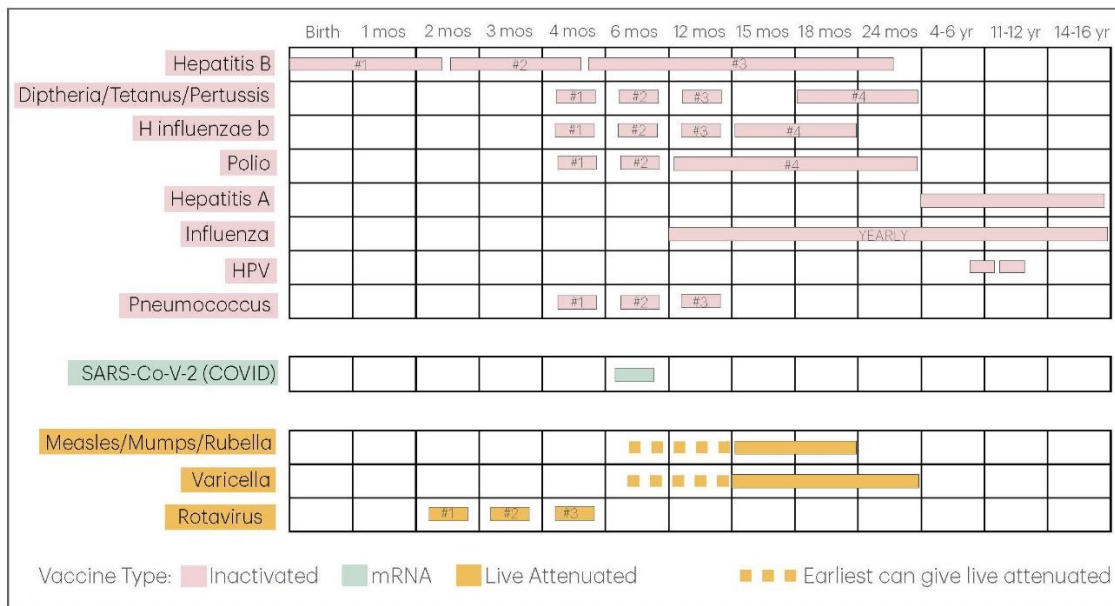
- a. SARS-Co-V-2 (COVID) (mRNA Vaccine).
- b. Human Papilloma Virus (Inactivated).
- c. Meningococcus (Inactivated).
- d. Rotavirus (Live-Attenuated).

3. Infant transplantation considerations:

3.1. A live vaccine can be given a minimum 9 months of age, but must be at least 6 weeks prior to transplant:

3.1.1. 2 doses of MMR should be given 6 weeks apart, if possible.

3.1.2. 2 doses of varicella should be given 3 months apart, if possible.



4. Posttransplant vaccinations:

4.1. No live-attenuated vaccinations should be given after transplant:

4.1.1. MMR should never be given post-transplant unless there is a local epidemic.



-
- 4.1.2. Varicella should never be given post-transplant.
 - 4.2. Influenza vaccine should be given annually starting 1 month after transplant.
 - 4.3. SARS-Co-V-2 (COVID) booster vaccines should be given according to recommendations.
5. Post-Splenectomy vaccinations:
- 5.1. Prior to splenectomy, the following vaccinations should be given (minimum 2 days, optimal 14 days prior):
 - 5.1.1. Hemophilus influenzae type b.
 - 5.1.2. Pneumococcus.
 - 5.1.3. Meningococcus.
 - 5.2. Penicillin V 125 – 250 mg PO BID or Amoxicillin 20 mg/kg/d should be given following the splenectomy as prophylaxis.

APPENDIX 5: CHECK-LIST FOR PANCREAS TRANSPLANT CANDIDATE WORKUP

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 PANCREAS TRANSPLANT CANDIDATE WORKUP		CHECK
PRELIMINARY EVALUATION	Patient medical history.	
	Family medical history.	
	Physical examination, including weight/BMI.	
	Detailed evaluation of patient's history of diabetes, length of treatment, and medications for treatment.	
	Surgical evaluation confirming the need for transplant and identifying technical challenges such as prior abdominal surgery and portal vein thrombosis.	
	Anesthesiology consult to identify any challenges related to high operative risk.	
	Performance status and nutritional status.	
LABORATORY TEST	ABO blood typing (perform 2 separate tests at different times, prior to addition to wait-list).	
	Complete blood count (CBC).	
	Complete liver enzyme panel, including AST, ALT, GGT, alkaline phosphatase, total bilirubin, direct bilirubin.	
	C-Peptide test.	
	HbA1C test.	
	Full Lipid panel (including LDL, HDL, VLDL, triglycerides, total cholesterol).	
	Complete Metabolic Panel (CMP) (including electrolytes, renal panel, Na, K, Cl, CO ₂ , Cr, BUN, Ca, PO ₄).	
	Urinalysis (including urine sediment examination).	
	Complete coagulation function panel (PT/INR, PTT, Fibrinogen).	
	Plasma proteins levels and protein electrophoresis.	
MICROBIOLOGY ASSESSMENT AND INFECTIOUS DISEASE TESTING	Hepatitis Panel: <ul style="list-style-type: none"> • Hepatitis A antibody (HAAb). • Hepatitis B core antibody (HBcAb). • Hepatitis B surface antibody (HBsAb). • Hepatitis B surface antigen (HBsAg). 	



	<ul style="list-style-type: none"> Hepatitis C antibody. 	
	Hepatitis Quantitative Testing: <ul style="list-style-type: none"> HBV – DNA. HCV – RNA. 	
	HIV Testing: <ul style="list-style-type: none"> HIV RNA. HIV Ag/Ab. 	
	Syphilis Antibody Testing: <ul style="list-style-type: none"> VDRL. TPHA. 	
	Serologies: <ul style="list-style-type: none"> CMV (IgM, IgG). EBV (IgM, IgG). Toxoplasmosis (IgM, IgG). HTLV I - II (IgM, IgG). 	
	Tuberculosis Test: <ul style="list-style-type: none"> Mantoux tuberculin skin test or QuantiFERON. 	
	Infectious Disease Consultant Evaluation (if indicated).	
CARDIOLOGIC ASSESSMENT*	Cardiologic examination.	
	ECG.	
	Echocardiogram.	
	Exercise cardiac stress test: <ul style="list-style-type: none"> Exercise/treadmill. Chemical (Dobutamine/persantine, adenosine) if cannot tolerate exercise. 	
	Chest X-ray.	
	<i>*Patients with positive screening tests shall be referred to cardiologist for further evaluation usually including coronary angiography. Intervention may allow for future listing.</i>	
IMAGING ASSESSMENT	Cross Sectional Imaging <ul style="list-style-type: none"> CT scan of chest. CT scan (Chest/Abdomen/Pelvis) with triple-phase contrast. MRI of abdomen/pelvis with gadolinium (if contrast CT contraindicated). 	
OTHER TESTING	Ophthalmic exam, including fundus exam.	



	Colonoscopy.	
	Esophagogastroduodenoscopy (including H Pylori test).	
	Dermatologic exam.	
	Psychological exam.	
	Anesthesiologist evaluation.	
GENDER- AND AGE-APPROPRIATE ONCOLOGICAL STUDIES	For females: <ul style="list-style-type: none"> • PAP cervical screening test. • Mammogram. 	
	For males: <ul style="list-style-type: none"> • Digital Prostate Exam. • PSA Testing. 	
DENTAL EXAM	Dental Examination, (including orthopantomogram).	
IMMUNOLOGIC EVALUATION	HLA Typing.	
	Panel reactive antibodies (PRA).	
	<p>Immunization Records Review or Catch-up: All patients shall receive the following vaccinations prior to transplant:</p> <ul style="list-style-type: none"> • Td or Tdap. • IPV. • Hepatitis B. • Meningococcal (conjugate). • Pneumococcal (conjugate and/or polysaccharide). • Hib. • Influenza (administered annually). • MMR. • Varicella. <p><i>Liver vaccines (MMR and varicella) administered before the transplant must be completed at least six weeks before transplantation.</i></p>	

APPENDIX 6: PRE-OPERATIVE LIVER 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-LIVER TRANSPLANT CHECK-LIST	
RECIPIENT CANDIDATE CHECKLIST	CHECK
Select an appropriate recipient candidate according to: <ul style="list-style-type: none"> • Donor/recipient medical compatibility. • Donor/recipient clinical match. • Donor demographics appropriate for recipient. • Medical urgency, time on waiting list. 	
Call the selected recipient candidate and admit to hospital (if not already an admitted patient).	
Confirm recipient identity and basic medical information, including: <ul style="list-style-type: none"> • Recipient unique identifier (i.e. Medical Record Number). • Recipient blood type. 	
Review pre-liver transplant workup 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.	
Request for Anesthesiologist re-evaluation.	
Alert ICU if postoperative ICU admission is expected.	
Order: <ul style="list-style-type: none"> • FOR ADULT PATIENTS: 4 units packed red blood cells (PRBC) and 4 units fresh frozen plasma (FFP). • FOR PAEDIATRIC PATIENTS: 2 units packed red blood cells (PRBC) and 2 units fresh frozen plasma (FFP). 	
Activate the operating teams and alert staff of OT times.	
Obtain written informed consent for Liver Transplant.	
Perform patient preoperative surgical preparation.	
Administer induction immunosuppression (including premedications).	
Prescribe antibiotic prophylaxis.	
If donor/recipient CMV mismatch, prescribe postoperative CMV prophylaxis.	



LIVER GRAFT CHECKLIST	CHECK
Confirm donor identity and donor/recipient matching, including blood type.	
Review donor demographic and clinical characteristics.	
Review organ procurement surgical report and description of allograft vascular anatomy.	
Review any pathological reports and histologic slides for steatosis and fibrosis.	
Evaluate the allograft quality at the back table and prepare the allograft for implantation including any required vascular reconstruction of aberrant vascular anatomy.	
Place allograft either in static cold storage in sterile bags on ice, or on a machine perfusion pump.	
Monitor machine perfusion pump for bile production, blood chemistries and lactate clearance (if applicable).	
LIVER TRANSPLANT CHECKLIST	CHECK
Prior to induction of anesthesia, confirm with the patient their identity, planned procedure, informed consent, any reported allergy.	
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: <ul style="list-style-type: none"> • Donor and recipient identification. • Organ type. • Blood type and subtype (if applicable) of both donor and recipient. • Blood type compatibility or intended incompatibility. • Liver segment laterality. 	



APPENDIX 7: PRE-OPERATIVE PANCREAS 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-PANCREAS TRANSPLANT CHECK-LIST	
RECIPIENT CANDIDATE CHECKLIST	CHECK
Select an appropriate recipient candidate according to <ul style="list-style-type: none"> • Donor/recipient medical compatibility. • Donor/recipient clinical match. • Donor demographics appropriate for recipient. • Medical urgency, time on waiting list. 	
Call the selected recipient candidate and admit to hospital.	
Confirm recipient identity and basic medical information, including: <ul style="list-style-type: none"> • Recipient unique identifier (i.e. Medical Record Number). • Recipient blood type. 	
Review transplant recipient pre-operative evaluation 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, ABO, Type and Crossmatch.	
Evaluate if Pre-transplant dialysis is required, and what type.	
Alert ICU of pending postoperative ICU admission.	
Order 2 packed red blood cells units.	
Activate the operating teams and alert staff of OT times.	
Obtain written informed consent for SPK or pancreas alone transplant.	
Perform patient preoperative surgical preparation.	
Administer induction immunosuppression (including premedications).	
Prescribe antibiotic prophylaxis.	
PANCREAS GRAFT CHECKLIST	CHECK
Confirm donor identity and donor/recipient matching including: <ul style="list-style-type: none"> • Donor identification, organ type • Donor blood type and subtype (if applicable), • Donor and recipient blood type compatibility (or intended incompatibility, if applicable) 	



<ul style="list-style-type: none"> • Correct donor organ has been identified for the correct recipient. 	
Review donor demographic and clinical characteristics.	
Review organ procurement surgical report and description of allograft vascular anatomy.	
Evaluate the allograft quality at the back table, prepare the allograft for implantation, and reconstruct the pancreas arterial anatomy with a vascular graft.	
Place allograft either in static cold storage in sterile bags on ice.	
PANCREAS TRANSPLANT CHECKLIST	CHECK
Prior to induction of anesthesia, confirm with the patient their identity, planned procedure, informed consent, any reported allergy.	
Mark site of implantation.	
Confirm the presence of the pancreas graft in the operation room and review machine perfusion data.	
Check availability of required specific surgical instruments and devices, such as aortic punch, urethral catheters, ureteral stents.	
Prepare 1L 0.9% saline with Centervidone for bladder insulation (for combined kidney-pancreas transplants only).	
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.	
<p>Conduct verification of the allograft upon organ receipts, with the intended recipient in the room, of:</p> <ul style="list-style-type: none"> • Donor and recipient identification. • Organ type. • Blood type and subtype (if applicable) of both donor and recipient. • Blood type compatibility or intended incompatibility. 	



APPENDIX 8: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DECEASED LIVER AND PANCREAS DONOR CANDIDATES

1. Health facility must maintain documentation in the donor's medical record to support that all elements of the protocol were followed.
2. Living liver donors must be evaluated as elaborated in the published DHA Standards for Living Donation Services.

CHECK-LIST FOR DECEASED DONOR EVALUATION		CHECK
PRELIMINARY EVALUATION	Physiologic and medical history of potential donor.	
	Family medical history.	
	Physical examination, including height, weight, blood pressure, temperature, heart rate.	
	Diagnosis (or cause of brain death).	
	Donor behavioural and social history.	
	Donor management information to date.	
	Demographic information, including age, sex, ethnicity, and race.	
	Organ Anatomy 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	Arterial blood gas results and ventilator settings.	
	Blood group (must be separate collections). <ul style="list-style-type: none"> • Sample 1 collection date, time, and result • Sample 2 collection date, time, and result. 	
	Complete blood count.	
	Complete Metabolic Panel (CMP) (including electrolytes, renal panel, Na, K, Cl, CO ₂ , Cr, BUN, Ca, PO ₄).	
	Full urine test with urine sediment exam, proteinuria in 24 hours.	
	Serum total and direct bilirubin.	



	Plasma protein levels and protein electrophoresis.	
	Full Lipid panel (including LDL, HDL, VLDL, triglycerides, total cholesterol).	
	Serum Liver Transaminases (AST, ALT), Gamma Glutamyl Transpeptidase (GGT), Alkaline Phosphatase (ALP), Lactate Dehydrogenase (LDH).	
	Complete coagulation function panel (PT/INR, PTT, Fibrinogen).	
MICROBIOLOGY TESTING	Urine culture test (2 times): <ul style="list-style-type: none"> Result 1 (day/time collected). Result 2 (day/time collected). 	
	Hepatitis B Panel: <ul style="list-style-type: none"> Hepatitis B core antibody (HBcAb). Hepatitis B surface antibody (HbsAb). Hepatitis B surface antigen (HbsAg). From donor samples obtained within 96 hours prior to organ procurement.	
	HCV Testing: <ul style="list-style-type: none"> HCV-RNA. HCV Ag/Ab. From donor samples obtained within 96 hours prior to organ procurement.	
	HIV Testing: <ul style="list-style-type: none"> HIV RNA. HIV Ag/Ab. From donor samples obtained within 96 hours prior to organ procurement.	
	Serologies: <ul style="list-style-type: none"> CMV (IgM, IgG). EBV (IgM, IgG). Toxoplasmosis (IgM, IgG). HTLV I – II (IgM, IgG). 	
	Syphilis Antibody Testing: <ul style="list-style-type: none"> 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.	
	MANTOUX, with blood testing if history of disease.	
	Additional testing may be considered in selected cases where clinically indicated such as endemic or geographic risks: <ul style="list-style-type: none"> • Coccidiomycosis antibody. • Malaria blood film. • Schistosomiasis antibody, urine microscopy. • Trypanosoma cruzi antibody. • Strongyloides steracoralis antibody. • West Nile Virus antibody/RN. 	
IMMUNOLOGICAL TESTS	HLA Typing.	
	Donor/Recipient cross match.	
OTHER PRELIMINARY EXAMINATIONS	Chest x-ray.	
	Specific examinations for previously suspected or diagnosed pathologies (chest CT scan, mammogram, and US).	
	Angio-CT scan or Angio-MR imaging.	
	Sputum gram stain, with description of sputum.	
ACCEPTABLE PANCREAS DONOR CRITERIA	Donor age less than 55 years old.	
EVALUATION OF DONOR LIVER AND/OR PANCREAS UPON ARRIVAL AT THE PROCUREMENT OPERATING THEATRE	Verification of consent for donation.	
	Verification of brain death.	
	Verification of ABO compatibility to the recipient.	
	Review recovery information, including: <ul style="list-style-type: none"> • Donor haemodynamics in donor O.T. prior to recovery. • Organ anatomy as described by recovering surgeon. • Any intraoperative findings noted by recovering surgeon. • Visualize organ in the back table basin. 	
	Review serologies.	
	Verify presence of donor iliac vessels for grafting.	
	Verify organ is appropriately packaged with triple barriers and the appropriate amount of ice is in cooler.	

APPENDIX 9: PARAMETERS FOR MONITORING LIVER 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.

ICU Clinical Parameters	Initial clinical markers of a functioning liver allograft: <ul style="list-style-type: none"> ● Body temperature (self-maintain >36°C). ● Urine output (> 50 ml per hour). ● Pressor requirements (decreasing number and dose of pressors). ● Improving neurological function, awake patient.
POD 0 – 2	<ul style="list-style-type: none"> ● Liver enzymes twice daily. ● Complete Blood Count (CBC) twice daily. ● Coagulation panel (PT/INR, PTT). ● Lactate (or Base Excess from ABG).
POD 3 – 10	<ul style="list-style-type: none"> ● Liver enzymes daily. ● Complete Blood Count (CBC) daily. ● Immunosuppressant (tacrolimus, cyclosporin) trough level daily.
POD 10 – 30	<ul style="list-style-type: none"> ● Liver enzymes twice per week. ● Complete Blood Count (CBC) twice per week. ● Immunosuppressant (tacrolimus, cyclosporin) trough level twice per week.
POD 30 – 90	<ul style="list-style-type: none"> ● Liver enzymes once per week. ● Complete Blood Count (CBC) once per week. ● Immunosuppressant (tacrolimus, cyclosporin) trough level once per week.
POD 90 - 180	<ul style="list-style-type: none"> ● Liver enzymes twice per month. ● Complete Blood Count (CBC) twice per month. ● Immunosuppressant (tacrolimus, cyclosporin) trough level twice per month.
POD 180 ->	<ul style="list-style-type: none"> ● Liver enzymes once per month. ● Complete Blood Count (CBC) once per month.



	<ul style="list-style-type: none"> Immunosuppressant (tacrolimus, cyclosporin) trough level once per month.
Color Doppler Ultrasound Liver	<p>On POD 1 and POD 7, and when clinically indicated by elevated liver enzymes to assess for vascular complications (hepatic artery, portal vein, hepatic vein):</p> <ul style="list-style-type: none"> Assess Liver Inflow: <ul style="list-style-type: none"> Hepatic artery flow: <ul style="list-style-type: none"> Measure left and right hepatic artery flow within liver parenchyma. Resistive Index (RI) normal range 0.6 – 0.9. Portal vein flow: <ul style="list-style-type: none"> Flow velocity and direction (normal range 20 cm/s – 40 cm/s). Assess Liver Outflow. Hepatic vein triphasic waveform.
Body Temperature	<p>In presence of fever, the following investigations are indicated:</p> <ul style="list-style-type: none"> Complete Blood Count (CBC). Urinalysis. Urine culture. Blood culture (obtained from venipuncture, not a central line). Wound secretion culture (if present). Duplex ultrasound liver. Chest x-ray. CT scan of Abdomen / Pelvis (if warranted by clinical suspicion).
CMV Viral Surveillance – ADULT	<ul style="list-style-type: none"> All donors and recipients should be tested for baseline CMV-IgG serology prior to transplantation. Risk should be determined for donor-recipient pair. Prophylaxis: <ul style="list-style-type: none"> Valganciclovir 900 mg PO daily. Duration: <ul style="list-style-type: none"> D+/R- 3-6 months. R+ 3 months. D-/R- None required. Preemptive: <ul style="list-style-type: none"> Weekly CMV QNAT weekly for 12 weeks after transplant. (+) threshold treat with valganciclovir 900 mg PO BID or IV ganciclovir 5 mg/kg every 12h until (-) test obtained. Test for any fever, gastroenteritis symptoms, persistent elevation of liver transaminases.
CMV Viral Surveillance –	<ul style="list-style-type: none"> All donors and recipients should be tested for baseline CMV-IgG serology prior to transplantation. Risk should be determined for donor-recipient pair.



PAEDIATRIC	<ul style="list-style-type: none"> ● Prophylaxis: <ul style="list-style-type: none"> ○ Ganciclovir 5 mg/kg IV daily for as long as the patient is NPO. ○ Duration: <ul style="list-style-type: none"> ● D+/R- 3-6 months. ● R+ 3 months. ● D-/R- None required. ● Preemptive: <ul style="list-style-type: none"> ○ Weekly CMV QNAT weekly for 12 weeks after transplant. ○ (+) threshold treat with 17 mg/kg valganciclovir (up to 900 mg) PO BID or IV ganciclovir 5 mg/kg every 12h until (-) test obtained. ● Test for any fever, gastroenteritis symptoms, persistent elevation of liver transaminases. ● Long-term Viral Monitoring: <ul style="list-style-type: none"> ○ CMV and EBV quantitative PCR <ul style="list-style-type: none"> ● 1st Year - CMV / EBV monthly ● 2nd Year - CMV / EBV every 3 months ● 3rd Year - CMV / EBV every 6 months ● >3rd Year - CMV / EBV annually
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APPENDIX 10: SURVEILLANCE FOR LONG-TERM IMMUNOSUPPRESSION 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.

Cardiovascular Complications	<ul style="list-style-type: none"> ● Cardiovascular disease reduction: <ul style="list-style-type: none"> ○ Weight loss strategies. ○ Management of dyslipidemia, hypertension, and diabetes mellitus. ● Routine cardiology examination.
Infectious complications	<ul style="list-style-type: none"> ● Cytomegalovirus (CMV) – As outlined in Appendix 8. ● Epstein Barr Virus (EBV) – EBV-DNA viral load for lymphadenopathy, persistent splenomegaly, fevers. ● Herpes Simplex Virus (HSV-1,-2) – Clinical examination for orolabial, genital or perianal lesions. ● Human Papilloma Virus (HPV) – if clinically indicated. ● Hepatitis C Virus (HCV) / Hepatitis B Virus (HBV) – if clinically indicated.
Oncologic complications	<ul style="list-style-type: none"> ● Yearly evaluation: <ul style="list-style-type: none"> ○ Skin Cancer – Dermatological examination every year. ○ Liver/Abdominal Cancer – Ultrasound every year. ● Per local guidelines: <ul style="list-style-type: none"> ○ Prostate Cancer – Urological exam, digital rectal exam, PSA level. ○ Breast Cancer – Mammogram. ○ Cervical Cancer – PAP smear. ○ Gastrointestinal Cancer – Fecal occult blood test, colonoscopy, esophagogastroduodenoscopy. ● Posttransplant Lymphoproliferative Disease – EBV-DNA.
Bone complications	<ul style="list-style-type: none"> ● Increased mobilization and avoidance of smoking. ● Labs: Measure serum calcium, phosphate, alkaline phosphatase, magnesium, albumin, PTH every 6 months. ● Imaging (if indicated): <ul style="list-style-type: none"> ○ Dual energy x-ray absorptiometry (DEXA). ○ Bone mineral density (BMD). ○ Spinal x-rays (thoracic, lumbar spine). ● Serum 25-hydroxyvitamin. ● Endocrinology examination (if indicated).

APPENDIX 11: IMMUNOSUPPRESSIVE THERAPY FOR ADULT LIVER TRANSPLANT RECIPIENTS

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

POD 0	<p>Induction therapy:</p> <ul style="list-style-type: none"> • Methylprednisolone 1000 mg i.v. in the operating room prior to graft reperfusion. • Mycophenolate Mofetil 1000 mg i.v. • Anti-thymocyte globulin (ATG) 1 mg/kg i.v. on POD 1-3 (May be considered in select recipients with high immunologic risk or renal compromise).
POD 1-5	<ul style="list-style-type: none"> • Tacrolimus 0.5 mg/kg PO BID (Start POD3). • Mycophenolate Mofetil 1000 mg i.v. BID. • Steroid Taper: <ul style="list-style-type: none"> ○ Methylprednisolone 200 mg i.v. (POD 1). ○ Methylprednisolone 160 mg i.v. (POD 2). ○ Methylprednisolone 120 mg i.v. (POD 3). ○ Methylprednisolone 80 mg i.v. (POD 4). ○ Methylprednisolone 40 mg i.v. (POD 5).
POD 6->	<ul style="list-style-type: none"> • Tacrolimus 0.5 mg/kg PO BID (Dosing titrated to reach therapeutic level below). • Mycophenolate Mofetil 1000 mg PO BID. • Steroid Taper: <ul style="list-style-type: none"> ○ Prednisone 20 mg (POD 6 – POD 13). ○ Prednisone 15 mg (POD 14 – POD 20). ○ Prednisone 10 mg (POD 21 – POD 27). ○ Prednisone 5 mg. ○ Prednisone Discontinued. • Tacrolimus Therapeutic Level Goals <ul style="list-style-type: none"> ○ 0 - 3 weeks posttransplant: 10 – 12 mg/dL ○ 3 weeks – 6 weeks: 8 – 10 mg/dL ○ 6 weeks – 6 months: 6 – 8 mg/dL ○ 6 months – 1 year: 5 – 6 mg/dL



APPENDIX 12: IMMUNOSUPPRESSIVE THERAPY FOR PAEDIATRIC LIVER TRANSPLANT RECIPIENTS

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

<p>POD 0</p>	<p>Induction therapy</p> <ul style="list-style-type: none"> • Methylprednisolone 10 mg/kg i.v. in the OR prior to graft reperfusion <u>and</u> choose one of the following: <ul style="list-style-type: none"> ○ Basiliximab 10 mg (for patients <35 kg) or 20 mg (for patient >35 kg) on POD 0 and POD 4. • Premedicate with acetaminophen 10 mg/kg to a maximum 650 mg and diphenhydramine 1mg/kg to a maximum 50 mg. <p><u>OR</u></p> <ul style="list-style-type: none"> ○ Antithymocyte Globulin 1mg/kg IV daily starting POD 0 for 2 – 5 days (ATG used for autoimmune hepatitis and retransplant patients). • Premedicate with acetaminophen 10 mg/kg to a maximum 650 mg and diphenhydramine 1mg/kg to a maximum 50 mg.
<p>POD 1-5</p>	<ul style="list-style-type: none"> • Tacrolimus 0.1-0.3 mg/kg PO q12h. • Steroid Taper: <ul style="list-style-type: none"> ○ Methylprednisolone 5 mg/kg i.v. (POD 1). ○ Methylprednisolone 4 mg/kg i.v. (POD 2). ○ Methylprednisolone 3 mg/kg i.v. (POD 3). ○ Methylprednisolone 2 mg/kg i.v. (POD 4). ○ Methylprednisolone 1 mg/kg i.v. (POD 5).
<p>POD 6-></p>	<ul style="list-style-type: none"> • Tacrolimus 0.1-0.3 mg/kg PO q12h. • Steroid Taper: <ul style="list-style-type: none"> ○ Prednisone 0.3 mg/kg PO (POD 6 – POD 13). ○ Prednisone 0.225 mg/kg PO (POD 14 – POD 20). ○ Prednisone 0.15 mg/kg PO (POD 21 – POD 27). ○ Prednisone 0.075 mg/kg PO (POD 28 – POD 365). ○ Prednisone Discontinued. • Tacrolimus Therapeutic Level Goals <ul style="list-style-type: none"> ○ 0 - 2 weeks posttransplant: 12 – 15 mg/dL ○ 2 weeks – 4 weeks: 10 – 12 mg/dL ○ 4 weeks – 3 months: 6 – 8 mg/dL



- 3 months – 6 months: 4 – 7 mg/dL
- 6 months – 1 year: 3 – 7 mg/dL

2. Generally, dual therapy is used in paediatric patients to limit the risks of PTLD. In those recipients with autoimmune disorders or a history of rejections, a third agent can be added:

- 2.1. Mycophenolate Mofetil 300 mg/m² BID to a maximum of 2000 mg/dL.
- 2.2. Patients with BSA 1.25 - 1.5m² may be dosed 750 mg PO BID.
- 2.3. Patients with BSA >1.5m² may be dosed at 1000 mg PO BID.



APPENDIX 13: PROTOCOLS OF ACUTE LIVER REJECTION THERAPY IN ADULT RECIPIENTS

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. Exclude all other causes of graft dysfunction including vascular causes.
3. Liver graft biopsy is performed either by an ultrasound-guided transcutaneous approach, or an interventional radiology transjugular approach.
4. The Banff Schema is used to grade the liver biopsy for acute cellular rejection (ACR):
 - 4.1. Rejection Activity Index (RAI) score of 3-4 (Mild) or 5-6 (Moderate) receives the following treatment:
 - 4.1.1. Methylprednisolone 1000mg i.v. on day 1-2 and 500mg i.v. on day 3.
 - 4.1.2. Tacrolimus levels must be maintained at 12-15mg/dl during this treatment.
 - 4.1.3. Continue mycophenolate mofetil 1000mg per os BID.
 - 4.1.4. Antiviral prophylaxis with valganciclovir 450mg per os daily should be initiated.
 - 4.2. Rejection Activity Index (RAI) score of 7-9 (Severe) or ACR unresponsive to steroids as demonstrated on repeat liver biopsy, or recurrent ACR, is treated with:
 - 4.2.1. Anti-thymocyte globulin (ATG) 1mg / kg for 7 days (ATG needs platelets > 50 and WBC > 2 to receive daily dose).
 - 4.2.2. Antiviral prophylaxis with valganciclovir 900 mg PO daily should be initiated.



APPENDIX 14: PROTOCOLS OF ACUTE LIVER REJECTION THERAPY IN PAEDIATRIC RECIPIENTS

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. Exclude all other causes of graft dysfunction including vascular causes.
3. Liver graft biopsy is performed either by an ultrasound-guided transcutaneous approach, or an interventional radiology transjugular approach.
4. The Banff Schema is used to grade the liver biopsy for acute cellular rejection (ACR):
 - 4.1. Rejection Activity Index (RAI) score of 3-4 (Mild) receives the following treatment:
 - 4.1.1. Maintain tacrolimus levels at 12-15 mg/dL during this treatment.
 - 4.1.2. Consider adding mycophenolate mofetil 300 mg/m² BID to a maximum of 2000 mg/d .
 - a. Patients with BSA 1.25 - 1.5m² may be dosed 750 mg PO BID.
 - b. Patients with BSA >1.5m² may be dosed at 1000 mg PO BID.
 - 4.1.3. Move to steroid bolus if no clear improvement in LFTs.
 - 4.2. Rejection Activity Index (RAI) score of 5-6 (Moderate) receives the following treatment:
 - 4.2.1. Methylprednisolone 1000 mg i.v. on Day 1 and Day 2 and 500 mg i.v. on Day 3.
 - 4.2.2. Maintain tacrolimus levels at 12-15 mg/dL during this treatment.
 - 4.2.3. Add mycophenolate mofetil 300 mg/m² BID to a maximum of 2000 mg/d.



- a. Patients with BSA 1.25 - 1.5m² may be dosed 750 mg PO BID.
 - b. Patients with BSA >1.5m² may be dosed at 1000 mg PO BID.
- 4.2.4. Valganciclovir 15 mg/kg daily once tolerating PO intake (to a maximum dose of 450 mg).
- 4.3. Rejection Activity Index (RAI) score of 7-9 (Severe), or ACR unresponsive to steroids as demonstrated on repeat liver biopsy, or recurrent ACR, is treated with:
- 4.3.1. Anti-thymocyte globulin (ATG) 1 mg/kg for 7 days (ATG needs platelets > 50 and WBC > 2 to receive dose).
 - 4.3.2. Maintain tacrolimus levels at 12-15 mg/dL during this treatment.
 - 4.3.3. Add mycophenolate mofetil 300 mg/m² BID to a maximum of 2000 mg/d.
 - a. Patients with BSA 1.25 - 1.5m² may be dosed 750 mg PO BID.
 - b. Patients with BSA >1.5m² may be dosed at 1000 mg PO BID.
 - 4.3.4. Valganciclovir 15 mg/kg daily once tolerating PO intake (to a maximum dose of 450 mg).



APPENDIX 15: PROTOCOLS OF LIVER CHRONIC ALLOGRAFT DYSFUNCTION (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. Elevated liver enzymes:
 - 2.1. Elevated liver enzymes can present as vascular, immunological, biliary, and infectious etiologies, and should be approached based upon the following urgency:
 - 2.1.1. Most urgent: vascular complications.

Diagnostic Evaluation	<ul style="list-style-type: none"> • Elevated liver enzymes: <ul style="list-style-type: none"> ○ Duplex Ultrasound liver to measure hepatic artery and portal vein flow and hepatic vein waveform. ○ Conventional or CT angiography for reduced RI or absent artery flow. ○ IVC venogram and anastomotic pressure gradient.
Therapeutic Management	<ul style="list-style-type: none"> • Hepatic Artery Stenosis (HAS): <ul style="list-style-type: none"> ○ Interventional radiology for angioplasty and stenting of stenosis. ○ Surgical revision with aortohepatic conduit. • Hepatic Artery Thrombosis (HAT): <ul style="list-style-type: none"> ○ Surgical thrombectomy. ○ Surgical revision with aortohepatic conduit. • Portal Vein Stenosis: <ul style="list-style-type: none"> ○ Interventional radiology for stenting or TIPS. • Portal Vein Thrombosis: <ul style="list-style-type: none"> ○ (Early) Surgical thrombectomy. ○ (Late) Anticoagulation. ○ Interventional radiology for TIPS + mechanical thrombectomy. • Hepatic Vein Stenosis: <ul style="list-style-type: none"> ○ Vena cava/hepatic vein balloon angioplasty. ○ Vena cava/hepatic vein stenting.

2.1.2. Second-most urgent: immunological complications.

Diagnostic Evaluation	<ul style="list-style-type: none"> Elevated liver enzymes: <ul style="list-style-type: none"> Liver Biopsy (Ultrasound-guided percutaneous or interventional radiology performed transjugular approach). Donor-Derived cell-free DNA assay or other commercial biomarkers.
Therapeutic Management	<ul style="list-style-type: none"> Pathological grading of acute cellular rejection: <ul style="list-style-type: none"> Treatment of ACR as outlined in Appendix 14.

2.1.3. Third-most urgent: biliary complications.

For ADULT recipients	
Diagnostic Evaluation	<ul style="list-style-type: none"> Elevated liver enzymes, particularly total bilirubin, and alkaline phosphatase: <ul style="list-style-type: none"> MRCP – screening test before more invasive biliary diagnostics. ERCP – for duct-to-duct biliary reconstruction. PTC – for hepaticojejunostomy biliary reconstruction.
Therapeutic Management	<ul style="list-style-type: none"> Biliary Leak: <ul style="list-style-type: none"> ERCP / PTC – Covered biliary stent. Surgical revision with hepaticojejunostomy creation. Biliary Stricture: <ul style="list-style-type: none"> ERCP / PTC - Balloon plasty and stent placement. Surgical revision with hepaticojejunostomy creation.
For PAEDIATRIC recipients	
Diagnostic Evaluation	<ul style="list-style-type: none"> Elevated liver enzymes, particularly total bilirubin, and alkaline phosphatase: <ul style="list-style-type: none"> MRCP – screening test before more invasive biliary diagnostics (US is not a sensitive-enough study). Liver biopsy – If performed, may show bile duct proliferation. PTC – this is the mainstay of biliary imaging for most paediatric cases, and for all hepaticojejunostomy. ERCP – Can consider for older/larger paediatric cases.
Therapeutic Management	<ul style="list-style-type: none"> Biliary Leak: <ul style="list-style-type: none"> PTC with stent (can consider ERCP in older paediatric



	<p>patients).</p> <ul style="list-style-type: none"> ○ Surgical revision with hepaticojejunostomy creation. ● Biliary Stricture: <ul style="list-style-type: none"> ○ PTC with balloon plasty and stent placement (can consider ECRP in older paediatric patients). ● Surgical revision with hepaticojejunostomy creation.
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2.1.4. Fourth-most urgent: infectious complications, considered particularly in a setting of prior vascular and biliary complications.

For ADULT recipients	
Diagnostic Evaluation	<ul style="list-style-type: none"> ● Elevated liver enzymes, particularly total bilirubin, and alkaline phosphatase: <ul style="list-style-type: none"> ○ MRCP – screening test before more invasive biliary diagnostics. ○ ERCP – for duct-to-duct biliary reconstruction. ○ PTC – for hepaticojejunostomy biliary reconstruction.
Therapeutic Management	<ul style="list-style-type: none"> ● Cholangitis: <ul style="list-style-type: none"> ○ Associated with biliary obstruction. ○ Antibiotics +/- ERCP/PTC. ● Infected Biloma: <ul style="list-style-type: none"> ○ Associated with hepatic artery complications and biliary obstruction. ○ Antibiotics +/- ERCP/PTC. ● Abscess: <ul style="list-style-type: none"> ○ Antibiotics. ○ Percutaneous drainage for large abscess.
For PAEDIATRIC recipients	
Diagnostic Evaluation	<ul style="list-style-type: none"> ● Elevated liver enzymes, particularly total bilirubin, and alkaline phosphatase: <ul style="list-style-type: none"> ○ MRCP – screening test before more invasive biliary diagnostics (US is not a sensitive-enough study). ○ PTC – this is the mainstay of biliary imaging for most paediatric cases, and for all hepaticojejunostomy. ○ ERCP – Can consider for older/larger paediatric cases.



Therapeutic Management	<ul style="list-style-type: none"> ● Cholangitis: <ul style="list-style-type: none"> ○ Associated with biliary obstruction. ○ Antibiotics +/- PTC (or ERCP for older paediatric cases). ● Infected Biloma: <ul style="list-style-type: none"> ○ Associated with hepatic artery complications and biliary obstruction. ○ Antibiotics +/- PTC (or ERCP for older paediatric cases). ● Abscess: <ul style="list-style-type: none"> ○ Antibiotics. ○ Percutaneous drainage for large abscess.
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2.1.5. Next-most urgent: Other complications such as graft-versus-host-disease (GVHD) or posttransplant lymphoproliferative disease (PTLD).

Diagnostic Evaluation	<ul style="list-style-type: none"> ● Graft-Versus-Host Disease (GVHD): <ul style="list-style-type: none"> ○ Skin biopsy for unexplained maculopapular rash. ○ Colon biopsy for refractory diarrhea. ● Posttransplant Lymphoproliferative Disease (PTLD): <ul style="list-style-type: none"> ○ Elevated EBV-DNA for symptoms of fatigue and fever. ○ Lymph node biopsy.
Therapeutic Management	<ul style="list-style-type: none"> ● Graft-Versus-Host Disease (GVHD): <ul style="list-style-type: none"> ○ Poor prognosis and unclear therapeutic options. ○ Supratherapeutic immunosuppression or cessation to induce ACR. ● Posttransplant Lymphoproliferative Disease (PTLD): <ul style="list-style-type: none"> ○ Reduction of immunosuppression to 1/3 level or complete cessation. ○ Treatment with valganciclovir. ○ Treatment with rituximab for lymph node biopsy that stains CD-20+. ○ Treatment with chemotherapy +/- surgery.

2.1.6. Next-most urgent: Post-transplant ascites, usually for several weeks posttransplant. For postoperative ascites that persists >1 month posttransplant:



<p>Associated Conditions</p>	<ul style="list-style-type: none"> • Medical Conditions Associated with Ascites: <ul style="list-style-type: none"> ○ Renal failure / acute kidney injury. ○ Hypoalbuminemia. ○ Right heart failure. ○ Tuberculosis / Malignancy (rare). • Surgical Complications Associated with Ascites: <ul style="list-style-type: none"> ○ IVC / Hepatic vein anastomotic stenosis. ○ Portal vein anastomotic stenosis.
<p>Diagnostic Evaluation and Therapeutic Management</p>	<ul style="list-style-type: none"> • Labs: serum creatinine, BUN, albumin. • Echocardiogram: <ul style="list-style-type: none"> ○ Diagnose cardiac etiology including constrictive pericarditis, restrictive cardiomyopathy, or right heart failure. • IVC/Hepatic Vein Venogram/Anastomotic Pressure Gradient: <ul style="list-style-type: none"> ○ Transanastomotic gradient >3 mmHg -> balloon angioplasty + stent. ○ Transhepatic wedge pressure >10 mmHg -> Liver biopsy for fibrosis. • CT Angiogram with Portal Venous Phase: <ul style="list-style-type: none"> ○ Confirm via hepatic artery angiogram delayed portal vein images. ○ Interventional radiology transhepatic portal vein stenting. • Laparoscopic Peritoneal Biopsy: <ul style="list-style-type: none"> ○ For ascites refractory to all other diagnoses.

2.1.7. Next-most urgent: Side effects and complications associated with CNI, which can result in conversion of CNI to an m-TOR inhibitor such as sirolimus (Rapamycin):

<p>Indications for mTOR Inhibitors</p>	<ul style="list-style-type: none"> • CNI-associated side effects: <ul style="list-style-type: none"> ○ CNI nephrotoxicity. ○ CNI neurotoxicity. • Advanced hepatocellular carcinoma. • History of pretransplant skin malignancies. • Posttransplant malignancy. • Coronary artery disease progression (relative indication).
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	<ul style="list-style-type: none"> • Morbid obesity (relative indication).
Contraindication for mTOR Inhibitors	<ul style="list-style-type: none"> • Moderate/severe protein-calorie malnutrition. • Pre-existing significant proteinuria (>300 mg/d). • Pre-existing significant wound healing issues.
mTOR Inhibitor Conversion Protocol	<ul style="list-style-type: none"> • Aim for a conversion > 3 months posttransplant. • Rule out pre-existing proteinuria. • Start mycophenolate mofetil if not already taking: <ul style="list-style-type: none"> ○ For adult patients: 1000 mg PO BID. ○ For paediatric patients: 300 mg/m² BID to a maximum of 2000 mg/d. • ASA: <ul style="list-style-type: none"> ○ For adult patients: 325 mg PO daily. ○ For paediatric patients: 81 mg PO daily. • Sirolimus: <ul style="list-style-type: none"> ○ For adult patients: 2mg PO daily. ○ For paediatric patients: 0.04 mg/d. • Discontinue CNI after starting sirolimus (no overlap required). • Check sirolimus level at 10 days post initiation. Goal level of 4-12 ng/ml. • Avoid titration except for persistent repeat suprathreshold levels.
Treatment of mTOR Inhibitor Side Effects	<ul style="list-style-type: none"> • Proteinuria: <ul style="list-style-type: none"> ○ Treat with statins and ACE-inhibitors. ○ Discontinue mTOR inhibitor for nephrotic-level proteinuria > 1g/d. • Mouth Ulcers: <ul style="list-style-type: none"> ○ Treat with Kenalog-in-orobase topical therapy. • Hyperlipidemia / Hypertriglyceridemia: <ul style="list-style-type: none"> ○ Treat with statin and fish oil. ○ Discontinue mTOR inhibitor for triglycerides >1000 mg/dL. • Neutropenia: <ul style="list-style-type: none"> ○ Dose reduction of mTOR inhibitor for WBC < 3 10⁹/L cells. ○ Treat with neupogen for WBC < 2 10⁹/L cells. • Pneumonitis: <ul style="list-style-type: none"> ○ Discontinue sirolimus.

APPENDIX 16: PARAMETERS FOR MONITORING PANCREAS 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.

Diuresis	Daily urine output, creatinine clearance, urine sediment, urine culture.
Body temperature	<p>In presence of fever, the following investigations are indicated:</p> <ul style="list-style-type: none"> ○ Full blood count. ○ Renal function panel. ○ Full urine test. ○ Urine culture. ○ Haemoculture. ○ Microbiological culture of the abdominal drainage liquid and wound secretion (if indicated). ○ US scan. ○ Chest x-ray.
Abdominal drainage tube	<ul style="list-style-type: none"> ● Daily output. ● Measurement of creatinine, LDH, glucose; microbiological culture (if indicated).
Laboratory tests	<ul style="list-style-type: none"> ● Full blood count, glucose, BUN, creatinine, sodium, potassium; if indicated 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. <ul style="list-style-type: none"> ○ After 1-2 weeks post PT or earlier in presence of signs of gastroenteritis, fever, liver transaminases serum level increase. ○ Once a month for the first 4 months after transplant. ○ Thereafter when clinically indicated; in presence of Donor+ / Recipient-,



	<p>valganciclovir prophylaxis is indicated with CMV-DNA determination every 15 days.</p> <ul style="list-style-type: none"> ● BKV-DNA in blood and urine. <ul style="list-style-type: none"> ○ At 1, 3, 6 and 9 months after transplant. ○ Yearly from the 1st to the 5th year, or when clinically indicated. ● Immunosuppressant trough levels: <ul style="list-style-type: none"> ○ Daily following transplant. ○ Twice a week in the first month post-transplant. ○ Once a week in the second month post-transplant. ○ Twice a month for the following 3-4 months. ○ Thereafter once a month.
<p>Graft US scan with Color Doppler</p>	<p>When clinically indicated.</p>



APPENDIX 17: SURVEILLANCE FOR PANCREAS 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.

Cardiovascular diseases	Follow up cardiologic examination and tests as appropriate.
Infectious complications	<ul style="list-style-type: none"> • Urine culture when indicated. • CMV-DNA: once a month for the first 4 months after PT and thereafter when clinically indicated. • BKV-DNA in blood and urine: at 1, 3, 6 and 9 months after PT or when clinically indicated. • HIV/HCV/HBV NAT: Between 1 to 2 months post-transplant. • HBV and HCV: once a year in serum negative recipients, according to hepatologic indications in serum positive recipients. • HHV8 –HPV, if clinically indicated.
Oncologic complications	<ul style="list-style-type: none"> • 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.
Bone complications	<ul style="list-style-type: none"> • 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 18: IMMUNOSUPPRESSIVE THERAPY FOR PANCREAS TRANSPLANT RECIPIENTS

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

POD 0	<p>Induction therapy:</p> <ul style="list-style-type: none"> • Basiliximab (IL2 receptor antagonist): 20mg i.v., 2 hours before transplant. • Rabbit ATG (1.5mg/kg IBW) i.v. infusion to begin prior to reperfusion. <p>Maintenance therapy:</p> <ul style="list-style-type: none"> • Methylprednisolone 250 mg i.v. (o 500mg in selected cases) in the operating room.
POD 1-2	<ul style="list-style-type: none"> • Methylprednisolone 250 mg i.v. OD. • MMF 1g per os BID. • Tacrolimus 0.1mg/kg per os BID (in rapid steroid descaling protocol).
POD 3 -->	<p>Rapid steroid descaling protocol:</p> <ul style="list-style-type: none"> • Methylprednisolone 20 mg per os OD. • MMF 1g per os BID. • Tacrolimus 0.1mg/kg per os BID.
	<p>Gradual steroid descaling protocol:</p> <ul style="list-style-type: none"> • Methylprednisolone 150mg (POD3) --> 100mg (POD4) --> 75mg (POD5) --> 50mg (POD6) --> 20mg (POD7). • MMF 1g per os BID.

APPENDIX 19: PROTOCOLS OF PANCREAS 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. Exclusion of other potential cause of graft dysfunction; graft biopsy proven:

Acute cell-mediated rejection	<ul style="list-style-type: none"> • Methylprednisolone 250 – 500 mg i.v OD x 3 days. • In presence of non-responsive rejection or rapidly relapsing rejection: ATG 1-1.5 mg / Kg OD x 7-14 days.
Acute antibody mediated C4d positive rejection (BANFF grade I, II)	<ul style="list-style-type: none"> • Methylprednisolone 10 mg / Kg OD 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, STAT.
Severe Acute antibody mediated positive rejection (BANFF grade III), thrombotic microangiopathy	<ul style="list-style-type: none"> • Same protocol as for Grade II. + <ul style="list-style-type: none"> • Plasmapheresis on DAY 1, 2, 3, 5 and 7. • DAY 7, after plasmapheresis: High dose Immunoglobulins (2g/ Kg) or CMV specific Immunoglobulins (100mg / Kg), STAT. • DAY 8: Rituximab 375mg / m², STAT. • Monitoring of DSA: on DAY 1 before therapy initiation, DAY 3 after plasmapheresis, DAY 8 after Rituximab administration.

3. Tacrolimus therapy is maintained with target trough levels 10-15 ng/ml, and MMF 1g BID.
4. Antibiotic prophylaxis must be instituted:
 - 4.1. Ganciclovir at dosage adjusted to renal function, for CMV.
 - 4.2. Fluconazole 100mg OD x 1 month, Nistamine per os x 1 month.
 - 4.3. Trimetoprim Sulfamethoxazole 80 mg OD x 6 months, for Pneumocystis jiroveci.

APPENDIX 20: PROTOCOLS OF PANCREAS 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. In the presence of pancreatic function decline with arterial hypertension and proteinuria, graft biopsy indicated, multifactorial pathogenesis (non-immunologic and immunologic factors).

Treatment of non-immunologic factors	<ul style="list-style-type: none"> • Arterial pressure pharmacological therapy. • Anti-proteinuria therapy (ACE inhibitor). • Dyslipidemia therapy and weight loss in presence of obesity. • Glycemic control. • Minimization of Calcineurin Inhibitors (CNI) therapy, if GFR > 40 mL/min.
Treatment of immunologic factors	<ul style="list-style-type: none"> • Plasmapheresis followed by CMV specific Immunoglobulins (100mg / Kg) on DAY 1, 3, 5, 7. • On DAY 10: DSA dosage --> if still present, repeat the therapy up to a maximum of 3 times / year.

3. CNI therapy conversion to m-Tor inhibitors.

Indications for mTOR Inhibitors	<ul style="list-style-type: none"> • CNI-associated side effects: <ul style="list-style-type: none"> ○ CNI nephrotoxicity. ○ CNI neurotoxicity. • History of pretransplant skin malignancies. • Posttransplant malignancy. • Coronary artery disease progression (relative indication). • Morbid obesity (relative indication).
Contraindication for mTOR Inhibitors	<ul style="list-style-type: none"> • Moderate/severe protein-calorie malnutrition. • Pre-existing significant proteinuria (>300 mg/d). • Pre-existing significant wound healing issues.
mTOR Inhibitor Conversion Protocol	<ul style="list-style-type: none"> • Aim for a conversion > 3 months posttransplant. • Rule out pre-existing proteinuria.



	<ul style="list-style-type: none"> ● Start mycophenolate mofetil if not already taking: <ul style="list-style-type: none"> ○ For adult patients: 1000 mg PO BID. ○ For paediatric patients: 300 mg/m² BID to a maximum of 2000 mg/d. ● ASA: <ul style="list-style-type: none"> ○ For adult patients: 325 mg PO daily. ○ For paediatric patients: 81 mg PO daily. ● Sirolimus: <ul style="list-style-type: none"> ○ For adult patients: 2mg PO daily. ○ For paediatric patients: 0.04 mg/d. ● Discontinue CNI after starting sirolimus (no overlap required). ● Check sirolimus level at 10 days post initiation. Goal level of 4-12 ng/ml. ● Avoid titration except for persistent repeat supratherapeutic levels.
<p>Treatment of mTOR Inhibitor Side Effects</p>	<ul style="list-style-type: none"> ● Proteinuria: <ul style="list-style-type: none"> ○ Treat with statins and ACE-inhibitors . ○ Discontinue mTOR inhibitor for nephrotic-level proteinuria > 1g/d. ● Mouth Ulcers: <ul style="list-style-type: none"> ○ Treat with Kenalog-in-orobase topical therapy. ● Hyperlipidemia / Hypertriglyceridemia: <ul style="list-style-type: none"> ○ Treat with statin and fish oil. ○ Discontinue mTOR inhibitor for triglycerides >1000 mg/dL. ● Neutropenia: <ul style="list-style-type: none"> ○ Dose reduction of mTOR inhibitor for WBC < 3 10⁹/L cells. ○ Treat with neupogen for WBC < 2 10⁹/L cells. ● Pneumonitis: <ul style="list-style-type: none"> ○ Discontinue sirolimus.



4. CMV Infection Therapy.

Prophylaxis	Receptive recipient (D+/R-)	<ul style="list-style-type: none"> Valganciclovir 450 mg OD (then according TDM) x 6-9 months. Viremia control every 2 weeks.
	Patient under acute-rejection therapy or ATG	<ul style="list-style-type: none"> Ganciclovir i.v. x 6 weeks. Viremia control every week.
Preemptive therapy	Patients with CMV-DNA positivity but no clinical manifestation	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.

5. BKV Infection Therapy

Diagnosis		<ul style="list-style-type: none"> Increased creatinine Viruria >6 log 10 / ml and viremia >4 log 10 / ml for more than 4 weeks Graft biopsy is indicated
Therapy	STEP 1	<p>Lowering of immunosuppression:</p> <ul style="list-style-type: none"> Decrease of antimetabolite dosage (MMF, AZA, m-TOR inhibitor) 50% decrease of CNI dosage (target trough level <6 for tacrolimus) Minimization of steroid therapy
	STEP 2	<ul style="list-style-type: none"> Withdrawal of antimetabolites
	STEP 3	<ul style="list-style-type: none"> Leflunomide 100 mg OD x 5 days --> 40 mg OD x 5 days --> 20 mg OD as maintenance dosage or switch to Cidofovir



APPENDIX 21: KEY PERFORMANCE INDICATORS (KPIs)

1. Process.

1.1. Referral To Listing.

Referral to Listing	
Main Domain:	Process.
Subdomain:	Efficiency.
Indicator Definition:	Average 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:	<u>Numerator:</u> Total count of days from referral to listing. <u>Denominator:</u> The total number of patients listed.
Target:	< 60 days.
Methodology:	Numerator / Denominator.
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 Liver and Pancreas Transplant Services.



1.2. Observed Pre-Transplant Mortality Rate.

Observed Pre-Transplant Mortality Rate	
Main Domain:	Process.
Subdomain:	Effectiveness.
Indicator Definition:	<p>The rate at which patients expire while on the waiting list for either a liver or pancreas transplant due to complications from organ failure.</p> <p>The denominator is calculated as person-years, i.e. the cumulative number of years all waitlisted liver or pancreas transplant patients at a hospital have been on the waitlist.</p>
Calculation:	<p><u>Numerator:</u> Total number of deaths of patients waiting for either a liver or pancreas transplant due to complications from organ failure.</p> <p><u>Denominator:</u> The total number of person-years individuals are on the waiting list.</p>
Target:	<p>< 15% for liver transplant.</p> <p>< 5% for pancreas transplant.</p>
Methodology:	Numerator / Denominator.
Measuring Unit:	Percentage of patients who expire while waiting for a transplant.
Reporting Frequency:	Annually.
Desired Direction:	Lower is better.
Rationale:	Metric of access to transplant.
KPI Source:	DHA Standards for Liver and Pancreas Transplant Services.



2. Outcomes

2.1. ICU Length of Stay.

ICU Length of Stay	
Main Domain:	Outcomes.
Subdomain:	Effectiveness and efficiency.
Indicator Definition:	Average number of days in the ICU after transplant surgery.
Calculation:	Numerator: Sum of the number of days in the ICU for all liver or pancreas recipients post-transplant. Denominator: Total number of liver or pancreas transplant.
Target:	< 5 days for liver transplant. < 3 days for pancreas transplant.
Methodology:	Numerator / Denominator.
Measuring Unit:	Calendar days.
Reporting Frequency:	Monthly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and effectiveness.
KPI Source:	DHA Standards for Liver and Pancreas 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:	<p><u>Numerator:</u> Total number of liver or pancreas patients readmitted to the hospital within 14 days after discharge post-transplant.</p> <p><u>Denominator:</u> The number of patients who receive a liver or pancreas transplant.</p>
Target:	<p>< 40% for liver transplant.</p> <p>< 40% for pancreas transplant.</p>
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 Liver and Pancreas Transplant Services.

2.3. Ninety (90) Day Graft Survival Rate.

Ninety (90) Day Graft Survival Rate	
Main Domain:	Outcomes.
Subdomain:	Effectiveness.
Indicator Definition:	<p>The percentage of transplanted liver or pancreas where the graft is still functioning after 90-days post-transplant.</p> <p>A graft is considered failed if there has been graft failure, a retransplant, or death due to failure of the transplanted organ.</p>
Calculation:	<p><u>Numerator:</u> The total number of transplanted liver or pancreas that have not encountered graft failure within ninety (90) days post-transplant.</p> <p><u>Denominator:</u> The total number of transplanted liver or pancreas.</p>
Target:	<p>>92% for liver transplant.</p> <p>>85% for pancreas transplant.</p>
Methodology:	$\text{Numerator} / \text{Denominator} \times 100.$
Measuring Unit:	Percentage of ninety (90) day graft survival.
Reporting Frequency:	Quarterly.
Desired Direction:	Higher is better.
Rationale:	Metric of success with surgical outcomes and effectiveness.
KPI Source:	DHA Standards for Liver and Pancreas Transplant Services.



2.4. One-Year Graft Survival Rate.

One-Year Graft Survival Rate	
Main Domain:	Outcomes.
Subdomain:	Effectiveness.
Indicator Definition:	<p>The percentage of transplanted liver and pancreas where the graft is still functioning after one-year post-transplant.</p> <p>A graft is considered failed if there has been graft failure, a retransplant, or death due to failure of the transplanted organ.</p>
Calculation:	<p><u>Numerator:</u> The total number of transplanted liver or pancreas that have not encountered graft failure within one-year post-transplant.</p> <p><u>Denominator:</u> The total number of transplanted liver or pancreas.</p>
Target:	<p>>90% for liver transplant.</p> <p>>75% for pancreas transplant.</p>
Methodology:	$\text{Numerator} / \text{Denominator} \times 100.$
Measuring Unit:	Percentage of ninety (90) day graft survival.
Reporting Frequency:	Quarterly.
Desired Direction:	Higher is better.
Rationale:	Metric of success with surgical outcomes and effectiveness.
KPI Source:	DHA Standards for Liver and Pancreas Transplant Services.