Standards for Kidney Transplant Services

Version 2.0

Issue date: 27/11/2024

Effective date: 27/01/2025

Health Policies and Standards Department

Health Regulation Sector (2024)

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with the Donation and Transplantation Institute (DTI Foundation), The National Center for Organ Donation and Transplant (MOHAP), and Subject Matter Experts. We would like to acknowledge and thank these stakeholders for their dedication toward improving the quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

TABLE OF CONTENTS

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (14) of the year (2021) amending some clauses of law No. (6) of 2018 pertaining to the Dubai Health Authority (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 with 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 Standards for Kidney Transplant Services aims to fulfill the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a model for accessible value-based health care.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.

EXECUTIVE SUMMARY

Kidney transplantation is the removal of a kidney from a deceased or living donor and transferring it to a patient with end-stage kidney disease. It is classified as deceased-donor or living-donor transplantation depending on the source of the donor organ. This document is developed to ensure that kidney 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 kidney transplant service, the health facility requirements, the healthcare professional requirements, the consent for organ transplant, medication requirements, criteria for continuity of the kidney transplant service, dialysis unit requirements, 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:

- Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.
- Federal Decree Law (18) of 2023 concerning Medical Liability.
- Federal Law no. (8) of 2023 amending some provisions of Federal Law no (4) of 2015 concerning the Private Health Facilities.
- Ministerial Decision no. (19) of 2022 concerning the Standards of Death Determination.
- Cabinet Decision No. (25) of 2020 concerning Federal Decree No. (5) of 2016 concerning regulating the transfusion and transplantation of human organs and tissues.
- DHA standards for Human organ and tissue donation Services (Deceased donor)

- DHA Guidelines for Organ and Tissue Donation Registry and KPIs
- DHA Standards for Renal Dialysis Services

ABBREVIATIONS

ATG : Antithymocyte Globulin

AZA : Azathioprine

BKV : B.K. Virus

CAD : Chronic Allograft Dysfunction

CNI : Calcineurin Inhibitors

CMV : Cytomegalovirus

DHA : Dubai Health Authority

DNC : Death by Neurological Criteria

ESRD : End Stage Renal Disease

HRS : Health Regulation Sector

ICU : Intensive Care Unit

LDKT : Living-Donor Kidney Transplantation

MOHAP: Ministry of Health and Prevention

OT : Operating Theatre

OTU : Organ Transplant Unit

RN : Registered Nurse

SOP : Standard Operating Procedure

UAE : United Arab Emirates

DEFINITIONS

Critical Care Support Unit (CCSU): 24/7 operating unit within the health facility ICU responsible for all organ donation matters, run by the critical care support unit director and coordinator/s. Formerly known as the *Organ Donation Unit (ODU).*

Critical Care Support Unit Director (CCSUD): an ICU intensivist who leads the CCSU including all standard operation procedures required for the unit, supervises the critical care support unit team and coordinators and oversees implementation of all steps of the organ donation process. This position was previously known as the *Organ Donation Unit Director.*

Critical Care Support Unit Coordinator (CCSUC): Critical Care Nurse, Intensivist, or other trained clinical staff assigned by the health facility management, responsible for ensuring that all organ and tissue donation process steps occur as per protocol and all communications between the CCSU, DHA, and the National Center for Donation and Transplant (NCDT) are done on a timely manner to facilitate organ donation and transplant. This role was previously known as the *Organ Donation Unit Coordinator (ODUC).*

Donation: a legal act indicating that a living individual has legally accepted to donate, during his lifetime or after death under a legal will left for his heirs or permitted successors 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: 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.

Healthcare Professionals: healthcare personnel working in healthcare facilities are required to be licensed as per the applicable laws in the United Arab Emirates (UAE).

Informed Consent: 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: 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.

Kidney 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.

Next of kin: a person authorized to make decisions on behalf of the patient, in cases where the patient is incompetent, or the relatives up to the fourth degree available in the country or by telephone or computer visual and audio/sign language communication, based on the below order:

A. The father.

B. The mother.

C. The children.

D. The spouse.

E. The grandfather.

F. The siblings.

G. The paternal uncle and the full uncle is precedent to the half uncle.

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

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

Workup: a thorough potential donor or recipient review, which may include diagnostic assessments such as laboratory tests, imaging, cancer screening, and other evaluations to ensure successful transplant outcomes.

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

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

Kidney transplant surgery is done to place a healthy kidney from a donor into a recipient whose kidneys no longer function well enough to support independent existence.

The donor kidney for a kidney transplant may come from a deceased donor or a living donor.

2. SCOPE

2.1. Kidney transplant services in Dubai Health Authority (DHA) licensed health facilities

[1] Referred to as The National Center throughout this document.

3. PURPOSE

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

4. APPLICABILITY

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

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing kidney transplant services shall adhere to Consultant Renal Transplant Surgeon the UAE Laws and DHA requirements.

5.2. Licensed health facilities opting to add kidney transplant services shall apply to the Health Regulation Sector (HRS) and comply with the DHA licensure and administrative requirements available on the DHA website (https://www.dha.gov.ae) to obtain permission to provide the required service.

5.3. Accreditation

5.3.1. The health facility shall be accredited as per the DHA Hospital accreditation policy, before commencing with a kidney transplant service.

5.3.2. The health facility laboratory must be accredited as per the DHA Clinical Laboratory accreditation policy, before commencing with a kidney transplant service.

5.4. The health facility shall employ trained and experienced healthcare professionals as identified and described in this document.

5.5. The health facility shall have Standard Operating Procedures (SOPs) related to the Kidney Transplant Service. The relevant staff shall be trained to abide by these SOPs. The SOPs shall be made available to HRS upon request.

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

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.

5.7.3. Patient assessment and workup.

5.7.4. Blood type determination of the candidate.

5.7.5. Recipient selection criteria.

5.7.6. 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

5.7.7. ABO Compatibility verification and documentation for organ transplantation, conducted by the transplant surgeon and another healthcare professional.

5.7.8. Pre-Transplant workup process.

5.7.9. Health facility 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 these standards specific to kidney deceased donor assessment and evaluation.

5.7.10. Post-transplant follow-up protocol.

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

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 and hazardous waste management.

5.7.14. Incident reporting to DHA.

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 requirements.

5.8.7. Housekeeping services.

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

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

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

5.12. A DHA licensed health facility providing kidney 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 health facility to manage the care of transplant patients independently.

5.12.2. The health facility must inform its patients if a single surgeon or a single physician staffs kidney transplant service.

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. Kidney transplant services shall only be performed in DHA licensed health facilities.

6.2. The health facility shall have an Organ Transplant Unit (OTU) to ensure integrated and seamless organ transplant services, including the kidney transplant service.

6.3. The health facility providing kidney transplant services shall have the following services:

6.3.1. Cardiology

6.3.2. Gastroenterology with endoscopy.

6.3.3. Pulmonology with bronchoscopy.

6.3.4. Infectious disease.

6.3.5. Radiology, with skills in interventional radiology.

6.3.6. Hematology.

6.3.7. 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, tacrolimus, or similar drugs should be available.

6.3.8. Biochemistry laboratory.

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

6.3.10. Intensive Care Unit (ICU).

6.3.11. Quality management.

6.3.12. Blood banking services.

6.3.13. Microbiology services.

6.3.14. Histocompatibility testing.

6.3.15. Necessary resources to monitor treatment with immunosuppressive medications.

6.4. The health facility shall provide the following:

6.4.1. Minimum of two (2) Operating Theatres (OTs).

6.4.2. Minimum of two (2) positive pressure rooms for the management of post-transplant patients.

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

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

6.7. The health facility shall provide assurance of patient and staff health and safety.

6.8. 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.

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

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

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS

7.1. A DHA licensed hospital providing kidney 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. A DHA licensed hospital providing kidney transplant services shall have consultant general surgeons or consultant renal transplant surgeons with training and experience in kidney transplant surgery and privileged by the health facility in alignment with the DHA privileging policy.

7.3. Physician responsible for the pre and post care of the transplant patient shall be DHA licensed consultant internal medicine/nephrologist with training and experience in the subject and privileged by the health facility in alignment with the DHA privileging policy.

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

7.5. The consultant kidney transplant surgeon must meet the following conditions:

7.5.1. Performed thirty (30) kidney transplants as primary or consultant surgeon, co-surgeon, or first assistant within the last five (5) years.

7.5.2. Performed at least ten (10) kidney transplants as a primary surgeon or co-surgeon.

7.5.3. Performed at least fifteen (15) kidney procurements as primary surgeon or first assistant. At least 10 of these procurements must be from deceased donors.

7.5.4. The surgeon has maintained a current working knowledge of kidney transplantation, defined as direct involvement in kidney transplant patient care in the last 2 years. Participated in preoperative assessments of kidney candidates and postoperative care of these recipients.

7.6. The consultant nephrologist must meet the following conditions:

7.6.1. Been directly involved in the primary care of thirty (30) or more transplanted kidney recipients at a hospital designated to perform kidney transplants in the last two years.

7.6.2. 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.

7.6.3. The physician was directly involved in the evaluation of twenty (20) potential kidney recipients and the evaluation of ten (10) potential living kidney donors, including participation in selection committee meetings.

7.6.4. Observed at least three (3) kidney procurements and at least three (3) kidney transplant surgeries.

7.6.5. To verify this transplant experience, a log documenting the 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 paediatric kidney transplant services shall employ a DHA licensed paediatric consultant renal transplant surgeon who meets the following conditions:

7.7.1. Performed at least fifteen (12) kidney transplants as the primary or consultant surgeon in recipients less than eighteen (18) years old at the time of transplant.

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

7.8. A DHA licensed hospital providing paediatric kidney transplant services shall employ a DHA licensed paediatric consultant nephrologist who meet the following conditions:

7.8.1. Been directly involved in the primary care of ten (10) or more newly transplanted paediatric kidney recipients and followed thirty (30) newly transplanted kidney recipients for a minimum of six (6) months from the time

of transplant.

7.8.2. Been directly involved in the pre-operative, peri-operative, and post-operative care of twenty-five (25) or more paediatric kidney transplant recipients

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

7.9. A DHA licensed hospital providing kidney transplant services shall have a detailed plan and procedures for continuity of patient care as also mentioned above.

7.10. A DHA licensed hospital providing pancreas transplant services shall also have the following DHA licensed healthcare professionals to support the above-mentioned physicians:

7.10.1. Registered Nurses (RNs) are experienced and trained to care for patients during and after kidney transplants.

7.10.2. Transplant coordinator, a 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.

7.10.3. Clinical dietician to provide nutritional services to transplant candidates, recipients, and living donors.

7.10.4. Clinical social worker to coordinate psychosocial needs of transplant candidates, recipients, living donors, and their families.

7.10.5. Clinical pharmacist to provide comprehensive medication management to transplant candidates, recipients, and living donors.

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

7.11. The following healthcare professionals shall provide support to the above team, but not limited to:

7.11.1. Infectious disease specialist

7.11.2. Cardiologist

7.11.3. Critical care physician

7.11.4. Anaesthesiologist (with experience in intra-operative management of kidney transplant recipients)

7.11.5. Radiologist

7.11.6. Radiographer

7.11.7. Psychiatrist/Clinical psychologist

7.11.8. Clinical pharmacist

7.11.9. Physiotherapist

7.11.10. Transplant pathologist

7.12. A DHA licensed hospital providing kidney transplant services shall have a kidney transplant committee to ensure efficient and safe kidney transplant services. The kidney transplant committee shall consist of:

7.12.1. Consultant renal transplant surgeon

7.12.2. Consultant nephrologist

7.12.3. Kidney transplant coordinator

7.12.4. Registered Nurse representative

7.12.5. Quality coordinator

7.12.6. Dietician (optional)

7.12.7. Social worker (optional)

7.12.8. Cardiologist (optional)

7.12.9. Anaesthesiologist (optional)

7.12.10. Urologist (optional)

7.12.11. Psychiatrist (optional)

7.12.12. Legal representative (optional).

7.13. Kidney transplant coordinators shall be assigned in each OTU providing kidney transplant services, with the following responsibilities:

7.13.1. Acts as liaison between The National Center for Regulating Donation and Transplantation of Human Organs and Tissues (NCDT) and the hospital OTU.

7.13.2. Work closely with the coordinator(s) of NCDT and the CCSU of the donor facilities to facilitate donation and subsequent transplant.

7.13.3. Ensure that all potential transplant recipients and living donors meet transplant or donation criteria, respectively.

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

7.13.5. Ensure that all activities of the OTU adhere to policy and procedures for transplant and living-related donation.

7.13.6. Prepare a waiting list for the hospital OTU.

7.13.7. Report the names of all patients fit for transplantation (workup patients) to NCDT to include them in the national waiting list.

7.13.8. Inform NCDT when a suitable patient fit for transplantation is not available on the local waiting list.

7.13.9. Send and update all information related to patients with end-stage kidney failure fit for transplantation.

7.13.10. Oversee post-transplant care of patients.

7.14. A DHA licensed hospital providing kidney transplant services shall have a kidney transplant committee to ensure efficient and safe kidney transplant services.

7.15. The responsibilities of the kidney transplant committee are as follows:

7.15.1. Review the health records of patients to undergo pre-transplant evaluation. A pre-transplant checklist is elaborated in **Appendix 1**.

7.15.2. Make clinical decisions on the eligibility of patients to the waitlist and who are rejected based on criteria set forth by NCDT.

7.15.3. Review the patients every 6 months to ensure that they continue to meet program requirements for transplant and wait-listing.

7.15.4. Ensure that transplant and living donation activities abide by the highest ethical and legal standards.

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

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

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

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

7.15.9. Develop and regularly update Policies and Procedures related to Kidney Transplant Services to ensure efficient and safe provision of services.

7.16. The privileging committee and/or medical director of the health facility shall privilege the physicians mentioned above aligned with his/her education, training, experience, and competencies. The privilege shall be reviewed and revised at regular intervals aligned with the DHA clinical privileging policy.

7.17. It is strictly prohibited for transplant healthcare professionals to take part in diagnosing the death of possible donors or obtaining consent for donation.

8. **STANDARD FOUR:** INFORMED CONSENT FOR ORGAN TRANSPLANT

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

8.2. Kidney transplant surgery consent shall include the following:

8.2.1. Potential psychosocial risks post-transplant.

8.2.2. OTU's observed and expected one-year survival rate, beginning one year after the hospital's first kidney transplant.

8.2.3. Prospective transplant candidate of alternative treatments.

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

8.2.5. If the organ donor has risk factors present that could increase the risk of disease transmission, this information was disclosed to the potential recipient prior to transplant, and ensure those details are documented in the recipient's medical record.

8.3. 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).

8.4. Consent for living kidney donation shall include the following:

8.4.1. Potential psychosocial risks of donation.

8.4.2. Alternative treatments for the transplant candidate.

8.4.3. Donors have the right to opt out of donation at any time during the donation process.

8.5. When the death by neurological criteria is confirmed and consent is obtained from the family for organ donation, distribution, and transplantation shall be carried out as per

the Federal Decree Law No. (25) of 2023 concerning the Human Organ and Tissue Donation and Transplantation.

8.6. Before performing transplantation from a living donor, the following conditions should be fulfilled:

8.6.1. Exclusion criteria for donation in Living-Donor Kidney Transplantation (LDKT) are elaborated in the published DHA Standards for Living Donation Services.

8.6.2. Living related donors and their intended recipients shall provide attested documents by relevant authorities as proof of relationship.

8.6.3. The organ donor shall sign a written consent that he/she has read and understood the donation process and the possible and probable hazards resulting from organ removal and this should be documented in his/her health record.

8.6.4. The patients shall sign a separate Transplant consent, along with the surgical consent.

8.6.5. Living donors can unconditionally withdraw consent at any time; up until the kidney is removed, after which time they cease to have jurisdiction over the organ.

8.6.6. Transplantation of single organs on which the life of the donor is dependent is prohibited.

8.6.7. Organ donation should be accepted by the donor without any social or financial pressure.

8.6.8. Relevant medical examinations should be performed on the donor and recipient before the transplantation.

8.7. Before performing deceased donor transplantation, the following conditions should be fulfilled:

8.7.1. It is not permissible to remove an organ unless the donor's wish is conclusively confirmed before death and formally documented either by the notary public or through the Emirates Identity card.

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

8.8. Each hospital and organ transplant center should send a list of the names of end-stage organ failure patients to NCDT which in turn establishes national and local waiting lists for each organ transplant in accordance with priority. This waiting list is sent back to each organ transplant center to act accordingly.

8.9. Always ensure donor and recipient confidentiality.

9. **STANDARD FIVE:** MEDICATION REQUIREMENTS

9.1. Hospitals providing kidney transplant services shall ensure the in-house availability of the following drugs, but not limited to:

9.1.1. Immunosuppressive drugs:

a. Cyclosporine

b. Tacrolimus

c. Azathioprine

d. Mycophenolate Mofetil

e. Prednisolone

f. Sirolimus

g. Everolimus

h. Other similar drug categories.

9.1.2. Drugs for induction immunosuppressive regimen and treating rejection episodes:

a. Methylprednisolone

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

c. Monoclonal Antibodies.

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

9.1.4. Drugs for treating bacterial, viral, fungal, and parasitic infections.

10. STANDARD SIX: DIALYSIS UNITS REQUIREMENTS

10.1. Every kidney transplant service shall render the necessary technical assistance to all dialysis units requesting their assistance. This includes the following:

10.1.1. Constitutes a referral center for difficult cases, surgical or non-surgical, concerning kidney transplantation.

10.1.2. Performs tissue typing and anti-donor antibody screening on all End Stage Renal Disease (ESRD) patients fit for transplantation.

10.1.3. Decides the fitness of patients for transplantation and sends their names and results of investigations clearly documented to the kidney transplant unit.

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

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

11.2. The pre-operative assessment and evaluation of the recipient candidate is elaborated in **Appendix 2** and **Appendix 4.**

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

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

12.2. The surveillance for kidney transplant complications after hospital discharge is elaborated in **Appendix 6.**

12.3. Immunosuppressive therapy for kidney transplant recipients is elaborated in **Appendix 7** and it shall individualize and be under the supervision of a specialist/consultant.

12.4. The protocol for acute rejection therapy is elaborated in **Appendix 8.**

12.5. The protocol for cytomegalovirus infection management after transplant is elaborated in **Appendix 9.**

12.6. The protocols for kidney Chronic Allograft Dysfunction (CAD) management are elaborated in **Appendix 10.**

13. STANDARD NINE: KEY PERFORMANCE INDICATORS (KPIs) FOR KIDNEY TRANSPLANT SERVICE

13.1. Health facilities shall report the KPIs, and all tissue transplantation information defined by these Standards for DHA HRS by monitoringKPIS@dha.gove.ae.

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

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

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

13.3. Key Performance Indicators (KPIs)

13.3.1. 1-Year Kidney Transplant Recipient Survival

1-Year Kidney Transplant Recipient Survival	
Main Domain:	Patient Outcome
Subdomain:	Survival Rate
Indicator Definition:	Percentage of kidney transplant patients who are alive 1-year post-transplant.
Calculation:	Numerator: Number of patients alive at 1-year post-transplant* Denominator: total number of patients transplanted

Target:	≥ 90%
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage (%)
Reporting Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Indicates the short-term success of transplantation and patient care
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS)

*In cases of patients with graft failure within the first 12 months post-transplant, patient survival should be censored at 90 days following the date of graft failure

13.3.2. Estimated 1-Year Kidney Transplant Recipient Survival

Estimated 1-Year Kidney Transplant Recipient Survival	
Main Domain:	Patient Outcome
Subdomain:	Survival Rate
Indicator Definition:	Estimated rate of kidney transplant patients' survival at 1-year post-transplant, calculated using data from centers previous 5 years.
Calculation:	Kaplan-Meier estimates for patient survival at 12months including accrued patient survival from all patients transplanted at the centre in the last five years*
Target:	≥ 95%
Methodology:	Kaplan-Meier estimated survival
Measuring Unit:	Percentage (%)
Reporting Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Indicates the short-term success of transplantation and patient care, reducing biases of potential pitfalls from isolated events in center with smaller volumes of transplantation
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS)

*In cases of patients with graft failure within the first 12months post-transplant, patient survival should be censored at 90 days following the date of graft failure.

13.3.3. 1-Year Kidney Graft Survival

1-Year Kidney Graft Survival	
Main Domain:	Graft Outcome
Subdomain:	Survival Rate
Indicator Definition:	Percentage of transplanted kidneys functioning 1-year post-transplant.
Calculation:	Numerator: Number of functioning grafts at 1-year post-transplant Denominator: total number of transplanted grafts
Target:	≥ 90%
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage (%)
Reporting Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Measures short-term graft viability, crucial for patient quality of life.
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS)

13.3.4. Waitlist for Kidney Transplant Mortality Rate

Waitlist for Kidney Transplant mortality rate	
Main Domain:	Patient Outcome
Subdomain:	Mortality Rate
Indicator Definition:	Percentage of patients on the kidney transplant waitlist who die before receiving a transplant
Calculation:	Numerator: Number of deaths on the waitlist Denominator: total number of patients on the waitlist
Target:	< 20%
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage (%)
Reporting Frequency:	Annual
Desired Direction:	Lower is better
Rationale:	Reflects the effectiveness of transplant centers in evaluating the candidates for transplant and following these patients until the procedure. Reflects too the efficiency of organ allocation and the urgency of transplant care.
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS), Canadian Blood Services (Organs and Tissues practices, guidelines and initiatives).

13.3.5. Time for Kidney Transplant

Time to Kidney Transplant	
Main Domain:	Operational efficiency
Subdomain:	Wait time
Indicator Definition:	The average time between listing on the kidney transplant waitlist and receiving a transplant.
Calculation:	Numerator: total time to transplant for all patients Denominator: number of patients transplanted
Target:	≤3 years
Methodology:	Numerator/Denominator
Measuring Unit:	years/patient
Reporting Frequency:	Annual
Desired Direction:	Lower is better
Rationale:	Reducing the time to transplant improves patient outcomes and reduces waitlist mortality.
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS).

13.3.6. Kidney Allograft Acute Rejection Rate

Kidney Allograft Acute Rejection Rate	
Main Domain:	Clinical Outcome
Subdomain:	Rejection Episodes
Indicator Definition:	Percentage of patients who experience an acute rejection episode within the first-year post-transplant.
Calculation:	Numerator: number of patients with acute rejection Denominator: total number of transplanted patients
Target:	< 20%
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage (%)
Reporting Frequency:	Annual
Desired Direction:	Lower is better
Rationale:	Lower rejection rates indicate effective immunosuppressive therapy and patient management.
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS).

13.3.7. Percentage of Kidney Transplant by Living Donor

Percentage of Kidney Transplant by Living Donor	
Main Domain:	Donor Utilization
Subdomain:	Donor type
Indicator Definition:	Percentage of kidney transplants performed using living donors.
Calculation:	Numerator: number of living donor transplants Denominator: total number of transplants
Target:	>10%
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage (%)
Reporting Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Increasing living donor transplants can shorten wait times and improve patient outcomes.
KPI Source:	Scientific Registry of Transplant Recipients (SRTR), United Network for Organ Sharing (UNOS).

REFERENCES

1. British Transplant Society (2021) UK Guideline on Imlifidase Enabled Deceased Donor Kidney Transplantation. (Available at): https://bts.org.uk/uk-guideline-on-imlifidase-enabled-deceased-donor-kidney-transplantation/ (Accessed on 12/11/2024).
2. Dr. Baker R, Dr. Mark P, Dr Patel R, et al, The Renal Association (2022) Post-Operative Care in the Kidney Transplant Recipient. (Available at): https://bts.org.uk/wp-content/uploads/2017/06/FINAL_PostOperative_Care_Guideline.pdf (Accessed on 12/11/2024).
3. British Transplant Society (2014) Management of Failing Kidney Transplant. (Available at):https://bts.org.uk/wp-content/uploads/2016/09/13_BTS_Failing_Graft-1.pdf (Accessed on 12/11/2024).
4. British Transplant Society (2018). Guidelines for Living Donor Kidney Transplantation Forth Edition. (Available at): https://bts.org.uk/wp-content/uploads/2018/07/FINAL_LDKT-guidelines_June-2018.pdf (Accessed on 12/11/2024).
5. Chadban, S.J., Ahn, C., Axelrod, D.A., Foster, B.J., Kasiske, B.L., Kher, V., et al. (2020) 'KDIGO clinical practice guideline on the evaluation and management of candidates for kidney transplantation', Transplantation, 104(4S1), pp. S11–S103. Available at: https://journals.lww.com/transplantjournal/fulltext/2020/04001/KDIGO_Clinical_Practice_Guideline_on_the.9.aspx (Accessed on 12/11/2024).

6. Eckardt, K.U., Kasiske, B.L. and Zeier, M.G. (2009) 'KDIGO clinical practice guideline for the care of kidney transplant recipients', American Journal of Transplantation, 9(Supplement 3), pp. S1–S15.
7. Kendra E. Brett, Lindsay J. Ritchie, Emily Ertel, Alexandria Bennett, and Greg A. Knoll. Quality Metrics in solid Organ Transplantation: A Systematic Review. Transplantation, V(102), N(7):e308-e330.
8. Manyalich, M., Guasch, X., Gomez, M.P., Páez, G. and Teixeira, L.; ODEQUS Consortium (2013) 'Organ Donation European Quality System: ODEQUS project methodology', *Transplantation Proceedings*, 45(10), pp. 3451–3455.
9. National Institute for Health and Care Excellence (2009). Machine perfusion systems and cold static storage of kidneys from deceased donors. (Available at): https://www.nice.org.uk/guidance/ta165 (Accessed on 12/11/2024).
10. Federal Decree- Law No. (5) of 2016 on the Regulation of Human Organs and Tissue Transplantation. (Available at): https://mohap.gov.ae/app_content/legislations/php-law-en-094a/mobile/index.html#p=1 (Accessed on 12/11/2024).
11. National Institute for Health and Care Excellence (2017). Immunosuppressive therapy for kidney transplant in adults. (Available at): https://www.nice.org.uk/guidance/ta481 (Accessed on 12/11/2024). National Institute for Health and Care Excellence (2017). Immunosuppressive therapy for kidney transplant in children and young people. (Available at): https://www.nice.org.uk/guidance/ta482 (Accessed on 12/11/2024).

12. Organ Donation European Quality System (ODEQUS) 'Quality Criteria and Quality Indicators in Organ Donation'. Available at: http://www.odequs.eu/results.html (Accessed: 6/11/2024).

APPENDICES

APPENDIX 1: PRE-KIDNEY TRANSPLANT CHECK-LIST

PRE-KIDNEY TRANSPLANT CHECK-LIST	
RECICIPENT CANDIDATE CHECKLIST	CHECK
- Select an appropriate recipient candidate according to o Donor/recipient Cross Match o Donor/recipient clinical/demographic match o Medical urgency, time on waiting list	
- Call the selected recipient candidate and hospital admission	
- Confirm Recipients identity	
- Review pre-KT workup	
- Order Urgent chest x-ray	
- Order Urgent ECG	
- Order Urgent blood exams (full blood count, renal function, blood gas test, coagulation function)	
- Evaluate type of routine dialysis (hemodialysis, peritoenal dialysis)	
- Evaluate if Pre-KT dialysis is required	
- Request for Anesthesiologist re-evaluation	
- Alert ICU if postoperative ICU admission is expected	
- Order 4 packed red blood cells units	
- Activate the operating room	
- Request written informed consent for KTx	

- Prepare the patient for surgery	
- Administer immunosuppressive induction therapy	
- Prescribe antibiotic prophylaxis	
- If donor/recipient CMV mismatch, prescribe postoperative CMV prophylaxis	
KIDNEY GRAFT CHECKLIST	CHECK
- Confirm donor identity and donor/recipient matching	
- Review donor demographic and clinical characteristics	
- Review organ procurement surgical report	
- Review pathologic examination and Karpinsky scoring on kidney graft biopsy (if performed)	
- Evaluate graft quality at back-table	
- Prepare the graft for implantation at back-table	
- Perfuse the organ with 1L cool preservation solution	
- Place the graft in static cold storage or machine perfusion	
- Monitor the machine perfusion activity	

KIDNEY TRANSPLANT CHECKLIST	CHECK
- Confirm patient identity, procedure, informed consent, and any reported allergy	
- Mark the site of implantation	
- Review pre-KT CT angiogram	
- Confirm the presence of the kidney graft in the operation room and review machine perfusion data	
- Check availability of required specific surgical instruments and devices (aortic punch, uretheral stents)	
- Prepare 1 L Saline 0.9% with Iodopovidone for bladder instillation	
- 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	

APPENDIX 2: CHECK-LIST FOR KIDNEY TRANSPLANT CANDIDATE'S WORKUP

CHECK-LIST FOR KIDNEY TRANSPLANT CANDIDATES' WORKUP		CHECK
PRELIMINARY EVALUATION	- Medical history, family medical history, physical examination - Detailed evaluation of the underlying renal disease, type of dialysis - Performance status and nutritional status	
LABORATORY TEST	- Blood group	
	- Complete blood count	
	- Blood gas test	
	- Complete renal function panel	
	- Full electrolyte panel	
	- Full urine test with urine sediment examination (if residual diuresis present)	
	- Complete liver function panel	
	- Full lipid panel	
	- Complete coagulation function panel	
	- Plasma proteins levels and protein electrophoresis	
	- CPK, CPK-MB	
	- ESR, ASLOT	
	- Fecal occult blood test	
	- Urine culture (if residual diuresis present)	

MICROBIOLOGY ASSESSMENT	- HBV markers	
	- HCV-RNA	
	- HIV-RNA	
	- VDRL, TPHA	
	- Serology (IgG, IgM) CMV	
	- Serology (IgG, IgM) Toxoplasma	
	- Serology (IgG, IgM) EBV	
	- Serology (IgG, IgM) HTLV I-II	
	- MANTOUX (if required)	
	- Infectiology's examination	
IMMUNOLOGIC ASSESSMENT	- HLA typing	
	- Panel reactive antibodies (PRA)	
CARDIOLOGIC ASSESSMENT	- Cardiologic examination	
	- ECG	
	- Echocardiography	
	- Exercise Cardiac Stress Test	
	- Myocardial Perfusion scintigraphy (if indicated)	

IMAGING ASSESSMENT	- Chest-abdomen-pelvis CT scan	
	- Uro-CT scan or perfusion urography	

	- Color Doppler of the iliac-femoral axis and supraaortic vessels	
	- Brain MR imaging (in pts with polycystic disease)	
ENDOSCOPIC ASSESSMENT	- EGDS with HP test	
	- Colonoscopy	
	- Cystometry	
OTHERS	- Gynecologic examination, PAP TEST Mammography and US scan (women), urologic examination with prostate US scan (men) - Dental examination with orthopantomogram	
	- Fundus oculi	
	- Dermatologic examination	
	- Psychological evaluation	
	- Anesthesiologist evaluation	

APPENDIX 3: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DONOR CANDIDATES

1. The health facility must maintain documentation in the donor's medical record to support that all elements of the protocol were followed.
2. Living kidney donors must be evaluated as elaborated in the published DHA Standards for Living Donation Services.
3. Deceased kidney donors must be evaluated as elaborated in the published DHA Standards for Human Organs & Tissues Donation Services (Deceased Donor) – Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD).

APPENDIX 4: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF RECIPIENT CANDIDATES

1. The pre-operative examination shall include the following:
    1.1. Physiologic and medical history, family medical history, physical examination
    1.2. Detailed evaluation of the underlying renal disease, type of dialysis
    1.3. Performance status and nutritional status
2. Laboratory Tests
    2.1. Blood group
    2.2. Complete blood count
    2.3. Serum creatinine, Blood Urea Nitrogen (BUN), Sodium, potassium, calcium, chloride, CO2, glucose, phosphate, uric acid
    2.4. Full urine test with urine sediment examination (if residual diuresis is present)
    2.5. Serum Liver Transaminases (AST, ALT), Gamma Glutamyl Transpeptidase (GGT), Alkaline Phosphatase (ALP), Lactate Dehydrogenase (LDH)
    2.6. Serum total and direct bilirubin
    2.7. Full lipid panel dosage
    2.8. Plasma proteins levels and protein electrophoresis
    2.9. PT, PTT, Fibrinogen
    2.10. CPK, CPK-MB
    2.11. ESR, ASLOT
    2.12. Fecal occult blood test

3. Microbiology Tests

3.1. Urine culture test (if residual diuresis is present)

3.2. HBV markers: HBsAg, HBsAb, HBcAb, HBeAg, HbeAb

3.3. HCV-RNA, HIV-RNA

3.4. Serology test for CMV (IgG - IgM), Toxoplasma, Epstein Barr, HTLV I-II

3.5. Screening for syphilis (VDRL, TPHA)

3.6. MANTOUX test (if required)

4. Cardiologic Evaluation

4.1. All potential transplant candidates are at higher risk of coronary artery disease, but there are some very high-risk subgroups. High-risk subgroups include the following:

a. Prolonged duration of dialysis (greater than 5 years)

b. Family history of coronary artery disease in first degree relative, history of smoking, dyslipidemia (HDL less than 0.9 mmol/L, LDL greater than 3.4 mmol/L)

c. Body mass index (BMI) greater than 30

d. History of hypertension

e. Diabetes mellitus.

4.2. Cardiologic examination, ECG, echocardiography,

4.3. Exercise Cardiac Stress Test

4.4. Myocardial Perfusion scintigraphy (if indicated)

4.5. Patients with a positive screening test should be referred to a cardiologist for further evaluation usually including coronary angiography.

4.6. Suitable patients with critical disease should undergo intervention with bypass surgery or angioplasty and stenting. Some patients with severe diffuse disease will be turned down for transplantation because of their poor prognosis.

5. Other Examinations include the following:

5.1. Chest-abdomen-pelvis CT scan

5.2. EGDS with HP test

5.3. Colonoscopy

5.4. Uro-CT scan or perfusion urography

5.5. Cystometry

5.6. Color Doppler of the iliac-femoral axis and supraaortic vessels

5.7. Gynecologic examination e PAP TEST, PSA serum levels, urologic examination with prostate US scan

5.8. Mammography and US scan

5.9. Brain MR imaging (in pts with polycystic disease)

5.10. Dental examination with orthopantomogram

5.11. Fundus oculi

5.12. Dermatologic examination

5.13. Psychological evaluation

6. Immunologic Tests

6.1. HLA typing

6.2. Donor/Recipient Cross Match

7. Immunization

7.1. All potential transplant recipients should have been immunized before transplant according to past immunization history. Antibody levels are determined at time of referral.

7.2. Patients should receive the following vaccinations prior to transplant:

a. Td or Tdap

b. IPV

c. Hepatitis B

d. Meningococcal (conjugate)

e. Pneumococcal (conjugate and/or polysaccharide)

f. Hib

g. Influenza

h. MMR

i. Varicella

7.3. Live vaccines (MMR and varicella) administered before the transplant must be completed at least six weeks before transplantation. Yearly influenza immunization is indicated for all immunosuppressed individuals.

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

PARAMETER	COMMENTS
Diuresis	Daily urine output, creatinine clearance, urine sediment, urine culture
Body temperature	In the presence of fever, the following investigations are indicated: • Full blood count, • Renal function panel, • Full urine test, • Urine culture, • Hemoculture, • Microbiological culture of the abdominal drainage liquid and wound secretion, • US scan, • Chest x-ray
Abdominal drainage tube	Daily output; measurement of creatinine, LDH, glucose; microbiological culture
Laboratory tests	• Full blood count, glucose, BUN, creatinine, sodium, potassium, venous blood gas test; if indicated total and pancreatic amylases, calcium; frequency: TID on POD 1, 2, 3 --> BID from POD 4 to POD 6 --> OD from POD 6 to POD 10 • Liver function panel, frequency: on POD 1 --> thereafter once a week; • CMV-DNA in blood: after 1-2 weeks post-KT or earlier in presence of signs of gastroenteritis, fever, leucopenia, liver transaminases serum level increase --> once a month for the first 4 months after KT --> thereafter when clinically indicated; in presence of Donor+/Recipient-, valganciclovir prophylaxis is indicated with CMV-DNA determination every 15 days. • BKV-DNA in blood and urine: at 1, 3, 6, and 9 months after KT--> yearly from the 1st to the 5th year, or when clinically indicated

	• Immunosuppressant trough levels: twice a week in the first month of KT --> twice a month for the following 3-4 months -->thereafter once a month.
Graft US scan with Color Doppler	Three times a week until POD 10 or when clinically indicated.

APPENDIX 6: SURVEILLANCE FOR KIDNEY TRANSPLANT COMPLICATIONS AFTER HOSPITAL DISCHARGE

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

PARAMETER	COMMENTS
Cardiovascular diseases	• Follow up cardiologic examination and tests as appropriate
Infectious complications	• Urine culture every 15 days for the first 4 months, every month until 1 year after KT, thereafter every 6 months or when indicated • CMV-DNA: once a month for the first 4 months after KT and thereafter when clinically indicated; • BKV-DNA in blood and urine: at 1, 3, 6, and 9 months after KT or when clinically indicated • HBV and HCV: once a year in serum-negative recipients, according to hepatologic indications in serum-positive recipients • HHV8 –HPV, if clinically indicated
Oncologic complications	• Standard clinical screening for prostate cancer (PSA, urologic examination), breast cancer (mammography, US), cervix cancer (PAP test), GI cancer (fecal occult blood test, EGDS, colonoscopy), according to local guidelines • Dermatologic examination: every year • Abdomen US: every year
Bone complications	• Serum calcium, phosphates, ALP, magnesium, albumin, complete urine test, PTH: every 6 months • 25OHD3 e CTX, lumbar spine x-ray, DEXA, endocrinologic examination, if clinically indicated

APPENDIX 7: IMMUNOSUPPRESSIVE THERAPY FOR ADULT KIDNEY TRANSPLANT RECIPIENTS

1. The health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. All medical treatment must be patient-centered and customized, in accordance with international best practices and best medical judgment, so the following protocol constitutes a standard management guide.

POD 0	**Induction therapy** Methylprednisolone 500mg-1000mg i.v. in the OR before graft reperfusion For intermediate/high immunologic risk recipients or for expanded criteria donors use associated with: • Antithymocyte Globulin 1-1.5mg/kg/dose i.v. (total dose <6mg/kg) starting POD 0, guide use by CD3 lymphocyte count. • Premedicate with acetaminophen 10 mg/kg to a maximum 650 mg and diphenhydramine 1mg/kg to a maximum 50 mg.
POD 1-30	**Maintenance Therapy** • Tacrolimus 0.1-0.3 mg/kg PO q12h (Therapeutic Level Goals 9-12 ng/mL) • Mycophenolate 1000 mg/q12h (CellCept) or 720 mg/q12h (Myfortic) • Prednisone 20mg/d
POD 31->	**Tacrolimus** • POD31-POD90: 9-12 ng/mL • POD91-POD180: 8-10 ng/mL • POD181-POD365: 7-9 ng/mL • POD366->: 6-7 ng/mL

	Mycophenolate • POD0 Mycophenolate 1000 mg/q12h (CellCept) or 720 mg/q12h (Myfortic) • P180-> When the recipient follows with recurrent infections or other immunosuppressive complications and low immunologic risk, consider: • Mycophenolate 500 mg/q12h (CellCept) or 360 mg/q12h (Myfortic)
	Prednisone: • POD31-POD60: 15 mg/d • POD61-POD90: 10 mg/d • POD91->: 5 mg/d After 1-year post-transplant, if cPRA 0%, correct eGFR, no rejection episodes and stable tacrolimus levels during follow up, consider STOP If steroid withdrawal is not feasible, consider reducing at 2.5 mg/d.

APPENDIX 8: PROTOCOL FOR ACUTE KIDNEY REJECTION THERAPY IN ADULT RECIPIENTS

1. The health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. All medical treatment must be patient-centered and customized, in accordance with international best practices and best medical judgment, so the following protocol constitutes a standard management guide.
3. Graft rejection diagnosis should be confirmed by a graft biopsy, which must be interpreted according to the current Banff Classification for Kidney Graft Rejection.

PROTOCOL FOR ACUTE KIDNEY REJECTION THERAPY IN ADULT RECIPIENTS	
T Cell-Mediated Rejection (TCMR)	
Borderline	Intravenous methylprednisolone 250 mg/day for 3 days.
Banff IA	Intravenous methylprednisolone 500 mg/day for 3 days. After three pulses, oral prednisone 0.5 mg/kg/day with 5 mg tapering every 2 days until maintenance dose. Consider immunosuppressive intensification (increase tacrolimus and/or mycophenolate).
Banff IB	Same as Banff IA.
Banff IIA	Same as Banff IA, but add thymoglobulin 1.25 mg/kg/day for 7 days. CMV prophylaxis with valganciclovir for 1 month and cotrimoxazole for 6 months is recommended.
Banff IIB	Same as Banff IIA.
Banff III	Same as Banff IIA.

Active Antibody-Mediated Rejection (aABMR)
• Rituximab: 2 doses of 400 mg intravenous. The first dose was given the day before starting Plasma Exchange (PLEX), and the last dose after the final PLEX session. CMV prophylaxis with valganciclovir for 1 month and cotrimoxazole for 6 months is recommended. • Plasma Exchange (PLEX): 5 sessions, separated by 24 hours. • Intravenous Immunoglobulin (IVIg): One intravenous dose of at least 200 mg/kg after every two PLEX sessions. • Methylprednisolone: 3 pulses of at least 250 mg/day for the first 3 days of treatment.
Chronic Active Antibody-Mediated Rejection (caABMR)
The treatment must be case-by-case. In cases with signs of activity in the biopsy, a similar approach to aABMR can be considered to reduce eGFR decline.

APPENDIX 9: CYTOMEGALOVIRUS (CMV) PROTOCOL FOR ADULT KIDNEY TRANSPLANT RECIPIENTS

1. The health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. All medical treatment must be patient-centered and customized, in accordance with international best practices and best medical judgment, so the following protocol constitutes a standard management guide.
3. CMV reactivation/infection risk assessment is crucial before the transplant.

Donor/Recipient Serologies (IgG)	Prophylaxis Recommendation
Donor (+) / Recipient (-)	Prophylaxis is recommended during at least 3 months after transplantation
Donor (-) / Recipient (-)	No prophylaxis is required (consider in case of transfusions after transplantation).
Donor (±) / Recipient (+) **(No Thymoglobulin induction)**	Prophylaxis is not required. If close CMV monitoring is unavailable, consider prophylaxis for 1 month post-transplant.
Donor (±) / Recipient (+) **(With Thymoglobulin induction)**	Prophylaxis for 1-month post-transplant is recommended.

4. Oral valganciclovir (Valcyte®) is recommended for CMV prophylaxis. It can be started 1 week after transplantation, and its dose needs to be adjusted according to the kidney function. Recommended doses are summarized in the following table:

eGFR (mL/min)	Prophylaxis dose
> 60	450 mg/q12h
40 – 60	450 mg/d
25 – 40	450 mg/q48h
10 – 25	450 mg twice a week

5. CMV monitoring is performed by measuring CMV viral load in blood using a PCR technique. It is recommended to early identify CMV reactivation after prophylaxis completion or as a marker of good response during CMV infection treatment.

CMV MONITORING DURING POST-KIDNEY TRANSPLANT PROPHYLAXIS AND TREATMENT
Monitoring in the group without prophylaxis (preemptive therapy)
Detection technique: PCR Monitoring: • 0-3 months post-transplant: at least every 2 weeks • 3-6 months post-transplant: every month
Monitoring in the group with prophylaxis
Detection technique: PCR Monitoring is only necessary after prophylaxis is finished and it is performed until the 6th month post-transplant: • 0-3 months post-transplant: at least every 2 weeks

• 3-6 months post-transplant: every month
Monitoring in the high-risk group (D+/R-)
Detection technique: PCR Monitoring is only necessary after prophylaxis is finished and it is performed until the 12th month post-transplant: • 0-3 months post-transplant: at least every 2 weeks • 3-12 months post-transplant: every month
Monitoring during CMV infection/reactivation treatment
Detection technique: PCR Monitoring is recommended every 1 or 2 weeks. In severe cases, it is recommended to be performed 2 times per week.
Monitoring after CMV infection/reactivation treatment
Detection technique: PCR Monitoring is recommended at 7 and 14 days after finishing the treatment.

6. CMV disease should be considered and its respective treatment started in kidney transplant recipients followed with:

   - **Fever syndrome** (fever, leukopenia with or without increase in transaminases) and PCR positive for CMV. The recommended treatment is valganciclovir or ganciclovir at therapeutic doses for 2-3 weeks, monitoring weekly viral clearance by CMV PCR.
   - **Invasive disease**: Digestive involvement is the most frequent manifestation, usually with fever and gastritis or colitis (diarrhea) with positive CMV PCR. Diagnostic confirmation can be performed through a biopsy of the digestive epithelium (viral inclusions in the immunochemistry analysis). Other less frequent manifestations are pneumonitis, hepatitis, pancreatitis, retinitis, or CNS involvement. In these cases, it is recommended to admit the patient to the hospital to initiate intravenous ganciclovir. Once the patient has improved, treatment can be changed to oral valganciclovir. The total duration of the

treatment is recommended around 3-4 weeks, depending on the patient's improvement and viral load.

7. Ganciclovir dose (adjusted according to eGFR) for severe CMV disease:

eGFR (mL/min)	**Ganciclovir dose**
> 90	5 mg/kg/12h
50 – 90	5 mg/kg/12h
25 – 50	2.5 mg/kg/12h
10 – 25	2.5 mg/kg/24h
< 10	1.25 mg/kg/24h
Hemodialysis	1.25 mg/kg/24h (post-HD)

APPENDIX 10: PROTOCOL FOR KIDNEY CHRONIC ALLOGRAFT DYSFUNCTION (CAD) MANAGEMENT

1. The health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. All medical treatment must be patient-centered and customized, in accordance with international best practices and best medical judgment, so the following protocol constitutes a standard management guide.
3. A general rule in monitoring transplant recipients is that a 20% to 25% increase in serum creatinine (SCr) concentration above baseline warrants attention. Evaluation includes at a minimum kidney ultrasound to rule out obstruction, as might be seen with inadequate bladder emptying, stone, or ureteral stricture. Doppler studies should be included with ultrasound to assess vascular inflow if blood pressure is elevated or bruit is appreciated over the kidney.
4. Assessment for BK viremia can also shed light on the cause of an elevated SCr level. Serum viral load > 10,000 copies is associated with BK nephropathy, although its confirmation requires a kidney graft biopsy to detect BK inclusions.
5. Proteinuria is another indication for kidney allograft biopsy. Non–nephrotic-range proteinuria may be seen with early transplant glomerulopathy associated with chronic antibody-mediated rejection. Nephrotic-range proteinuria can be associated with transplant glomerulopathy as well but may be an indicator of diabetes or recurrent or de novo diseases such as focal segmental glomerulosclerosis (FSGS), membranous glomerulopathy, or other immune complex deposition diseases.

6. The gold standard in the assessment of an increased SCr concentration is the kidney graft biopsy. The biopsy may identify acute or chronic rejection, recurrent or de novo kidney disease, viral or other infections, or progressive scarring with interstitial fibrosis and tubular atrophy.
7. Biopsy tissue should be evaluated by a nephropathologist familiar with transplant pathology.

KIDNEY ALLOGRAFT DYSFUNCTION CAUSES		
Decreased Kidney Perfusion		
Condition	**Comments**	**Evaluation**
Volume depletion	Poor intake or diarrhoea	Physical examination, assess electrolytes
Renal artery stenosis	Typically associated with hypertension	Ultrasound with Doppler study
Calcineurin inhibitor toxicity	Causes vasoconstriction	Tacrolimus or cyclosporine level
Obstructive Causes		
Condition	**Comments**	**Evaluation**
Ureteral stricture	May be seen with BK infection	Ultrasound with evaluation of the ureter
Bladder dysfunction	Neurogenic bladder	Ultrasound, postvoid residual
Bladder outlet obstruction	Prostatic enlargement	Ultrasound and postvoid residual
Intrinsic Kidney Injury		
Condition	**Comments**	**Evaluation**
Acute cellular rejection	Can be triggered by recent infection or immunosuppression reduction	Renal allograft biopsy

Acute antibody-mediated rejection	Especially if immunosuppression has been reduced	Donor-specific antibodies, renal allograft biopsy
Drug toxicity	Calcineurin inhibitors, antibiotics	Therapeutic drug level monitoring, kidney allograft biopsy
Infection	Transplant pyelonephritis, BK virus infection	Urine culture, BK viral load in plasma
Post transplantation lymphoma	Rare occurrence	EBV plasma viral load, kidney allograft biopsy
Recurrent disease	IgA, MN, FSGS, MPGN, immune complex disease	Kidney allograft biopsy
Abbreviations: EBV, Epstein-Barr virus, FSGS, Focal Segmental Glomerulosclerosis, IgA, Immunoglobulin A, MN: Membranous Nephropathy, MPGN: Membranoproliferative Glomerulonephritis		